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Outline

- The Making of EUnetHTA
- EUnetHTA and the HTA Network
- EUnetHTA Achievements and Tools
General Information about HTA
Definition of Health Technology

Health technology is the application of scientific knowledge in health care and prevention

Examples of Health Technology
- Diagnostic and treatment methods
- Medical equipment
- Pharmaceuticals
- Rehabilitation and prevention methods
- Organisational and support systems within which health care is provided
Definition of HTA

- Health technology assessment (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.

- Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.

- Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.
The Development of EUnetHTA
The timeline of reaching a sustainable and permanent HTA network in Europe

<table>
<thead>
<tr>
<th>Health Programme</th>
<th>Legislation</th>
<th>DG R&amp;I</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2005</strong> Call for project proposals</td>
<td><strong>2006-2008</strong> EUnetHTA Project</td>
<td><strong>2011-2013</strong> Draft Cross Border Healthcare Directive. Article on HTA network</td>
</tr>
<tr>
<td><strong>2009</strong> Call for joint action</td>
<td><strong>2009</strong> EUnetHTA Collaboration</td>
<td><strong>2011</strong> HTA Network Implementing Decision</td>
</tr>
<tr>
<td><strong>2011</strong> Call for joint action</td>
<td><strong>2010-2012</strong> EUnetHTA JA</td>
<td><strong>2013</strong> CBHC Directive now decided</td>
</tr>
<tr>
<td><strong>2012-2015</strong> EUnetHTA JA2</td>
<td><strong>2013+</strong> HTA Network</td>
<td><strong>2011</strong> FP7-Health</td>
</tr>
<tr>
<td><strong>2015-2020</strong> EUnetHTA Collaboration</td>
<td></td>
<td><strong>2012-Innovation-1</strong></td>
</tr>
<tr>
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<td></td>
<td><strong>New methodologies for HTA</strong></td>
</tr>
<tr>
<td></td>
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<td><strong>Horizon 2020 Calls Health Care</strong></td>
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</tbody>
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EUnetHTA Project (2006-2008)

Objectives

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

- To reduce overlap and duplication of effort and hence promote more effective use of resources
- To increase HTA input to decision-making in Member States and the EU and hence to increase the impact of HTA
- To strengthen the link between HTA and health care policy making in the EU and its Member States
- To support countries with limited experience with HTA

Total budget: € 3,233,858.10
EUnetHTA Project (2006-2008) Deliverables

- A generic methodological HTA framework based on current best practices (HTA Core Model®)
- Handbook on Core HTA development
- HTA Adaptation toolkit – from existing HTAs into other contexts
- An open EUnetHTA Stakeholder Forum to exchange views, expectations/feedback on HTA with stakeholders
- Web-based toolkit to facilitate European collaboration on evidence generation on promising health technologies
- A handbook on HTA capacity building and institutionalising HTA
- EUnetHTA Conference “HTA's Future in Europe”
EUnetHTA Joint Action 1 (2010-2012) 
Objectives

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

- Development of a general strategy and business model for sustainable European collaboration on HTA
- Development of HTA tools and methods
- Application and field testing of developed tools and methods
- To facilitate efficient use of resources available for HTA

Total budget: € 5.959.525
EUnetHTA Joint Action 1 (2010-2012) Deliverables

- An online Tool for producing, publishing, storing and retrieving HTA information and a new application of the HTA Core Model
- A common methodology for the relative effectiveness assessment (REA) of pharmaceuticals
- An operational web-based toolkit including database containing information on evidence generation on new technologies
- An Information Management System (IMS) and the related documentation, processes and policies
- Further development of a stakeholder involvement policy
- Development of a collaborative business model for sustainability
- A relative effectiveness assessment of a pharmaceutical
Croatian participation (AAZ)

JA1

Involvement in work on

- Facilitation of national strategies for continuous development and sustainability of HTA
- HTA training and capacity building
- Anti-VEGF in diabetic macular oedema: A systematic review
- The pre-market clinical evaluation of innovative high-risk medical devices
- Core HTA on Prognostic tests for breast cancer relapse
- Core HTA on Abdominal Aortic Aneurysm (AAA) screening
EUnetHTA Joint Action 2 (2012-2015) 
Objectives

- To strengthen the practical application of tools and approaches to cross-border HTA collaboration

- To achieve a better understanding for the European Commission and Member States of ways to establish a sustainable structure for HTA work in the EU

- To produce recommendations regarding the design and management of the future EU HTA cooperation

Total budget: € 9,428,550
EUnetHTA Joint Action 2 (2012-2015) Planned deliverables

- Recommendations on the implementation of sustainable European network for HTA
- Full Core HTAs
- Pilot rapid assessments
- Methodological guidelines and Templates to support production of core HTA information and rapid assessments
- Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation
- Upgraded and updated application package of HTA Core Model
- Report on yearly training courses on EUnetHTA tools and methodology
- Report on evaluation of project completion including assessment of impact on secondary users of HTA information
Croatian participation (AAZ)

JA2, 2013

Involvement in work on

• Feacal Immunochemical Test (FIT) versus guaiac-based feecal occult blood test (FOBT) for colorectal cancer screening

• Duodenal-jejunal bypass sleeve (EndoBarrier®) for the treatment of obesity with or without type 2 diabetes

• Rapid REA on a new antidiabetic drug (T2DM)

• EUnetHTA Plenary Assembly, Zagreb, March 21-22 2013

• AAZ representative – elected Chair of EUnetHTA Plenary Assembly in a two years mandate 2012-14
Establishment  →  Putting into practice  →  Strengthening practical application
Organisational and Governance Structure

EU Institutions

Plenary Assembly

Executive Committee

The Secretariat

Stakeholder Forum

SAGs

WP1 WP2 WP3 WP4 WP5 WP6 WP7 WP8

EUnetHTA Organigram
Composition of the Stakeholder Forum

Payers
Patients/Consumers
Industry
Providers
Purpose of the Stakeholder Forum

To provide stakeholders with the opportunity

- to participate as stakeholder representatives in the EUnetHTA Joint Actions
- to observe and comment on the EUnetHTA Joint Action work
- to provide advice to overarching governance questions in the Joint Actions, and
- to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Actions
Participants JA2

EUnetHTA Partners and Associates in JA2.

