



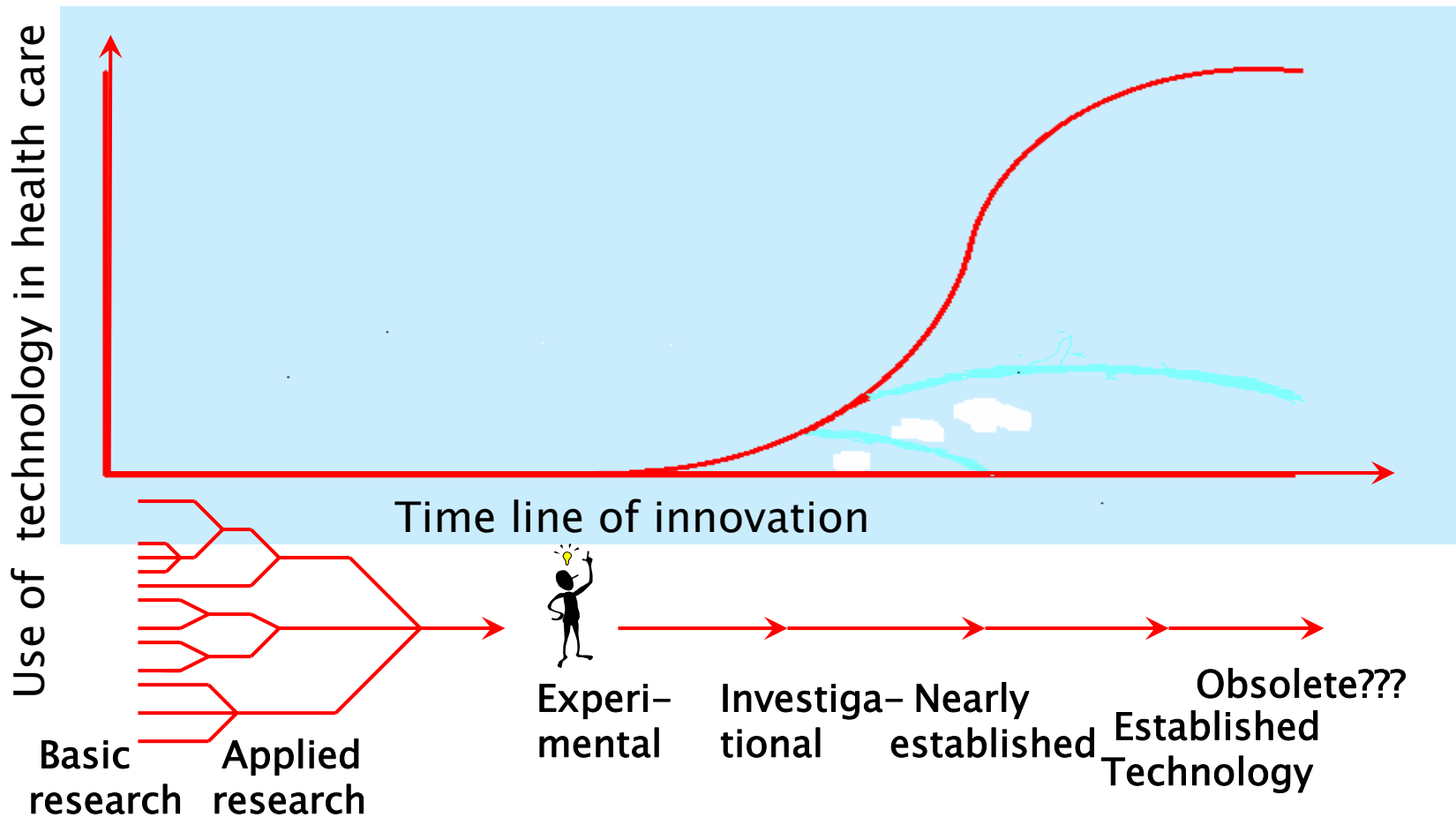
## THE ROLE OF HEALTH TECHNOLOGY ASSESSMENTS IN EUROPE'S REGULATION OF HEALTH TECHNOLOGY – PRESENT AND FUTURE

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# Technology "diffusion"





# What is HTA

- **Healthcare technology** is defined as prevention and rehabilitation, vaccines, pharmaceuticals and devices, medical and surgical procedures, and the systems within which health is protected and maintained
- **Technology assessment** in health care is a multidisciplinary field of policy analysis. It studies the medical, social, ethical, and economic implications of development, diffusion, and use of health technology

