

# Update EUnetHTA JA3

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Director EUnetHTA JA3 Directorate

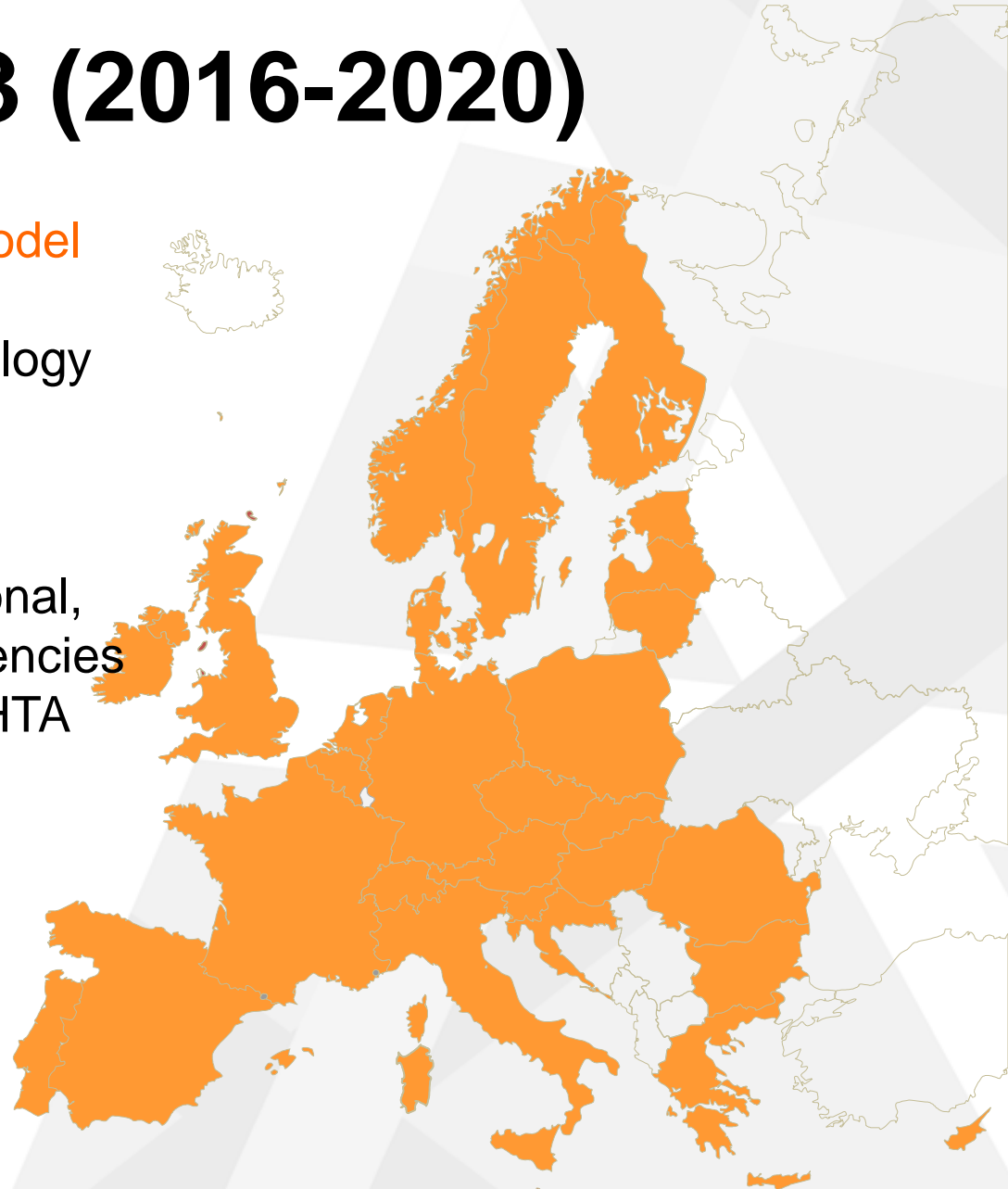
Brussel, March 29, 2017

# 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)



# 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-ISCIH 	Lead: TLV 	Lead: NIPHNO  Co-lead: LBI  ZIN 	Lead: HAS  Co-lead: GBA 	Lead: IQWiG  Co-lead: KCE 	Lead: NICE  Co-lead: Agenas 																												
<table border="0"> <tr> <td>Spain</td> <td>Sweden</td> <td>Norway</td> <td>Austria</td> <td>Netherlands</td> <td>Germany</td> </tr> <tr> <td>United Kingdom</td> <td>Belgium</td> <td>Croatia</td> <td>Cyprus</td> <td>Czech Republic</td> <td>Denmark</td> </tr> <tr> <td>Finland</td> <td>France</td> <td>Greece</td> <td>Hungary</td> <td>Ireland</td> <td>Latvia</td> </tr> <tr> <td>Malta</td> <td>Poland</td> <td>Portugal</td> <td>Romania</td> <td>Slovakia</td> <td>Slovenia</td> </tr> <tr> <td>Italy</td> <td>Estonia</td> <td>Lithuania</td> <td>Bulgaria</td> <td>Switzerland</td> <td></td> </tr> </table>						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	
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# Summary of select activities in JA3

## WP4 Joint Production

- To produce **43** rapid REA on other technologies and **37** on pharmaceuticals
- 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

# WP4 Joint Production

- Pharmaceuticals joint assessment
  1. midostaurin for acute myeloid leukemia (*awaiting submission file, scoping meeting planned*)
  2. regofarenib for hepatocellular carcinoma (*scoping phase*)
  
- Non-pharmaceuticals collaborative assessments
  1. Wearable cardioverter-defibrillator (WCD) therapy in primary and secondary prevention of sudden cardiac arrest in patients at risk (*finished*)
  2. Antibacterial-coated sutures versus non-antibacterial-coated sutures for the prevention of abdominal, superficial and deep, surgical site infection (SSI) (*assessment phase*)
  3. Screening of fetal aneuploidies whereby non-invasive prenatal test (NIPT), (*finalization project plan, 1<sup>st</sup> draft assessment*)
  4. MammaPrint for personalized management of adjuvant chemotherapy decisions in early breast cancer (*scoping phase, finalization project plan*)
