ACT TOGETHER AGAINST
LUNG CANCER

CENTRAL AND EASTERN EUROPE FORUM
OF CANCER PATIENT ORGANIZATIONS

Health Care & Economy: understanding the complexity

Isabelle Durand-Zaleski

MD, PhD. Professor of Medicine, University of Paris XII. Stanford Health Policy Adjunct Affiliate. Santé Publique, Hôpital Henri Mondor

ONCHQ15NP06216, 09-15

Health Technology Assessment (HTA)

- Key step in the process of innovative treatment evaluation

- European network for health technology assessment (EUnetHTA) core model
- Local adaptation of the Transparency directive
- The issue of price and reimbursement
- Stakeholder’s involvement

HTA role in access decision making

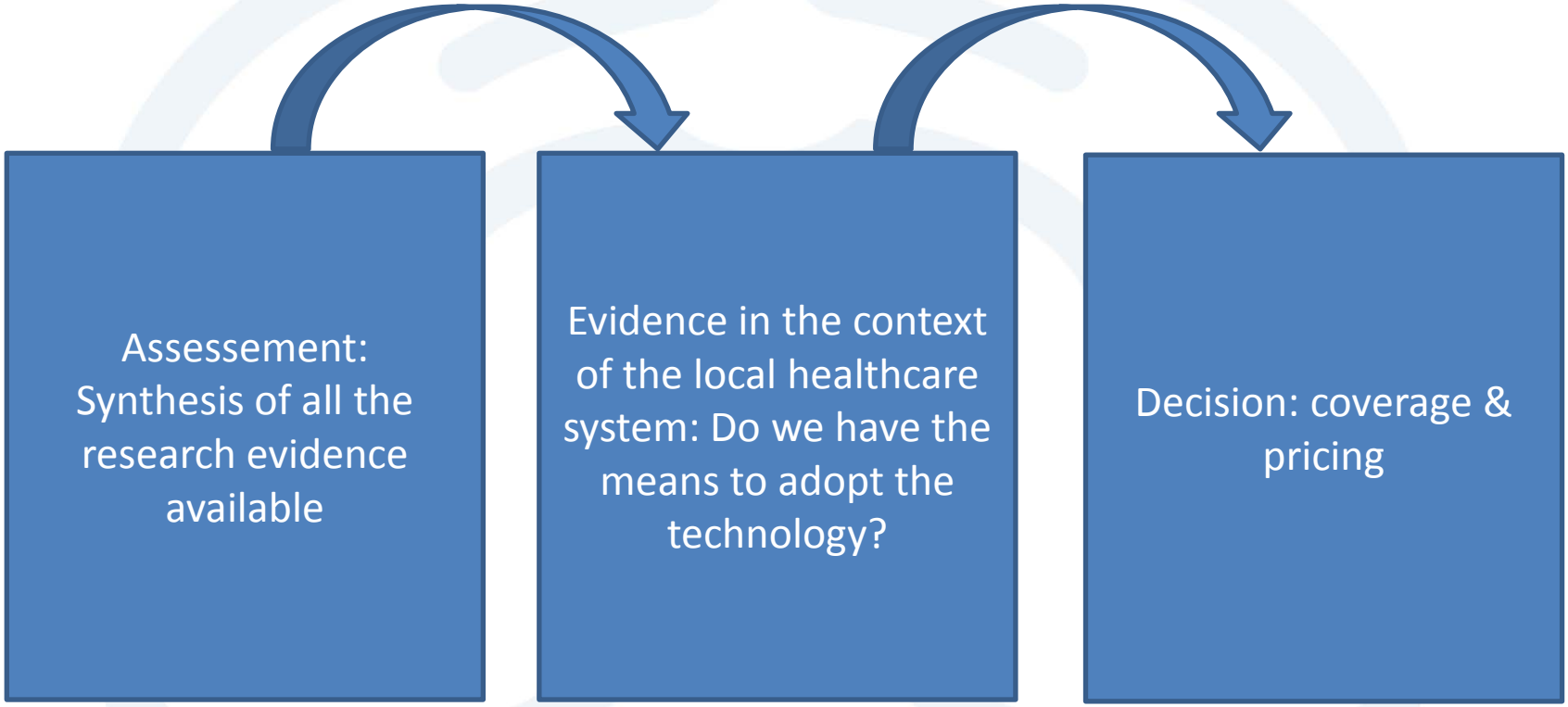
HTA decision making process

- Formal decision-making processes (EU)= assessment and appraisal
- But heterogeneity in the stakeholders involved:
  - Market authorization: agencies for drugs /devices
  - HTA: MoH, specific agencies (AOTM; Slovenia Health Institute), payer
  - Reimbursement decision (MoH, health insurance)
  - Pricing (MoH, Health Insurance Institute of Slovenia)

