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Current work of EUnetHTA Joint Action 1 and planned work for Joint Action 2

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Methodological Guidance for the Life Sciences Industry





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European network for HTA 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

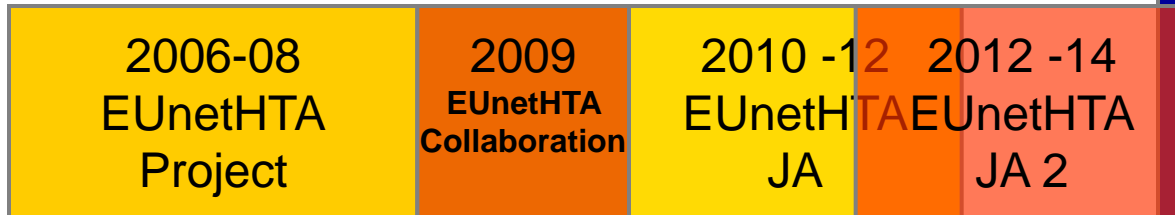


2005
Call for project proposals

2009
Call for Joint Action

2011
Call for Joint Action

2015+
European network for HTA



Legal basis:
Cross Border Healthcare Directive



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

2011
CBHC Directive now decided

2011 +
CBHC Directive Expert Group for HTA network implementation

Financial support:
1) EU Budget
2) Member States



FP7-HEALTH-2007-B - Health Services Research

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



EUnetHTA JA main objective

To put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level



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EUnetHTA Joint Action 2010-12

