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European Collaboration in Health Technology Assessment

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Setting the Framework



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

HTA definition

HTA is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a **systematic, transparent, unbiased, robust** manner



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HTA aim

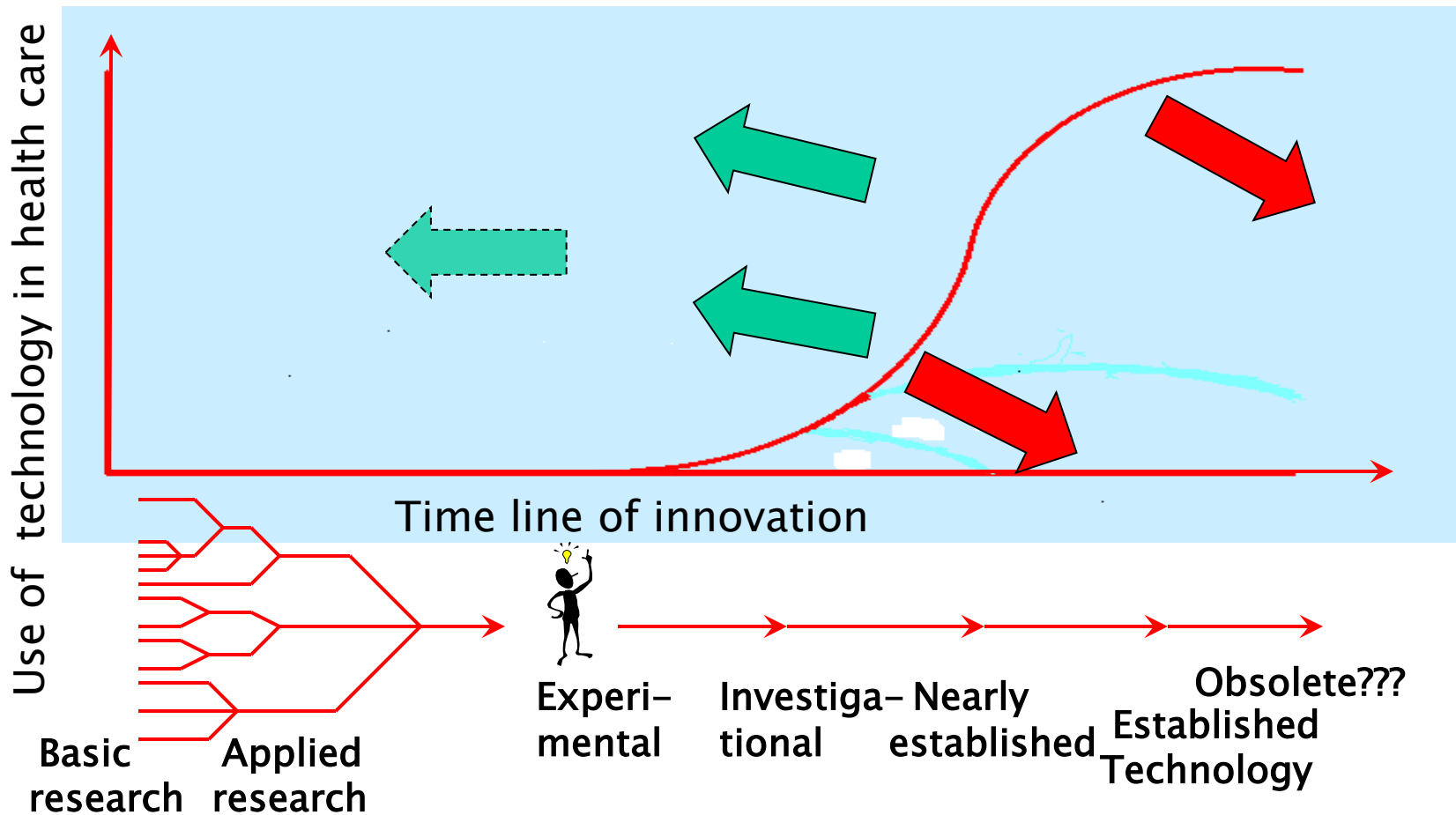
The aim of HTA is to **inform** the formulation of safe, effective, **health policies** that are **patient focused** and seek to achieve **best value**