Local organization of HTA

- Relationship between HTA and coverage decisions = improve value for money in healthcare
- Pricing (UK, Poland and Slovakia)
- Market Access
- Guidelines for health professionals and patients

How HTA is used to make funding decisions



Examples of HTA in Europe

- England = The National Institute for Health and Care Excellence (NICE); Here an Appraisal Committee comprised of independent experts makes the final recommendations for reimbursement
- Poland = The Agency for Health Technology Assessment (AOTM) is independent of the body responsible for reimbursement and coverage decision. Recommendations are made a committee comprised of independent experts
- Croatia = The Agency for Quality and Accreditation in HealthCare and Social Welfare undertakes the assessment of the technology while the Croatian Institute for Health Insurance (CIHI) is responsible for the appraisal

Who initiates the process?

- In most jurisdictions in Europe, the manufacturer initiates the HTA decision-making process (e.g. Belgium, Germany, Sweden, Denmark, Finland, Italy, and Ireland)
- It can be initiated by the HTA agency (e.g. Sweden) or other institution such as the Ministry of Health (e.g. England and Spain)

Type of information used

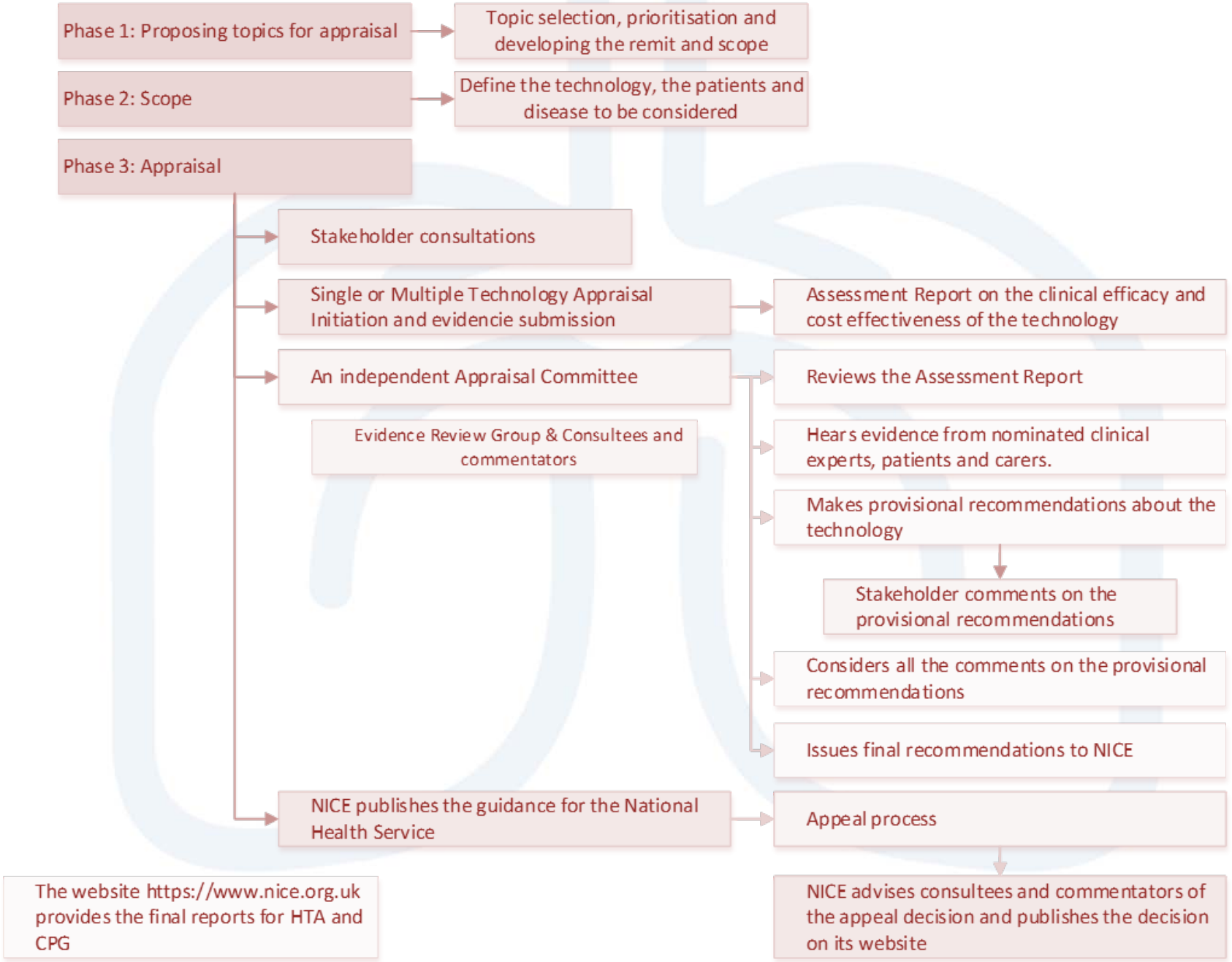
- Manufacturers' submissions
  - Clinical evidence (clinical trials and real world data)
  - Burden of illness with existing therapy
  - Economic evidence showing value for money of treatment (cost-effectiveness in some markets)
  - Budget impact
- Internal reports based on HTA analysis
- Internal & external (commissioned) reports

