EUnetHTA Assembly & Forum

2018

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Welcome

We would like to welcome you to the 2018 EUnetHTA Assembly & Forum in Cologne. It is a great pleasure to see constant growth and interest in our annual gathering! This year we are extending our reach even further by making parts of our meetings available online. Web-streaming will allow more stakeholders to participate in the Forum, follow the discussions and directly interact by asking live questions.

Since the last Assembly and Forum in 2017, EUnetHTA teams of all Working Packages have been working hard across Europe at further strengthening and fine-tuning procedures and templates that support our products. Joint Assessments remain one of the major focus of our activities. Early Dialogues have received overwhelming interest and the involved EUnetHTA partners are currently implementing a sustainable mechanism allowing Early Dialogues to deliver increasing scientific advice.

January of 2018 saw the publication of the long-awaited proposal by DG SANTE for a new HTA-focused regulation. This initiative has launched intensive debates far beyond the members of EUnetHTA and is currently the focus of discussions in the European Parliament and Council. It is the outlook of the regulation that should also inspire EUnetHTA to clearly define collaboration beyond 2020.

In light of these developments EUnetHTA will especially place focus in 2018 on further, stronger and more sustainable stakeholder involvement. Working programs are being developed and outreach to individual stakeholder groups is being strengthened.

In March, the Secretariat launched the new EUnetHTA website. Development of the site included the transfer of more than 800 documents and sub-sites. The new website allows EUnetHTA to reposition itself as a one-stop shop for HTA collaboration in Europe and sets the tone for a sustainable working environment for the future.

EUnetHTA grew even further since 2017, with the inclusion of our first Ukrainian partners. This demonstrates that collaboration on HTA is of increasing relevance in a growing number of countries.

As we move forward, expanding upon our catalogue of Joint Assessments & Early Dialogues and encouraging national uptake, we are confident that EUnetHTA is equipped with the expertise and tools to continue fostering progressive, cross-country partnerships.

Again, I would like to thank all our partners and guests for joining us here in Cologne and we hope that the events provide a useful insight into EUnetHTA's role in the European HTA landscape.

Marcus Guardian, *Chief Operating Officer EUnetHTA*

25 MAY 2018

Forum agenda

Time	Programme item	Invited speakers
8.30-9.00	Coffee and registration	
9.00-9.15	Welcome and opening remarks	- Prof. Juergen Windeler, *IQWiG* - Marcus Guardian, *EUnetHTA*
9.15-10.45	**Session 1: Relevance, quality, and timeliness as drivers for uptake of EUnetHTA's work**	
9:15-10.15	Completed, on-going, and planned updates to the Work Package (WP) 4 (Joint Production) procedure for both Other Technologies and Pharmaceuticals will be discussed. This update will focus on how WP4, WP6 (Quality Management), and WP7 (Implementation) have cooperated to address the important issues of relevance, quality, and timeliness through updates to the EUnetHTA procedures, templates, and via SOP development. An open Question & Answer (Q&A) will follow the session.	- Nick Crabb, *WP7 Lead Partner* - Claudia Wild, *WP4 Co-Lead Other Technologies* - Anne Willemsen, *WP4 Co-Lead Pharmaceuticals* - Miriam Luhnen, *WP6 Lead Partner*
10.15-10.45	Q&A	
10.45-11.15	Coffee break	
11.15-12.45	**Session 2: How can EUnetHTA predict and assist European health systems prepare for potentially disruptive innovation?**	
11:15-12:15	A multi-stakeholder panel will discuss the the opportunity for EUnetHTA's work to assist in identifying and assessing potentially disruptive and innovative technologies. Aspects addressed will reflect EUnetHTA's current thinking on topic selection, as well as collaboration in the horizon scanning space between regulators, EUnetHTA, and payers. Panelists will reflect on how the opportunities and challenges presented by these new technologies can be best managed. An open Q&A session will follow the panel.	- Pascale Brasseur, *Medtronic* - Ingvil Sæterdal, *WP4 Lead Partner* - Chantal Bélorgey, *WP5 Lead Partner* - Michael Berntgen, *EMA*
12.15-12.45	Q&A	
12.45-14.00	Lunch	
14.00-14.15	Remarks from the European Commission	Flora Giorgio, *DG SANTE*
14.15-15.15	**Session 3: Taking lifecycle approach to EUnetHTA's work: Current and future collaboration between Early Dialogues and Relative Effectiveness Assessments**	
14.15-15:00	Representatives from WP4 and WP5 will provide short presentations focused on harnessing the potential of cross-WP collaboration. More specifically, by means of EUnetHTA's activities in Early Dialogues, through the incorporation of learnings from joint Relative Effectiveness Assessments (REA), and via discussions on additional evidence generation needs, EUnetHTA has the tools in place to to think about technologies along the lifecycle continuum. The advantages of such a lifecycle approach will be discussed and followed by an open Q&A session.	- Sari Ormstad, *WP4 Lead Partner* - Claudia Wild, *WP4 Co-Lead Other Technologies* - François Meyer, *WP5 Lead Partner* - Hannah Brühl, *WP5 Co-Lead Partner*
15.00-15.15	Q&A	
15.15-15.45	Coffee break	
15.45-17.20	**Session 4: Start, Stop, Stay, Shift – How should EUnetHTA respond to the dynamic landscape of EU cooperation on HTA?**	
15.45-16.50	EUnetHTA is nearing the halfway point of Joint Action 3 (JA3). In light of this milestone and coupled with the European Commission's recent proposal regarding collaboration on HTA, should EUnetHTA consider changes to or a re-focus of planned activities for the remainder of JA3 – or should it stay the course? A multi-stakeholder panel will reflect on this question. An open Q&A session will follow the panel.	- Valentina Strammiello, *EPF* - Ancel.la Santos, *HAI* - Daniel Widmer *(UEMO)* - Ansgar Hebborn *(Roche/EFPIA)* - Flora Giorgio, *DG SANTE* - Marcus Guardian, *EUnetHTA*
16.50-17:20	Q&A	
17:20-17:30	Closing remarks	- Prof. Stefan Lange, *IQWiG* - Marcus Guardian, *EUnetHTA*

Work package review

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WORK PACKAGE 1

Network Coordination

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

Work Package 1 consists of

- the Executive Board, which is comprised of Work Package Lead and Co-Lead partners, observers (DG SANTE, CHAFEA), five elected members (FIMEA, OCSC, INFARMED, UniBA FOF, SNHTA), Chair (HIQA) and Vice-chair (AOTMIT) of the EUnetHTA Assembly;
- the Project Managers Group, which is comprised of Project Managers from each Work Package.