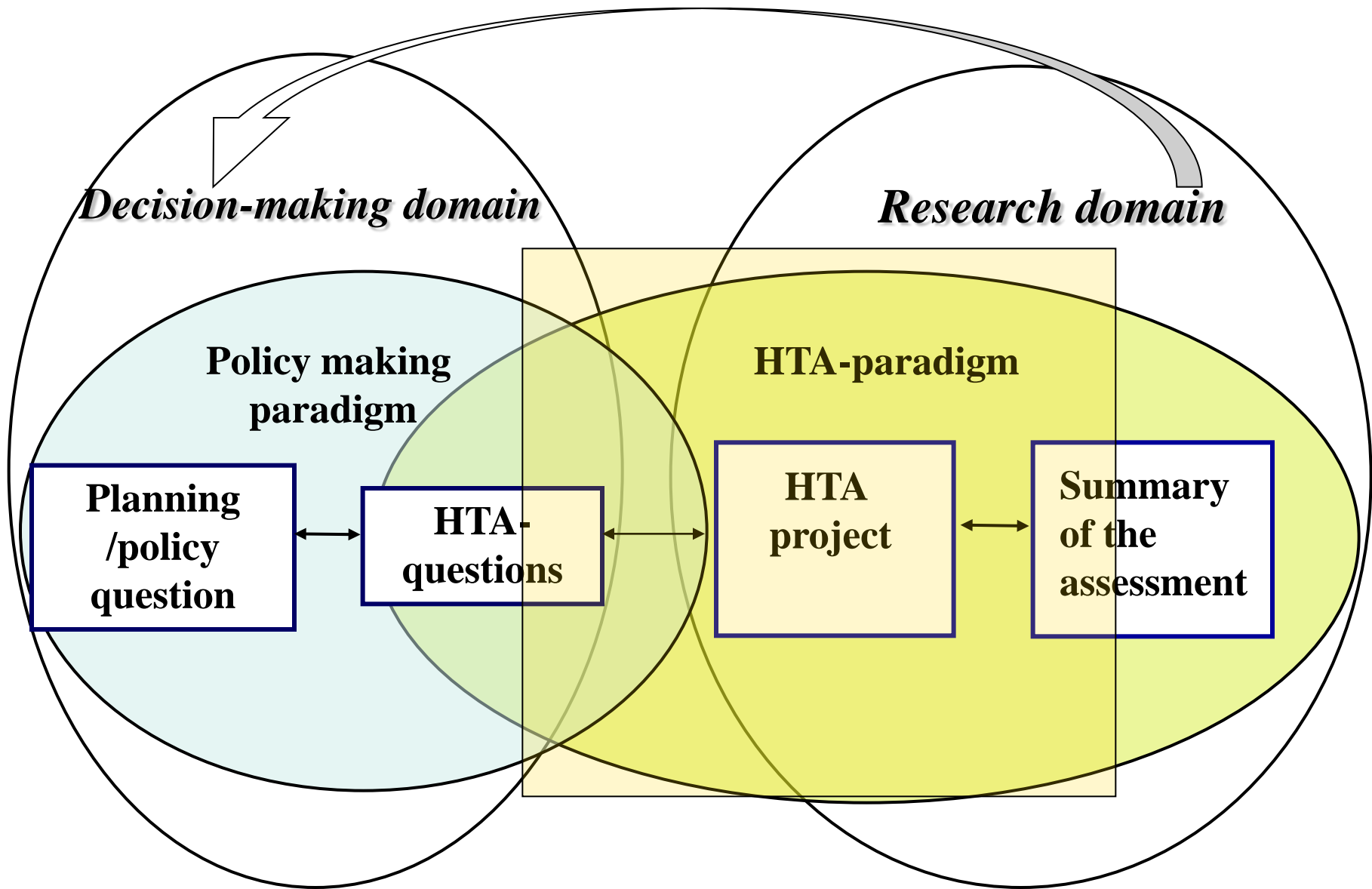
HTA must always be **firmly rooted** in **research** and the **scientific method**



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Acceleration / deceleration of technology "diffusion"







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European network for HTA / EUnetHTA Joint Action between European Commission and EU Member States