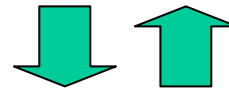
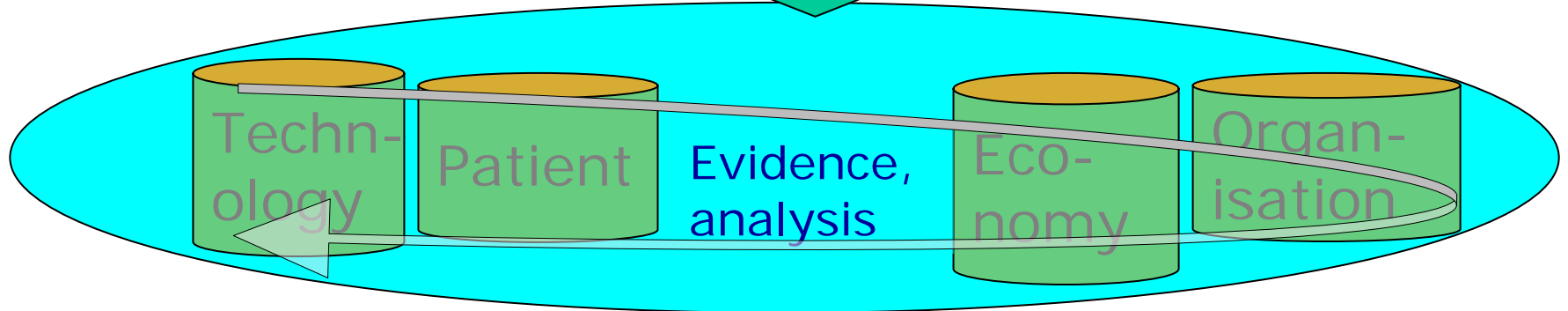
INAHTA

- HTA does not mandate policies or decisions
- HTA may inform regulatory control measures, and have a defined role in regulation, but is not regulation in itself
- Despite its policy goals, HTA must always be **firmly rooted in research and research methods**

