

European Health Technology Assessment (HTA): Advantages and Experiences

HERCA Multi-Stakeholder Workshop 25th Oct 2016 , Paris

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Outline

- European Network for Health Technology Assessment (EunetHTA)
- Achievements of EunetHTA
- EUnetHTA Joint Action 3 (JA3)
- HTA Core Model

Health Technology Assessment, HTA

- Supports decision making by analysing best available evidence on health technologies
- Includes pharmaceuticals, devices, diagnostics, procedures and interventions
- Multidisciplinary approach: clinical, economic, organisational, social, legal and ethical aspects of health technology
- Uses transparent, systematic and rigorous processes and methods

European Network for Health Technology Assessment (EunetHTA)



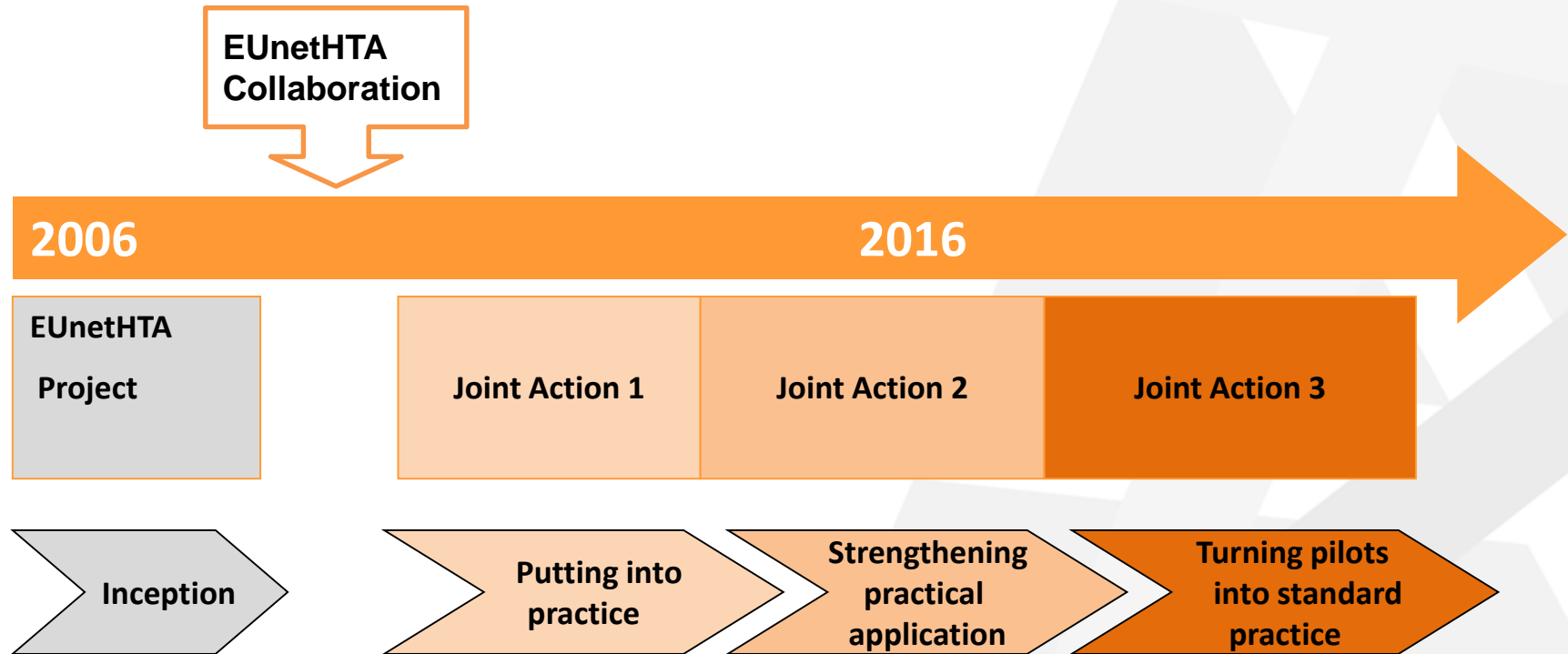
European collaboration

- European Network for HTA supports collaboration between European HTA organisations that brings added value at the European, national and regional level through
 - facilitating efficient use of resources available for HTA
 - creating a sustainable system of HTA knowledge sharing
 - promoting good practice in HTA methods and processes.