Objectives

- Provide scientific and technical coordination support for European collaboration activities in HTA to the integration of the HTA activities in the whole life cycle of technologies.
- Provide coordination support to the network and the JA3 activities that increase the use, quality and efficiency of joint HTA work at European level to support evidence-based, sustainable and equitable choices in healthcare and health technologies and ensure re-use in regional and national HTA reports and activities, in order to avoid the duplication of assessments.

Changes to governance structure

Since the start of Joint Action 3 (JA3), the Zorginstituut (ZIN) has established a Directorate for the Joint Action consortium, divided into two separate entities – the Director's office and the EUnetHTA Secretariat. The Director's office supported the day-to-day work of the Director of EUnetHTA. The EUnetHTA Secretariat functions as a management unit for EUnetHTA activities implemented via Work Packages 1 to 7, for cross Work Package activities and for the relevant governance and other bodies of the consortium.

The role of the Director of EUnetHTA, primarily leading the Executive Board as Chair, was originally appointed to Dr. Wim Goettsch. Dr Goettsch is an internationally recognised expert on scientific research for HTA and implementation through collaboration within the EU and globally. Recently, Dr. Goettsch accepted a new position as special HTA-advisor at ZIN. In this new role, he is responsible for the alignment of European Health Technology Assessment methods with the processes of Zorginstituut Nederland. Due to the new role, Dr. Goettsch discontinued his position as Director of EUnetHTA on March 15, 2018.

The Secretariat, together with EUnetHTA's Executive Board, are considering the necessary changes to the governance of EUnetHTA in order to ensure continued progress during the current phase of EU collaboration on HTA. The representative position of EUnetHTA Director and corresponding duties will be transferred to the new duly-elected Chair of the EUnetHTA Executive Board. This is a first but important step in a new phase

of collaboration that potentially supersedes the project character and continues the opportunity to build a sustainable future for collaboration post 2020.

Update on activities and stakeholders engagement

WP1 activities are divided between 1) scientific and technical coordination and 2) network coordination and support.

1. Scientific and technical coordination

- The European Medicines Agency (EMA) and EUnetHTA developed and agreed upon a joint work plan outlining key areas of collaboration for the next three years. The EMA-EUnetHTA collaboration aims to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine whilst respecting their different remits. The overall goal is to improve the efficiency and quality of processes and ensure mutual understanding and dialogue on evidence needs. The collaborative activities are directly related to the core activities of both organisations. More information regarding the joint work plan can be found here: https://www.eunethta.eu/ema-eunethta-joint-work-plan-for-2017-2020/

- A technical meeting was organised in December 2017, bringing together HTA agencies, EFPIA, patient representatives, the European Medicines Agency and the European Commission. The meeting focused on presenting the procedures for joint REA and explored how both sides, HTA Agencies and industry, can ensure the submission of dossiers for joint work within EUnetHTA JA3.

- A Payer-EUnetHTA meeting was organised in March 2018 to provide an update on EUnetHTA activities to payer representatives and identify how to further engage payers and in what topics, payer involvement and consultation would be useful. A meeting with Patient & Consumer organisations has also taken place with similar themes being discussed. Work Package 1, in collaboration with the other work packages, is planning to organise similar meetings in the future with other types of stakeholders.

- A new body composed of the relevant Heads of Agencies of the HTA countries represented in the EUnetHTA Executive Board was established in June 2017. Its role is to ensure relevance and progress in joint work and national implementation of the joint work results. The 2018 Heads of HTA Agencies meeting took place in April, during which the Heads of HTA Agencies agreed that there needs to be a significant increase of relevant EUnetHTA Joint Assessments. In this regard, the Heads of Agencies invite representatives of industry to engage actively with EUnetHTA. For the purpose of increasing the number of relevant Joint Assessments, the Heads of Agencies will agree and communicate on relevant topics they collectively believe to be of substantial importance and invite industry to align their submissions to these priorities.

- Work Package 1 has also sought to engage with various regional HTA initiatives currently active in Europe. These include FiNoSe (encompassing Finland, Norway and Sweden), La Valletta (comprising of Malta, Cyprus, Greece, Italy, Spain, Slovenia, Croatia, Ireland and Portugal) and Beneluxair (made up of Belgium, The Netherlands, Luxembourg and Austria). Members of the EUnetHTA Executive Board represent some of these groups and act as regular channels of communication.

- Work Package 1 established two cross work package task groups at the request of the Executive Board: Conflict of Interest and Confidentiality Undertaking in EUnetHTA Task Group (DOICU TG) represented by WP 1, 4 and 5 and Patient and Health Care Provider Involvement in EUnetHTA Task Group (P&C/HCP TG) represented by WP 1, 2, 4 and 5. The objective of DOICU TG is to ensure consistent understanding and application of the EUnetHTA Declaration of Interest and Confidentiality Undertaking (DOICU) procedure, identifying any limitations of the current procedure and providing recommendations for improvements. The objective of P&C/HCP TG is to explore ways of stakeholders' engagement in EUnetHTA specific tasks, particularly in Work Package 4 and 5 activities.

2. Network coordination and support:

- Work Package 5 has a limited budget for Early Dialogues (EDs), which covers only the first EDs so a sustainable financial solution has to be identified. The Secretariat, in collaboration with WP5 Lead and Co-lead partners, looked into several viable options. After careful evaluation and external legal analysis, a mechanism has been identified upon which a EUnetHTA partner organisation can function as the Early Dialogue Financing Mechanism Secretariat (EDFMS). The EDFMS will be responsible for receiving and distributing all fees under the Early Dialogue Mechanism. The involved parties are currently drafting an inter-institutional framework agreement.

- The 1st EUnetHTA JA3 Interim Report was finalised and submitted to CHAFEA. The Interim Report is comprised of a Technical Report and a Financial Report. The Technical Report presents the progress and the achievement of JA3 in the period between June 2016 and November 2017 while the Financial Report provides information regarding partners' costs between June 2016 and November 2017. The Interim Report is currently under evaluation by CHAFEA and will form the basis for the reimbursement of partners' costs.