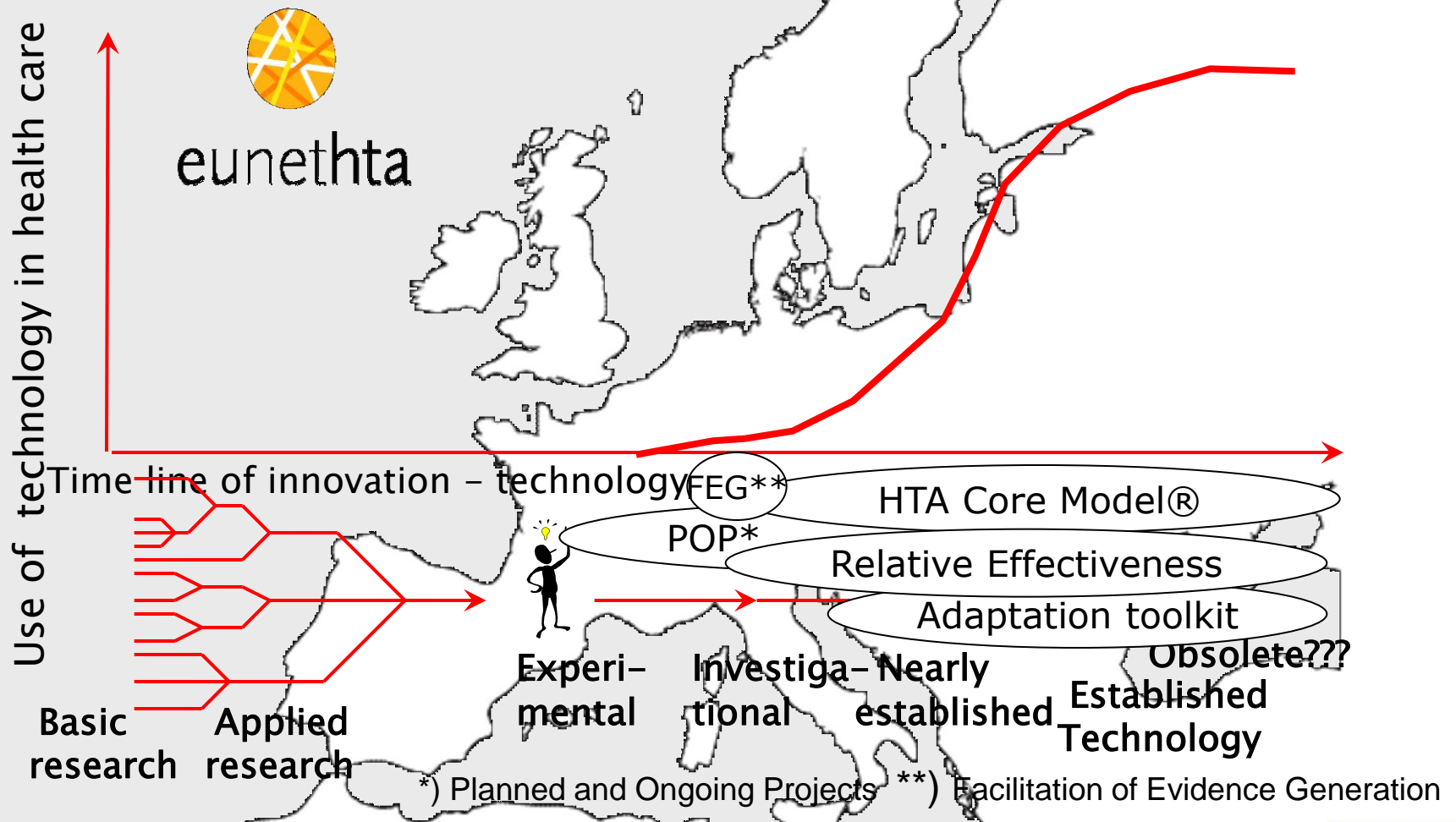
Focus on HTA in Europe to

- 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
- Budget: € 5.959.525
- Work progresses according to plans, a few delays will be caught up



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EUnetHTA tools and life cycle of technologies



Orientation on the EUnetHTA JA2 proposal (2012-15)

- Proposal submitted May 23, 2011
- Official title - "EUnetHTA JA2"
- 37 APs from 26 MS, Norway, Croatia
- 15 CPs (currently)
- Proposed JA2 timing: October 2012-
Sept 2015
- Budget € 9.428.550



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Objectives of the EUnetHTA JA2

General Objective

The general objective of this complimentary Joint Action on Health Technology Assessment (JA2) is to strengthen the practical application of tools and approaches to cross-border HTA collaboration. The JA2 aims at bringing collaboration to a higher level resulting in better understanding for the Commission and Member States (MS) of the ways to establish a sustainable structure for HTA in the EU.

Specifically, the JA2 will develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the Directive for cross-border healthcare.



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EUnetHTA JA2 WP 7 Specific objectives

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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EUnetHTA JA2 WP 7 Specific objectives

Develop

- methodological guidelines on pertinent issues of assessment (e.g. for devices) or update existing guidelines according to needs and resources
- guidelines for improving evidence generation in early dialog with manufacturers
- a uniform data template for submissions enabling sound, common rapid assessments and national adaptation



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Work in JA 2 WP 7

- Tools (guidelines and templates) will be developed on the basis of the HTA Core Model to facilitate and help standardizing technology developers' data files for submissions of dossiers for rapid HTAs (standardizing the presentation of data, completeness of submitted data)



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Work in JA 2 WP 7

- New developments to improve the robustness and efficiency of HTA comprise actions and measures to support and guide the generation of higher quality and more appropriate evidence for initial assessment “upstream” in the technology “pipeline” where innovations undergo research and development before introduction to healthcare practice