A total of 35 government appointed organisations from 24 EU Member States, Norway and Croatia and a large number of regional agencies and non-for-profit organisations that produce or contribute to HTA



The time-line of reaching a sustainable and permanent HTA network in Europe



2005
Call for
project
proposals

2009
Call for
Joint Action

2011
Call for
Joint
Action

2014+
European
network for
HTA



2006-08
EUnetHTA
Project

2009
EUnetHTA
Collaboration

2010 -12
EUnetHTA
JA

2012 -15
EUnetHTA
JA 2

Legal basis:
Cross Border
Healthcare
Directive



2008 - 11
Draft Cross Border
Healthcare Directive
Article on HTA network

2011
CBHC
Directive
now
decided

2011 - 13
CBHC Directive
Expert Group
for
HTA network
implementation

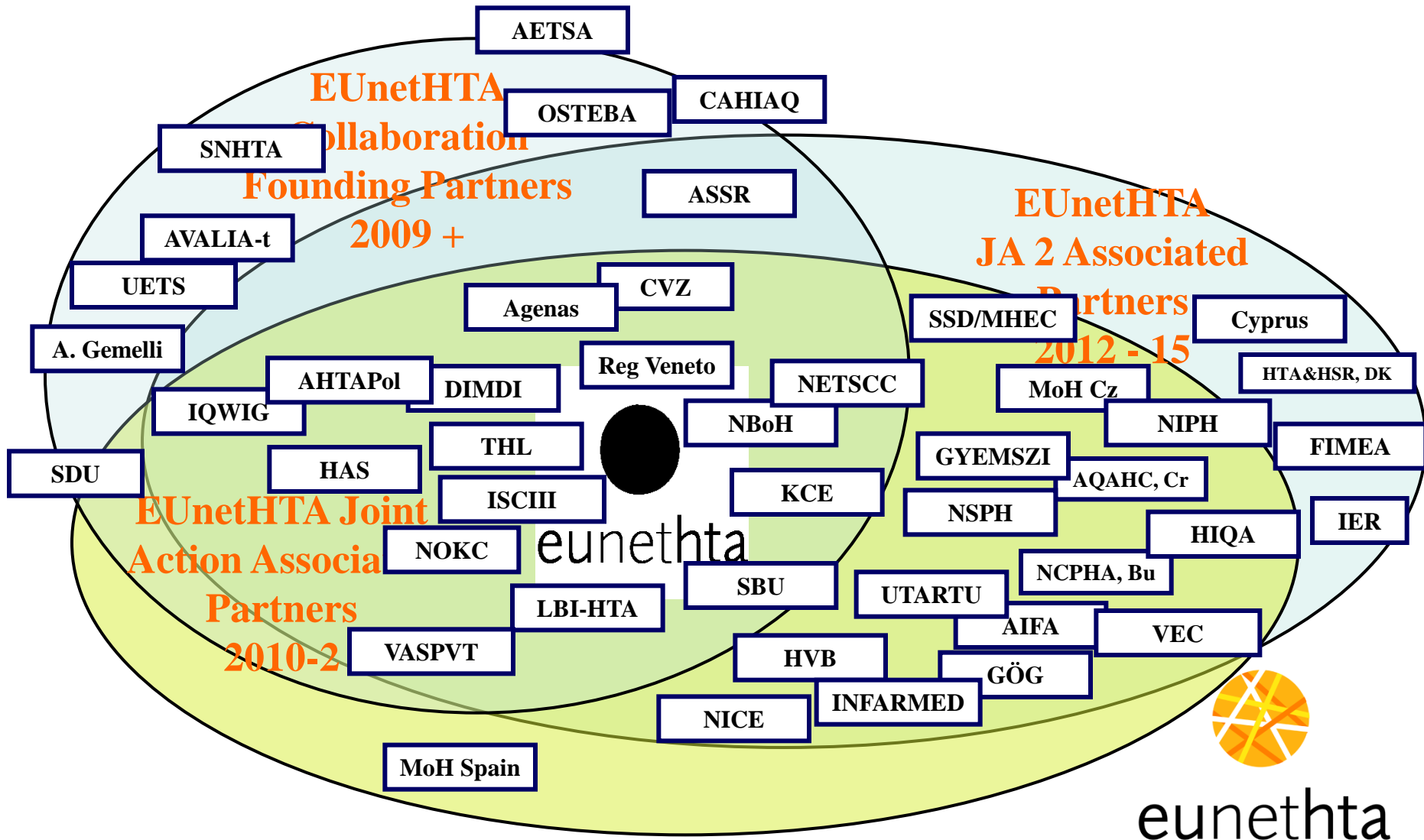
Financial
support:
1) EU Budget
2) Member
States