- A network infrastructure (SharePoint/Intranet) was created to provide consortium partners a platform for collaboration and support them in their project activities.

- A new EUnetHTA website was created and launched, making the transition from EUnetHTA Joint Action 1 and 2 to EUnetHTA Joint Action 3. We invite you to visit our new website at eunethta.eu to find out more about EUnetHTA's latest activities.

If you have questions or you would like to hear more about Work Package 1 activities, please contact us at EUnetHTA@zinl.nl.

WORK PACKAGE 2

Dissemination

Lead partner: Agencia de Evaluación de Tecnologías Sanitarias - Instituto de Salud Carlos III (AETS-ISCIII, Spain)

Activities (1 -2 years)

Communication strategy
- EUnetHTA Welcome Package
- EUnetHTA Graphical Guide
- Newsletter (internal); Quarterly Magazine (external)
- Use of social networks for EUnetHTA Dissemination (i.e. LinkedIn, Twitter)
- Intranet development and Internet rebuild in partnership with the Executive Board and the Secretariat
- Participation in events
- Leaflets, templates, general EUnetHTA JA3 presentation, icons, logos, infographics, images
- ARCI: Cross Work Package (WP) Working Group on Authoring Rules and Copyright Issues in collaboration with other WPs

Training activities
- Training Strategy, which summarises needs, methods and procedures for training actions
- EUnetHTA Virtual Classroom (Intranet): Webinars, webcasts and training options and materials, in collaboration with other WPs.
- Calendar of internal and external events

Dissemination strategy
- Intensification of EUnetHTA's presence in the world, supporting the uptake of its products and tools
- Acknowledge and encourage partner, stake-holder and public involvement in EUnetHTA activities
- Dissemination registry: Ongoing tool to analyse JA3 dissemination and make proposals for improvement
- 98 activities disseminating EUnetHTA have been registered so far

Stakeholder involvement activities

Stakeholder Analysis
WP2 analysed the definition, collaboration modes and involvement policies related to the EUnetHTA Collaborating Stakeholders activity. General stakeholder involvement processes were also reviewed, particularly in relation to potential post-2020 scenarios. This led to the proposed development of specific procedures on stakeholder collaboration in Early Dialogues and Joint Assessments.

Stakeholders Registry
This is a collection of the historical and current mode of stakeholder involvement in EUnetHTA. An analysis of their engagement and participation throughout the years (2006-present) also took place. 154 stakeholder collaborations (regulators, payers, manufacturers, healthcare providers, patients and consumers and academia/researchers) in 28 assessments have been reviewed so far. This represents the basis for future databases and further analyses.

The Patients, Consumers, and Healthcare providers Involvement Work Group
This group represents cross WP cooperation between WP1, WP2, WP4 and WP5 in order to explore the current mode of stakeholder engagement in EUnetHTA specific tasks. A series of e-meetings were held by the group, as well as a face-to-face meeting with patient and consumer organisations in Brussels on 26 January 2018. The objective was to discuss EUnetHTA engagement with patients and consumers in Assessments and Early Dialogues.

The Future

The commitment to stakeholders continues
WP2 continues to maintain, review and validate the Stakeholders Registry with data from ongoing assessments and other types of involvement, such as horizontal activities (participation in the EUnetHTA Forum, participation in EUnetHTA surveys...).

WP2 is also exploring the possibility of utilising the Stakeholders Registry as a framework for a future collaboration platform/system between stakeholders and partners (for example, a Stakeholders & Partners Communication Extranet).

The work package is also providing partners with tools to search for experts with a view to build an expert database in the future. This would refine individual expert roles and their subsequent engagement.

WP2 will continue with the activities carried out by the Patients, Consumers & Healthcare Providers Task Group to enhance the actions on eligibility, and explore engagement modes, confidentiality, conflict of interest issues, and processes for stakeholders' involvement.

Dissemination of future Standard Operating Procedures on the involvement of patients, manufacturers and experts in Assessments and Early Dialogues will also continue as the project enters its third year.

The strategy on training is dynamic
- Updating training materials and improving the virtual classroom to make it more simple and accessible.
- Exploration of training options for engaged stakeholders.
- Ongoing collaboration with WP6 for training on Quality Management and the Companion Guide.

The dissemination keeps going on
- Participation of stakeholders in the magazine will continue to be pursued.
- Website being completed and improved.
- Communication Strategy is currently under review.
- Exploring new strategies for promoting EUnetHTA activities.

WORK PACKAGE 3

Evaluation

Lead partner: Dental and Pharmaceutical Benefits Agency (TLV, Sweden)

Objective

The objectives of the evaluation work in WP3 is to verify if the Joint Action is being implemented as planned, if the project is reaching its objectives and to identify, to what extent, the individual WPs enable the achievement of JA3 goals. WP3 will also evaluate the uptake and added value of EUnetHTA products at a national, regional and local level. WP3 is also due to review measures taken to build a sustainable network and co-operation for the period post-2020. However, it is important to note that this task will progress as per the development of the 2020 EC proposal on HTA.

Deliverables

WP3 has 11 deliverables, all of which are evaluation reports. These are broken down into seven bi-annual reports, three yearly interim reports and one final report.

Year 2 summary

During the second project year WP3 has finalised two bi-annual reports, number II and III and the first yearly interim evaluation report.

The general outline of the bi-annual reports mean they all contain a description of the scope of the individual report, the methods used, the financial resources used, the deliverables fulfilled and a section with conclusions. This is where the evaluation team presents their encouraging findings, their findings for consideration and, when appropriate, recommendations for the Executive Board to consider. Each bi-annual report also has one or two sections, of the above or separate, where the evaluation team has completed a distinctive piece of work, for example, an interview round or a survey.