  5. Repetitive transcranial magnetic stimulation for treatment-resistant major depressive disorder (*assessment phase*)
  
- Development of system of closer alignment of single joint assessment pharma with EMA processes including access to parts of the CHMP report

# WP5 Evidence Generation

## Early dialogues

1. Call for expression of interest multi-HTA Early Dialogues (Jan 2017)
2. HTA working party (preliminary group finalized)
3. Collaboration with EMA on one system for parallel early dialogues

## Additional data collection

1. Finalization of the preparatory work for pilots; review of first results by WP5B partners and relevant stakeholders
2. Selection of candidates for first pilots is ongoing
3. Draft report on current use registry data by HTA organisations (March 2017)

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## Call for Expression of Interest Multi HTA Early Dialogues - Pharmaceuticals

🕒 26 January 2017

A call for Expression of Interest to participate in EUnetHTA JA3 Early Dialogues has now been published.

A call for Expression of Interest to participate in EUnetHTA JA3 Early Dialogues has now been published. It is directed at healthcare product/technology developers and sponsors. Please note, the current call is restricted to pharmaceuticals, but medical devices will soon be added. Once candidates have been selected for the 13-15 EDs, additional applications may be considered for a 'reserve' list.

**Expression of interest and questions about EUnetHTA EDs should be directed to the WP5 coordinating team at: [early-dialogues@eunethta.eu](mailto:early-dialogues@eunethta.eu)**

The Early Dialogues to be performed by EUnetHTA will build on the experience gained from the EDs conducted within EUnetHTA (EUnetHTA JA2 WP7) and the SEED Consortium. The European Medicines Agency, EMA, is invited to participate as observer in all EUnetHTA Early Dialogues on medicinal products.

-  [EUnetHTA Multi-HTA \(Pharma\) – Call for Expression of Interest](#)
-  [EUnetHTA Multi-HTA \(Pharma\) – Letter of Intent Template](#)
-  [EUnetHTA Multi-HTA \(Pharma\) – Procedure](#)
-  [EUnetHTA Multi-HTA \(Pharma\) – Briefing Book Template](#)

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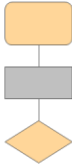
## Activity Centre A Quality Management

