



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



European Network of Centres  
for Pharmacoepidemiology and Pharmacovigilance

# Health Technology Assessment (HTA) & integration in Pharmacoepidemiology

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Pharmacovigilance & Risk Management

*ENCePP Plenary, London, 03.05.2012*

An agency of the European Union





# What is HTA?

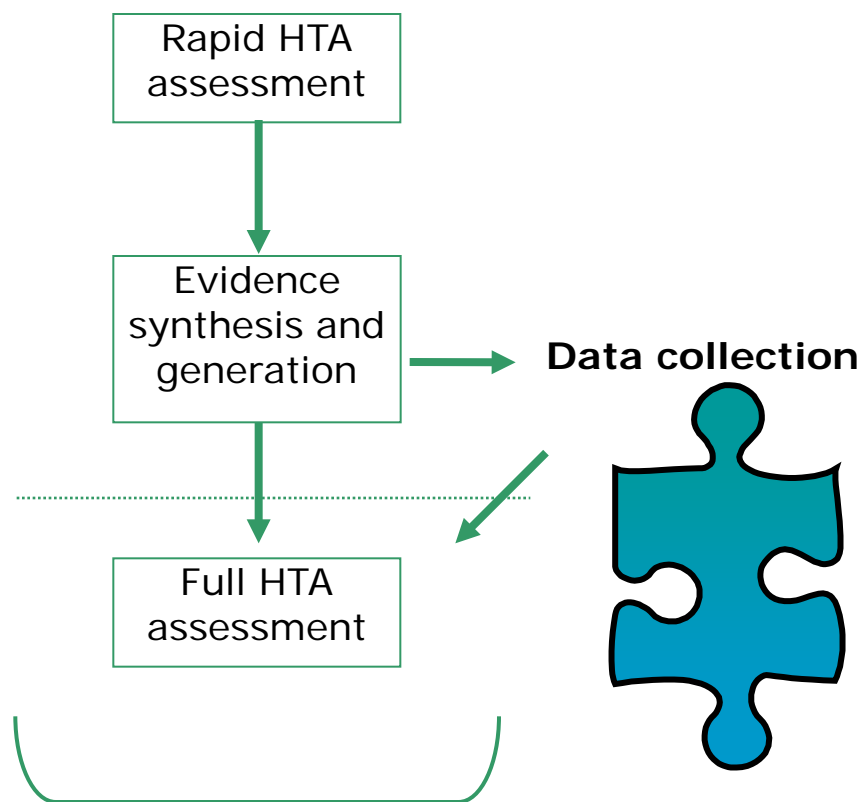
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- **HTA** is a field of scientific research to inform policy and clinical decision-making around the introduction and diffusion of health technologies.
- **Health technologies** include pharmaceuticals, devices, diagnostics and treatments, and other clinical, public health, and organizational interventions.
- HTA is a **multidisciplinary** field that addresses the health impacts of technology, considering its specific healthcare context as well as available alternatives. Contextual factors addressed by HTA include economic, organizational, social, and ethical impacts. The scope and **methods** of HTA may be adapted to respond to the policy needs of a particular health system.
- In health systems throughout the world, HTA plays an essential role in supporting **decision-making** about access to technology, its diffusion, and innovation.

Source: <http://www.htai.org>



# The HTA process



Health Technology Agencies



## Agencies for HTA in Europe (i)

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- **Regional**
- **National**

