

8° Congresso Nazionale SIHTA
HTA tra decisione e consenso

L'esperienza regionale di networking europeo e nazionale

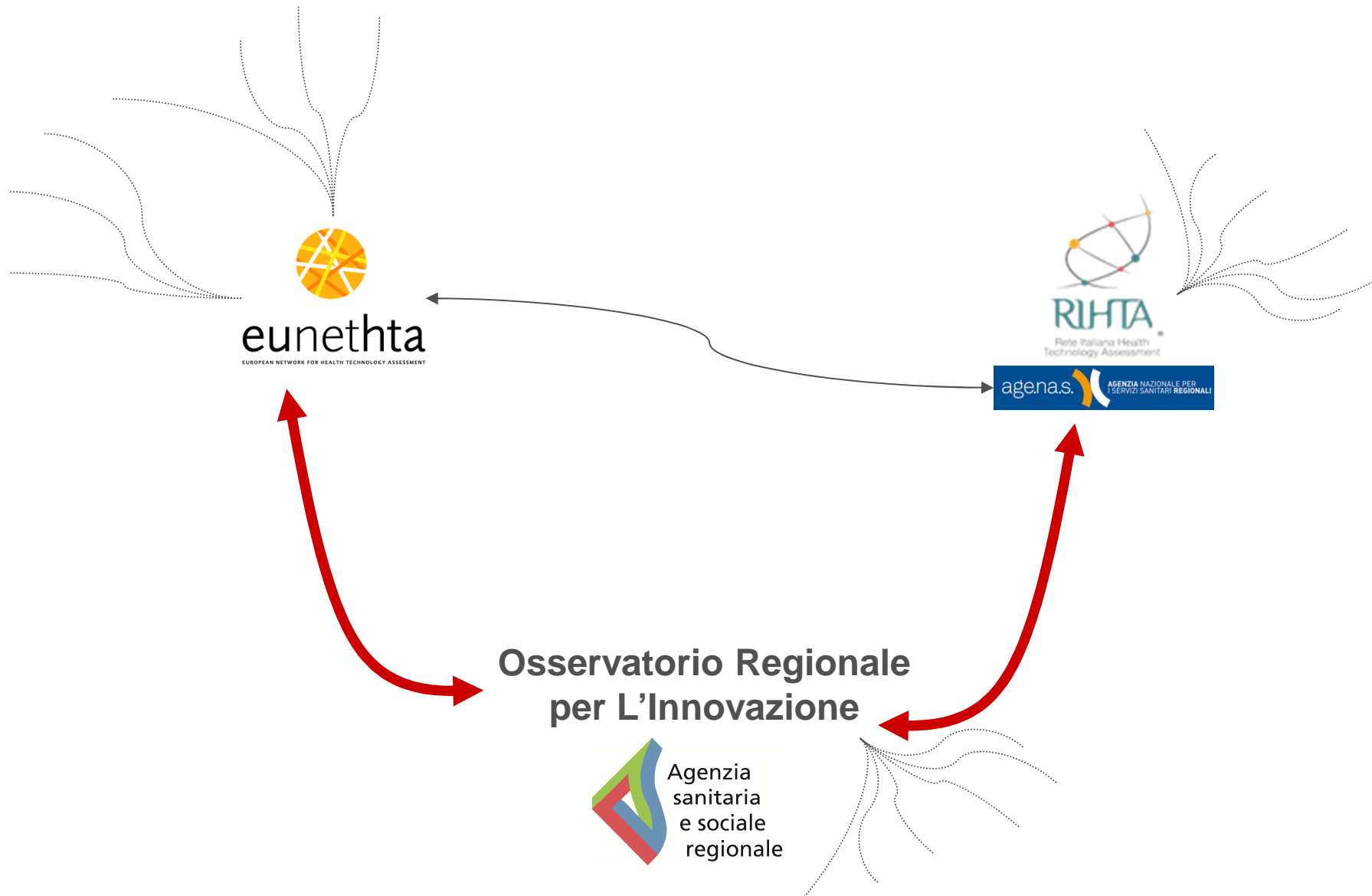
F. Trimaglio, L. Ballini, M. Camerlingo, S. Maltoni, A. Negro