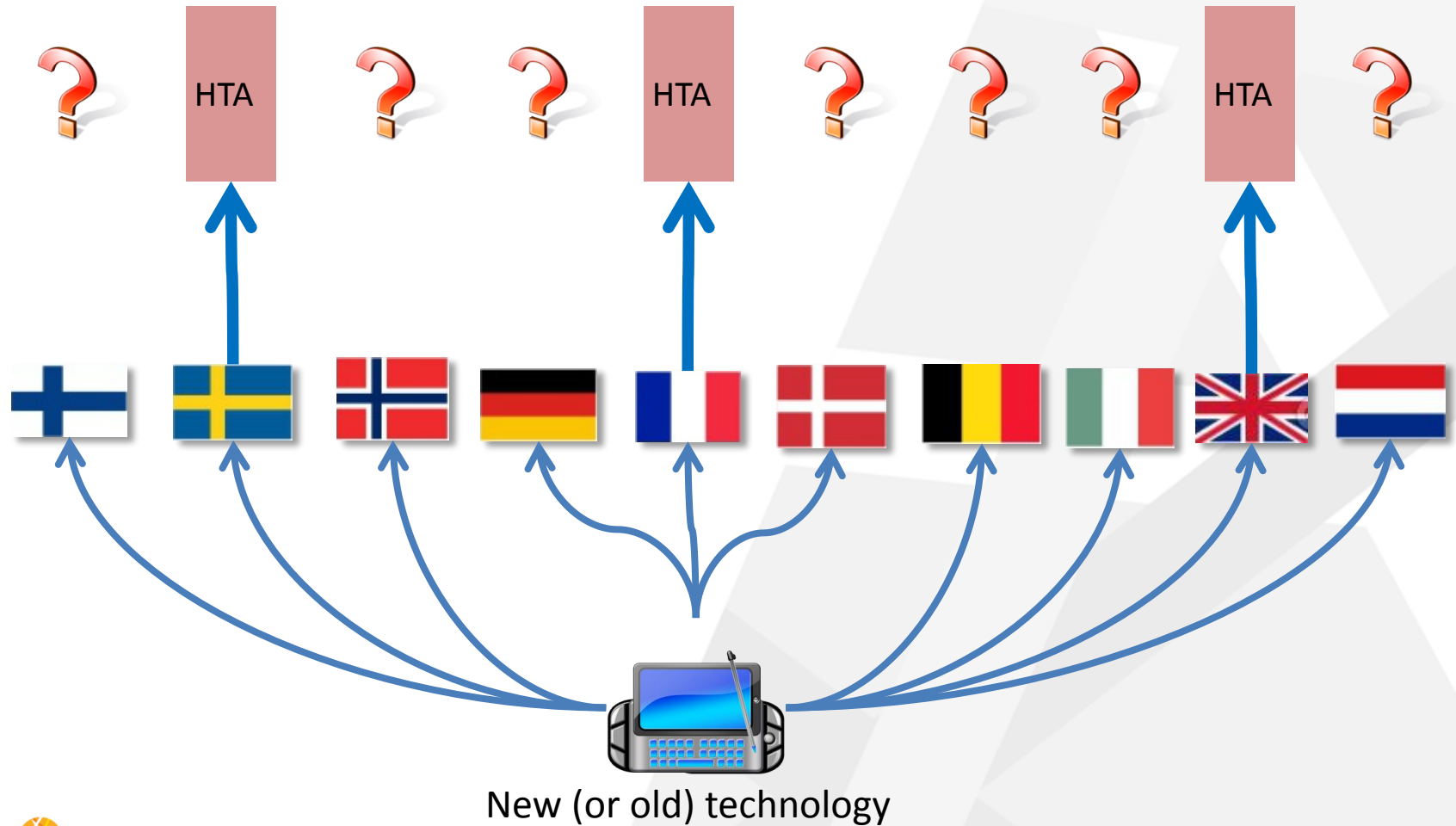
European network on HTA

- EUnetHTA was established to create an effective and sustainable network for HTA across Europe
 - work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries
- Activity started in 2006
- Strengthened after launching the directive on the application of patients' rights in cross-border healthcare (2011/24/EU)

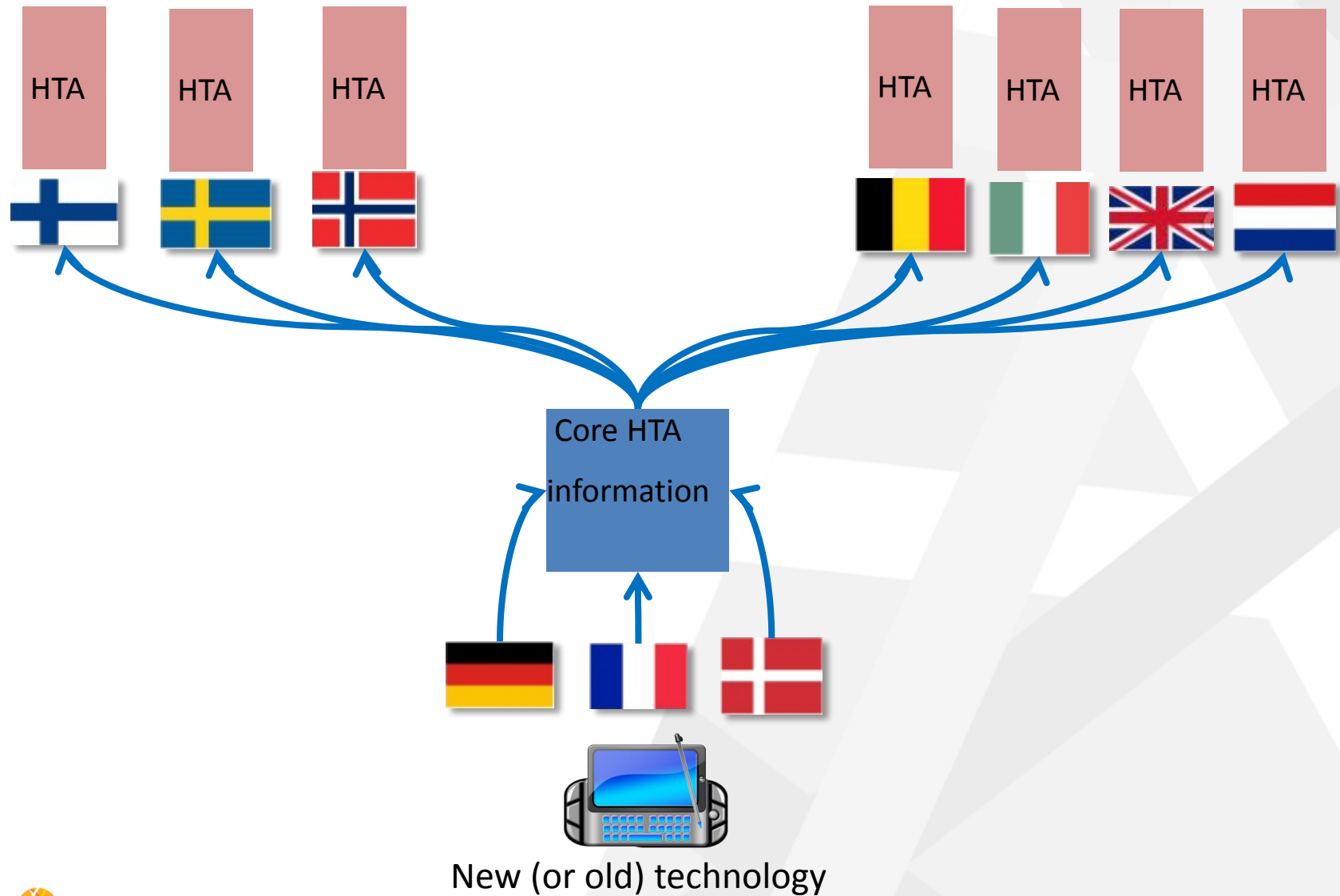
Historical timeline of EUnetHTA



Before...



