

EUnetHTA in few slides

EUnetHTA JA3 (2016-2020)

Aims to build a sustainable model for the scientific and technical cooperation on Health Technology Assessment (HTA) in Europe

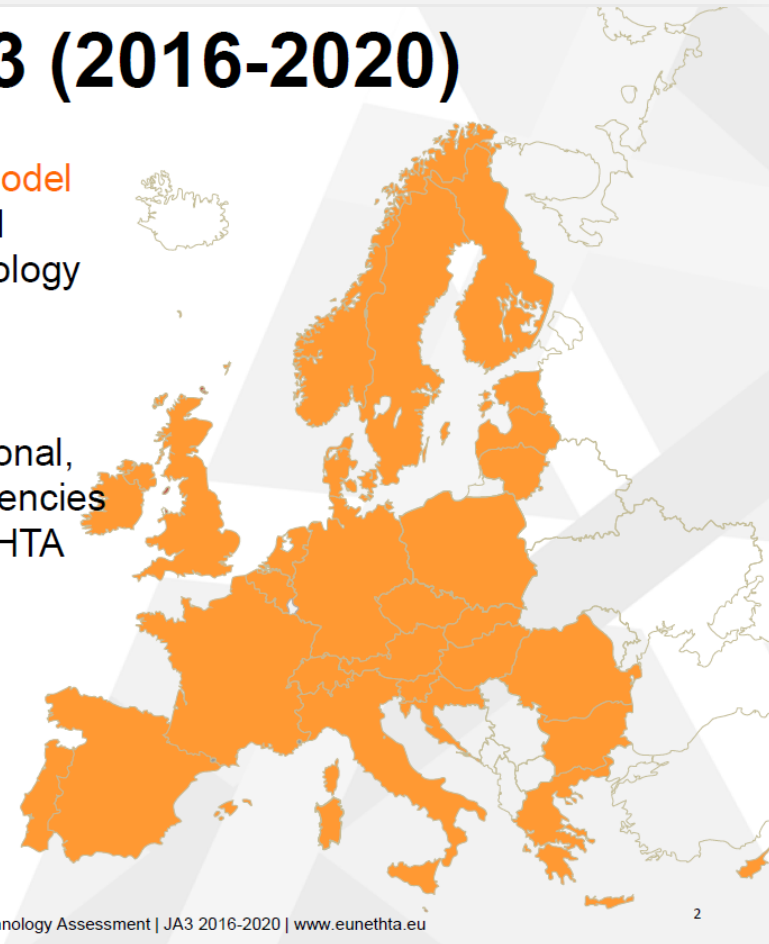
80 partners consisting of national, regional and non-for-profit agencies that produce or contribute to HTA

Project Coordinator:
Dutch National Health Care Institute (ZIN)



European network for Health Technology Assessment | JA3 2016-2020 | www.eunetha.eu

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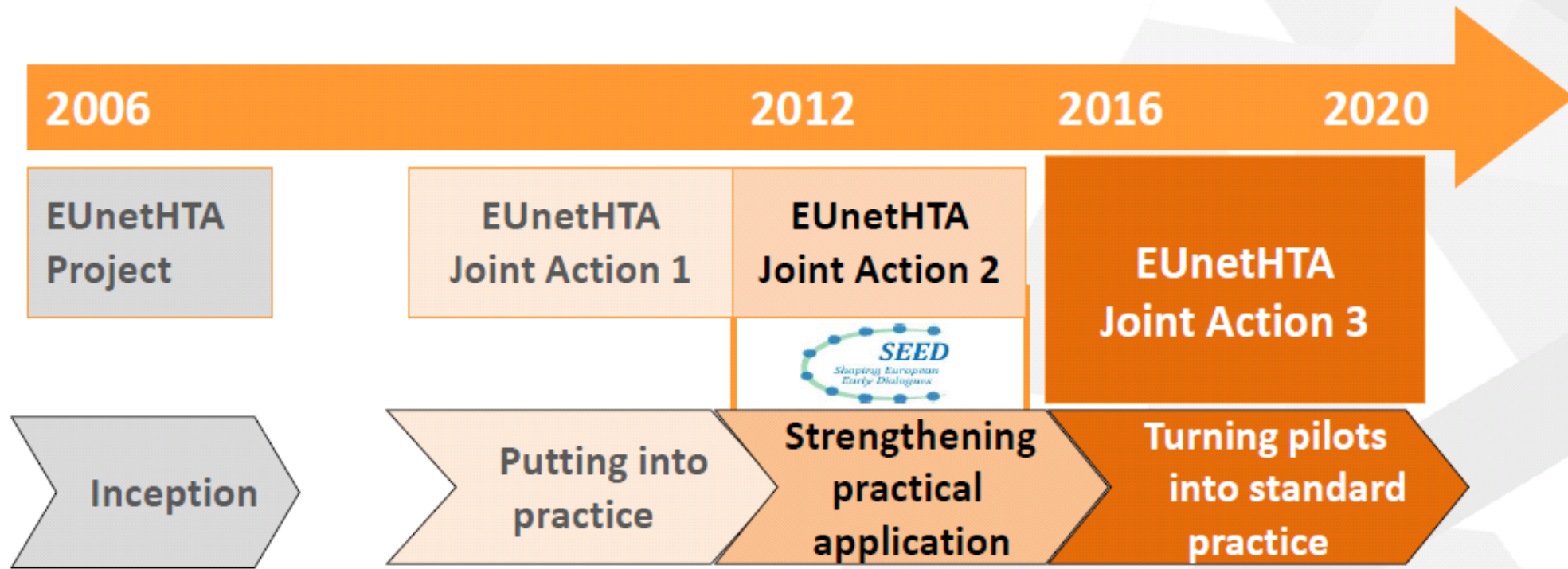