Osservatorio Regionale per l'Innovazione

Agenzia Sanitaria e Sociale Regionale **Emilia Romagna**

Verso il programma nazionale HTA: L'esperienza internazionale nel contesto italiano dalla produzione collaborativa al coinvolgimento degli stakeholder

ORI-ASSR, le reti di collaborazione

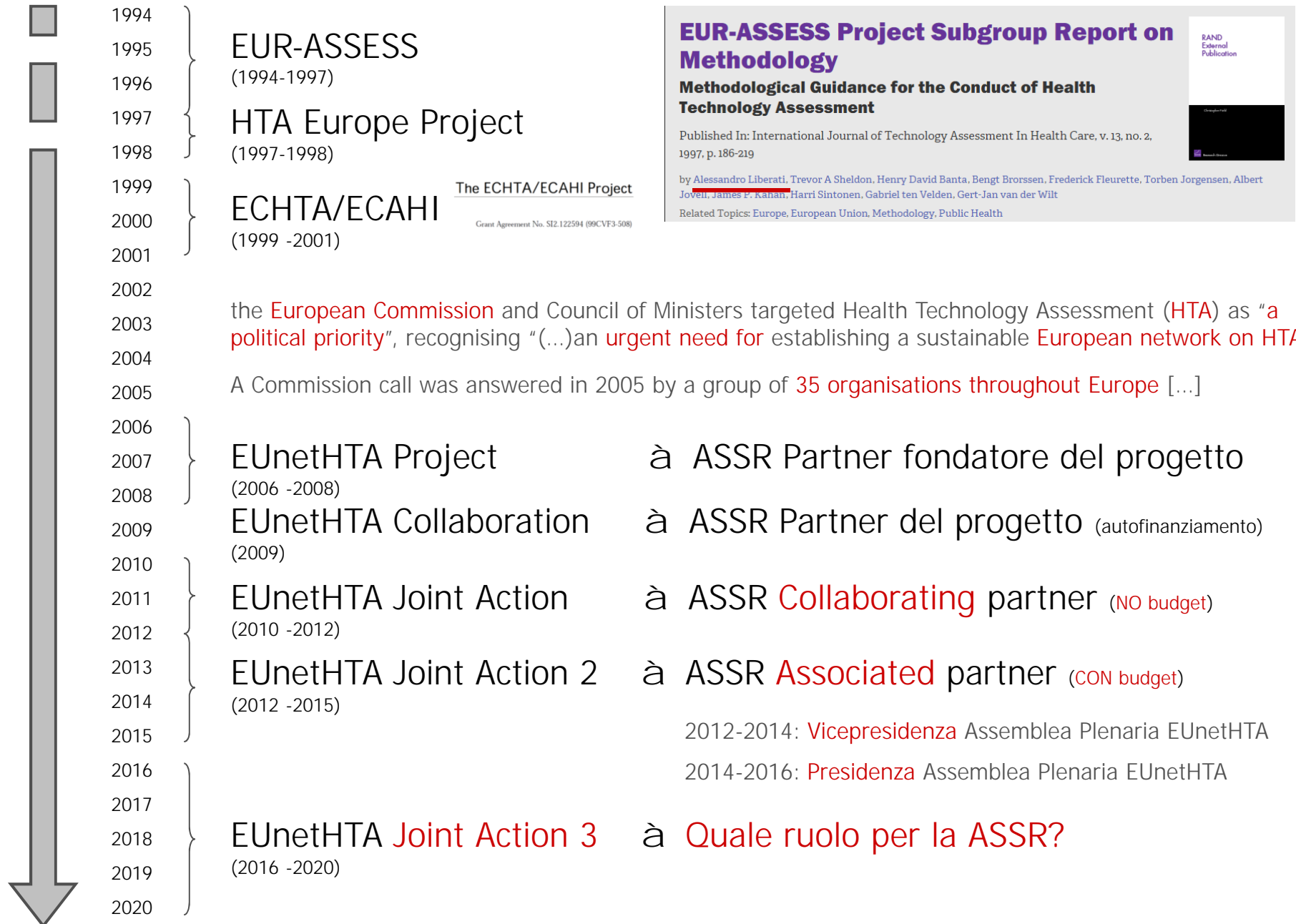


RIHTA e ORI-ASSR

La RIHTA è una rete di **collaborazione tra le tecno-strutture delle Regioni** e Agenas. L'iniziativa è nata nel 2009 con lo scopo di realizzare e sviluppare iniziative, progetti e interventi **volti a ottimizzare le valutazioni sistematiche delle tecnologie sanitarie** (Health Technology Assessment) nell'ambito dei Servizi sanitari regionali.