After...



Achievements of EunetHTA

Achievements EUnetHTA (products)

- Tools
 - HTA Core model (full model and rapid REA)
 - EUnetHTA Planned and Ongoing Projects (POP) database
 - EVIDENT database
 - Evidence submission templates
- Methodology
 - Guidelines for REA
 - Handbook for full HTA
- Products
 - Early dialogues (EUnetHTA and SEED, medical devices and pharmaceuticals)
 - Rapid REAs (pharmaceuticals, medical devices, surgical procedures)
 - Full core HTA's (different types of interventions)

Examples of assessments

Full HTAs

- Use of Intravenous immunoglobulins for Alzheimer's disease including Mild Cognitive Impairment, 2014
- Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening, 2013
- Abdominal Aorta Aneurysm (AAA) Screening, 2011
- Prognostic tests for breast cancer recurrence (uPA/PAI-1 [FEMTELLE], MammaPrint, Oncotype DX, 2011
- Drug Eluting Stents, 2008
- MSCT Angiography, 2008

Rapid Relative Assessments

- Zostavax for the prevention herpes zoster, 2013
- Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus, 2013
- Renal denervation systems for treatment-resistant hypertension, 2013
- Zostavax for the prevention herpes zoster, 2013

Full and rapid assessments are available through www.eunethta.eu

Achievements EUnetHTA (structure)

- Strong collaboration with the HTA organisations in Europe
 - **BRAND** and **TRUST!**
- Well defined interactions with other stakeholders and other organisations
 - Structure for collaboration with regulators in pharma (EMA)
 - Interactions with other stakeholders, such as technology producers and patients in assessments, early dialogues, preparation of methodology
- Interaction with political and strategical activities
 - Link to initiatives such as HTA Network, STAMP, CAPR and MEDEV
- Embedded in the scientific HTA community
 - Link to societies like INAHTA, HTAi and ISPOR
 - Involved in multistakeholder projects in IMI such as GetReal, but also FP7 projects such as INTEGRATE-HTA, ADVANCE-HTA and ADOPTHTA

Joint Action 3

EUnetHTA Joint Action 3 (JA3)

- Building a sustainable network on HTA in Europe
- 2016-2020, then to continue

www.eunetha.eu

EUnetHTA JA3 Participants

79 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA












Project Coordinator:
Dutch National Health Care
Institute (ZIN)



Objectives of JA3

- To increase production of high-quality HTA joint work
- To increase uptake and implementation of joint HTA work at the national, regional, and local level
- To support evidence-based, sustainable, and equitable choices in healthcare and health technologies

Organisational and governance structure

DG SANTE and CHAFAEA 						
EUnethTA Assembly	Executive Board	Work Package 1 Network Coordination - Dutch Health Care Institute 				
		Work Package 2 Dissemination	Work Package 3 Evaluation	Work Package 4 Joint Production	Work Package 5 Evidence Generation	Work Package 6 Quality
		Lead: AETS-ISCIH 	Lead: TLV 	Lead: NIPHNO  Co-lead: LBI  ZIN 	Lead: HAS  Co-lead: GBA 	Lead: IQWiG  Co-lead: KCE 
		Spain	Sweden	Norway	Austria	Netherlands
		United Kingdom	Belgium	Croatia	Cyprus	Czech Republic
		Finland	France	Greece	Hungary	Ireland
		Malta	Poland	Portugal	Romania	Slovakia
		Italy	Estonia	Lithuania	Bulgaria	Switzerland
						Germany
						Denmark
						Latvia
						Slovenia

Summary of select activities in JA3

WP4 Joint Production

- To produce **43** rapid REA on other technologies and **37** on pharmaceutical
- To provide a system for topic selection and prioritization