Different countries, different HTA practices

Data requirements in 8 countries + EUnetHTA



European Cooperation on HTA



Final objective of JA3














Set up practical conditions for a permanent (post-2020) collaboration

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Structure

Organisational and Governance Structure

DG SANTE and CHAFEA 							
EUnetHTA Assembly	Executive Board	WP1 Network Coordination - Dutch Health Care Institute 					
		WP2 Dissemination	WP3 Evaluation	WP4 Joint Production	WP5 Evidence Generation	WP6 Quality Management	WP7 Implementation
		Lead: AETS-ISCIII 	Lead: TLV 	Lead: NIPHNO Co-lead: LBI ZIN   	Lead: HAS Co-lead: GBA  	Lead: IQWiG Co-lead: KCE  	Lead: NICE Co-lead: Agenas  
Spain	Sweden	Norway	Austria	Netherlands	Germany		
United Kingdom	Belgium	Croatia	Cyprus	Czech Republic	Denmark		
Finland	France	Greece	Hungary	Ireland	Latvia		
Malta	Poland	Portugal	Romania	Slovakia	Slovenia		
Italy	Estonia	Lithuania	Bulgaria	Switzerland			

EUnetHTA Early Dialogue



- **Work Package 4 for Evidence Generation** is led by: HAS-GBA
 - Full members: HAS, GBA, NICE, AIFA, NIPN (HU)
 - Shared seat: RIZIV, ZIN
 - Alternate: RER (IT) for AIFA
- Expectations: carrying out > 30 EDs throughout JA3
 - 5 by Year 1 and 10 by Year 2
 - 1st ED ongoing (MS)

EUnetHTA Joint Assessment (REA)



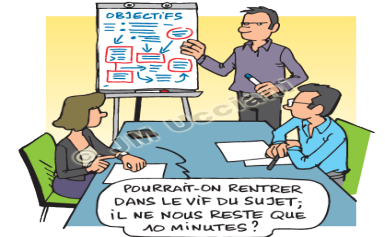
- **Work Package 5 for Joint Production** is led by: LIB-ZIN-NIPHNO (Norway)
 - Expectations: 33 Joint Assessments throughout JA3
 - 2 by Year 1 and 6 for Year 2 (2+3 in Year 1 and 2+6 in Year 2 on non-pharma)
- Outputs (Joint Reports)
 - **Regorafenib** [Stivarga] monotherapy for the treatment of adult patients with **hepatocellular carcinoma (HCC)** who have been previously treated with sorafenib (available)
 - **Alectinib** [Alecensa] as monotherapy for the first line treatment of adult patients with ALK-positive advanced **non-small cell lung cancer (NSCLC)** (ongoing)
 - **Midostaurin** with standard chemotherapy in FLT3 positive **Acute Myeloid Leukaemia** (ongoing)

STEPS FORWARD (1)

Parallel procedure: Early Dialogue (HTA) / Scientific Advice (EMA)

Key aspects

- It's an advice: not binding
- It addresses Regulatory and HTA issues



What's new

- An **EARLY DIALOGUE WORKING PARTY** has been established (EDWP), in charge of
- **CENTRAL RECRUITEMENT** of HTA Bodies (among partners and beyond) for each Parallel Procedure with EMA
- Level of engagement of HTA Bodies (**COORDINATION**) and Interaction with EMA
- Prioritisation

Patient engagement recognised and integral part of the Agency's work

For Parallel Consultations - Individual patient experts identified

- through patient organisations under the EMA [framework for interaction](#) - EMA - patients – consumers (EMA/637573/2014)
- Capacity-building / training / briefing
- A pool of patients acting as experts in their disease and its management
- Invited to attend all teleconferences and the EMA HTA Applicant meeting;
- Also declare conflicts of interest, managing barriers to participation

Item on EMA-EUnetHTA workplan

Task force on patient involvement established at EUnetHTA level (cross workpackage)

32 Parallel Consultation

14 Sept 2017

STEPS FORWARD (2)

EUnetHTA Task Force for Patient Engagement

Key aspects

- Gathering leaders of WP 4 and 5 on Early Dialogue and Joint Assessment
- Establishing new framework of interaction and guidelines for CoI and Confidentiality
- Keeping patients' organisations up-to-date on the ongoing discussion

Main Issues

For EARLY DIALOGUE (so far)

- HTA experts have several weeks to become familiar with the dossier
- Patients receive the briefing book only few days ahead of the meeting
 - Mentorship is crucial
- Travel and accommodation expenses need to be prepaid

For EARLY DIALOGUE & JOINT ASSESSMENT

- There is still no standard procedure for patient engagement

For JOINT ASSESSMENT: NATIONAL UPTAKE

- Prevent Member States reassessing the same domain of the Joint Report?



*"When we want your opinion,
we'll give it to you."*



Thank you for your attention

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