EUnetHTA e ORI-ASSR, la storia in breve



EUR-ASSESS Project Subgroup Report on Methodology

Methodological Guidance for the Conduct of Health Technology Assessment

Published In: International Journal of Technology Assessment In Health Care, v. 13, no. 2, 1997, p. 186-219

by Alessandro Liberati, Trevor A Sheldon, Henry David Banta, Bengt Brorssen, Frederick Fleurette, Torben Jorgensen, Albert Jovell, James P. Kahan, Harri Sintonen, Gabriel ten Velden, Gert-Jan van der Wilt

Related Topics: Europe, European Union, Methodology, Public Health

RAND
External
Publication



EUnetHTA e ORI-ASSR, la collaborazione

Work Packages	EUnetHTA Project (2006-08)	EUnetHTA Joint Action (2010-12)	EUnetHTA Joint Action 2 (2012-15)
	Partner fondatore	Collaborating Partner	Associated Partner
WP 1	Coordination	Coordination	Coordination
WP 2	Communications	Dissemination	Dissemination
WP 3	Evaluation	Evaluation	Evaluation
WP 4	Common Core HTA	Core HTA	Testing collaborative production of HTA information for national adaptation and reporting
WP 5	Adapting HTA	Relative Effectiveness Assessment of Pharmaceuticals	Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting
WP 6	HTA and Health Policy	Information Management System	Information Management Infrastructure and Services (IMIS)
WP 7	New Technologies	New Technologies	Methodology development and evidence generation: Guidelines and pilots production
WP 8	System to support HTA	Strategy and Business Model Development	Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information

JA2 – WP4: Testing collaborative production of HTA information for national adaptation and reporting

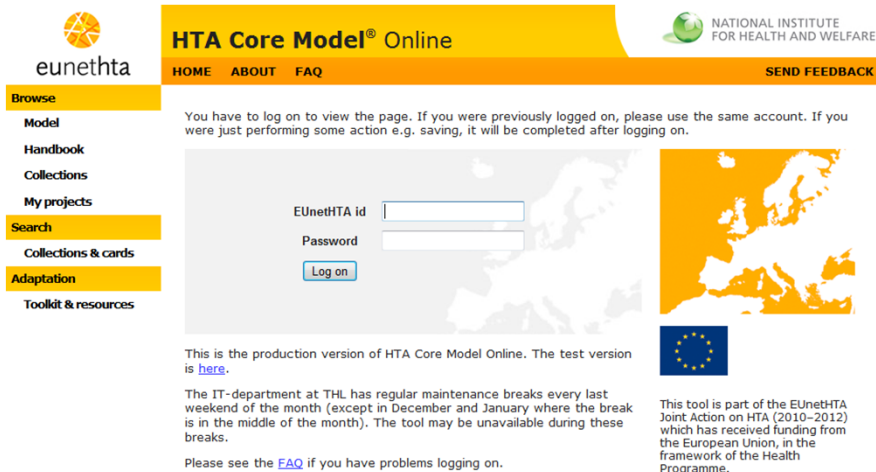
Lead partner: **Agenzia Nazionale per i Servizi Sanitari Regionali (Agenas), Italia**

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.



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



JA2 – WP4: Testing collaborative production of HTA information for national adaptation and reporting