Bi-annual evaluation report II

In the second bi-annual evaluation report, interviews conducted with a selection of external stakeholders was the special focus. In brief, the stakeholder interviews showed that:

- Many stakeholders were familiar with EUnetHTA at a general level. However, they tended to confuse EUnetHTA with the HTA Network. This is probably due to the fact that the HTA Network has established a stakeholder pool and a more select group representing the pool, which was activated for the HTA Network meeting in March 2017.
- The stakeholders who participated in the EUnetHTA JA2 Stakeholder Forum expressed that they experience a lack of formal participation in EUnetHTA JA3. Some stakeholders also point to agreements reached in the framework of the JA2 Stakeholder Forum, regarding both procedures and content.
- Majority of the stakeholders expressed a strong interest in being involved in EUnetHTA and requested further methods of communicating with EUnetHTA.

Bi-annual evaluation report III

In the third bi-annual evaluation report prepared by WP3, a combination of quantitative and qualitative approaches was used to follow the progress of the Joint Action from various perspectives. The focus topic was a descriptive analysis of the first Partner Survey, performed in 2017.

The partner survey covered topics such as: production of HTA, language, communication and collaboration, expectations of EUnetHTA, time, resources and priorities.

Summary of conclusions

- 6 out of 10 partners had been involved in the JA3 production process, of these, 7 out of 10 thought the EUnetHTA procedures were working well or at least at an acceptable level.
- Regarding language, 6 out of 10 partners said that they consistently produce an English summary of their HTA reports but a majority still felt that the language issue is a concern.
- The partners had very high expectations on information sharing, and on enhanced collaboration but did not expect any economic gains.

First yearly interim report

The interim reports are written with the aim of providing an alternative perspective. Taking into account the first two bi-annual reports and the findings and recommendations in them, the first interim report contained analyses under the themes: Continuity and experience, Intranet and administration, Stakeholder involvement and stakeholder communication, Governance and transparency and finally, Production, output, tools and use.

Summary of conclusions

- EUnetHTA must continue to work on finding an optimal path for stakeholder involvement and stakeholders cite communication with JA3 as an area for improvement.
- Although EUnetHTA JA3 is a network of more than 80 partners, the start-up processes of various governance bodies have been efficient but decision structures need further clarification.
- The success of the first products delivered by EUnetHTA paves the way for the further development of the project as a whole.

WORK PACKAGE 4

Joint Production

Lead partner: The Norwegian Institute of Public Health (NIPHNO, Norway)

Co-lead partners: The Dutch National Health Care Institute (ZIN, Netherlands), Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA, Austria)

- The WP4 key activity is the production of Joint and Collaborative Assessments
- WP4 develops the production processes of assessments for a sustainable model of collaboration, and generates recommendations for stakeholder (patients, consumers and healthcare providers) involvement in assessments
- WP4 develops recommendations for topic selection and topic prioritisation in the European context
- WP4 supports the process for the implementation of EUnetHTA assessments in national contexts
- WP4 is involved in several cross work package activities:
  - with WP6 to ensure quality management for assessments and the production of Standard Operating Procedures (SOPs)
  - with WP7 to ensure usability and timeliness of EUnetHTA assessments; ensure topics are relevant to WP4 partners
  - task group on Conflict of Interest (DOICU TG) and, task group on Patient/Consumer and Health Care Providers (P&C/HCP TG)

Update on activities and stakeholder engagement

Activity: Produce Joint and Collaborative Assessments for health technologies
So far, Joint Action 3 WP4 has published 3 pharmaceutical Joint Assessments and 6 non-pharmaceutical Collaborative Assessments. You may read more about the two variants by going to our website and clicking on Assessments. Currently, there are 8 ongoing Collaborative and 2 Joint Assessments in Other Technologies.

During the production of assessments, various stakeholders are involved: manufacturers, clinical experts, and patients/patient representatives. Patients/patient representatives have been involved in various ways and WP4 is currently developing recommendations for a long-term model for patient involvement in Joint and Collaborative Assessments. This will be completed in collaboration with WP2 and WP5 in the cross work package task group concerning patient and consumer involvement.

Activity: Recommendations for a sustainable production process of European Joint and Collaborative Assessments
The production processes of Assessments in EUnetHTA are continuously being improved. The work is based on experiences from Joint Action 1 and 2. In Joint Action 3, experiences from the authoring team, as well as the involved manufacturer, are also proactively sought.

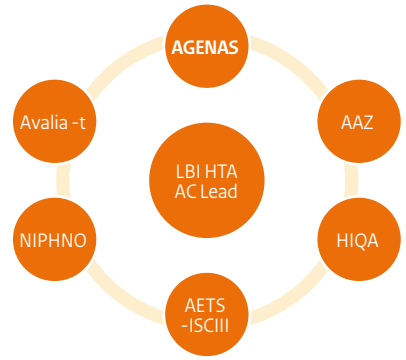
Ongoing process revision activities include:

Pharmaceuticals
- Revision of procedures in the production process
- Revision of documents and templates

Other Technologies
- Decentralised project management of Collaborative Assessments
  - Training and support for Activity Centre Department Leads
- Revision of procedures in the production process
- Revision of documents and templates

The work and changes carried out is, amongst others, based on feedback from the authoring teams of previous assessments and input from WP4 partners. WP4 also collects feedback from manufacturers who have been involved in the EUnetHTA process. This valuable information is used to further enhance the production process. WP4 works closely with WP6 to produce Standard Operating Procedures (SOPs) which will be integrated in to the Companion Guide (WP6). The tools, templates and guidelines that support the production of assessments will also be available in this guide.

Activity: Decentralised project management of Collaborative Assessments: Activity Centre Department Leads in Other Technologies
The Activity Centre Department Leads conduct project management for some Collaborative Assessments. The purpose of this model is to generate a designated pool of agencies with established roles and growing experience in a sustainable form of collaboration, which could facilitate continuation of joint work after 2020.



Activity: Development of draft recommendations for a model for patient involvement in Joint and Collaborative Assessments
The work concerning patient involvement in assessments has been of high priority, especially in the last few years. A task group, Patients & Consumers and Health Care Provider Involvement in EUnetHTA, is developing recommendations for such involvement. Part of these recommendations concern patient involvement in assessments. The goals of patient contribution in assessments are to gain better insights into disease and treatment, as well as outcomes which are important from patients' perspectives. Patients can also describe the advantages and disadvantages of health interventions based on their own experiences and can state what they value in a new intervention. For patients, participation in assessments will provide useful insights into HTA-methods and decision-making processes. In total, patient involvement and contribution can enhance the relevance of HTA and help facilitate the implementation of decisions. Various forms for how to best gain input from patients are being tested in Joint Action 3.