WP5 Evidence Generation

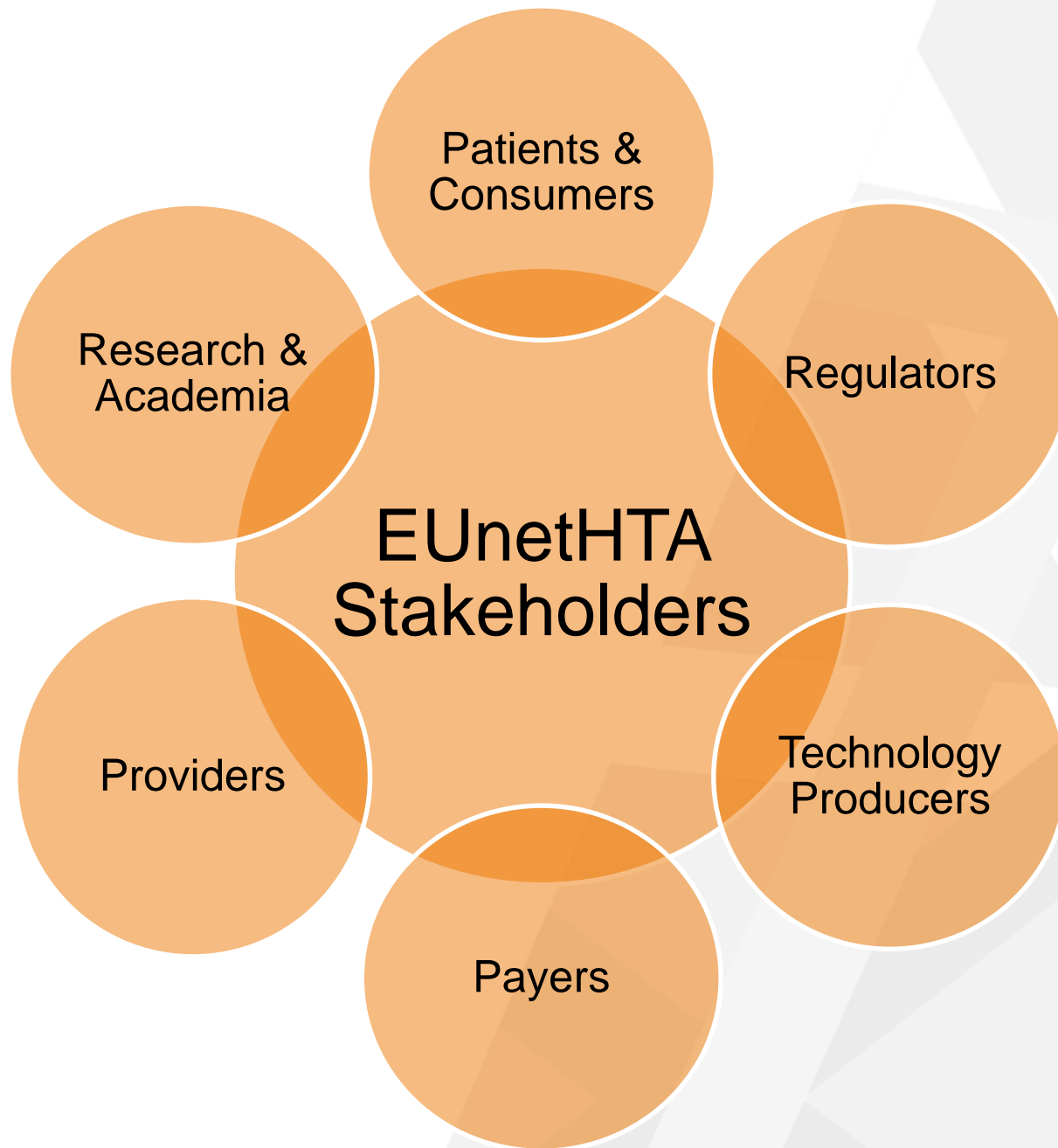
- To conduct Early Dialogues (joint HTA or parallel/joint with regulators)
- To link additional data collection to on-going activities

WP6 Quality Management

- To provide quality management for EUnetHTA joint products
- To further develop methodologies and tools for joint work if necessary

WP7 National implementation and impact

- To facilitate the uptake of joint products at the national/local level
- To measure the impact of joint work in collaboration with other work packages



Stakeholder Involvement in JA3

1. Participation in the EC/EUnetHTA Forum
 - October 21st (yearly interactions)
2. Participation in Work Packages
 - Facilitation of the provision of specific subject-matter information/knowledge on specific technical questions
 - Public consultations on deliverables
 - Interaction on the level of specific activities like the Early dialogues (WP5) and Joint Assessments (WP4)
 - Interaction on the level of methodologies, guidelines and procedures (WP6)

Practical examples of early involvement

- Technology producers
 - Meeting with EFPIA on Joint Assessments
 - Meetings with individual pharma companies on pilots
 - Participation in meetings with medtech industry
- Patients organisations
 - Several meetings with and without Commission to discuss involvement of patients
- Health care providers
 - Involvement in several Horizon2020 projects
 - Collaboration in registry projects in WP5.
- Payers
 - First contacts in the light of WP5.

HTA – public consultation (dl 13th Jan 2017)

Public consultation x

ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en.htm

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 PUBLIC HEALTH

European Commission > DG Health and Food Safety > Public health > Health technology assessment > Consultations

HEALTH TECHNOLOGY ASSESSMENT

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All topics Policy Joint action on health technology assessment

Go back to Health technology assessment > Consultations

Public consultation on strengthening EU cooperation on Health Technology Assessment (HTA)

Policy fields

Public health, Internal Market, Industry, Entrepreneurship and SMEs, Research and Innovation

Target group(s)

All citizens and organisations are welcome to contribute to this consultation. Contributions are particularly sought from patient organisations, public authorities and government-appointed bodies responsible for commissioning or executing HTA reports, national health insurance and social security institutions and associations representing such bodies, companies developing pharmaceuticals, medical devices and other technologies as well as associations representing these industries, healthcare providers and professional associations, as well as academic institutions.

Period of consultation

From 21/10/2016 to 13/01/2017

Please note that we cannot guarantee to take account of replies received after the deadline.

Definitions

Health Technology is a term used to cover certain aspects of healthcare products or services, such as:

- Pharmaceuticals (any medicinal products, from simple pain killers and gastro-protectors to anti-cancer medicines)
- Medical devices/equipment (for example X-ray machines, pacemakers, insulin pumps)
- Medical and surgical procedures (for example laparoscopy, hip replacement surgery)
- Other measures for disease prevention, diagnosis or treatment used in healthcare (such as vaccination programmes, pregnancy tests, screening test for early diagnosis of cancers, etc.)

Health technology assessment (HTA) measures the added value of a new health technology in comparison to existing technologies/current standard of care. HTA is defined as a multidisciplinary process that summarises information in a systematic, unbiased and robust manner about the medical, economic, organisational, social and ethical issues related to the use of a health technology. The goal of HTA is to support decision makers at national, regional or local level in their efforts to ensure that patients are treated with the best available treatment while

 Zika outbreak >

 EU HEALTH AWARD FOR NGOs 2016 Antimicrobial Resistance >

e-newsletter 13 October 2016

Strengthening Vigilance in the field of Substances of Human Origin >

Latest updates

Commission launches public consultation on strengthening EU cooperation on Health Technology Assessment

Released 21 October 2016

European cooperation on HTA: what's next? Register TODAY!