Evidence used to inform coverage & reimbursement decisions

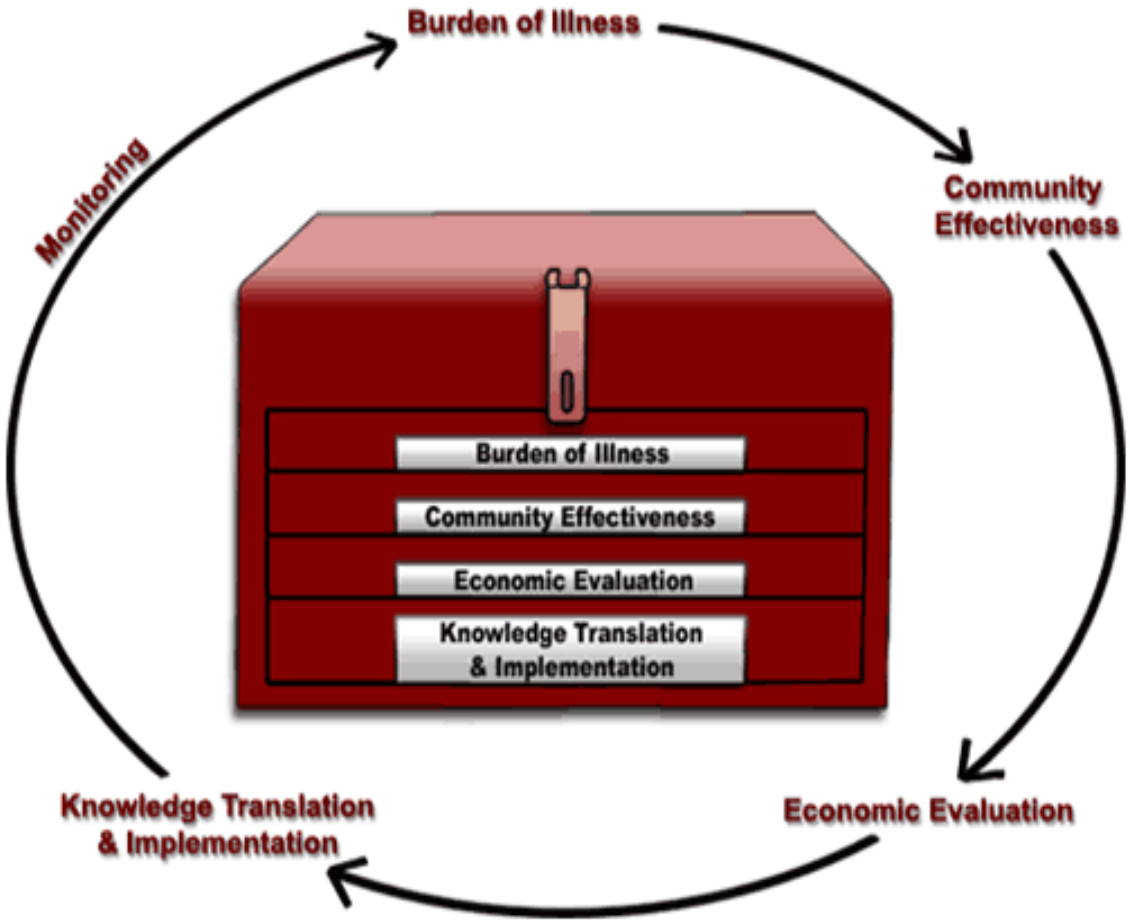
- Therapeutic relevance: medical benefit / improvement in medical benefit
- Public health issues
- Orphan disease, unmet needs
- Economic aspects: cost effectiveness, budget impact

HTA is transparent and unbiased

- Stakeholder involvement: health professionals, patient representatives, industry representatives
- Comments and appeals
- Contributions posted on the websites


