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Focus on HTA

Marina Cerbo, Sc D

Innovation and Development Director
National Agency for regional Healthcare- AGENAS-Italy

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Outline

The HTA Network

The timeline of reaching a sustainable and permanent HTA network in Europe

The EUnetHTA Joint Actions

The collaborative models

The core HTA production

Directive on cross-border health care

Article 15 Cooperation on health technology assessment

1. 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**

The Steps toward ...

Implementing Act on Establishment, management and transparent functioning of the network - Process in the Cross-Border Healthcare Committee

- 22 Oct 2012 CBHC meeting : Introduction and the first round of comments
 - 16 January 1 February 2013 : HTA expert group to discuss substance on the HTA network.
 - 11 March 2013 CBHC meeting: discussion on the draft IA
 - 30 March: MS deadline for further comments on draft IA
 - 3 June: Vote on the draft
- ⇒ Adoption within the transposition date of the Directive – 25 October 2013
- ⇒ Adoption of the rules of procedures, by the HTA Network

Governance of the network

- Key lines:
 - **2 levels structure:** the political and the operational
 - Political level in charge of overall strategic issues
 - Operational scientific independent level
 - Lessons to be learnt from EUnetHTA governance

The HTA Network – strategic level

Members

- national authorities or bodies responsible for HTA designated by the participating Member States
- Representatives can be accompanied by one national expert

The HTA Network - structure

- cooperation is necessary both at strategic level and at scientific and technical level
- the Network will be supported, by a scientific and technical cooperation mechanism
- Up to 30 September 2015 **EUnetHTA Joint Action 2** ensures scientific and technical cooperation for the HTA Network

The HTA Network - objective

Long term cooperation on HTA at European level, agree on:

- *Scope*
- *Financial sustainability*
- *Future trends*

The HTA Network – objective (2)

Specific objectives

- Guidance to WP of post EUnetHTA scientific cooperation mechanism.
- Conditions/guidance to facilitate national take up and re-use of HTA joint work
- Interaction between Regulatory and HTA issues

"Permanent" tasks ("other tasks")

- Involvement of all interested parties in HTA process (longer term)
- Proposes strategic directions on how to allocate EU funding for HTA (R&D, deployment, etc) (medium term)
- Provide input/being informed on EU semester Agenda and HTA issues (yearly)

The HTA Network - timelines

- Implementing Decision : June 26 2013 ✓
- Member designation ✓
- 1st meeting HTA Network: October 16 2013
discussion on:
 - strategic discussion on European Cooperation on HTA
 - work programme
 - rules of procedure

Uncertainties ...

Financing provisions

Permanent network... without permanent funding, according to Directive 2011/24.

Principle of the funding in the upcoming Health programme 2014/2020... but amount unknown.

Provisions of the programme will apply (joint action?)