Released 14 October 2016

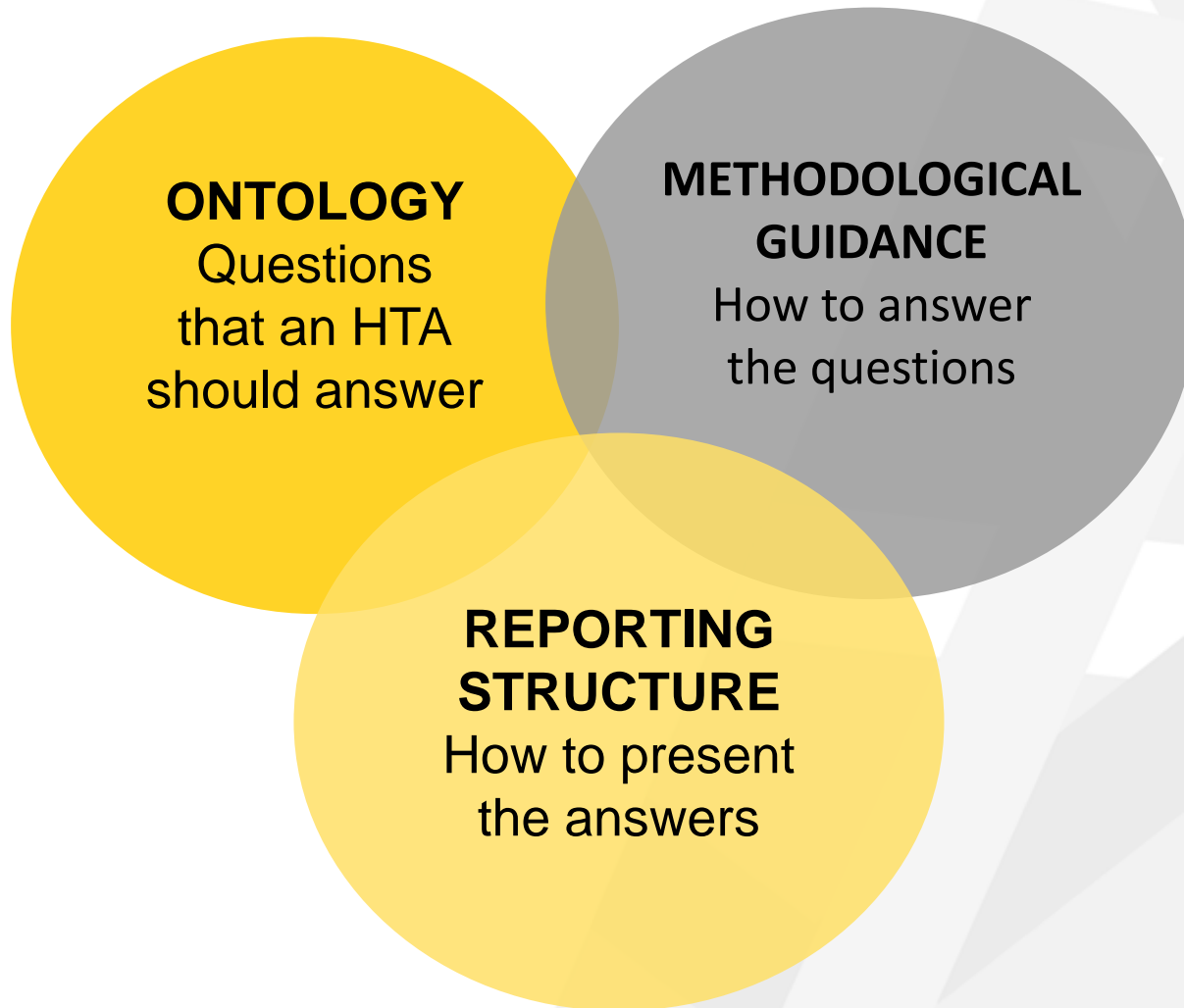
Registration open - EC/EUnetHTA Forum (Brussels, 21 October 2016)