Large number of regional agencies and non-for-profit organisations that produce or contribute to HTA.
EUnetHTA and the HTA Network

Implementing the legislation on Patients’ Rights in Cross-border Healthcare
Article 15 of the Directive 2011/24/EU on cross-border health care

“The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States… That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations”
EUnetHTA’s Role in the Implementation of Article 15

EUnetHTA JA2 General Objective (Grant Agreement p. 35)

“to strengthen the practical application of tools and approaches to cross-border HTA collaboration bringing it to a higher level and resulting in a better understanding for the Commission and the EU Member States of ways to establish a sustainable structure for HTA work in the EU that avoids unnecessary duplication of assessment efforts”
EUnetHTA’s Role in the Implementation of Article 15

EUnetHTA will

• develop a general strategy, principles and recommendations for a sustainable European network for scientific and technical cooperation

• work within a structure for HTA in EU according to the requirements of the Directive for cross-border healthcare.
EUnetHTA Output
EUnetHTA has facilitated…

- increased collaboration between European HTA organisations
- practical efforts in improving efficient use of resources available for HTA
- the creation of a sustainable system of HTA knowledge sharing
- the promotion of good practice in HTA methods and processes
- the delivery of reliable, timely, transparent and transferable information contributing to HTAs in European countries
EUnetHTA Tools

- EUnetHTA HTA Core Model Online
- EUnetHTA Planned and Ongoing Projects Database (POP)
- EUnetHTA Evidence database on new technologies (EVIDENT)
- EUnetHTA Adaptation Toolkit
- EUnetHTA Contact Database
- EUnetHTA Intranet Groups
- EUnetHTA E-meeting facility
- EUnetHTA Document Repository
- EUnetHTA News Aggregator
The HTA Core Model®

**Description**

The HTA Core Model® is a methodological framework for shared production and sharing of HTA information.

**Purpose**

To enable production of high quality HTA information in a structured format to support the production of local (national or regional) HTAs and reuse of existing information.
The Structure of the HTA Core Model®

**Ontology**
Questions that an HTA should answer

**Methodological Guidance**
How to answer the questions

Common reporting structure that enables standardised reporting of HTAs. Results are presented as collections of *result cards*. The theme of each result card is outlined by the assessment element cards.
The **Domains of the HTA Core Model**®

### DOMAINS

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
The HTA Core Model Online®

Access to the HTA Core Model®: www.htacoremodel.info
The POP Database

Description
The EUnetHTA Planned and Ongoing Projects (POP) database allows EUnetHTA Partners and Associates to share information on planned, ongoing or recently published projects of participating agencies and identify similar projects through a matching system provided by the online database.

Purpose
To facilitate collaboration among European HTA agencies and reduce duplication of work.
The POP Database Online

Access to the POP Database: [http://eunethta.dimdi.de/PopDB/](http://eunethta.dimdi.de/PopDB/)
POP Statistics: Quarterly Updates

In Spring 2013, POP Database contained: 1,240 planned, ongoing and recently published projects from 42 EUnetHTA JA partners and 23 countries

10th (Sept/Oct 2012) POP Request

Out of 55 EUnetHTA JA partners:
- 31 responded and entered projects into the database
- 12 responded but DID NOT feed the database
- 12 did not respond at all (29%)
- Total number of projects: 1,259
- Alert (SAME) topics: 143 (11%)
- Similar projects (within alert topics): 394
- Access-rights: 43 partners

11th (Feb/March 2013) POP Request

Out of 59 EUnetHTA JA partners:
- 23 responded and entered projects into the database
- 19 responded but DID NOT feed the database (no current changes in the projects)
- 17 did not respond at all (29%)
- Total number of projects: 1,240
- Alert (SAME) topics: 120 (9.7 %)
- Similar projects (within alert topics): 290
- Access-rights: 43 partners
9 Methodological Guidelines for Rapid REA

Development
9 Methodological Guidelines for Rapid REA of Pharmaceuticals developed in JA1 by WP5.

Content
Guidelines on methodological challenges that are encountered by health technology assessors while performing a rapid relative effectiveness assessment of pharmaceuticals.

Primary Aim
To help the assessors of evidence interpret and process the data that are presented to them as part of a REA
9 Methodological Guidelines for Rapid REA

Endpoints used for REA of pharmaceuticals

1. Clinical endpoints
2. Composite endpoints
3. Surrogate endpoints
4. Safety
5. Health-related quality of life

Comparators and comparisons

6. Criteria for the choice of the most appropriate comparator(s)
7. Direct and indirect comparison

Levels of evidence

8. Internal validity
9. Applicability of evidence in the context of a relative effectiveness assessment

Link to the guidelines

http://www.eunethta.eu/outputs/methodological-guideline-rea-pharmaceuticals-clinical-endpoints
External Collaboration
EUnetHTA-EMA Collaboration

- To identify opportunities for and undertake specific steps to improve the efficiency of the process and conditions for patients’ timely access to an effective medicine.
Thank you
Any questions?

This presentation arises from the EUnetHTA Joint Action 2 which has received funding from the European Union, in the framework of the Health Programme