The HTA network should send clear signal, on the amount needed and duration

DG SANCO explores H2020 provisions for funding specific activities

European network for HTA

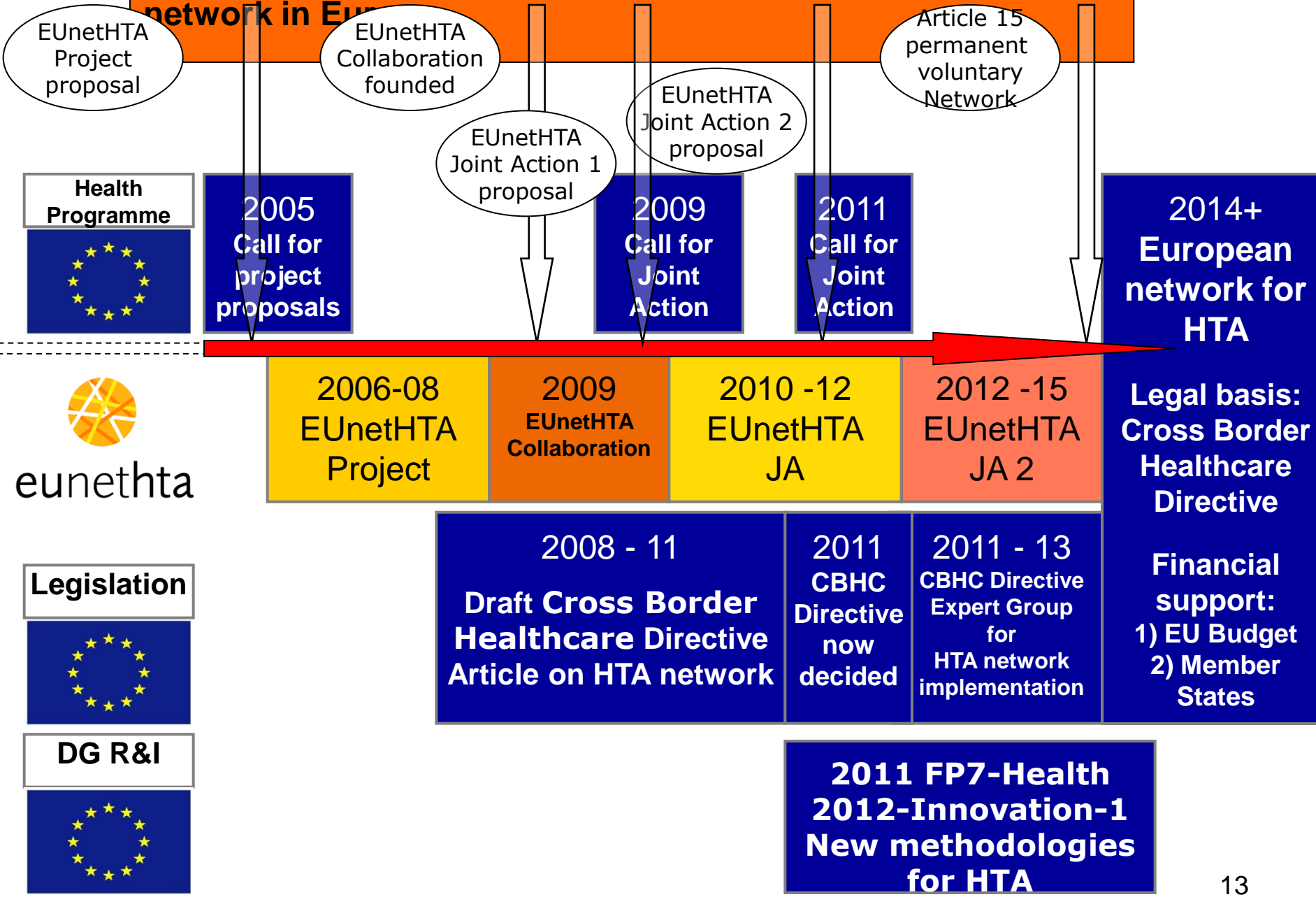
2nd Joint Action between

European Commission and EU

Member States

A total of 44 government appointed organisations from 28 EU Member States, Norway 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



- **Technologies become more ‘international’**
 - Not only for pharmaceuticals (European market authorisation) but also for medical devices, surgical procedures etc
- **Patients become more ‘European’**
 - EU Directive on cross-boarder healthcare
- **Decrease duplication on HTA assessments**
 - For some technologies like drugs in oncology assessments are performed simultaneously by different national and regional organisations
- **Increase consistency between different national HTA assessments**
 - Variety in type of assessments seems to be common: does this lead to different assessment results?

I Partner italiani

4 Associated Partners

- AGENAS
- Regional Agency for health and social care – Emilia Romagna (Italy)
- Regione Veneto (Italy)
- AIFA

4 Collaborative Partners

- CEIS University of Roma Tor Vergata (Italy)
- Laziosanità – Agenzia di Sanità Pubblica, Regione Lazio (Italy)
- University Hospital “A. Gemelli” (Italy)

JA1 WP4 objectives

Development of HTA Tool and methods

Strand A LP FINOHTA-THL

Application and field testing of developed tools and methods

Strand B LP AGENAS



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WP4 Strand B

Core HTA production - Participants

- **AGENAS (Italy) LP**
- **32 partners** \Rightarrow **19 Countries**
- **Deliverables:** two comprehensive and multidimensional Core HTAs



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3. Collaborative models for the Core HTA reports production

Collaborative Model 1

(researchers from different agencies contributing to one domain)

Each of the 9 domains is managed by researchers from different agencies participating in WP4/B.

Framework of Domain Teams:

- **1 Primary Investigator**, to coordinate the work and interact with Coordinator of the Project (Agenas)
- **n° of Investigators**, to develop the work and interact with PI
- **n° of reviewers**, to review the document produced by each domain team

Collaborative Model 2

(one agency contributing to one domain)

Each of the 9 domains is managed by one agency participating in WP4/B.

Framework of Domain Teams:

- **1 Primary Investigator**, to coordinate the work and interact with Coordinator of the Project (Agenas)
- **n° of Investigators**, to develop the work and interact with PI
- **n° of reviewers**, to review the document produced by each domain team



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- **Core HTA 1:** Prognostic tests for breast cancer recurrence (Oncotype DX, Mammaprint, Femtelle)
- **Collaborative Model 1:** *each domain is managed by researchers from different Agencies*

- **Core HTA 2:** *Abdominal Aorta Aneurysm Screening*
- **Collaborative Model 2:** *each domain is managed by 1 Agency*



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Disclaimer

This information collection is a core HTA, i.e. an extensive analysis of one or more health technologies using all nine domains of the HTA Core Model. The core HTA is intended to be used as an information base for local (e.g. national or regional) HTAs. Notice that from the collection's cover page you may modify which sections of the full collection to view.