Phase 1: Proposing topics for appraisal
Topic selection, prioritisation and developing the remit and scope
Phase 2: Scope
Define the technology, the patients and disease to be considered
Phase 3: Appraisal
Stakeholder consultations
Single or Multiple Technology Appraisal Initiation and evidencie submission
Assessment Report on the clinical efficacy and cost effectiveness of the technology
An independent Appraisal Committee
Reviews the Assessment Report
Evidence Review Group & Consultees and commentators
Hears evidence from nominated clinical experts, patients and carers.
Makes provisional recommendations about the technology
Stakeholder comments on the provisional recommendations
Considers all the comments on the provisional recommendations
Issues final recommendations to NICE
NICE publishes the guidance for the National Health Service
Appeal process
The website https://www.nice.org.uk provides the final reports for HTA and CPG
NICE advises consultees and commentators of the appeal decision and publishes the decision on its website

Equity-Oriented Toolkit for HTA



http://www.cgh.uottawa.ca/WHOCC/projects/eo_toolkit/index.htm

Transnational HTA

- Central and Eastern European Society of Technology Assessment in Health Care (CEESTAHC); http://www.ceestahc.org/en

- EUnetHTA; http://www.eunethta.eu/

- International Society For Pharmacoeconomics and Outcomes Research (ISPOR); http://www.ispor.org/

HTA AGENCIES IN EU

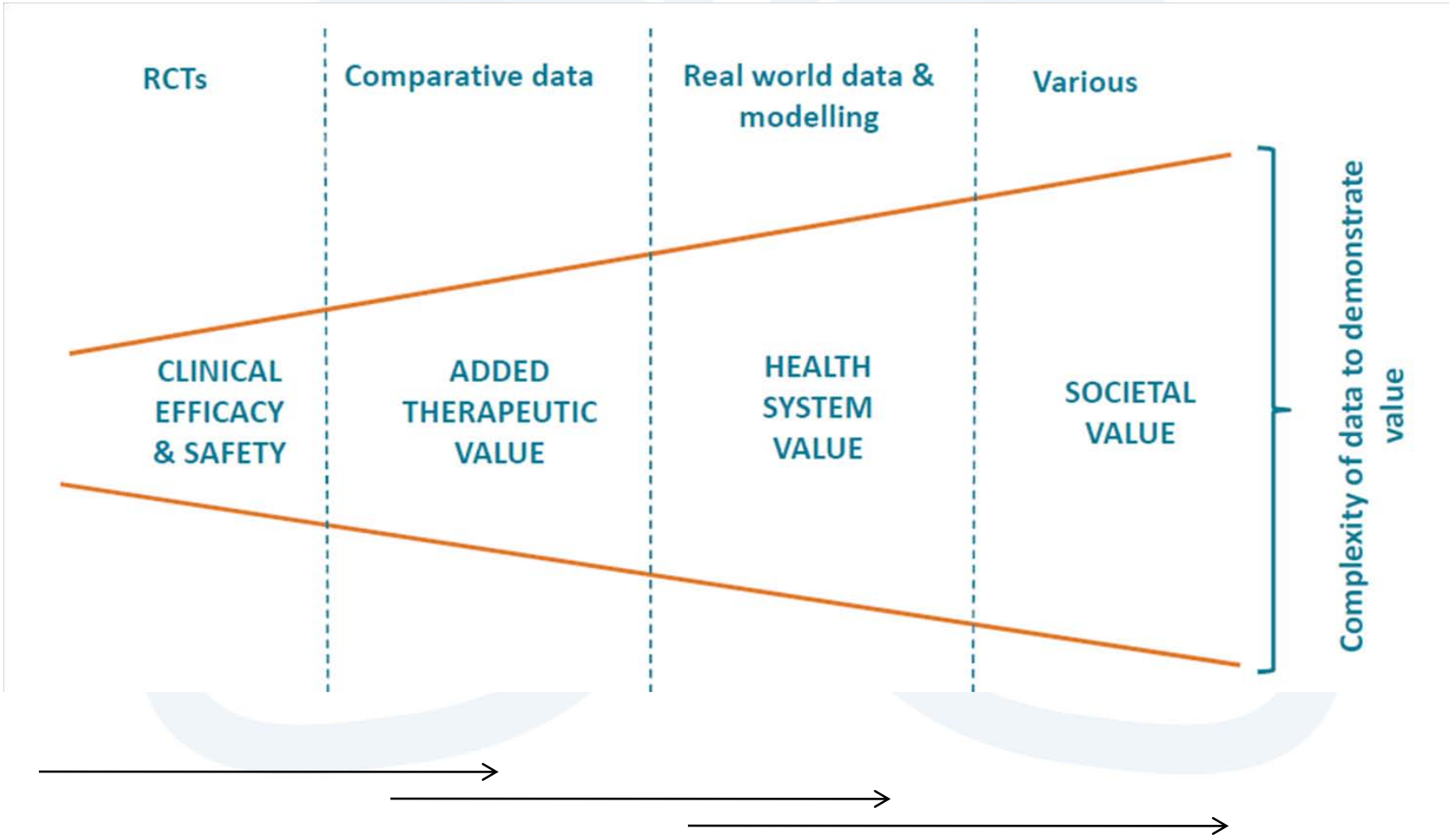
Countries with formal HTA	Countries without formal HTA
Austria	Bulgaria
Belgium	Cyprus
Denmark	Czech Republic
Finland	Estonia
France	Greece
Germany	Ireland
Hungary	Italy
Latvia	Lithuania
Netherlands	Luxembourg
Poland	Malta
Spain	Portugal
Sweden	Romania
UK	Slovakia
	Slovenia