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JA 2 WP 7 Deliverable 8

Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation



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Deliverable 8

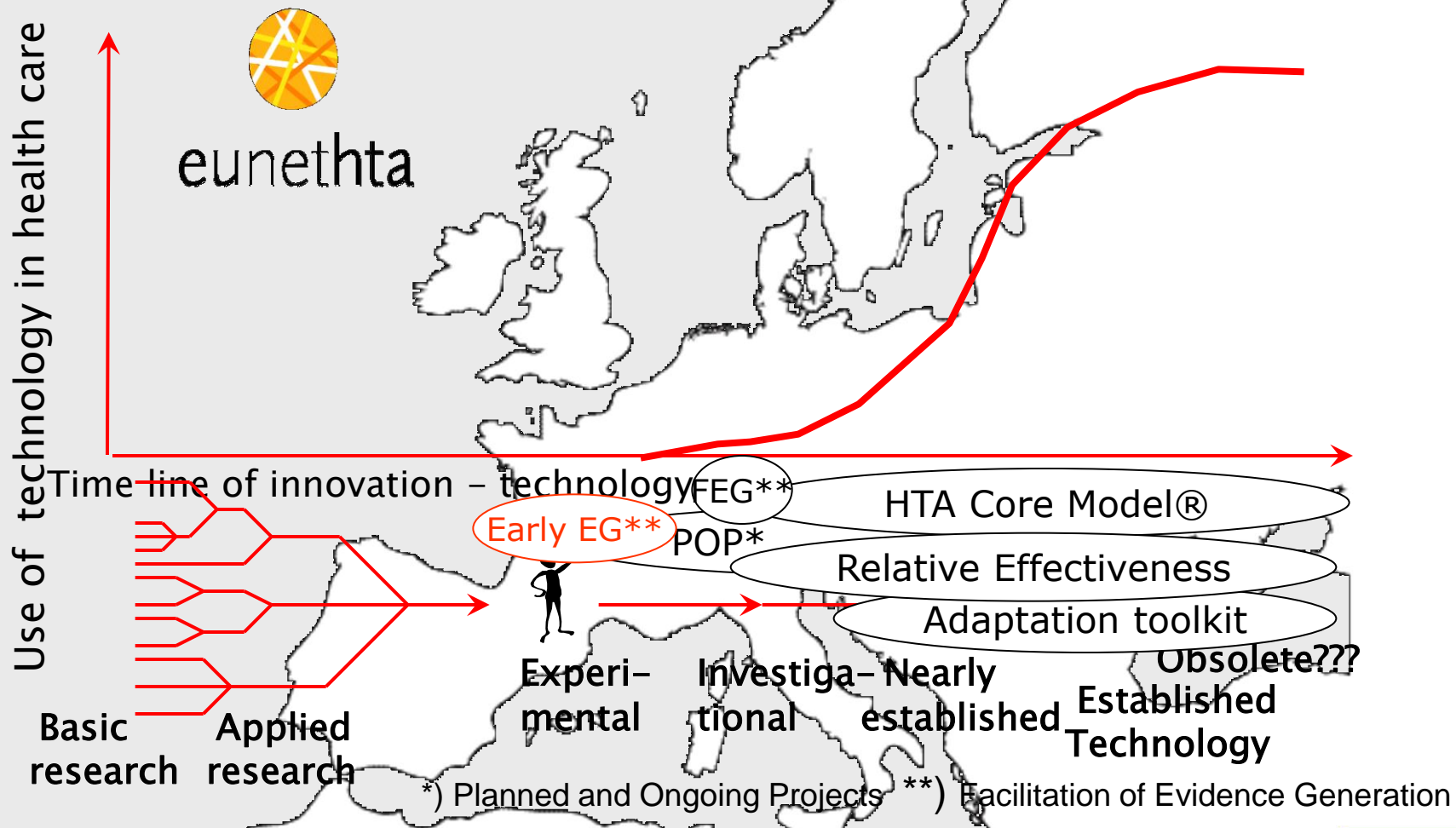
Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation

- (i) Early dialogue:
 - (a) **overview**
 - (b) **piloting**
- (ii) Additional evidence generation:
 - (a) **questions for additional data collection**
 - (b) **guidelines on appropriate study design**
 - (c) **pilot common protocol for collection of additional data for a technology of interest**