So far, 9 out of 16 assessments have involved patients/patient representatives.

Activity: Recommendations for a system for topic selection and prioritisation
This activity is led by WP4 Lead Partner and the working group has members from several WP4 partners. The working group is developing recommendations for horizon scanning and topic prioritisation in the European context. These recommendations will be shared for a stakeholder consultation, which will include patient organisations, payers/decision makers, health care providers, regulators and industry. The consultation will take place in June 2018 and the recommendations will be piloted in autumn 2018.

Activity: Production of a draft Roadmap for coordinated activities on HTA and Medical Device authorities
The 1st workshop of the EUnetHTA Task Force on HTA and Medical Devices will take place on 29 May 2018 in Vienna. This is a bilateral workshop between regulators (EC, national competent authorities) and HTA (EUnetHTA) to have an initial exchange on the mutual understanding of definitions, concepts and methodologies. A meeting report will be publicly available after the workshop. There will be a second workshop in May 2019 and this will be open to all stakeholders (for example, patient representatives, clinicians, industry).

Aim of the roadmap	Final aim
To develop coordinated activities between the Competent Authorities, Notified Bodies and EUnetHTA (supported by the EU-Commission and in cooperation with stakeholders)	To reduce the evidence gap between market approval (CE marking) and market access (reimbursement and coverage decisions)

Activity: Process for the implementation of EUnetHTA assessments in national/ regional practice
WP4 works to ensure the usability and timely availability of assessments. The collaboration with 'WP7 National Implementation and Impact' is essential as they collect data on whether and how EUnetHTA assessments are being used in national, regional and local contexts; the decisions that the assessments are informing; and factors that limit national/regional use of assessments. This data is highly valuable because it shows, not only uptake and impediments for uptake, but topics that are relevant for partners and thus could be useful for future topic selection.

Promotion of EUnetHTA assessments and support for uptake is formalised in the WP7 Implementation Network.

If you are interested in submitting a topic for a Joint or Collaborative Assessment, or wish to learn more about the EUnetHTA assessment process, please contact WP4.LP_EUnetHTA.JA3@fhi.no.

WORK PACKAGE 5

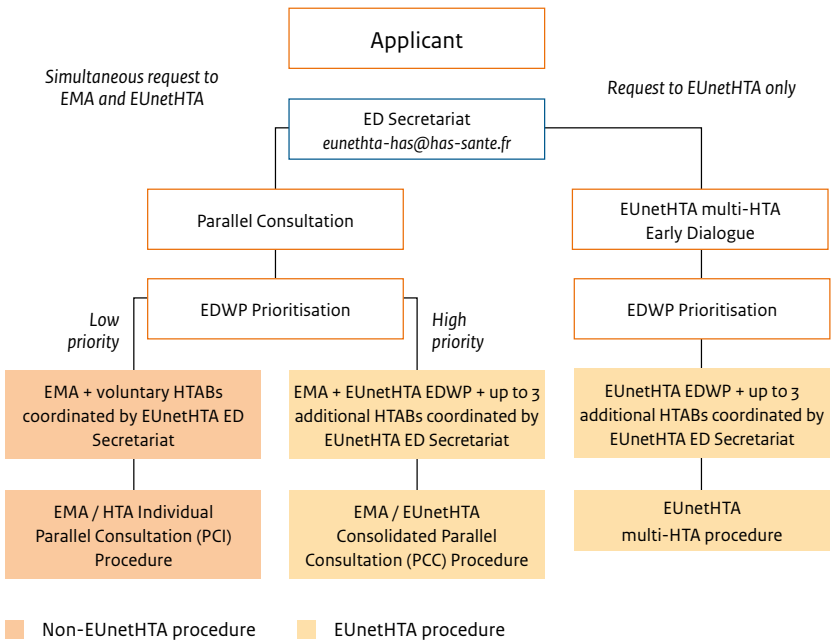
Life cycle approach to improve Evidence Generation

Lead partner: Haute Autorité de Santé (HAS, France)
Co-lead partner: Gemeinsamer Bundesausschuss (GBA, Germany)

Objectives

The main objective of WP5 is to help generate, all along the technology lifecycle, optimal and robust evidence for different stakeholders, bringing benefits for patient access and public health. WP5 is broken down into two main strands: Strand A, focusing on Early Dialogues and Strand B, focusing on Post-Launch Evidence Generation (PLEG) and improving the use of registries for HTA purposes.

Figure 1: Early Dialogues options for applicants



Update on activities and stakeholders engagement

Strand A: Early Dialogues

The core focus of WP5A throughout year two has been the conduct of Early Dialogues for pharmaceuticals. The multi-HTA procedure was launched in January 2017, followed by the launch of the Parallel Consultation process in July 2017.

The official launch of EUnetHTA-EMA Parallel Consultations has provided an opportunity for companies to seek not only advice from EUnetHTA but in parallel with regulators, too. Figure 1 on page 18 outlines the different options available to companies seeking early advice through EUnetHTA.

The EUnetHTA ED Secretariat at HAS, acts as a gateway for all requests for EU-level HTAB advice and ensures the recruitment and coordination of HTAB participation. Furthermore, it is the liaison between the HTABs, the Applicant and EMA.

Early Dialogues since the beginning of JA3

33 Letters of Intent

1 Auto-immune disease/dysfunction
12 Cancer
3 Neurodegenerative disorder
2 Vaccine
1 Viral disease
14 Other (ex: asthma, hemophilia, migraine etc.)

16 Individual Parallel Consultations (~1-3 HTABs)

Including 2 vaccines currently postponed

13 EUnetHTA EDs (Multi-HTA + Consolidated Parallel Consultations)

5 Cancer
1 Neurodegenerative disorder
1 Viral disease
6 Other
7 *Completed (as of 26/04)*

2 withdrawn (by the company)
2 declined (procedure not followed)

**The multi-HTA procedure was launched in January 2017 and the Parallel Consultations procedure was launched in July 2017*

As of May 2018, 33 requests have been received and treated by the Early Dialogues Working Party (EDWP). Interest in Early Dialogues continues to be strong with an average of three to four requests per month.