Policy-questions



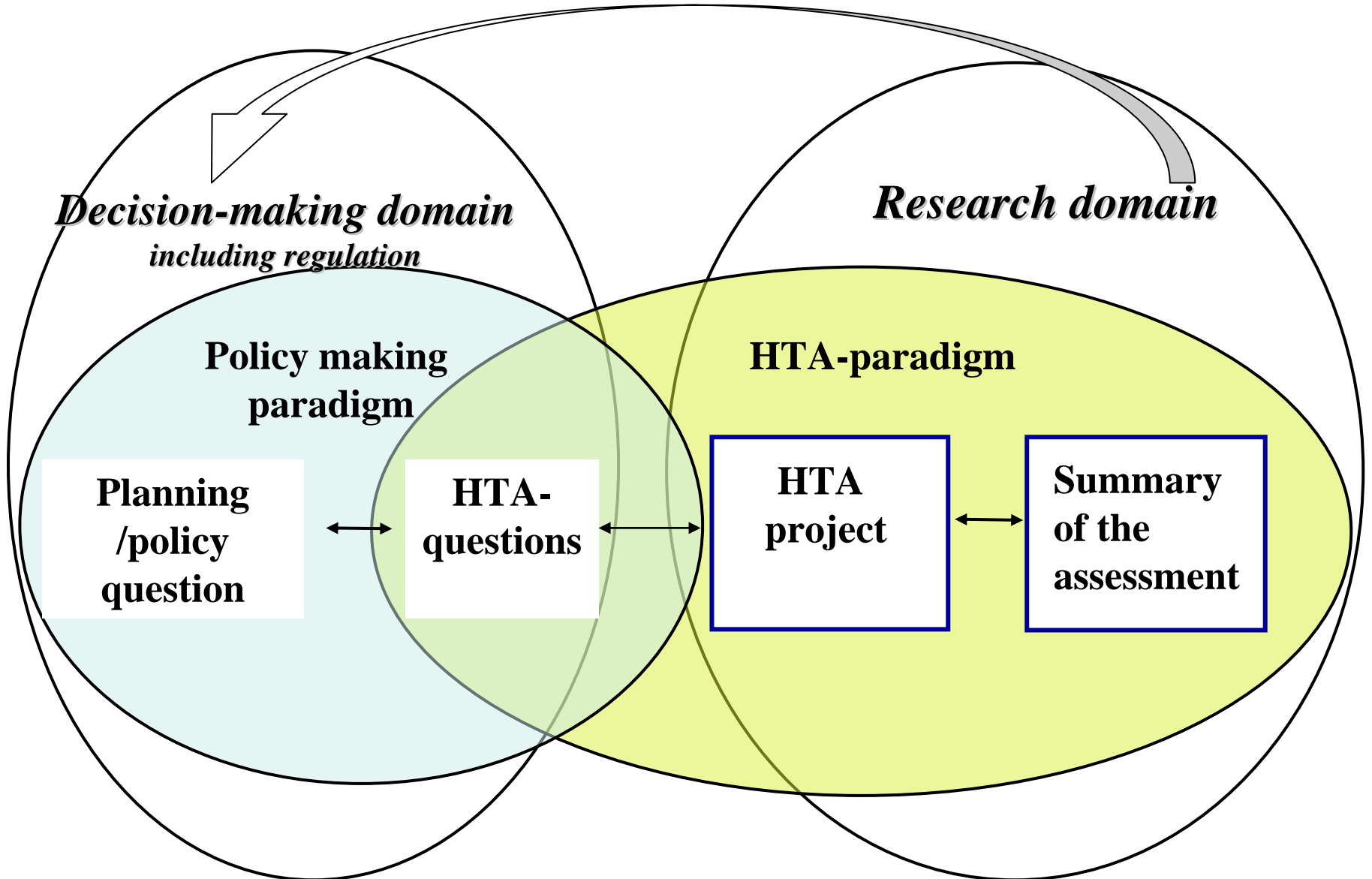
HTA-questions



Synthesis



HTA-report



# Regulation in EU

- Pharmaceuticals
  - Market approval highly formalised
- Medical devices, CE marking
  - Limited to purely technical aspects
- Therapeutic interventions (e.g. surgical procedures, psychiatric therapies)
  - Very limited
- Diagnostics
  - Limited to e.g. X-ray Regulative
-

# Pharmaceuticals

- Market approval (licensing)
  - EMEA
  - National with EU endorsement
  - National