Released 30 September 2016

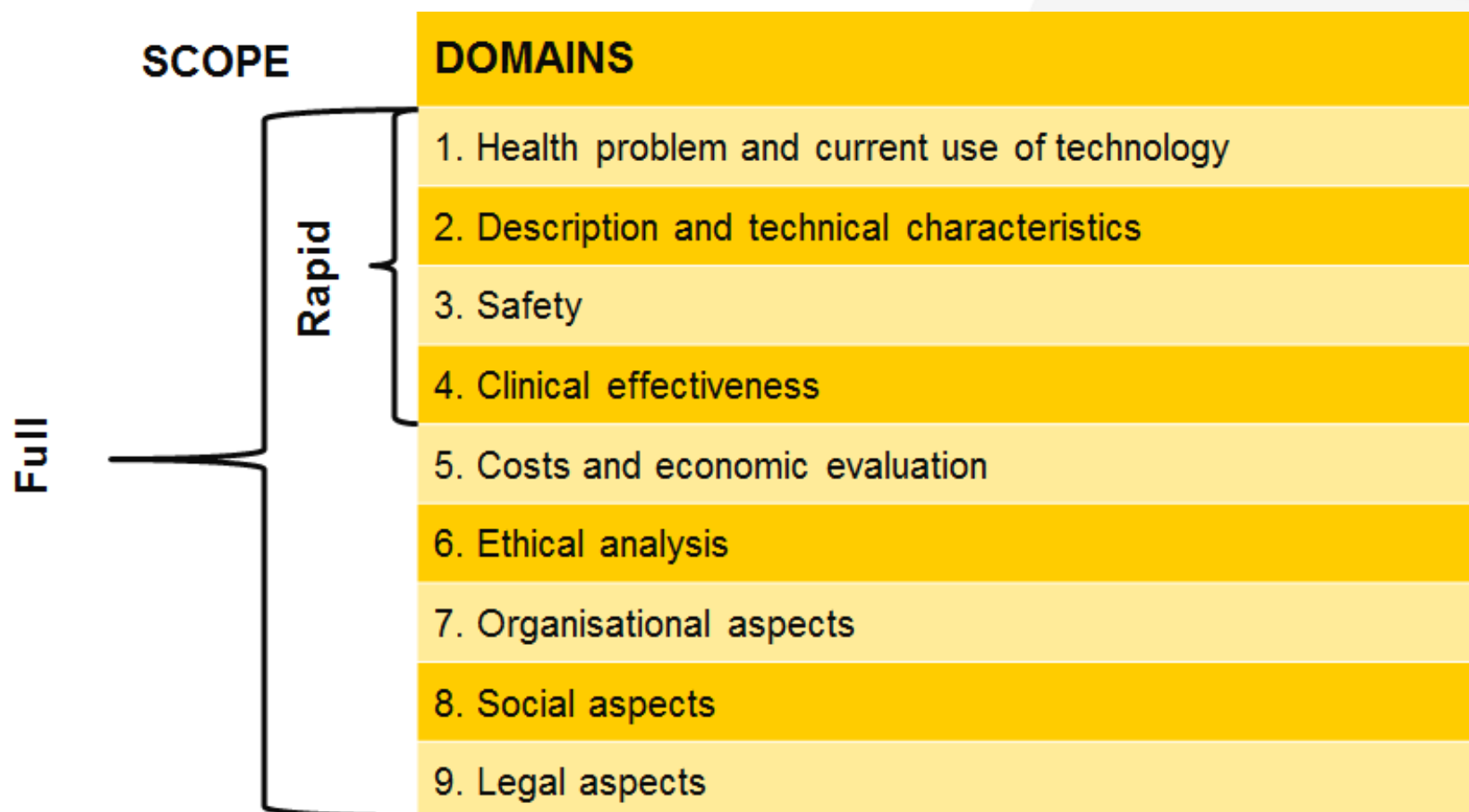
http://ec.europa.eu/health/technology_assessment/consultations/cooperation_hta_en.htm

The HTA Core Model®

The Structure of the HTA Core Model



The Domains of the HTA Core Model



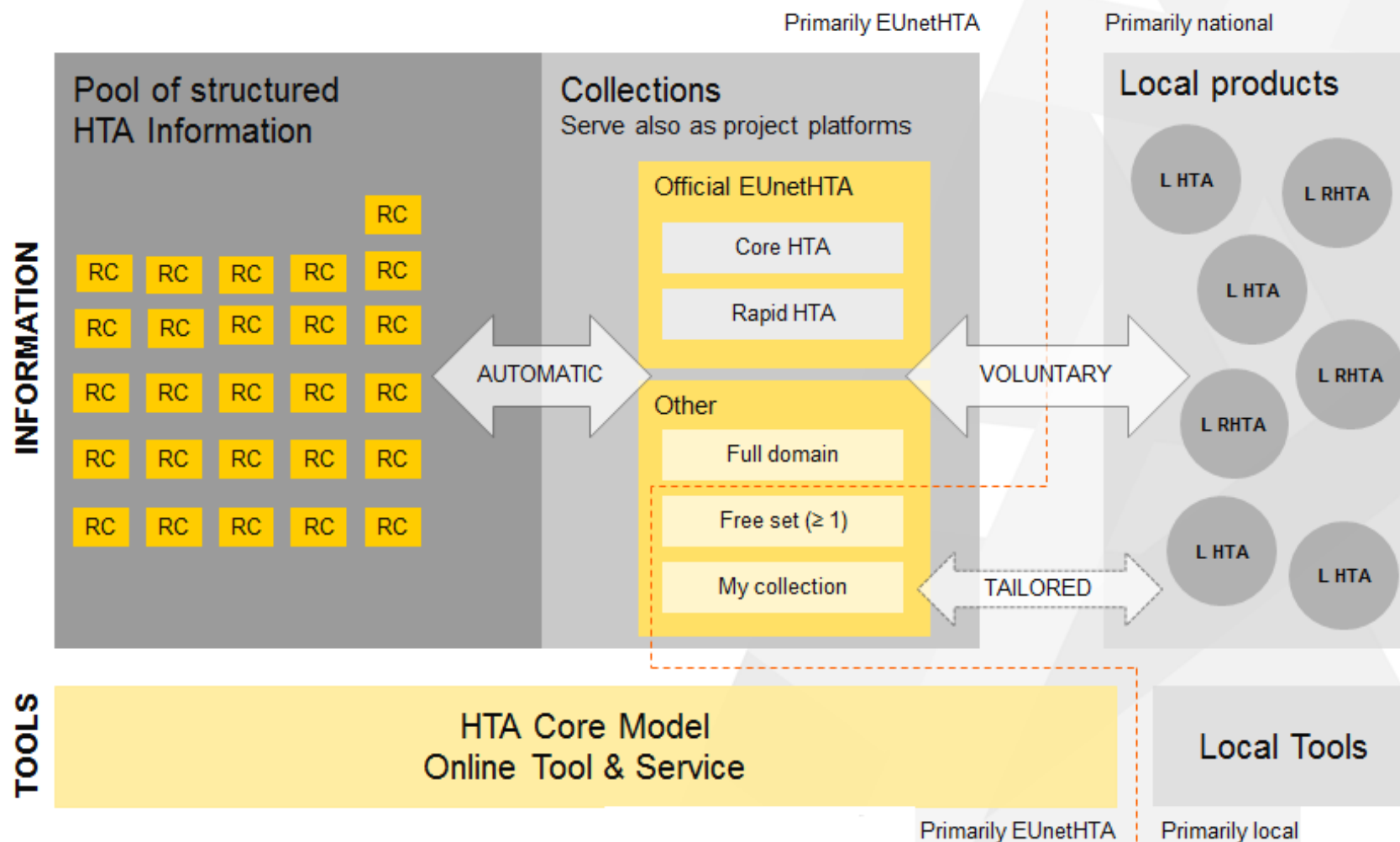
Topics of safety domain

Safety
Topic 1: Patient safety
Topic 2: Occupational safety
Topic 3: Environmental safety
Topic 4: Safety risk management