2011 FP7-Health
2012-Innovation-1
New methodologies
for HTA



A Diagram to illustrate the distribution of Partners on EUnetHTA Collaboration Founding Partners, EUnetHTA Joint Action Partners and EUnetHTA Joint Action 2 Partners



EUnetHTA Joint Action 2010-12

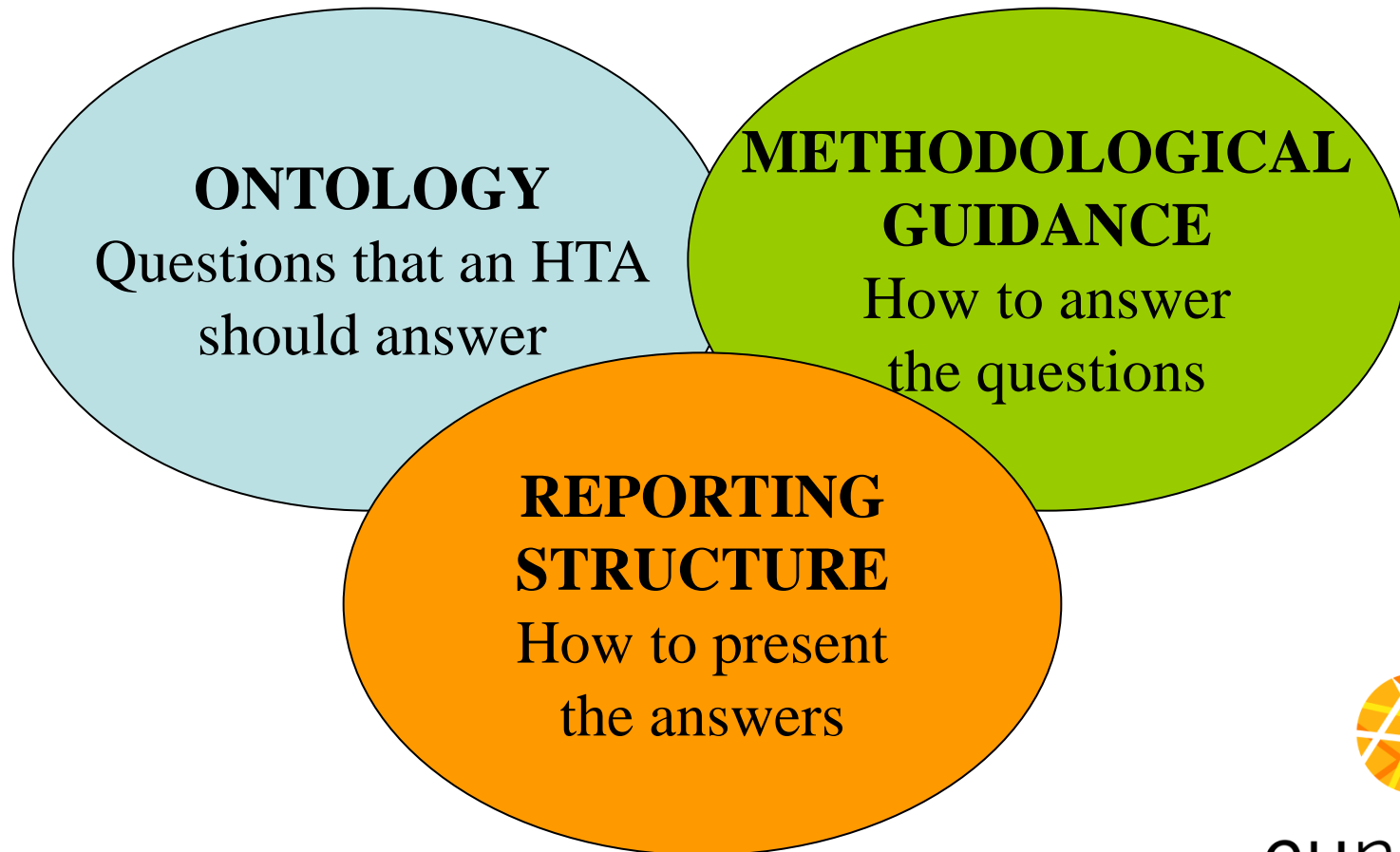
Focus on HTA in Europe to

- facilitate efficient use of resources available for HTA,
- create a sustainable system of HTA knowledge sharing, and
- promote good practice in HTA methods and processes



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The HTA Core Model



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Domains of the HTA Core Model

1. Health problem and current use of technology
2. Description and technical characteristics
3. Safety
4. Clinical effectiveness
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Social aspects
9. Legal aspects



Project phases

[Project home](#)

1 [Project definition](#)

2 [Protocol design](#)

3 Research

4 Results

5 Review and publishing

C. Safety

Think of each element: is this issue relevant in the context of *Ultrasound screening*? Be practical, do not try to find "artificial" relevance, but do not reject issues too easily as irrelevant either. Comment on the elements you regard as irrelevant: why do you think this element is irrelevant? Your comments are included in the Core HTA and are likely to be useful for those who are not experts on the topic.

[Show only incomplete elements](#)

Patient safety

C0001: What kind of harms can use of the technology cause to the patient and what is the incidence, severity and duration of harms?

- Relevant
- Irrelevant
- Consider later

C0002: What is the dose relatedness of the harms to patients? [Clarify...](#)

- Relevant
- Irrelevant
- Consider later

Notes (optional)

Domain: Social aspects (1)

Which social areas does the use of the technology influence?

Map the major life areas of the patient and the important others (family life, day care, school, work, leisure time, lifestyle, or other daily activities), where the technology is going to be used or where its use may have a direct or indirect influence.