Collection name Abdominal Aorta Aneurysm Screening

Scope

AAA Screening compared to not doing anything in the screening of Abdominal Aorta Aneurysm (AAA) in elderly at moderate risk of developing AAA

(See detailed scope below)

Model version

HTA Core Model Application for Screening Technologies 1.0

Project type

Core HTA

Status

Published

Editors

Tom Jefferson (age.na.s, Italy), Nicola Vicari (age.na.s, Italy), Katrine Bjørnebek Frønsdal (NOKC, Norway)

Editorial team

Claudia Wild, LBI-HTA (Health problem and current use); Daniela Pertl and Sophie Brunner-Ziegler, GÖG (Description and technical characteristics); Iñaki Imaz, ISCIII-AETS (Safety); Katrine Frønsdal and Ingvil Sæterdal, NOKC (Clinical effectiveness), Suvi Mäklin and Taru Haula, THL-FINOHTA (Costs and economic evaluation); Gottfried Endel, HVB (Ethical analysis); Kristi Liiv and Raul Kiivet, UTA (Organisational aspects); Anne Lee, Lotte Groth Jensen and Claus Loevschall, SDU/CAST (Social aspects); Ingrid Wilbacher, HVB (Legal aspects)

Publishing organisation

Agenzia nazionale per i servizi sanitari regionali (age.na.s), Italy

Collaborating organisations

Central Denmark (Denmark), GÖG (Austria), HVB (Austria), ISCIII - AETS (Spain), LBI-HTA (Austria), NOKC (Norway), SDU/CAST (Denmark), THL - FINOHTA (Finland), UTA (Estonia)

Start date

4.5.2011 15:16:00

Published date

31.1.2013 18:04:00

Errata

Scope

Technology

AAA Screening

Description

Population-based systematic abdominal aortic aneurysm (AAA) screening. This includes one single invitation for the whole target population to do one ultrasound scan examination. Purpose of use: Detect abdominal aortic aneurysm in unruptured phase in order to treat those aneurysms with high risk of rupture.

Intended use of the technology

Screening

Screening programme for abdominal aortic aneurysm

Target condition

Abdominal Aorta Aneurysm (AAA)

Target condition description

All men and women aged 64 or more

Target population

Target population sex: Any. *Target population age:* Specific ages (please specify). *Target population group:* Possible future health condition.

Target population description

All men and women aged 64 or more

For: All men and women aged 64 or more.

There is some international variance in the prevalence of AAA. In the western countries the prevalence varies between 5 to 10 % for the 65 – 74 years old men.

In Japan the prevalence is 1 % for the same group of men. The prevalence increases with age.

In England the prevalence is 2 % for men aged 50 – 64 year and 12 % for men aged 80 years or older.

In Denmark the prevalence is 4 % for men aged 65 – 69 and 6 % for men aged 70 – 74 years old. The prevalence for women is significant lower than the prevalence for men.

Comparison

not doing anything

Description

No population-based AAA screening.

View content

Collection-level content

- Collection summary
- Collection methodology
- Collection introduction
- Collection scope
- Collection appendices

Domain-level content

Status

- Health Problem and Current Use of the Technology
- Description and technical characteristics of technology
- Safety
- Clinical Effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organisational aspects
- Social aspects
- Legal aspects