# Pharmaceuticals

- Pricing, reimbursement
  - National
  - Regional
  - Insurance specific

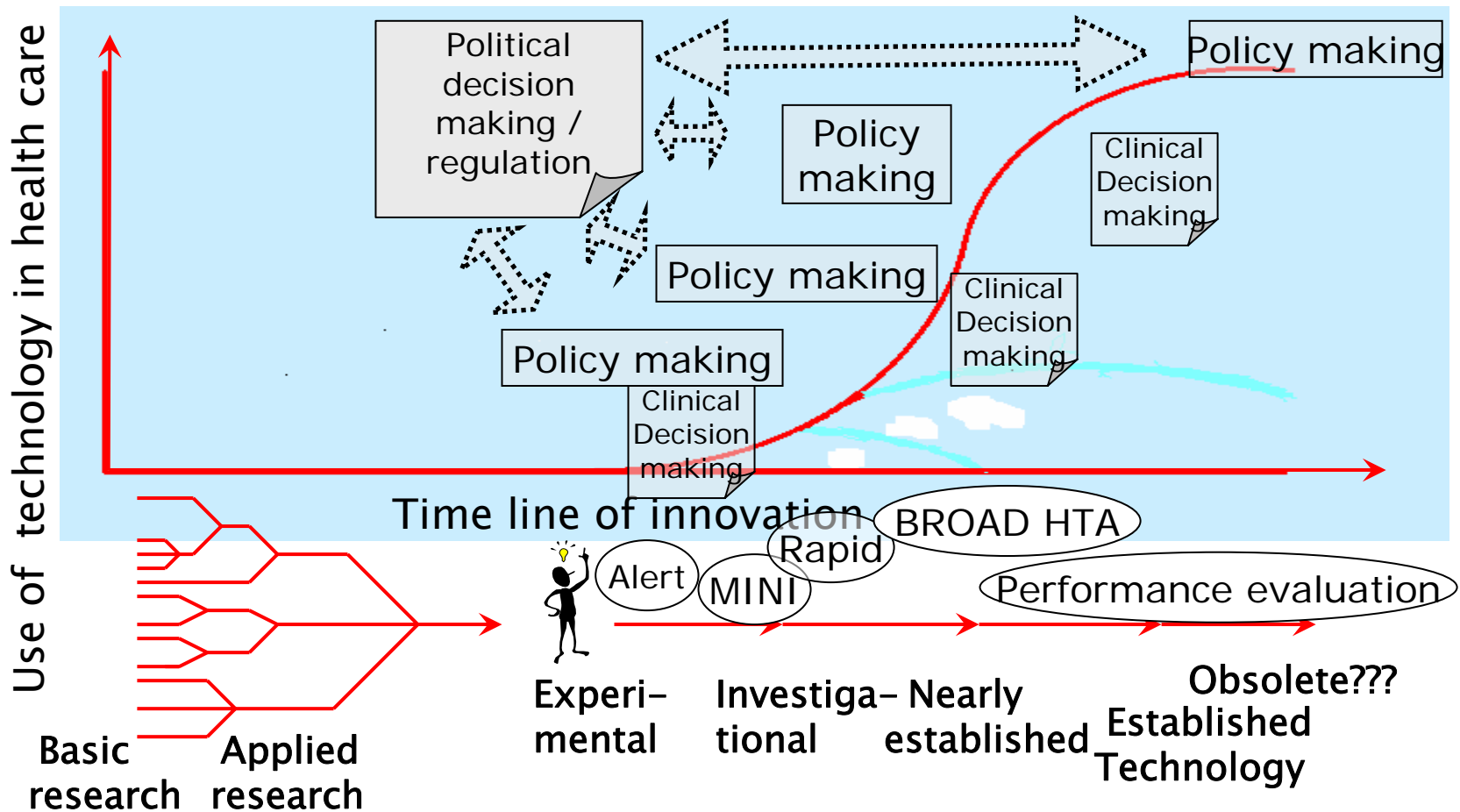
# Pharmaceuticals

- Role of HTA in licensing, pricing, reimbursement
  - according to surveys of EU country authorities in the pharmaceutical field:

negligible

Pharmaceutical Forum, unpulb. 2006  
OEBIG, PPRI 2007

# "Diffusion" of technology, HTA modalities, Policy making and Decision making



# HTA and regulation

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- Transnational HTA collaboration does not interfere with the maintaining of national competence for health care organisation
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November, 2004

Report of the EU Commission's High Level Group on Health Services and Medical Care (HLG) dated November 30<sup>th</sup> concluded:

*"HTA has become a political priority and there is an urgent need for establishing a sustainable European network for HTA".*

# Cox Report 2007

- HTA can play a valuable role in health care decision making, but the process must be transparent, timely, relevant, in-depth and usable
- Assessments need to use robust methods and be supplemented by other important criteria
- By maximising the potential of HTA, decision-makers will be better able to implement decisions that capture the benefits of new technologies, overcome uncertainties, and recognise the value of innovation, all within the constraints of overall health system resources

## Discussion on EU Strategy for Health Services

Informal meeting of EU Health Ministers,  
Aachen, Germany 20th of April 2007

*Health care across Europe: Striving for added value  
(first 5 points only)*

1. Common Values and Principles
2. National and European responsibility - unity in diversity
3. Common challenges
4. Politics first
  - We are determined to maintain the national competence for health care organisation
  - However, our common health care challenges call for a joint effort to identify **viable political solutions**

## Discussion on EU Strategy for Health Services

### 5. Linking Values and policies

In line with the **value of access to good quality care and the principle of patient safety**, we can improve the healthcare quality standards across the different health systems in the EU through the following:

- evidence-based medicine, health technology assessments, cost-benefit-analyses
- --
- --

# HTA must be international

- Avoiding unnecessary duplication
- Using best practice
- Sharing what can be shared
- Adaptation to national / regional setting
- Transfer to policy is a national / regional issue



# **EUnetHTA – The European Network for HTA**

FB Kristensen for European network for HTA, EUnetHTA



# EUnetHTA Partners

- **59 partners**
  - **34 Associated Partners** (national/regional HTA agencies, MoH, research institutions, international organisations (Cochrane Collaboration))
  - **25 Collaborating Partners** (e.g. WHO, OECD, CoE)
- **24 EU countries ( ÷ Slovakia)**
- **2 EEA (Norway, Iceland)**
- **Switzerland**
- **4 institutions in countries outside Europe (Israel, Australia, Canada, USA)**

# EUnetHTA Objectives

## The general objective:

To establish *an effective and sustainable European Network for Health Technology Assessment – EUnetHTA* - that informs policy decisions