**6A.1**




**QM Concept Paper**  
*(fundamental aspects and EUnetHTA specific means of QM for joint work)*

**6A.3**



**Processes and Process Flows**  
*(e.g. for Rapid REA)*



**SOPs (incl. Checklists and Templates)**  
*(e.g. data extraction)*


**6A.4**



**Training Activities**  
*(on how to apply QM measures)*

**6A.2**  
QM System

**WP6**




**EUnetHTA Companion Guide**  
*(web-based)*

**6B.4**  
Hand-book


## Activity Centre B Scientific Guidance and Tools

**6B.2**




**Methodological Guidelines**  
*(e.g. on information retrieval)*

**6B.3**




**HTA Core Model®**

**6B.5 - 6B.8**



**Practical Tools**  
*(existing tools such as POP database and new tools)*

**Training Activities**  
*(on how to use tools and methodology)*



**Assessment Teams (WP4)**



# WP6 Quality Management

## Quality management

1. Draft quality management paper is being circulated across partners of WP4 and WP6
2. Process flows and SOPs for rapid REA pharma and other technologies are drafted
  - Submission file template pharma being discussed
  - Topics for SOPs and their prioritization are discussed for other technologies
3. Start on concept paper on training activities

## Tools and methodology

<b>6B1 Prioritisation</b>	<b>6B2 Guidances</b>	<b>6B5 Planned and ongoing Project database</b>	<b>6B7 EVIDENT</b>
<ul style="list-style-type: none"><li>• <b>Workshop took place</b></li><li>• <b>Roadmap delivered</b></li></ul>	<ul style="list-style-type: none"><li>• Activity plan drafted</li><li>• Procedure JA2 being update</li><li>• 1 JA2 Guidance updated</li></ul>	<ul style="list-style-type: none"><li>• Activity plan drafted</li><li>• Running (873 projects described)</li></ul>	<ul style="list-style-type: none"><li>• Running (23 projects described)</li></ul>
<b>6B3 HTA Core Model®</b>	<b>6B6 HTA Core Model® online</b>	<b>6B4 Handbook</b>	<b>6B8 Early dialogs tool</b>
<ul style="list-style-type: none"><li>• On Hold (THL involvement uncertain)</li></ul>	<ul style="list-style-type: none"><li>• On Hold (THL involvement uncertain)</li><li>• Re assessment planned</li></ul>	<ul style="list-style-type: none"><li>• Delayed (Awaiting new Intranet)</li></ul>	<ul style="list-style-type: none"><li>• Under pre assessment</li></ul>



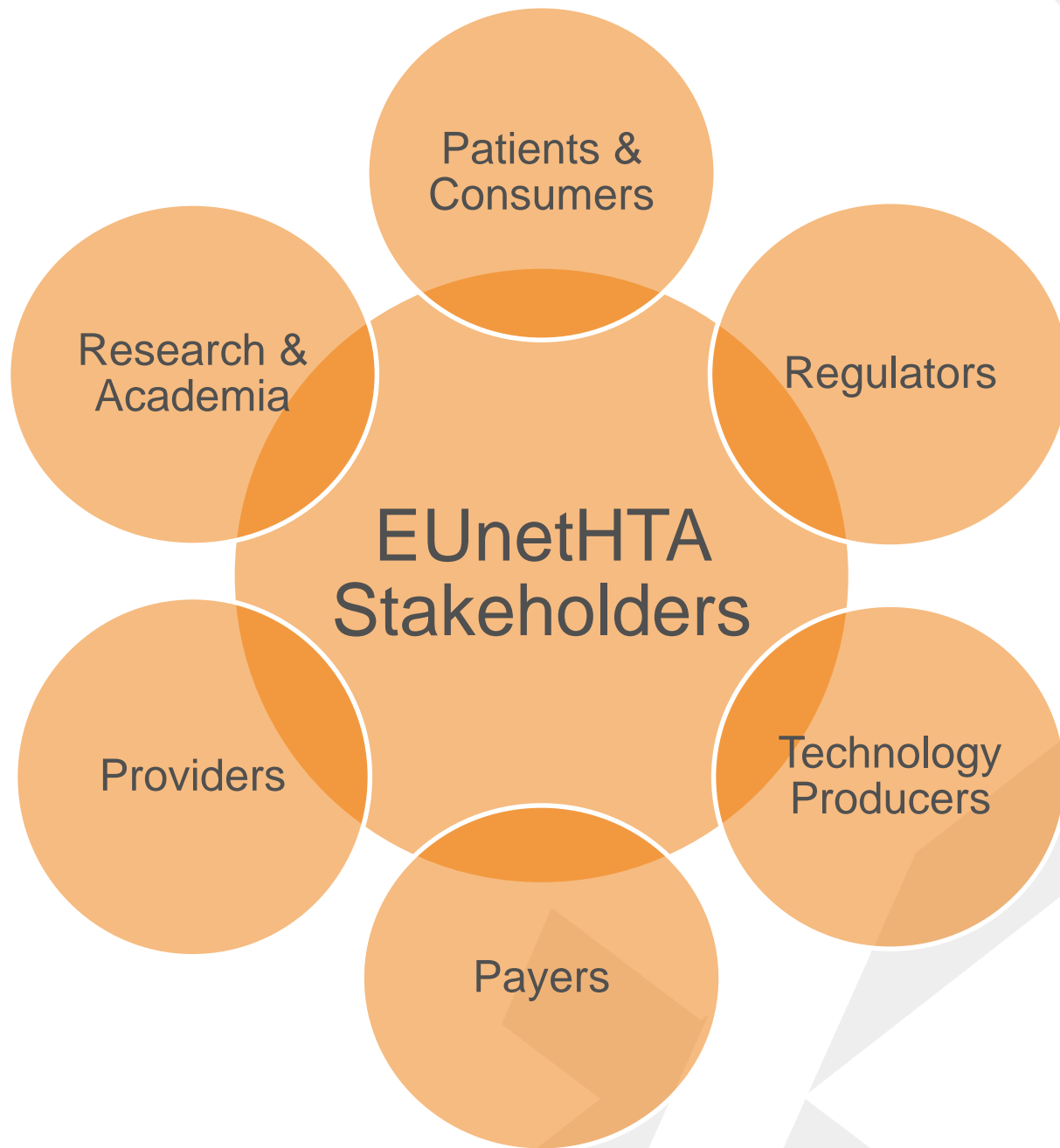
# WP7 National implementation and impact