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Domain: Social aspects (2)

What kinds of changes does the use of the technology generate in the patient's role in the major life areas?

This issue is about the patient's social roles and ability to manage and maintain relations with other people in a socially appropriate manner in major life areas.



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Domain: Social aspects (3)

What kind of changes does the implementation and use of the technology mean for the patient's physical and psychological functioning in his or her major life areas?

This issue is about the physical and psychological consequences the use of the technology may generate in the patient's main life areas e.g. on person's body functions and structures, activities on daily living, or performance at work, school, home or leisure time.

The issue covers whether, from a patient perspective, the technology leads to improvements or harms (a cross reference to effectiveness, safety domain issues), or generates any other unexpected effects on functioning.



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WP5: Development of (rapid) REA model for assessing Pharmaceuticals including pilot

HTA Core Model	WP5	
	Full Model	Rapid Model
Health problem and current use of technology	Health problem and current use of technology	Health problem and current use of technology
Description and technical characteristics of the technology	Description and technical characteristics of the technology	Description and technical characteristics of the technology
Safety	Safety	Safety
Effectiveness	Effectiveness	Effectiveness
Cost and economic considerations	Cost and economic considerations	Cost and economic considerations
Ethical analysis	Ethical analysis	Ethical analysis
Organisational analysis	Organisational analysis	Organisational analysis
Social aspects	Social aspects	Social aspects
Legal aspects	Legal aspects	Legal aspects
	<ul style="list-style-type: none"> •Multiple comparators •Years after market authorisation •Indication based 	<ul style="list-style-type: none"> •Limited number of comparators •Soon after market authorisation