## The general *strategic* objective of the Network:

To connect public national HTA agencies, research institutions and health ministries, *enabling*

- *effective exchange of information*
- *support to policy decisions by the Member States*

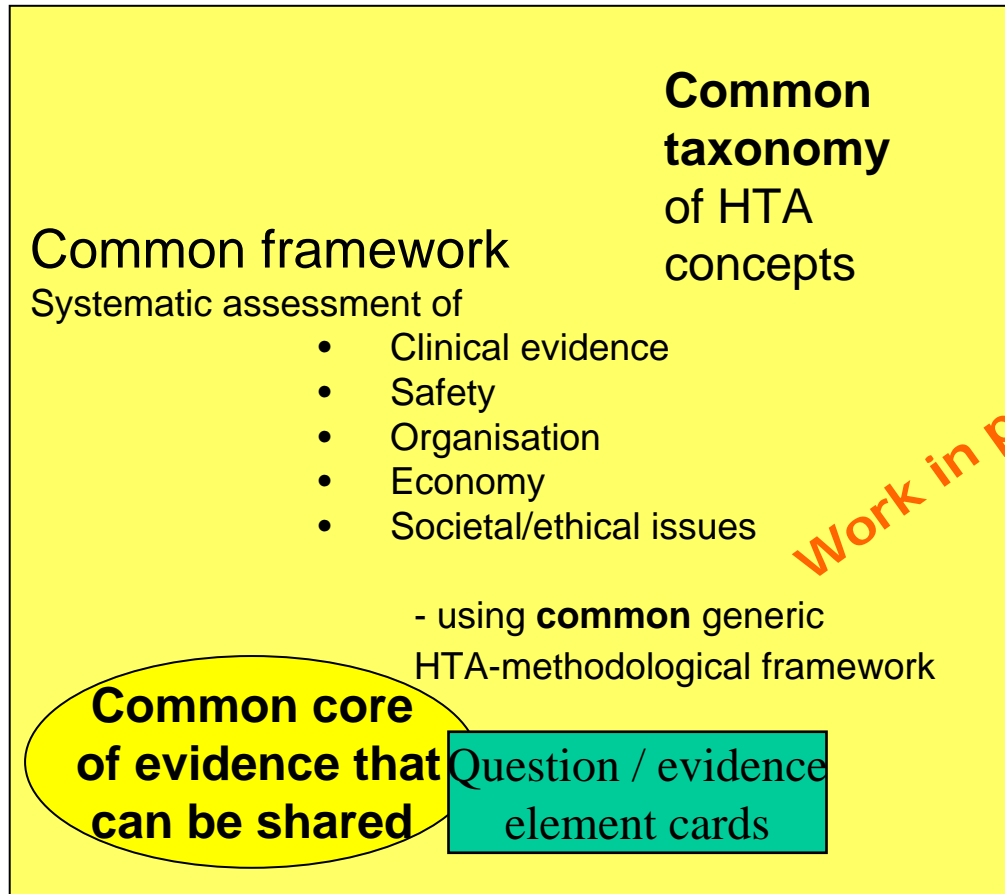
# EUnetHTA Strategic Objectives

- Better coordination of HTA activities
  - Less duplication
  - Increase the HTA output and input to decision-making in the Member States and EU
  - Strengthen the link between HTA and healthcare policy making
  - Support countries with limited experience with HTA
- More effective use of national resources put into HTA

# EUnetHTA Work Packages (WPs)

- WP1: Coordination (*DACEHTA, Main Partner*)
- WP2: Communications (*SBU, DAHTA*)
- WP3: Evaluation (*NOKC*)
  
- **WP4: Common Core HTA (*FinOHTA*)**
- **WP5: Adapting existing and Common Core HTAs to other settings (*NCCHTA*)**
- **WP6: Transferability to policy (*DACEHTA*)**
- **WP7: Monitoring emerging technologies and HTA prioritisation (*HAS*)**
  
- WP8: HTA support system in Member States without institutionalised HTA (*CAHTA*)