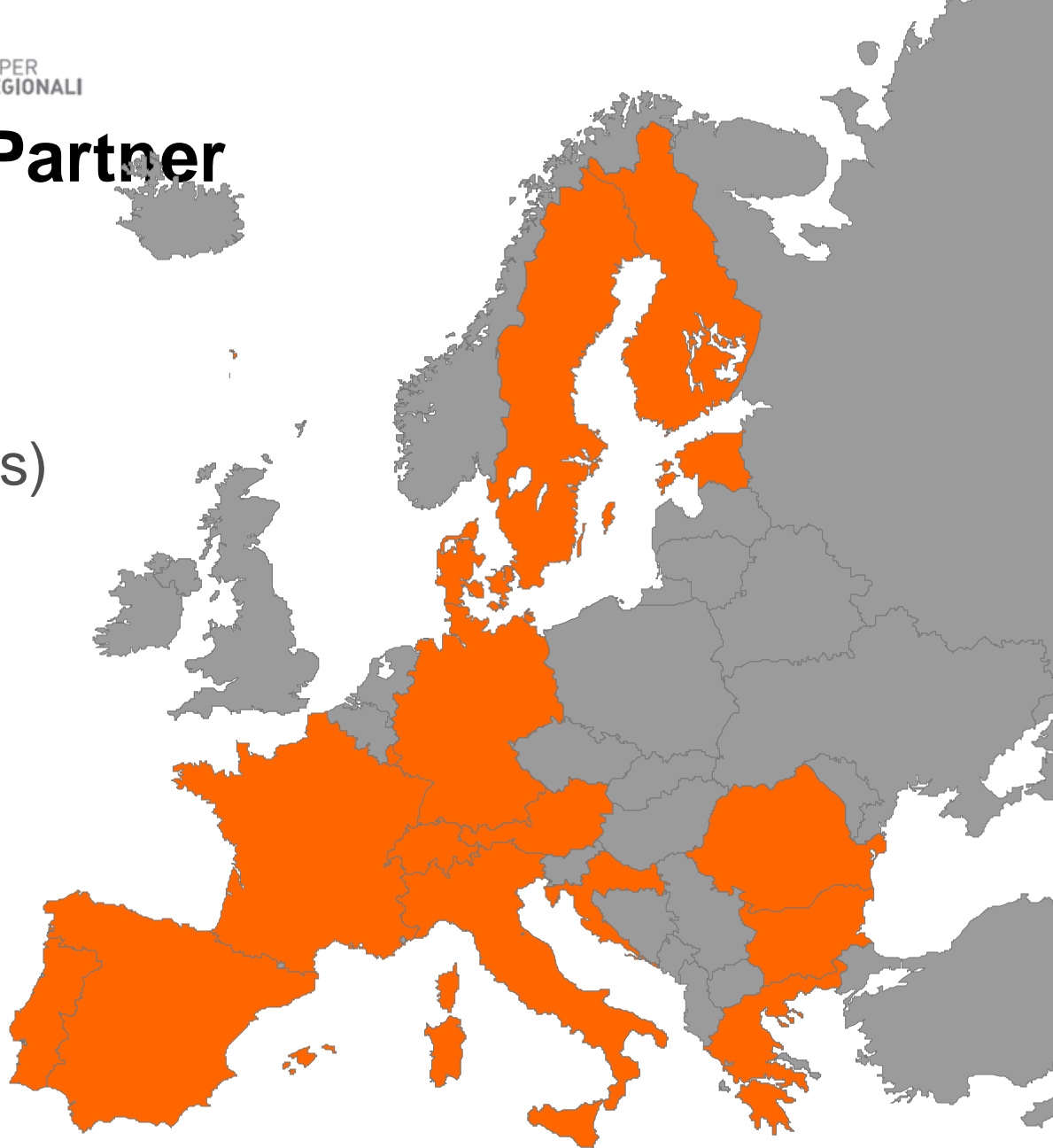
View

- Summary
- Introduction
- Methodology
- Result cards
- Discussion
- References
- Appendices

[View selected](#)

JA2 WP 4 Lead Partner

- **19 Associates (APs)**
from 16 countries
- **8 Partners (CPs)**
from 4 countries



Objectives

Title	Description
<p>Test the capacity of national HTA bodies to produce structured core HTA information (full core HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network).</p>	<p><i>A number of core HTAs and core HTA information based on the core model structure will be produced. The assessments produced will be used for local (i.e. national, regional) reports to inform decision-making. Data will be collected on costs and overall efficiency.</i></p>
<p>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</p>	<p><i>To provide guidance and testing in identifying and organising collaborations between partners for setting up a specific collaboration (e.g. around an assessment topic). Coordinating function of various activity clusters and overall partnership coordination will be further developed and streamlined.</i></p>



Deliverables	Deadline
1 st Core HTA	M14
2 nd Core HTA	M23
3 rd Core HTA	M34
Additional deliverables	
Methodological standards and procedures (MSP) for collaboration	M15
20 national reports piloted	M36

Core HTA production

Core HTA 1:

Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening

(mixed collaborative model)

Core HTA 2:

Topic will be selected in Sept-Oct 2013

Core HTA 3:

Scheduled in 2014



National reporting piloting

Specific projects will be developed to facilitate partners :

- to produce both core HTA information and local information on prioritized topics, for national reporting.
- to produce both core HTA information and local information on topics of interest for national reporting
- to integrate core HTA information already available into national reports.

All the national pilots initiatives will be notified to LP and will be monitored and supported by a Working group.

Partners involved in national production will gather also data for the evaluation work-package.

Rome October 30-31, 2014

HTA 2.0 Europe: teaming up for value

Host Organisation: AGENAS