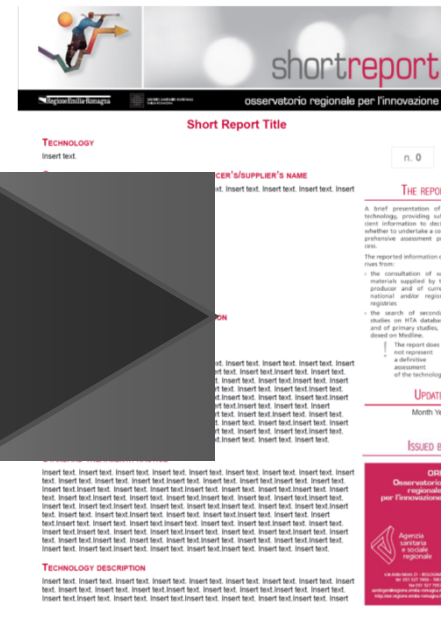
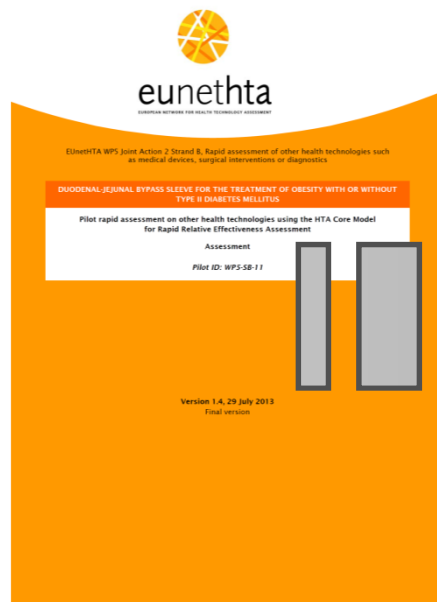
Lead partner: **Agenzia Nazionale per i Servizi Sanitari Regionali (Agenas), Italia**

Attività	Ruolo dell'ORI
2 nd Core HTA Intravenous immunoglobulins for Alzheimer's disease including Mild Cognitive Impairment	PRINCIPAL INVESTIGATOR per i domini: - SICUREZZA - EFFICACIA
1st Core HTA Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening.	Revisori
3rd Core HTA Home telemonitoring for adult patient with congestive heart failure	Revisori

JA2 – WP5: Testing collaborative production of HTA information for national adaptation and reporting

Lead partner: **National Health Care Institute (ZIN), Netherlands**

Co-Lead partner: **Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA), Austria**



First pilot rapid assessment of WP5 JA2 Strand B

“**Duodenal-jejunal bypass sleeve** for the treatment of obesity with or without Type II Diabetes Mellitus”

(Endobarrier®)

Gli **Short Report** sono **valutazioni rapide** e preliminari di **tecnologie emergenti e innovative** a medio costo il cui profilo di efficacia clinica non è ancora stato studiato e definito in modo esauriente. Lo scopo degli Short Report è quello di **individuare** le **tecnologie di maggiore interesse** e più promettenti per il Servizio sanitario regionale o nazionale [...]

EUnetHTA e ORI-ASSR

JA2 – WP7: Methodology development and evidence generation: Guidelines and pilots production

Lead partner: **French National Authority for Health (HAS), Francia**

Co-Lead partner: **Institute for Quality and Efficiency in Health Care (IQWiG), Germania**

SG 1: Pilots and guidelines to improve quality and adequacy of initial evidence generation: **Early Dialogue** and Disease specific guidelines

SG2: Guidelines and pilots to improve quality and adequacy of **additional evidence generation**

SG3: Guidelines on methodological issues, all health technologies

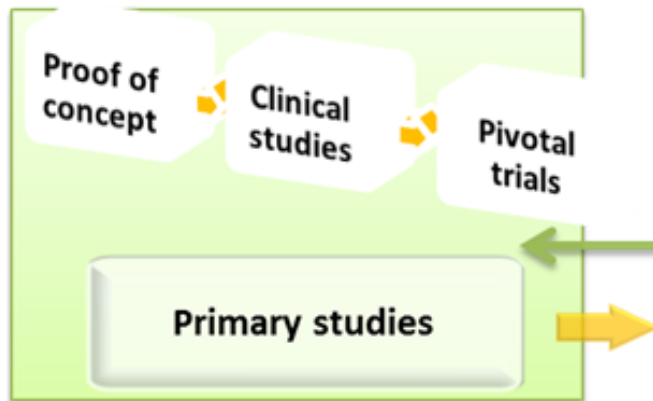
SG4: **Templates for manufacturers' submissions** to support production of core HTA information and rapid assessments.