HETA

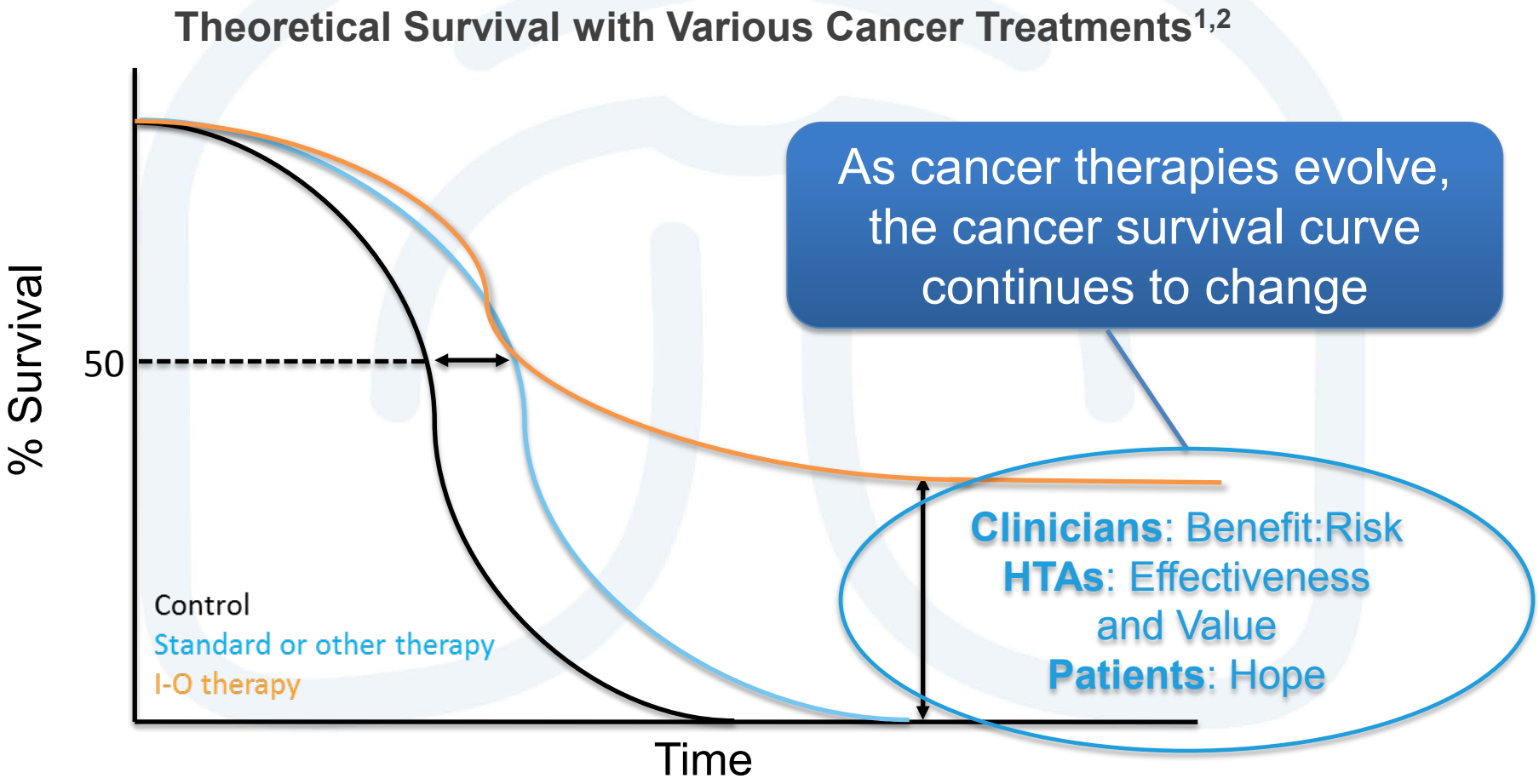
Eunethta – October 2008

Key driving factors of value assessment

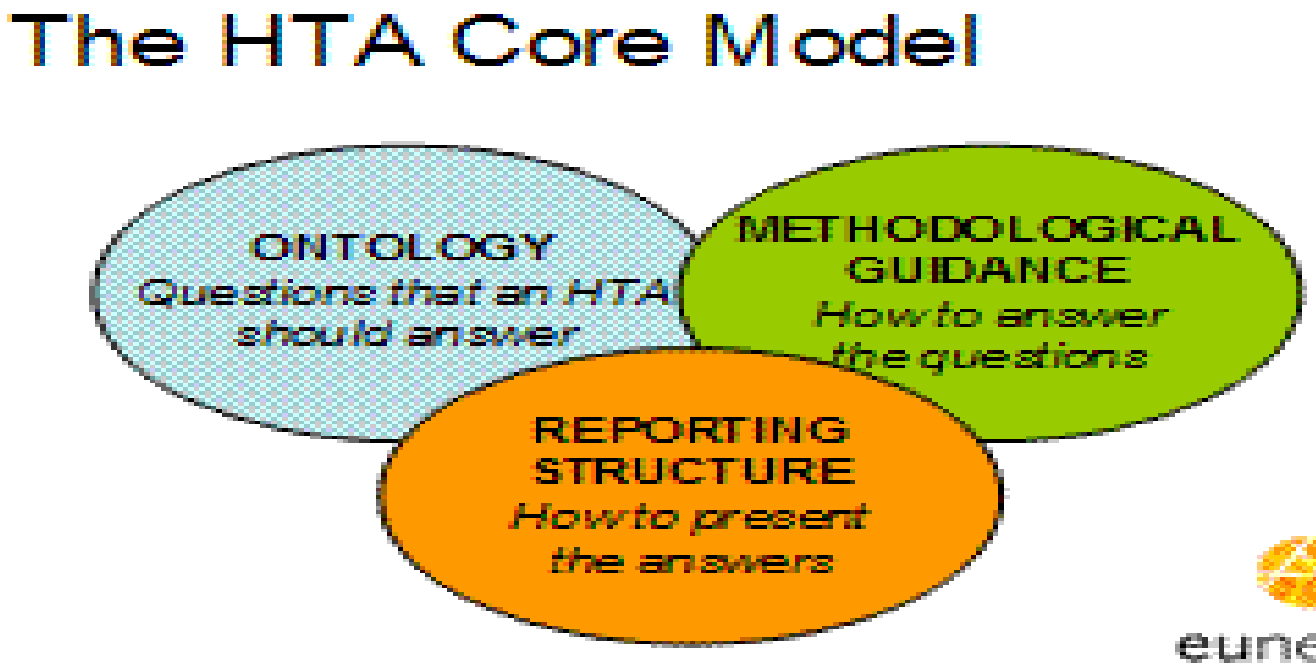
Value demonstration spectrum



The Aspirational Goal for I-O Therapies – Reaching a New Normal



The HTA core model focuses upon the research question, methodological approach and appropriate reporting



Within this structure, there are several domains to be addressed

EUetHTA Core Model

1. Health Problem and Current Use of the Technology