Health problem and current use of technology
Technical characteristics
Safety
Clinical effectiveness
Costs and economic evaluation
Ethical analysis
Organisational aspects
Social aspects
Legal aspects

Safety	Health problem and current use of technology
Topic 4: Safety risk management	Technical characteristics
Issue 1: How can one reduce safety risks for patients (including technology-, user-, and patient-dependent aspects)?	Safety
Issue 2: How can one reduce safety risks for professionals (including technology-, user-, and patient-dependent aspects)?	Clinical effectiveness
Issue 3: How can one reduce safety risks for the environment (including technology-, user-, and patient-dependent aspects)?	Costs and economic evaluation
Issue 4: What kind of data/records and/or registry is needed to monitor the use of the technology and the comparator(s)?	Ethical analysis
	Organisational aspects
	Social aspects
	Legal aspects

Core HTA Structure



HTA Core Model Applications

- The HTA Core Model is divided into several *applications*, each focusing on the assessment of a specific type of health technology
- Currently following applications exist:
 - Medical and surgical interventions
 - **Diagnostic technologies**
 - Screening technologies
 - Pharmaceuticals
 - Rapid REA of pharmaceuticals

HTA Core Model Online

- Assists in producing HTAs
 - Standardise structure of HTA products
 - Includes production phases
 - Facilitate production of global HTA
- Storage for HTA information
 - HTA result cards and collections, own projects
 - Reduce overlapping work
- Gather together guidance for HTA
 - Core Model applications, methodology, handbook, adaptation toolkit

www.htacoremodel.info



HTA Core Model® Online

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EUnetHTA id

Password

This is the production version of HTA Core Model Online. The test version is [here](#).

The IT-department at THL has regular maintenance breaks every last weekend of the month (except in December and January where the break is in the middle of the month). The tool may be unavailable during these breaks.

Please see the [FAQ](#) if you have problems logging on.



This tool is part of the European Joint Action on HTA (2013-2020) which has received funding from the European Union, in the framework of the Health Programme.

How to use the Model?

1. Select the assessment elements to be included in the collection.
2. Translate the included issues each into one or more practical research question(s).
3. Answer the questions using guidance within the Model.
4. Organise and present the answers according to the common reporting structure.
5. **RESULT:** a structured collection of HTA information in which information on a particular issue can be found at a standard location (whether in paper or electronic form).



HTA Core Model® Online



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HTA Collections

Name ^	Started	Scope	Actions
Abdominal Aorta Aneurysm Screening	4.5.2011	AAA Screening compared to not doing anything in the screening of Abdominal Aorta Aneurysm (AAA) in elderly at moderate risk of developing AAA	View
Prognostic tests for breast cancer recurrence (uPA/PAI-1 [FEMTELLE], MammaPrint, Oncotype DX)	13.6.2011	UPA/PAI-1 (FEMTELLE), MammaPrint, Oncotype DX compared to Standard of care in selecting treatment for Breast cancer recurrence in females	View
Fecal Immunochemical Test (FIT) versus guaiac-based fecal occult blood test (FOBT) for colorectal cancer screening	5.4.2013	Fecal Immunochemical Test (FIT) for colorectal cancer screening compared to CRC screening with Guaiac –based fecal occult blood test (gFOBT) in the screening of Adenomas, as non-malignant precursor lesions of ColoRectal Cancer (CRC), in healthy and/or asymptomatic adults and elderly Any adult over 50 years old, both men and women, with average risk of CRC.	View
Use of Intravenous immunoglobulins for Alzheimer's disease including Mild Cognitive Impairment	13.1.2014	Immunoglobulins (IGG) compared to placebo, not doing anything or Usual supportive care in the treatment of Alzheimer's disease in elderly AD is diagnosed mostly in people over 65 years of age, although there is an early-onset form that can occur much earlier. According to Wikipedia in 2006, there were 26.6 million sufferers worldwide.	View
Structured telephone support (STS) for adult patients with chronic heart failure	9.9.2014	Structured telephone support (STS) for adult patients with chronic heart failure compared to Usual care defined as regular schedules of visits of the patient at the heart center/ GP/cardiologist or patient has to move (≠ at home) in the prevention of Chronic cardiac failure in adults and elderly with chronic heart failure (CHF) AND hospitalization due to heart failure at least once AND without implanted devices	View


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Rapid assessments available as PDF

- Duodenal-jejunal bypass sleeve for the treatment of obesity with or without Type II Diabetes Mellitus, 2013 [View](#)
- Renal denervation systems for treatment-resistant hypertension, 2013 [View](#)
- Zostavax for the prevention herpes zoster, 2013 [View](#)
- Canagliflozin for the treatment of type 2 diabetes mellitus, 2014 [View](#)
- Balloon Eustachian Tuboplasty for the treatment of Eustachian tube dysfunction, 2015 [View](#)
- Biodegradable stents for the treatment of refractory or recurrent benign oesophageal stenosis, 2015 [View](#)
- Ramucirumab (Cyramza®) in combination with Paclitaxel as second-line treatment for adult patients with advanced gastric or gastro-oesophageal junction adenocarcinoma, 2015 [View](#)
- Sorafenib (Nexavar®) and its use for the treatment of progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma refractory to radioactive iodine, 2015 [View](#)

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HTA Core Model Handbook

Version 2.2, published 8 Apr 2016

This Handbook is the main source for instructions on using the HTA Core Model. The Handbook has during autumn 2015 undergone a major revision since its previous version (1.5, published in April 2014). Most content has been rewritten and included in two completely new user guides, one for using the Model in HTA projects and another for using the HTA Core Model Online. Practical instructions and key documentation are both included in the following table. Definitions for terms and concepts, as well as a brief introduction to the domains of HTA is available below the table.