JA2 – WP7: Methodology development and evidence generation: Guidelines and pilots production

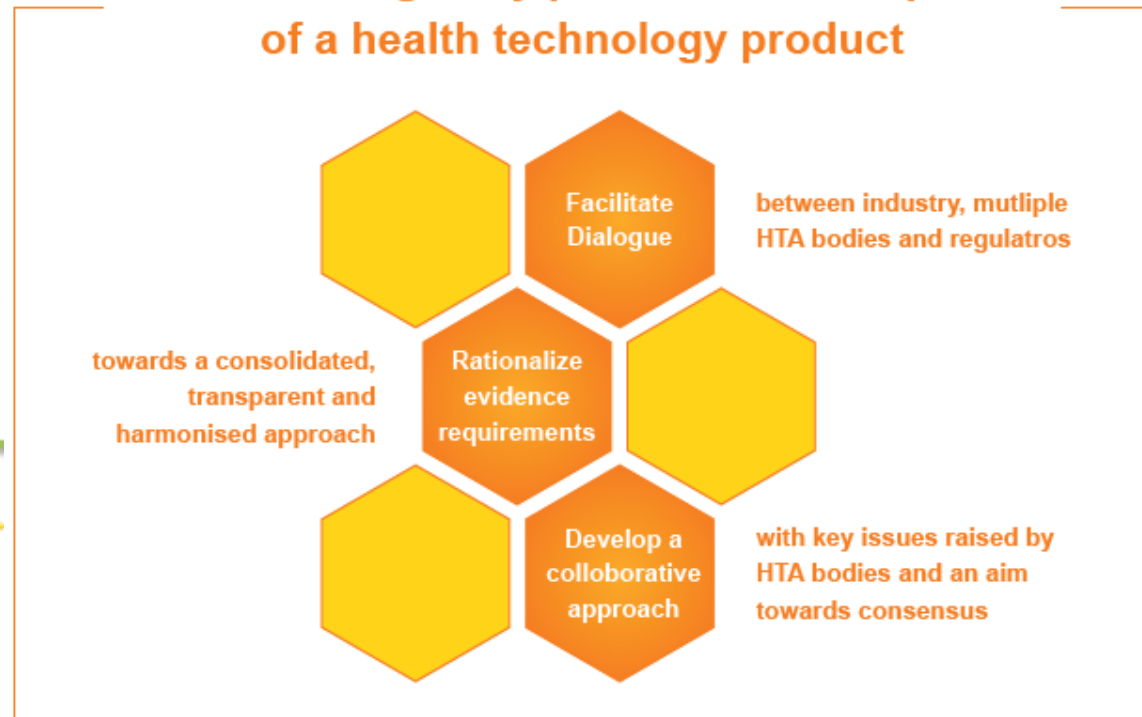
Lead partner: **French National Authority for Health (HAS), Francia**

Co-Lead partner: **Institute for Quality and Efficiency in Health Care (IQWiG), Germania**

SG 1: Pilots and guidelines to improve quality and adequacy of initial evidence generation: **Early Dialogue** and Disease specific guidelines



Advice during early phases of development of a health technology product



JA2 – WP7: Methodology development and evidence generation: Guidelines and pilots production

Lead partner: **French National Authority for Health (HAS), Francia**

Co-Lead partner: **Institute for Quality and Efficiency in Health Care (IQWiG), Germania**



SG 1: Pilots and guidelines to improve quality and adequacy of initial evidence generation: **Early Dialogue** and Disease specific guidelines

Date	Company	Indication	Tech	Type of ED
December 2012	EUnetHTA ED1 - Bristol Myers Squibb	rheumatoid arthritis	Med	multiHTA only
April 2013	EUnetHTA ED2 - Astellas	anemia in chronic kidney disease	Med	multiHTA only
June 2013	EUnetHTA ED3 - Merck Serono	relapsing forms of Multiple Sclerosis	Med	multiHTA only
June 2013	EUnetHTA ED4 - GSK	preterm labour in uncomplicated pregnancy	Med	multiHTA only
November 2013	EUnetHTA ED5 - EnVivo	mild to moderate dementia of Alzheimer's type	Med	multiHTA only
April 2015	EUnetHTA ED6 - Carmat	biventricular heart failure	MD	multiHTA only
June 2015	EUnetHTA ED7 - Lysogene	Sanfilippo syndrome (rare disease)	Med (orphan drug)	multiHTA only
September 2015	EUnetHTA ED8 - Roche	diabetes mellitus	MD	multiHTA only