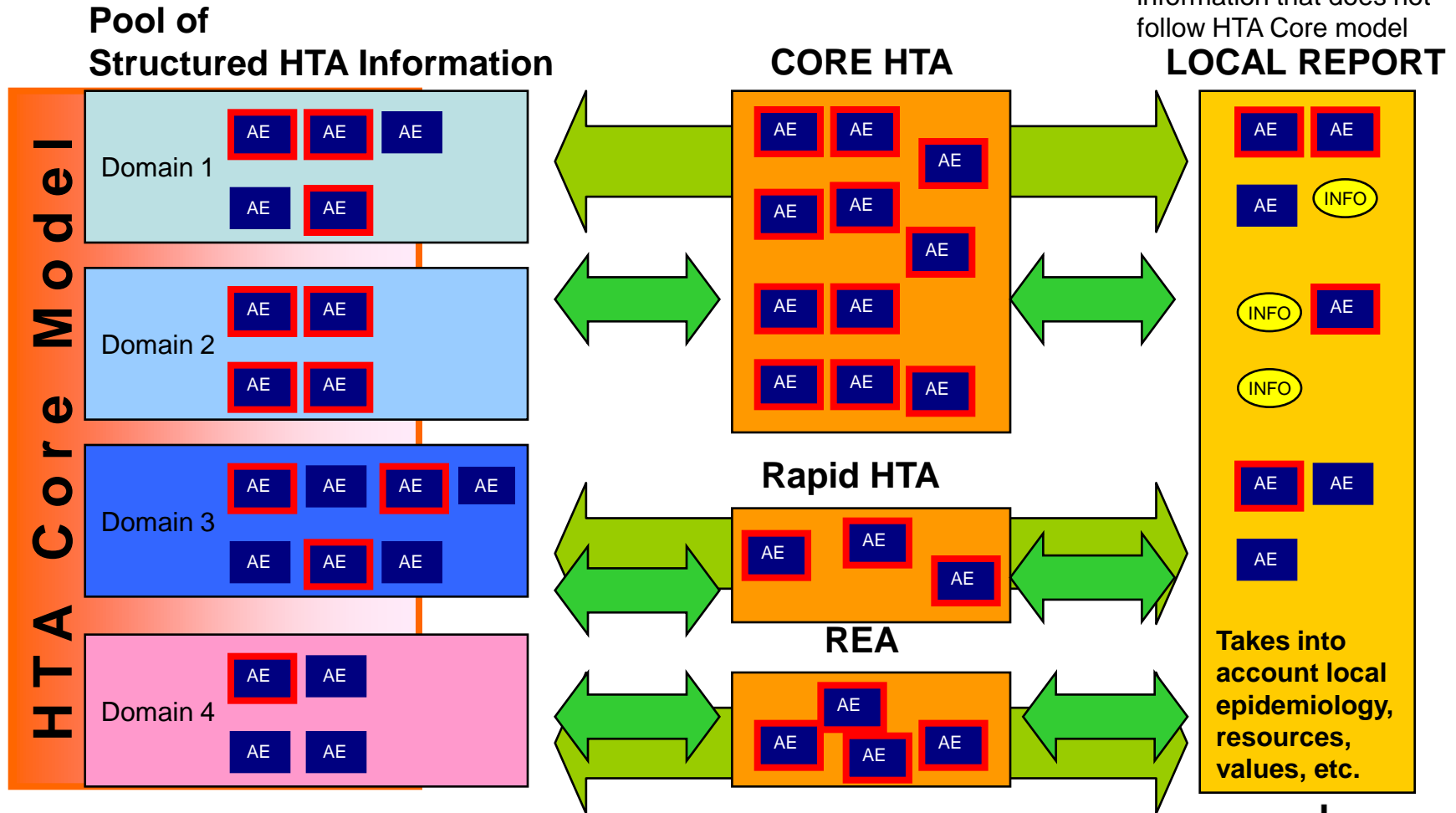
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EUnetHTA tools and life cycle of technologies