Instructions and key documentation

Document	Description	Format(s)	Producer
HTA Core Model User Guide	A general introduction to the HTA Core Model and practical guidance for HTA projects. Basic reading for anyone using the Model.	PDF	JA2/WP8
HTA Core Model Online User Guide	Practical guidance for using the HTA Core Model Online.	PDF	JA2/WP8
Methodological Standards and Procedures	Practical guidance for project groups working on a core HTA (i.e. a "full assessment")	PDF	JA2/WP4
Procedure Manual for Rapid REAs	Practical guidance for project groups working on rapid relative effectiveness assessments. Separate versions are available for pharmaceuticals and other technologies .	PDF	JA2/WP5
Overview of HTA Core Model training materials	Key documentation used in HTA Core Model training. Particularly aimed for new users of the Model. The majority of the material can be used for self-learning.	PDF	JA2/WP8
HTA Core Model	All Model documentation (including earlier versions) is available here .	HTML, PDF and DOCX	JA2/WP8
Assessment element tables	Key information regarding the assessment elements included in various model applications is available in separate tables. Locate the application you are interested in here and choose the respective link "Assessment elements fpdf".	PDF	JA2/WP8

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Roche Pharma reviews the HTA Core Model® from a pharmaceutical perspective

 29 January 2015

In a report published in December 2014, Roche Pharma reviews the usefulness of the EUneHTA Core model® for Roche's internal HTA assembling, storing and sharing purposes.

The report focuses on the Pharmaceutical application of the HTA Core Model® and the value assessment of Pharmaceuticals.

Find the report and its appendices attached below.

[roche_pharma_report_on_the_hta_core_model_december2014.pdf](#)

[appendix_2_unimportant_detail.pdf](#)

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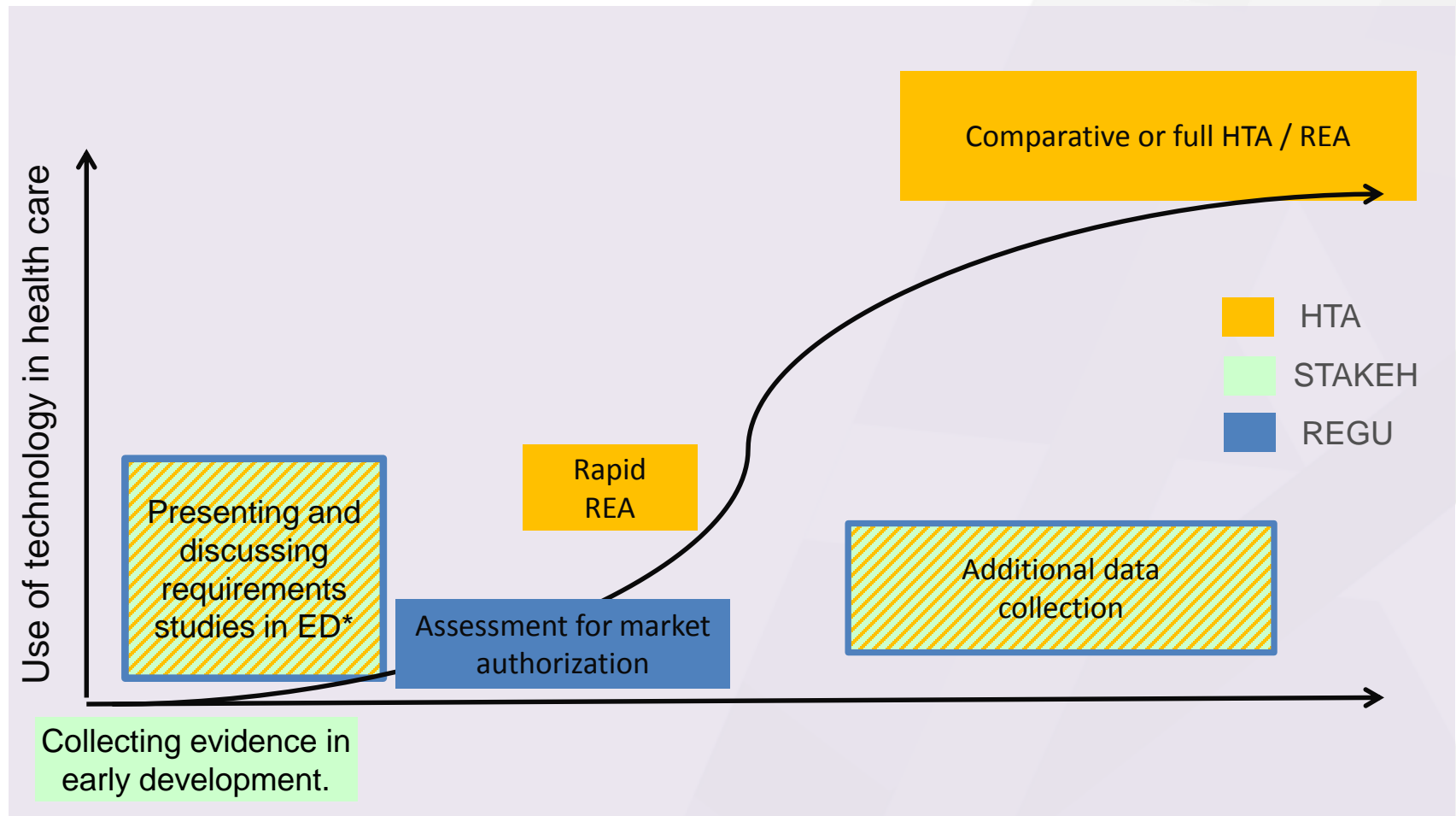


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European co-operation

- European countries are interested to co-operate
- A shared HTA is possible to produce
- Time-consuming process
 - to learn how to use new tools
 - to put shared practice into own process

HTA in the life cycle of technologies



**Early dialogue*

Thank you

Any Questions?