Date	Company	Indication	Tech	Type of ED
May 2014	SEED-ED1 Sanofi	relapsed/refractory multiple myeloma	Med	multiHTA only
September 2014	SEED-ED3 Transgene	advanced non-small cell lung cancer	Med	multiHTA only
October 2014	SEED-ED4 Genzyme	Niemann-Pick disease (rare disease)	Med (orphan drug)	EMA-multiHTA
December 2014	SEED-ED5 GSK	myasthenia gravis (rare disease)	Med	EMA-multiHTA
January 2015	SEED-ED6 Saint Jude Medical	heart failure	MD	multiHTA only
February 2015	SEED-ED9 Voisin	thyroid cancer diagnostic test	MD	multiHTA only
March 2015	SEED-ED10 Mesoblast limited	discogenic back pain	Med	EMA-multiHTA
July 2015	SEED-ED11 Roche	Haemophilia A	Med	EMA-multiHTA

Dicembre 2012



Settembre 2015

JA2 – WP7: Methodology development and evidence generation: Guidelines and pilots production

Lead partner: **French National Authority for Health (HAS), Francia**

Co-Lead partner: **Institute for Quality and Efficiency in Health Care (IQWiG), Germania**

SG2: Guidelines and pilots to improve quality and adequacy of **additional evidence generation**

Objectives

[...] providing a structured approach to **identify research gaps** and to **formulate research recommendations** targeted at:

- resolving **uncertainties related** to the **safety** and clinical **effectiveness** of a health technology, answerable with biomedical research (Section A);
- resolving **uncertainties** that may arise when the technology is **adopted** and implemented in **real world** practice (Section B).



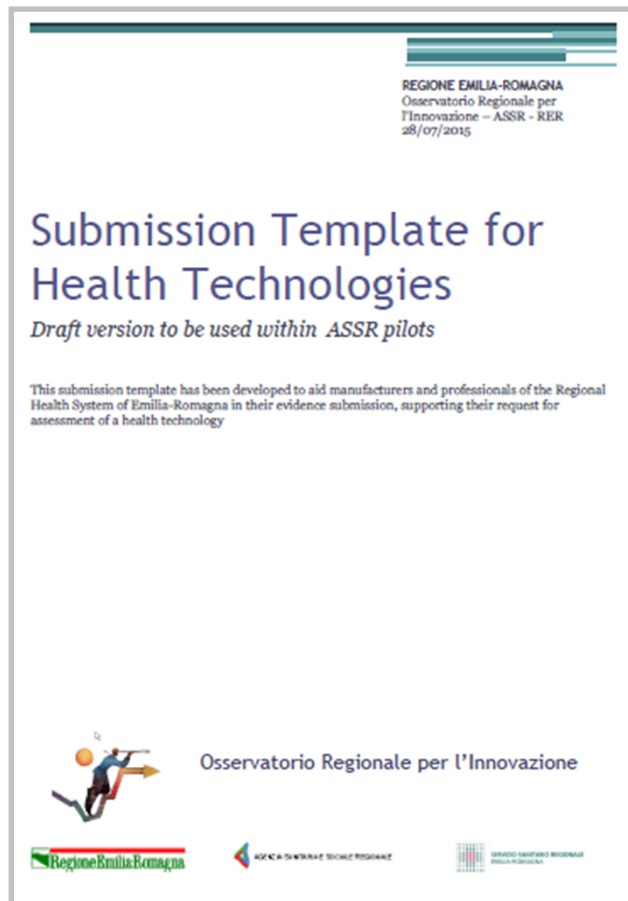
EUnetHTA e ORI -ASSR

JA2 – WP7: Methodology development and evidence generation: Guidelines and pilots production

Lead partner: **French National Authority for Health (HAS), Francia**

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SG4: Templates for manufacturers' submissions to support production of core HTA information and rapid assessments.



Adattamento locale della scheda per la richiesta di valutazioni da parte dell'industria

- In attesa dei commenti da parte del NICE
- In attesa dei risultati di una prima applicazione da parte di una impresa farmaceutica

L'esperienza delle reti, alcune considerazioni ...