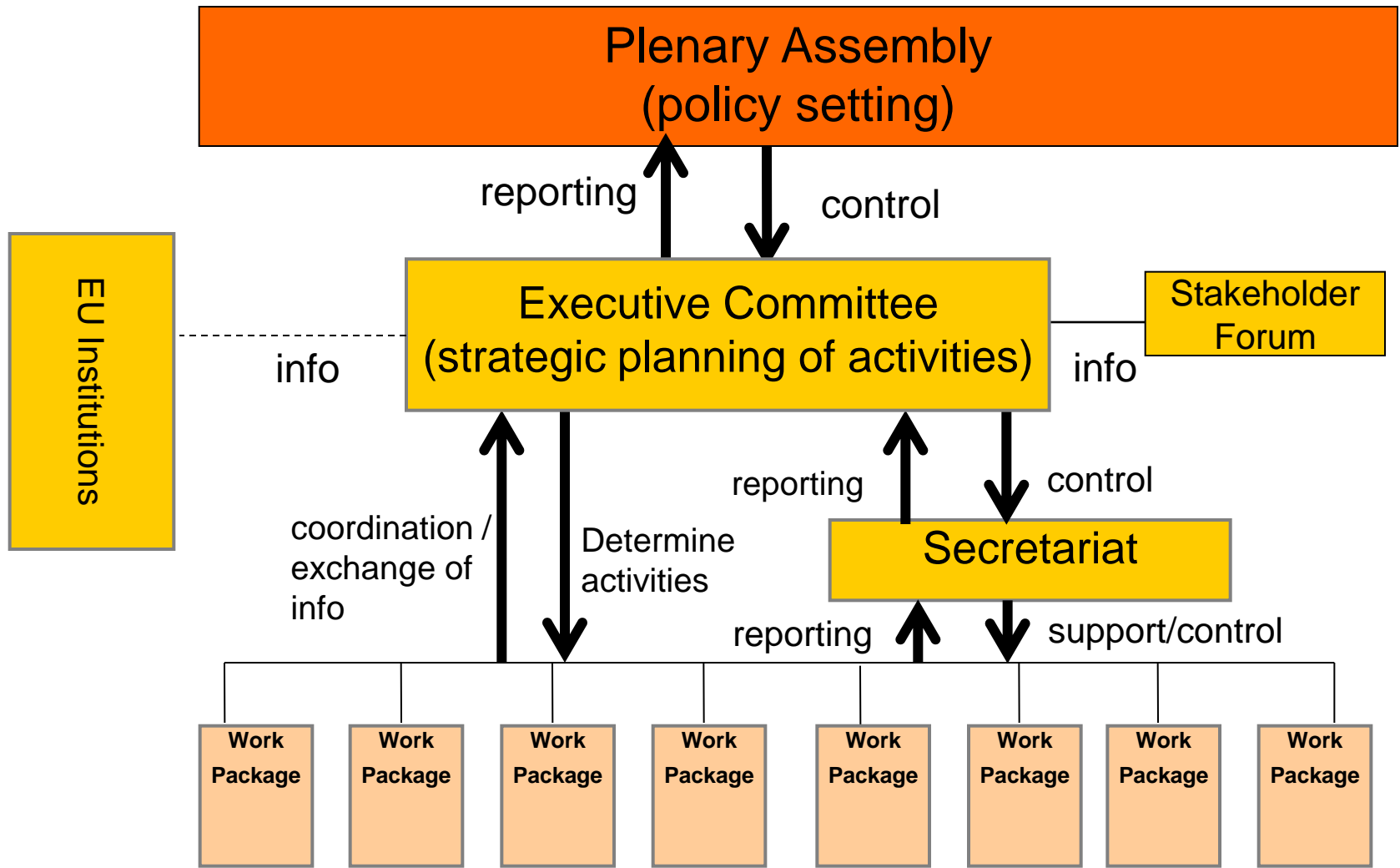
HTA Core Model® and its application

- AE = Assessment element
- AE = Core element
- AE = Non-core element
- INFO = Locally produced information that does not follow HTA Core model



Takes into account local epidemiology, resources, values, etc.

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EUnetHTA Conference 2011



<http://www.eunetha2011.pl/>



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