# The Common Core of evidence, concepts, and methods

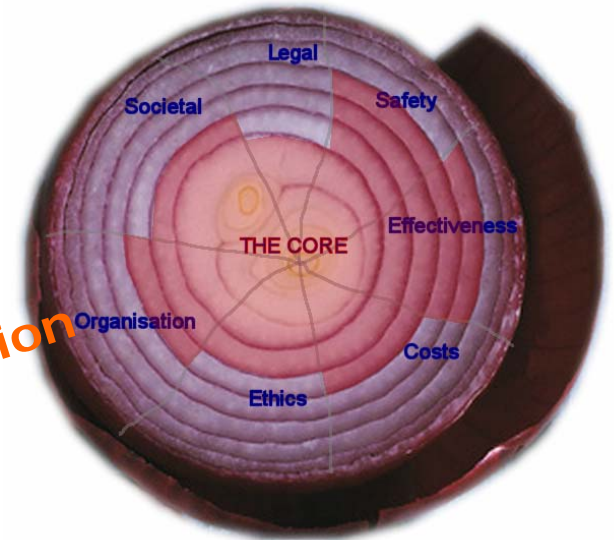
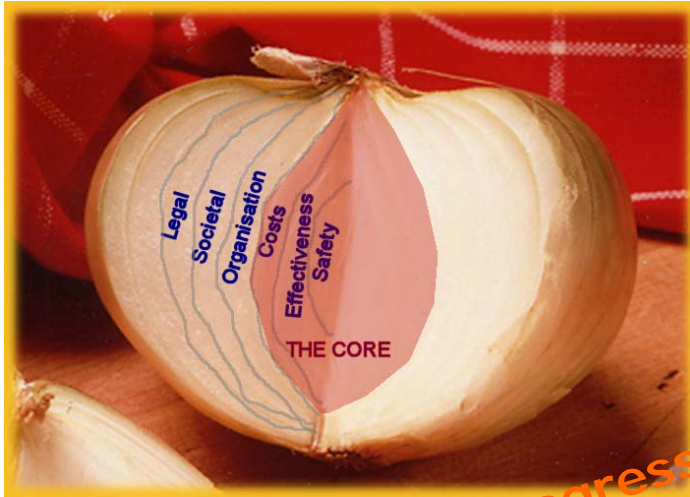


# Domain

*Work in progress, not for citation*

- Current use of the technology (implementation level)
- Description and technical characteristics of technology
- Safety
- Effectiveness
- Costs, economic evaluation
- Ethical aspects
- Organisational aspects
- Social aspects
- Legal aspects

# How does HTA split the onion?



Work in progress, not for citation



(K. Lampe)

# Basic concepts

Work in progress, not for citation

## Assessment elements

- The basic unit of the model is an *element*, i.e. a piece of information that describes the technology or the consequences or implications of its use. In the context of clinical research, an element may describe a clinical outcome (e.g. reduction of symptoms), whereas in social science an element may describe the impact of technology on patient's life (e.g. ability to work)
- The nature of elements may vary across research domains, since the consequences and implications are understood and studied differently in each domain
- The common denominator for all elements is that they provide information that may be useful when deciding on the use or non-use of any given technology

# Basic concepts

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## Domain

A wide framework within which the technology is considered. An angle of viewing the use, consequences and implications of any technology. A standard set of domains is agreed on within the project.

## Topic

A more specific area of consideration within any of the domains. One domain is divided into several topics. Similar topics may be addressed within more than one domain.

## Issue

An even more specific area of consideration within any of the topics. One topic typically consists of several issues, but it may also contain only one issue. *An issue is expressed as a question.* Such questions may be similar to research questions within scientific studies.

# Domain

*Work in progress, not for citation*

- Current use of the technology (implementation level)
- Description and technical characteristics of technology
- Safety
- Effectiveness
- Costs, economic evaluation
- Ethical aspects
- Organisational aspects
- Social aspects
- Legal aspects

# Topic

Work in progress, not for citation

*Examples:*

- Clinical effectiveness
  - Life expectancy
- Current use of technology
  - Regulatory status
- Societal aspects
  - Ability to work
- Societal aspects
  - Economic self-sustainability



# Issue

Work in progress, not for citation

## *Examples:*

- Clinical effectiveness / Life expectancy
  - What is the direct effect of the technology on the mortality of patients?
- Clinical effectiveness / Life expectancy
  - Does the technology affect the expected length of patients' lives in some other (indirect) manner?
- Current use of technology / Regulatory status
  - Has the technology been approved by relevant authorities in the EU?

# Elements are described in further detail in *element cards*

Work in progress, not for citation

The following information is available in each card:

- Element ID
- Domain
- Topic
- Issue
- Clarification
- Importance
- Information sources
- Transferability
- Reference
- Relations
- Status

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