With the intent of harnessing the experience gained through JA2 and the SEED initiative (in particular for medicinal products), EUnetHTA has established the Early Dialogues Working Party (EDWP). This robust and stable group is comprised of HTA bodies with substantial experience in EDs, high level of commitment and participation in JA3 EDs, and sufficient resources in terms of staff and level of expertise.

Currently, the EDWP is made up of five HTA bodies with a full seat: HAS (France), G-BA (Germany), NICE (UK), AIFA (Italy), NIPN (Hungary) and two HTA bodies, RIZIV-INAMI (Belgium) and ZIN (Netherlands) sharing a seat. In addition, for Italy, a model of having an alternate is being tested, with a regional HTA body (RER) substituting AIFA depending on availability.

The EDWP applies the EUnetHTA selection criteria to each ED request received and is involved (with the participation of all its members) in all "EUnetHTA EDs" (i.e. multi-HTA EDs and Consolidated Parallel Consultations). HTA bodies that are not members of the EDWP may participate in some Early Dialogues (on the basis of their availability and area of expertise). The HTA bodies participating in a given ED will constitute the EUnetHTA ED Committee (EDC) for each respective ED.

Publically available documents

Overview of EUnetHTA Early Dialogues
https://eunethta.eu/Early-Dialogues

Presentation of the Parallel Consultations procedure and links to relevant documents
https://www.eunethta.eu/early-dialogues/parallel-consultations/

Presentation of the multi-HTA Early Dialogue procedure and links to relevant documents
https://www.eunethta.eu/early-dialogues/multi-hta/

Stakeholder engagement

During year two, an effort to integrate patients into all Early Dialogues has been pursued. After discussion within the EDWP, it was decided to test several approaches for patient involvement in EUnetHTA EDs. Table 1 summarises the three options currently being tested. It should be noted that in some instances, more than one approach was utilised within the same Early Dialogue.

Table 1: Overview of patient engagement approaches and use

Patient contribution deliverables	Patient investment	Use to date
Approach 1: Interview individual patients *(living with the condition) in local language collecting general feedback on the disease + answer to specific questions related to the dossier (Min: 2 countries)*		
- Minutes of the interview - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire	~2 days	5 EDs (France, Spain, UK)
Approach 2: Interview national patient representative (living with the condition/ carer) *in local language collecting general feedback on the disease + patient representative position on applicant dossier*		
- Minutes of the interview - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire	~5 days	7 EDs (Germany)
Approach 3: Participation of EU patient representative (living with the condition/ carer) *in the overall ED process including interview with coordinator, F2F meeting, review final recommendation*		
- Minutes of the interview - Review final EUnetHTA recommendations - Feedback questionnaire	~7 days	3 EDs

Patients have now been involved in 10 out of the 12 completed EUnetHTA EDs. The EUnetHTA ED Secretariat is actively collecting feedback from each participant following the completion of each procedure in order to continually improve the process and identify areas for further development.

Following the focus on patient contribution, the next few months will be dedicated to the implication of health care professionals.

Strand B: Post-Launch Evidence Generation and registries

After preparatory work carried out in year one, the focus of WP5B during year two has been the launch of PLEG pilots. In parallel with the conduct of PLEG pilots, WP5B has been carrying out a supporting activity on the quality of registries, with the aim of adapting existing quality standards into a practical tool for HTA purposes.

Collaborative PLEG pilots
In year 2, Strand B has performed two pilots in collaboration with the European Medicines Agency, in the framework of the EMA procedure for the qualification of novel methodologies for drug development. The pilots consisted of qualifying registries, for a rare disease (first pilot) and for data collection relevant to a specific type of product (second pilot). Topics that were discussed were both quality aspects and the parameters to be recorded in the registries.

It is to be noted that, while the qualification procedure gives the applicant the possibility to receive input from both regulators and HTA bodies at the same time, it does not intend to produce a joint advice/opinion. Moreover, there is currently no equivalent to the EMA qualification opinion on the EUnetHTA side. Hence, the HTA outcome of this process is a qualification advice, i.e. non-binding confidential recommendations on the discussed topics.

Product specific PLEG pilots arising from HTA
Based on proposals made by WP5B activity centres, two calls for collaboration on PLEG for drugs were launched in spring 2018 (planned end mid-2019). These pilots consist of agreement, among participating agencies, on the data set for real world evidence generation and on the possibility of gathering evidence from different jurisdictions. The indications covered are a rare disease (first pilot) and oncology (second pilot). A third call, on a medical device in cardiology, is due in the upcoming weeks.

Standards tool to evaluate the quality of registries
Based on work in year one and the results of the PARENT Joint action, a draft Standards tool has been prepared and upgraded in year two. The latest version of the tool is currently under review by WP partners. Moreover, the tool used is being tested in parallel by three EUnetHTA partners in their everyday work (scheduled end January 2019). Finally, the first draft of a vision paper on sustainable availability of the tool was produced in spring 2018 and is currently under review by WP partners.

Stakeholder engagement

Strand B is continuously exploring possibilities to perform collaborative pilots with other projects/initiatives from various stakeholders. Moreover, in year three, the upgraded standards tool and the vision paper will be submitted for stakeholder consultation.

If you wish to learn more about WP5B activities, please contact WP5B LP HAS at eunethta-has@has-sante.fr.

WORK PACKAGE 6

Quality Management, Scientific Guidance and Tools

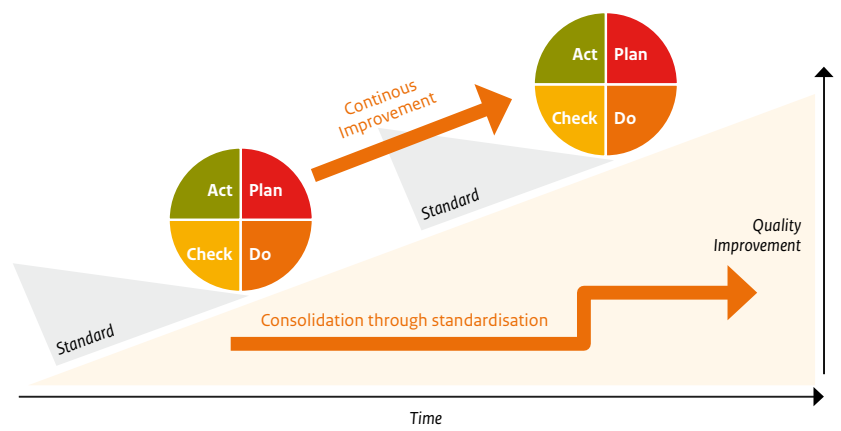
Lead partner: Institute for Quality and Efficiency in Health Care (IQWIG, Germany)
Co-lead partner: Belgian Health Care Knowledge Centre (KCE, Belgium)

Objective

The activities of WP6 aim at developing and establishing quality management for HTA collaboration at European level in order to improve efficiency and quality of joint work, favour adaptation at national and on EU level and increase its scientific relevance and acceptance.