## Analysis current state of play

1. Draft report on current barriers for implementation
2. Case studies in progress (for example Spanish Network, Italian collaboration, Benelux collaboration and many others)

## Implementation Network

1. Proposal developed, 3 working groups focusing on:
  - Implementation support
  - Reinforcing awareness and engagement
  - Obtaining feedback
2. Close interaction with production WPs especially WP4



# Stakeholder involvement in JA3

- Political and strategical involvement is moved to HTA Network
- Scientific and operational involvement will receive more attention in JA3
  1. Participation in the EC/EUnetHTA Forum
    - October 21<sup>st</sup> (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 involvement

- Technology producers
  - Meeting with EFPIA on Joint Assessments (June 2016), EFPIA HTA WG, national associations
  - Meetings with individual pharma companies on pilots
  - Participation in meetings with medtech industry
- Patients organisations
  - See next slides
- Regulators
  - Half yearly meetings EMA-EUnetHTA
  - Development working plan for collaboration
- Health care providers
  - Meeting with ECCO, February 2017
- Relevant research activities
  - Meeting with IMI on involvement in IMI projects

# Patient Involvement in JA3

- Meeting on March 8<sup>th</sup>
- WP4 (LP and Co-LPs); WP5 (LP); WP6 (Co-LP)
- Patient & Consumer Organisations
  - BEUC
  - EURORDIS
  - European Multiple Sclerosis Platform
  - European Patients' Forum
  - European Cancer Patient Coalition
  - IAPO (invited, did not attend)
- EUnetHTA Directorate
- DG SANTE

# Views from WPs on Involving Patients

- WP4
  - Examples from on-going assessments were shared
  - Working group to be established & there will be consultation with patient & consumer orgs
  
- WP5
  - Build on experience with SEED
  - Work with patient & consumer orgs to define possible approaches
  - Explore feasibility of leveraging tools available at EMA
  
- WP6
  - Build on experience from JA2

# Conclusions

- EUnetHTA JA3 is progressing
  - Final signature agreement late; end of September 2016
  - Resource issues at the level of coordinator and some LPs
  - Complex because high number of (new) partners
- Link of EUnetHTA JA3 to Commission activities on post-2020 scenarios is crucial
  - Involvement of ExBoard EUnetHTA in the discussion on the post-2020 scenarios
  - Members of the ExBoard EUnetHTA JA3 involved as experts in the different studies by the Commission for the post2020 scenarios
  - First results from EUnetHTA JA3 are input for the Commission activities



**Thank you**  
**Any questions?**