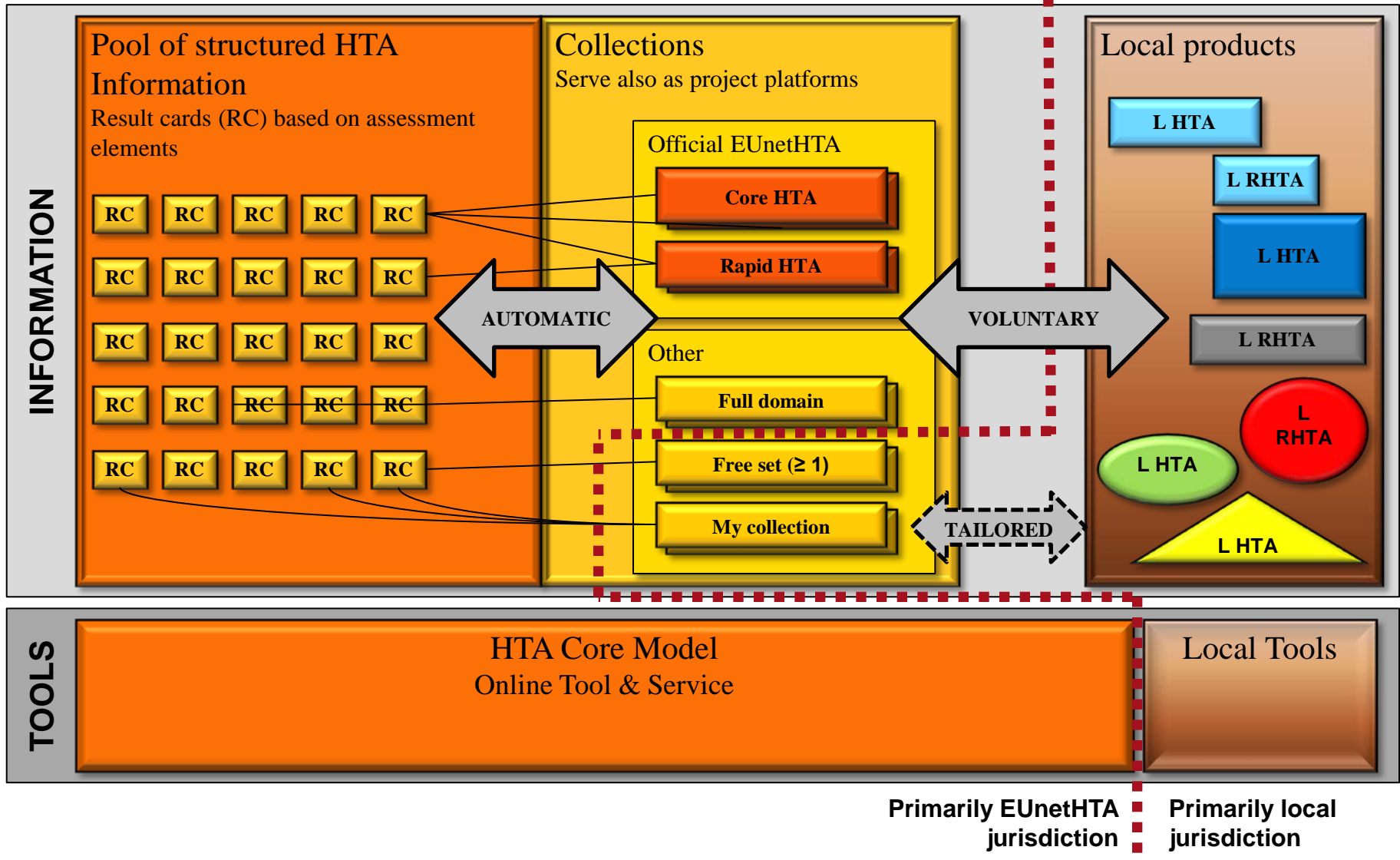
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Core HTA Structure 2012 currently being piloted

– DRAFT WORK IN PROGRESS

Primarily EUnetHTA
jurisdiction

Primarily local
jurisdiction



EUnetHTA Joint Action 2 (2012-15)

- Proposal submitted May 23, 2011
- Official title - "EUnetHTA JA2"
- 37 APs from 26 MS, Norway, Croatia
- 15 CPs (currently)
- Programme Committee approval for granting September 28, 2011
- **Contract signed April 2012**
- JA2 timing: October 2012 – end of 2015
- Budget € 9.428.550



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JA2 General Objective

- To strengthen the practical application of tools and approaches to cross-border HTA collaboration
- Achieving a better understanding for the Commission and Member States of ways to establish a sustainable structure for HTA work in the EU
- Producing recommendations regarding the design and management of the future EU HTA cooperation