Concept Paper for Quality Management

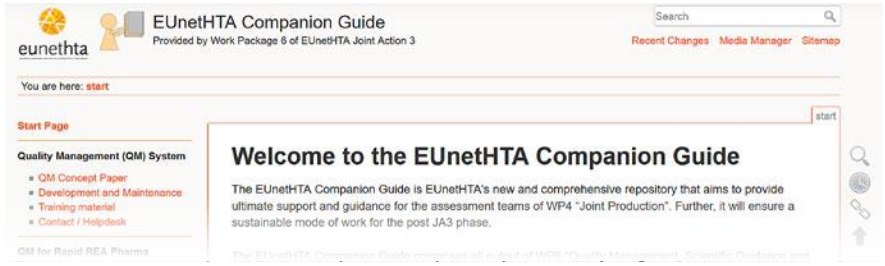
Based on experiences from Joint Action 2, valuable content from a workshop with the involvement of all WP6 partners and with the aid of relevant literature, the WP6 Lead together with 10 partner organisations created a concept paper for quality management.



The concept paper describes the fundamental aspects as well as EUnetHTA-specific means of quality management in the context of joint work. It describes the overarching policy on how quality management should be implemented in EUnetHTA.

Process Flows and Standard Operating Procedures

Overall, the development of around 40 SOPs describing all process steps of Rapid REA Pharma and Rapid REA Other Technologies (OT) is planned within Joint Action 3. As a first step, process flows depicting all assessment steps were developed. The first SOPs finalised in WP6 were related to the creation and maintenance of SOPs as well as the review procedures in the OT branch.



HTA Core Model®

A call has been placed for a new activity leader. Three candidates have sent a proposal, a jury has evaluated those proposals, identified a candidate and created a recommendation that will be proposed to the EUnetHTA Executive Board. Change requests related to the domains CUR, TEC, SAF and EFF have also been collected from the assessment teams feedback survey.

Methodological guidelines

One existing methodological guideline has already been updated (Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness), and another is in the process of being updated (Comparators & Comparisons: Direct and indirect comparisons). Additionally, change requests for four other guidelines have been collected from the assessment teams feedback survey.

Two new methodological guidelines are currently in development: "Critical assessment of clinical evaluations" (concept) and "Critical assessment of economic evaluations" (draft guideline).

EUnetHTA online tools

Project descriptions and statuses are continually and regularly being updated in the Planned and Ongoing Projects database. It currently holds approximately 700 project descriptions from 22 countries.

Options for amelioration have been collected through the assessment teams feedback survey, and from the dedicated work group and this will orientate future developments. The Evidence database on new technologies (EVIDENT database) is currently offline for a technical upgrade. Options for amelioration have been received from the dedicated working group and will also orientate future developments.

WORK PACKAGE 7

National implementation and impact

Lead partner: National Institute for Health and Care Excellence (NICE, United Kingdom)
Co-lead partner: National Agency for Regional Health Services (AGENAS, Italy)

Summary

- WP7 have four key work package activities; our research and analysis activity is now complete, the case studies and implementation network are ongoing and technical support for the development of a model of HTA cooperation is delayed pending work to be carried out by WP1.
- WP7 are involved in two key cross work package activities:
  - with WP3 to ensure WP7 implementation data can be used in the WP3 evaluation; and
  - with WP4, developing topic identification and selection processes.
- A key activity over year two has been setting up the WP7 implementation network. The network has 71 participating agencies including both EUnetHTA partners and non-EUnetHTA partners.
- Three aspects of the implementation network have been put in place (1) a named contact in WP7 for agencies to approach with implementation issues, (2) a feedback system to collect data about the use of EUnetHTA assessments, and (3) improved systems to support timely awareness of EUnetHTA activities and sharing examples of use between agencies.
- For the first five JA3 EUnetHTA assessments, 37 examples of use have been collected (up to March 2018). 18 of these were for non-pharmaceutical assessments and 19 for pharmaceutical assessments.

Update on activities

Activity 1: Research and analysis

Pharmaceutical and non-pharmaceutical HTA processes from 59 agencies in 31 countries were collected and analysed in order to identify key implementation challenges and understand how agencies within their existing processes could engage in HTA cooperation and use EUnetHTA assessments. Consultation and data validation took place in July and August 2017 and included EUnetHTA partners, HTA agencies not involved with EUnetHTA and the HTA Network stakeholder groups. The report was published in November 2017.

Publically available documents

Full report and data tables
https://www.eunethta.eu/national-implementation/analysis-hta-reimbursement-procedures-eunethta-partner-countries/

Presentation at ISPOR 20th Annual European Congress
https://www.ispor.org/Event/ReleasedPresentations/2017Glasgow

Poster at ISPOR 20th Annual European Congress
https://www.ispor.org/ScientificPresentationsDatabase/Presentation/76322?pdfid=51569

Activity 2: Case studies
Nine case studies were completed in the first year covering nine countries and involving 21 agencies (19 EUnetHTA partners and two other HTA agencies who were not EUnetHTA partners). The case studies explored agency processes and how agencies had used EUnetHTA JA2 assessments and the adaptations they were making. These case studies were made available in the final report from the WP7 research and analysis activity and this was published in November 2017. Further case studies will be carried out in years three and four of the JA through the WP7 implementation network, focusing on the use of the EUnetHTA JA3 assessments and post-2020 HTA cooperation arrangements.