2. Description and technical characteristics of technology
3. Safety
4. Clinical Effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organizational aspects
8. Social aspects
9. Legal aspects

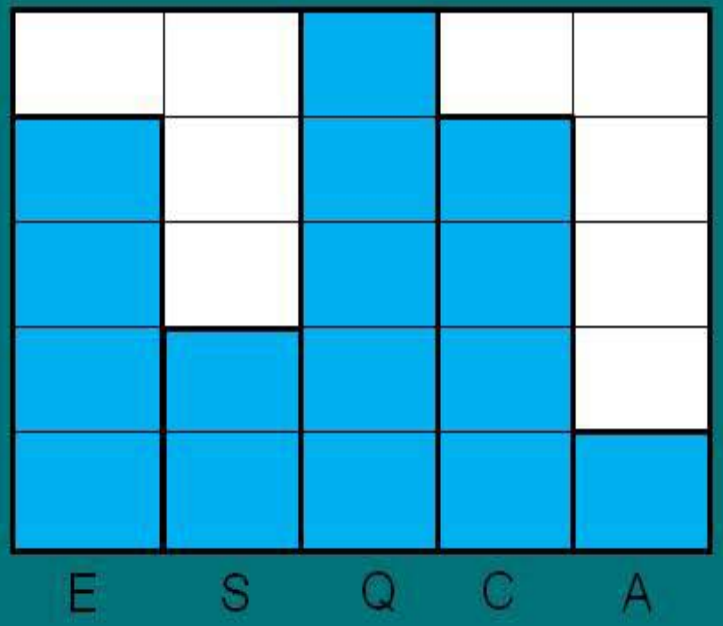
eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

network for HTA across Europe

Example of NCCN Evidence Block

- Retain Categories of Evidence but supplement them
- Dimensions
  - Efficacy
  - Safety
  - Quality of Evidence
  - Consistency of Evidence
  - Affordability
- More shading is better
- Patents filed