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JA2 Specific Objectives 1

Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context

Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function



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JA2 Specific Objectives 2

Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders

Develop and test a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues and quality improvement of evidence generation for HTA



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Stakeholder involvement

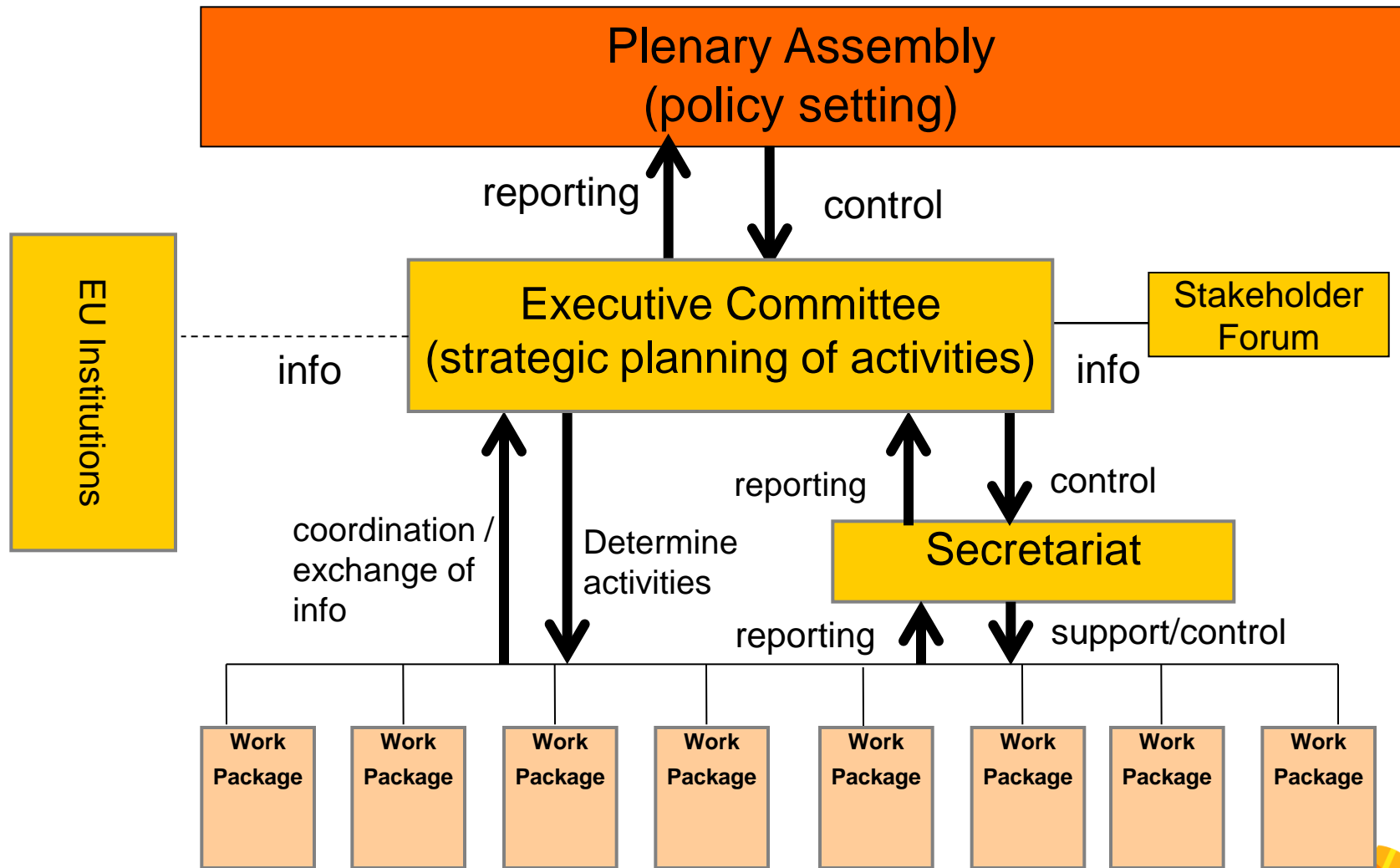


Stakeholder involvement

- Stakeholder Forum
- SAGs and other forms of interaction
- Stakeholder relations in a permanent network



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