Source: <http://www.inahta.net/>

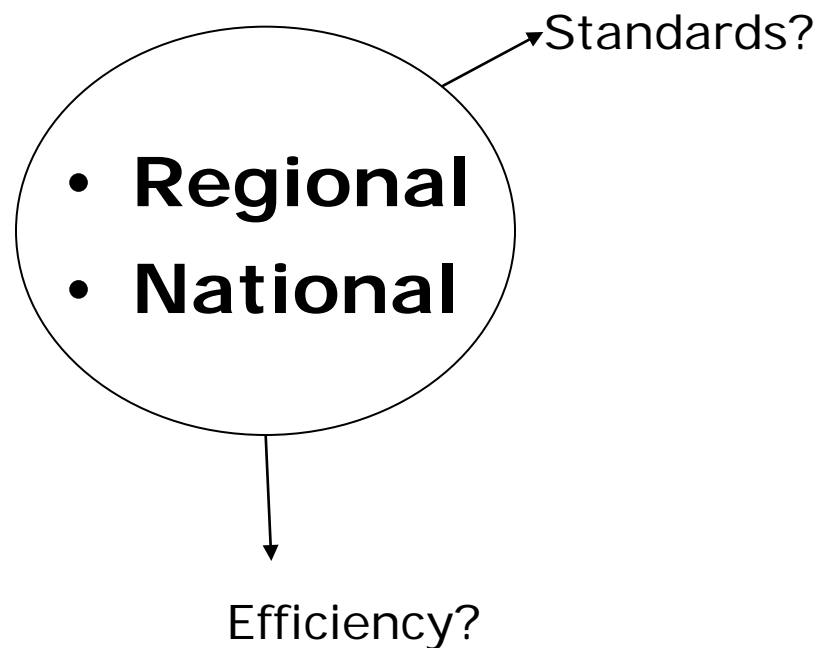


## Agencies for HTA in Europe (ii)

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Source: <http://www.inahta.net/>





## Agencies for HTA in Europe (iii)

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- Regional
- National
- **International**

Source: <http://www.inahta.net/>



# Agencies for HTA in Europe (iv)

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**EUnetHTA Joint Action – new phase in EUnetHTA development**



Focusing on scientific cooperation in **HTA** in Europe, thirty four government appointed organisations from the EU Member States, Accession Countries and EEA work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries.

The EUnetHTA Joint Action builds on the achievements of a number of the previous European initiatives including the **EUnetHTA Project (2006-2008)** and the **Pharmaceutical Forum** (on relative effectiveness).

[Read more](#) 


The EUnetHTA JA (2010-2012) has received funding from the European Union, in the framework of the Health Programme.

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## EUnetHTA tools

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Developed within the EUnetHTA context and available for EUnetHTA partners.

- [EUnetHTA Planned and Ongoing Projects \(POP\) Database](#)
- [HTA Core Model®](#)
- [EUnetHTA News aggregator](#)
- [EVIDENT](#)





## EUnetHTA's EVIDENT Database

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The Evidence database on new technologies (EVIDENT Database) allows to share information on promising health technologies: remaining evidence gaps, recommendation or request for further research, and additional data collection in development.



# Domains of EUnetHTA's HTA Core Model

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The HTA Core Model employs a multidisciplinary view of HTA. Any technology that is being assessed is considered through domains, each of which provides a wide framework for the analysis:

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



# Framework for ENCePP and EUnetHTA collaboration

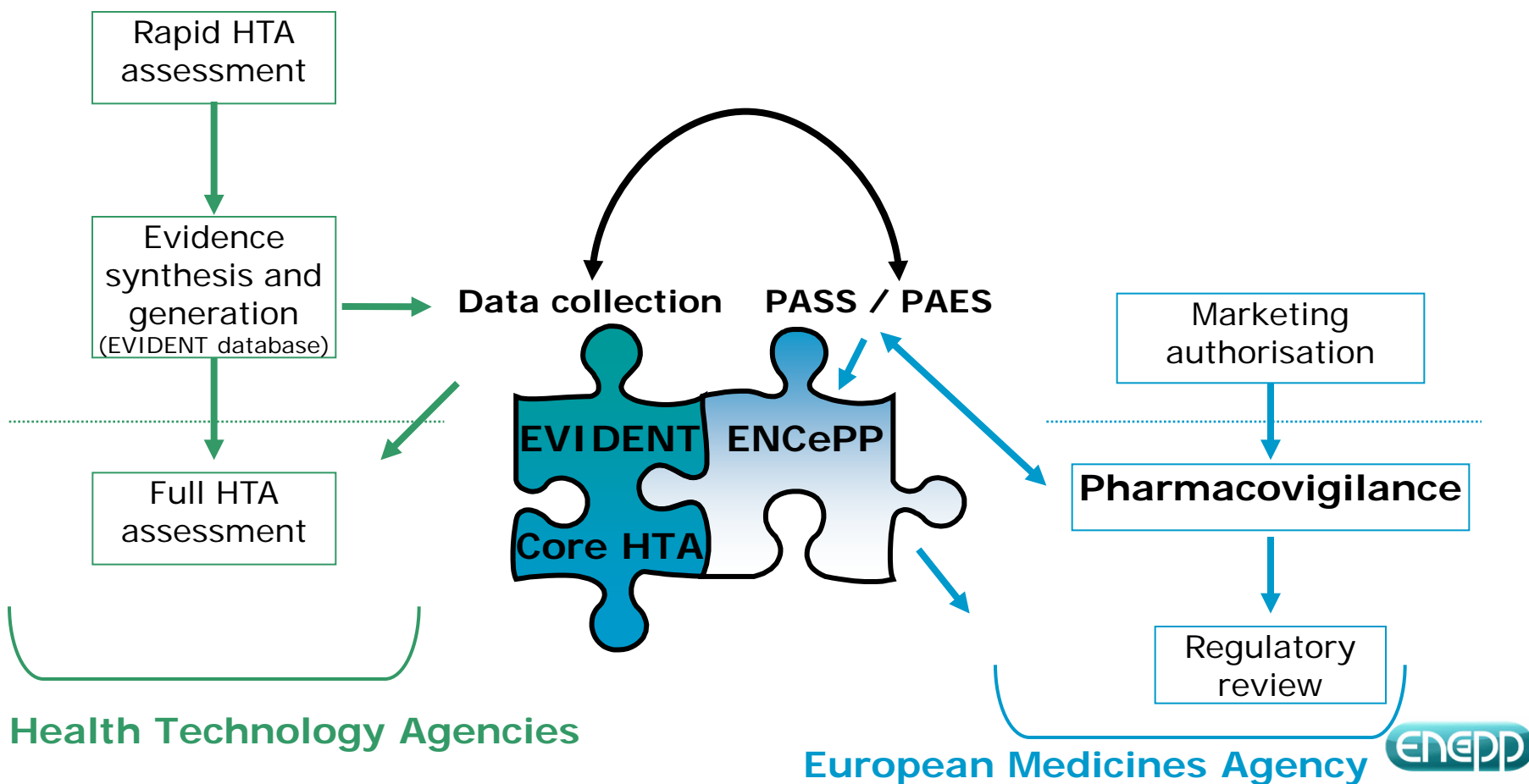
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## **EUnetHTA Joint Action (JA) 2010-12**

- JA WP7 - New Technologies:
  - Deliverable 4: Operational web-based toolkit including database containing information on evidence generation on new technologies (EVIDENT)
- JA WP4 - Core HTA
  - “Safety” domain definition, and practical application



# Bridging the gap





# Four opportunities for collaboration

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## 1. EPAR project

## 2. Continue collaboration between ENCePP studies database and EUnetHTA WP7 EVIDENT (focus in 2012):

- Linking the databases
- Common searches

## 3. WP4 - Core HTA

“Safety” domain definition, and practical application. An HTA to include an assessment of the adverse events resulting from the use of a health technology both to benefit individual patients and to inform policy makers. Definitions and terminology of safety used in HTA may need standardisation. Access to ADR data.

## 4. Relative effectiveness



# Relative effectiveness

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# Opportunities for collaboration & ENCePP

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- Methodological considerations at interface of pharmacoepidemiology and HTA
- Research access to insurance / healthcare delivery data
- ENCePP as service provider to HTA



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***“I look forward to hearing your proposals for what you can contribute to the regulation-HTA bridge”***

Guido Rasi

*ENCePP Plenary Nov 2011*





## Proposed actions

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- Establish an ENCePP **HTA Task-Force** to explore opportunities for collaboration
  - Please send your **expressions of interest** to take part on this initiative to the Secretariat by the **18th of May**
- Launch of an ENCePP **HTA Survey** aimed at collecting information on the experience the centres might have on this matter
  - To be sent to you in the coming days