- **Crescita** metodologica del gruppo tramite **scambio ed interazione** con altri gruppi

e.g. Early Dialogues (WP7-SG1)

- Possibilità di **esportare** il proprio **know how** rendendo le proprie esperienze una metodologia condivisa

e.g. raccomandazioni per la ricerca (WP7-SG2)

- Condivisione framework metodologico e **accesso ad applicativi di supporto**

e.g. Core Model, POP Database, EVIDENT Database

- Possibilità di riadattamento dei prodotti sviluppati

e.g. "Template for manufacturer submission" (WP7-SG4).

- Non sempre gli strumenti sono gestibili con semplicità o sfruttati appieno

e.g. Core Model Tool, Forum RiHTA

- Le collaborazioni sembrano essersi sviluppate più come suddivisione dei compiti tra organizzazioni che come lavoro congiunto di professionisti appartenenti a organizzazioni differenti

e.g. Intravenous immunoglobulins for Alzheimer's disease (WP4)

- Parziale perdita di autonomia nell'organizzazione del lavoro

L'esperienza delle reti, alcune considerazioni ...

Quali opportunità derivano dalle reti nel rafforzamento dell'HTA nei processi decisionali?

Da un lato la RER, come la maggior parte delle regioni italiane e come avviene in altri contesti europei, soffre ancora della **manca**za di **istituzionalizzazione del percorso di valutazione delle tecnologie**, lasciando tecnici e decisori ancora su differenti sponde della conoscenza.



L'esperienza delle reti, alcune considerazioni ...

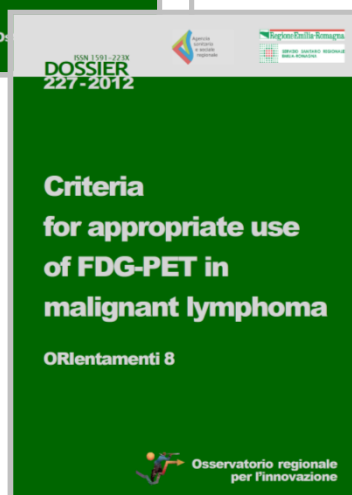
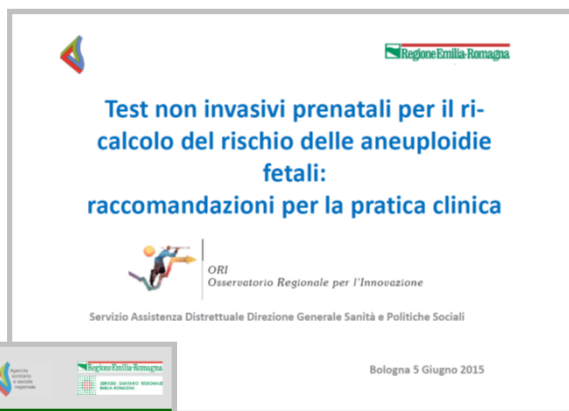
Quali opportunità derivano dalle reti nel rafforzamento dell'HTA nei processi decisionali?



Dall'altro si è riscontrato un grande interesse dei professionisti coinvolti nei diversi panel allorché erano chiamati a formulare raccomandazioni sull'utilizzo appropriato di una tecnologia.

L'esperienza delle reti, alcune considerazioni ...

Quali opportunità derivano dalle reti nel rafforzamento dell'HTA nei processi decisionali?



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"Vorrei dire no, ma non ci riesco..."

C'è dunque spazio per incidere nei processi decisionali ...

L'esperienza delle reti, alcune considerazioni ...

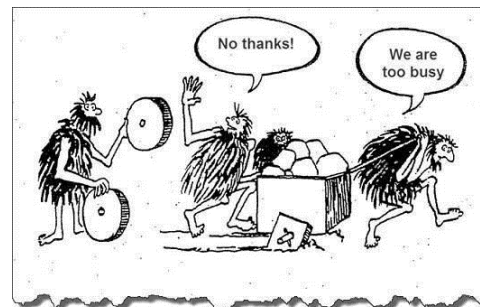
Quali opportunità derivano dalle reti nel rafforzamento dell'HTA nei processi decisionali?



Strumento di/per il potere



"Abbiamo sempre fatto così"?



Strumento per lo sviluppo