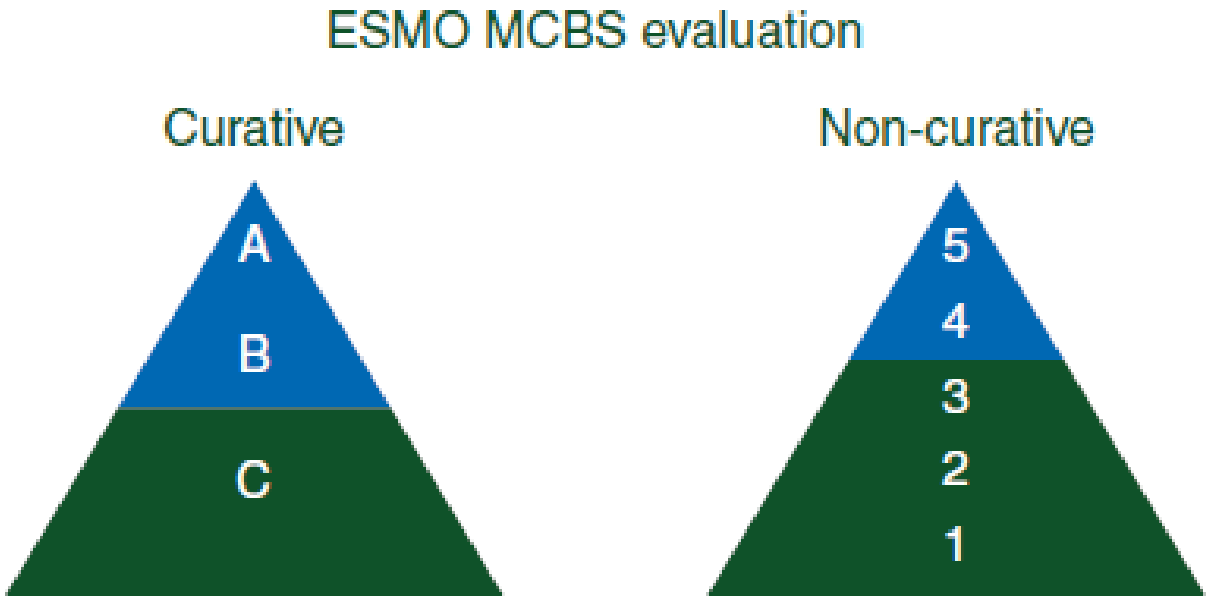


ESMO Magnitude of Clinical Benefit Scale

Table 1. Potential benefits of a new treatment

- Living longer
  - Improved OS
  - Improved surrogate of OS
    - DFS (when OS data are immature in adjuvant setting)
    - Improved PFS
- Living better
  - Improved quality of life
  - Improved surrogate of quality of life
    - Improved PFS
  - Reduced toxicity

Annals of Oncology 26: 1547–1573, 2015



Curative-Evaluation form 1: for new approaches to adjuvant therapy or new potentially curative therapies

Non-curative-Evaluation forms 2a, b or c: for therapies that are not likely to be curative

Figure 3. Visualisation of ESMO-MCB scores for curative and non-curative setting. A & B and 5 and 4 represent the grades with substantial improvement.

Annals of Oncology 26: 1547–1573, 2015

Estimating the clinical benefit

Characteristics of a good endpoint	
Objective	- Active follow-up
Reproducible	- Easy to interpret
Sensitive/specific	- Free of errors of ascertainment or measurement
Unbiased	- Stable
Clinically relevant	- Observable independent of assignment
Chosen a priori	

Estimating the clinical benefit, 2

Advantages of using the Surrogate endpoints	
Faster and easier to study	Cheaper
Follow up time required shorter than for others clinical outcomes	Proving effect on direct endpoint may not be feasible
Faster drug development & access	

Patient involvement and support to HTA decision making

Patients' perspective

Roles:

Public consultation
Identifed members:

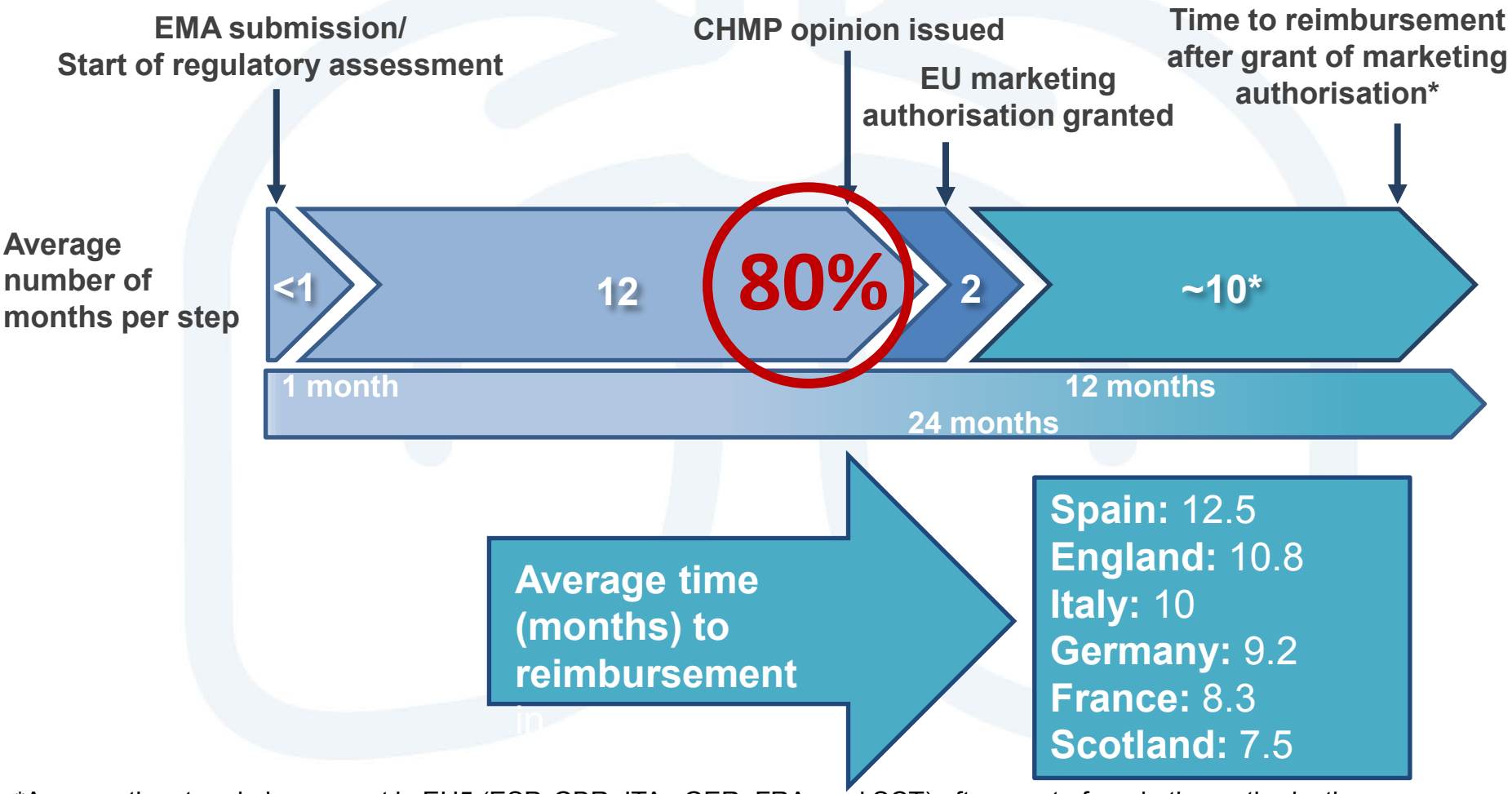
- Consultative
- Voting

Patient experts

Topics

Drugs
Devices
Procedures
Guidelines
Basic benefit package
Economic evaluation

Further perspective: Speed is of the Essence for Patients with Lung Cancer



*Average time to reimbursement in EU5 (ESP, GBR, ITA , GER, FRA, and SCT) after grant of marketing authorisation

Beishon M. *Cancer World* 2014; Jan-Feb: 12–17

Sun D, Beckerman R. Paper presented at: ISPOR 19th Annual International Meeting ; Montreal, QC, Canada; May 31–June 4, 2014

Examples from the UK

- Psoriasis
- Diabetic macular edema

- Patients' advocates argued about:
  - loss of independence and its implications for employment
  - impact on emotional wellbeing
  - quality of life

HTA products

- Importance of plain language summaries for technical reports and practice guidelines
- Patients information documents derived from guidelines (ex in France for cancer patients)

Conclusion

- Patients involvement improves the quality of HTA
- The roles and rules must be specified a priori and transparent

Back-up slides