Publically available documents

Case study write ups
https://www.eunethta.eu/wp-content/uploads/2018/02/Annex-2_case-studies.pdf

Activity 3: Technical support for the development of a model of HTA cooperation
This activity follows on from work to be undertaken in WP1 on the development of a model of sustainable HTA cooperation. The work to be undertaken by WP1 was delayed pending the publication of the EC proposal for a regulation on HTA. WP7's role has subsequently also been delayed and will restart in Q3/Q4 of 2018.

Activity 4: Implementation Network
The implementation network aims to support increased use of EUnetHTA outputs, obtain feedback from organisations about the experience of using EUnetHTA outputs and maximise awareness of EUnetHTA activities.

A group of 15 EUnetHTA partners act as implementation leads and supported the development of network procedures. 71 agencies are participants in the network including agencies who are EUnetHTA partners and agencies who use or produce HTA but are not part of EUnetHTA.

Three aspects of the implementation network have been put in place so far:
- A named contact in WP7 for each participating agency for them to use to raise implementation issues
- A feedback system to support agencies in reporting the experience of using EUnetHTA outputs (collecting survey and interview data)
- Support for implementation:
  - Collaborating with other WPs to ensure timely awareness among partners of EUnetHTA outputs
  - Sharing examples on how other agencies use EUnetHTA outputs

Over the second half of 2018, WP7 will work with WP lead partners and agencies in the network to identify activities that will support them to use EUnetHTA outputs and provide advice on how to use EUnetHTA outputs in routine work.

Table 1: Overview of use of the first 5 EUnetHTA JA3 assessments

Did not use	Used in HTA procedures*	Used in dissemination*	Overall rate of use
Assessment: OTC01: Wearable cardioverter-defibrillator (WCD) therapy			
1	3	4	7/8 (88%)
Assessment: OTCA02: Antibacterial-coated Sutures			
1	3	1	4/5 (80%)
Assessment: OTCA05: Repetitive transcranial magnetic stimulation			
5	2	5	7/12 (58%)
Assessment: PTJA01: Midostaurin for Acute Myeloid Leukaemia			
3	7	1	8/11 (73%)
Assessment: PTJA02: Regorafenib for hepatocellular carcinoma			
2	9	2	11/13 (85%)

**Two types of use of EUnetHTA assessments are reported: (1) use to support or as an alternative to the agency's existing HTA procedures and (2) use as part of dissemination practices to support awareness of EUnetHTA assessments and evidence informed decision-making.*

WP7 is currently preparing its first implementation report. The report will include a baseline calculated from the reported use of EUnetHTA JA2 assessments. This will be used to measure change in use in EUnetHTA JA3. The report will also include implementation data on the use of the first five EUnetHTA assessments. Table 1 on page 27 presents an overview of the use reported so far from data downloaded in March 2018. Detailed information describing the use shown in table 1 will be included in the report. The report will be published in May 2018.

Cross work package activities
WP7 have been engaging in two key cross work package activities.

The first activity is the development of the metrics tool to measure use of JA3 assessments. This work was led by WP3 and is now complete. The tool has been incorporated into the WP7 feedback procedures used in the implementation network. WP7 continue to work with WP3 to ensure that the JA2 baseline and JA3 implementation data collected by WP7 can be used in the WP3 evaluation.

The second activity is in collaboration with WP4 to develop topic selection processes. WP7 is involved in an authoring group to develop recommendations for a topic identification, selection and prioritisation system. WP7 use the information gathered in the research and analysis activity to support WP4 to develop procedures that support use of EUnetHTA assessments.

In September 2018, WP7 will start a piece of work with WP6 to understand how EUnetHTA tools and guidelines are used in local HTA procedures and the issues with using EUnetHTA tools and guidelines in local procedures.

Stakeholder engagement
Stakeholders were engaged in the consultation exercise for the research and analysis activity. WP7 continue to reach out to HTA users and producers who are not part of EUnetHTA to support awareness of EUnetHTA and use of EUnetHTA assessments and tools more widely.

Useful information

Venue Address
Lindner Hotel City Plaza
Magnusstrasse 20
50672 Cologne
Germany

Phone: +49 221 2034 0
Fax: +49 221 2034 777

Travel

Subway (0.1 km)	Station: Friesenplatz – *Lines: 3,4,5,12,15*
City train (1.0 km)	Station: Hansaring – *Lines: S 6, S 11, S 12*
Tram (0.1 km)	Station: Friesenplatz – *Lines: 3,4,5,12,15*
Bus (0.6 km)	Station: Rudolfplatz – *Lines: 136, 146*
Metro station	120 m away
Car (0.1 km)	For driving instructions, please visit lindner.de.

There are 104 parking spaces available in the venue car park.
Parking is charged at € 25,00 / per day.

Nearby

City centre (0.0 km)	Train station (1.0 km)
Airport (17.0 km)	Public transport (0.1 km)
Motorway A1 (2.0 km)	Fair (3.0 km)
Cologne Cathedral (1.0 km)	Chocolate museum (2.0 km)
Cologne zoo (3.0 km)	Europcar rental station (0.8 km)

On the day

Get Involved
Be part of the this year's Assembly and Forum by posting your questions, comments and pictures of the day on social media using the hashtag **#eunethta2018**. These will be collated and displayed throughout the day on our special social media wall.

You can also follow us **@EUnetHTA** on Twitter and LinkedIn for updates and polls over the course of the meeting.

Registration
Please bring your registration confirmation ticket with you when you arrive. This does not need to be printed and can be presented on a mobile device. If you are attending both the Assembly & Forum, please only register on the first day of your arrival.

WiFi
To access WiFi on the day, connect to **free** and enter the password **internet**.

Smoking
Smoking is forbidden inside the building. Please use dedicated smoking areas on the day.

Accessibility
The venue is fully accessible for disabled guests. Please contact the Secretariat on eunethta@zinl.nl if you have further questions or to make specific arrangements.

Contact
If you require assistance, or need further information on the day, please contact our general event helpline on +31 6 22 28 28 58.

Photography and video
The Assembly will be streamed live on the EUnetHTA Intranet and the Forum will be streamed on the EUnetHTA website. EUnetHTA reserves the right to use any photography/ video taken at the event, without the expressed permission of those included within the photography/video. EUnetHTA may use the photography/video in publications or other media produced or contracted by EUnetHTA.

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