10 - 11 april 2019 | West-Indisch Huis | the Nettherlands

EUnetHTA
ASSEMBLY & FORUM
AMSTERDAM

FOREWORD

We would like to welcome you to the 2019 EUnetHTA Assembly & Forum in Amsterdam.

It is a great pleasure to see you all here and to note the continuously increasing interest in our annual gathering! Again, this year we are making parts of our meetings more interactive with live polling in the Forum, allowing stakeholders to actively participate in shaping the discussions.

European cooperation on HTA has seen a lot of development since the last Assembly & Forum in Cologne in 2018. These developments have been initiated by both internal and external processes. Needless to say, the ongoing political process of bringing forward the European Commission proposal on a future model for HTA cooperation will be very important to EUnetHTA and all our partners. As this is an evolving process, we must make best use of our time and focus on collaborating in the most productive way possible.

The last year has also seen greater interaction. EUnetHTA, together with regional initiatives such as BeNeLuxAI, FAAP, and FINOSE, have aligned their respective aims and activities as a coherent whole through a collaboration that harnesses added value between European-level and regional actors. Such initiatives are beneficial as they can focus on issues that stand outside of the EUnetHTA mandate, such as joint health economic assessments and joint procurement.

Internally, EUnetHTA has continued its work to adapt and improve the governance structure for the network, initiated in early 2018. EUnetHTA teams of all Working Packages have been working hard across Europe at further strengthening and fine-tuning the procedures and templates that support our products.

Joint Assessments remain a major focus of our activities. To ensure the inflow of applications for Joint Assessments, the heads of those agencies represented in the Executive Board took the initiative to set up a proactive prioritisation list with products of special interest for EUnetHTA partners. The EUnetHTA Prioritisation List was launched in dialogue with the pharmaceutical industry to much success. Furthermore, the very high interest for Early Dialogues has continued and EUnetHTA partners have started to implement a process for Early Dialogues, also on non-pharma products.

To bring the good work of 2018 forward and, in the light of these developments, in 2019, EUnetHTA will place a special focus on broad and sustainable stakeholder involvement. Working programmes are being developed and outreach to individual stakeholder groups is being strengthened. Moreover, EUnetHTA has, on its own initiative and together with the European Commission, had individual interaction with, among others, patients, pharma industry, and payers, while plans have been made for interaction with healthcare providers and the non-pharma industry.

The Secretariat has continued to develop the EUnetHTA website which now provides a 'one-stop shop' for HTA collaboration in Europe and sets the tone for a future sustainable working environment. EUnetHTA is still growing and interest from new partners to join the network is still coming in.

As we move forward, expanding 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 Amsterdam and we hope that the event provides a useful insight into EUnetHTA's role in the European HTA landscape and results in constructive outcomes via the focused discussions.

Niklas Hedberg
Chair of EUnetHTA Executive Board

THE WEST-INDISCH HUIS

The rich history of the stately 'West-Indisch Huis' (West India House), located in the heart of Amsterdam, begins in 1617.

From this time and up till 1623, the ground floor and rear of 'Het Huis' (the House) was used as a fresh meat market, while the top floor served as waiting rooms for the citizen and municipal militias tasked with the public security of Amsterdam.

'Het Huis' owes its name to the subsequent period between 1623 and 1647 when the Heren Negentien (the Lords Nineteen), who founded the board of the West India Company two years prior in 1621, based their operations here. It was during this time that the decision was made, in the Compagnie Hall, to build a fort on the distant island of Manhattan and name it 'New Amsterdam'.

Peter Stuyvesant, whose bronze sculpture stands in the courtyard of the house, was appointed Governor General of the fort and the surrounding lands of New Netherland, which subsequently changed hands, and its name, to New York.

The West India Company was founded to prevent trade monopolies and to vie for a share of overseas commerce. To this end, it commissioned ships to intervene with foreign vessels in international waters, resulting in huge loots hauled back from distant engagements. The largest of these was the capture of the Silver Fleet by Admiral Piet Heijn in 1628, treasures that were stored in the very cellars of the West-Indisch Huis.

The end of war with Spain in 1648 put an end to such lucrative piratical endeavours, depriving the West India Company of a major source of income and forcing it to relocate to another site in the city for the next 168 years.

2019 EUnetHTA Assembly & Forum

From 1660, the West-Indisch Huis began a long spell as an official gentlemen's lodgings (the 'Nieuwezijds Heerenlogement'), finally falling into the caring hands of a Reformed Evangelical deaconess in 1825. Following significant renovation of the building façade, the structure was repurposed as a home for orphans and the elderly. The appearance as we now see it, with a triangular gable and engraved wooden swan, alludes to the symbolism of the Lutheran Church at this time.

The building sold in 1954 to a textile wholesaler, accommodating offices and showrooms within. However, disaster stcuk on 16th December, 1975, when a firecracker flew into a skylight in the textile storage area, ravaging the building with fire.

This prompted a foundation to be set up in the following year to purchase the structure and renovate it to its former grandeur. Works were finally completed in 1981, Peter Stuyvesant arrived in the courtyard, and the building became, among other things, an official municipal wedding hall popular among Amsterdammers.

We hope you will enjoy the location, architecture, and rich historical backdrop of the West-Indisch Huis during the 2019 EUnetHTA Assembly & Forum.

CONTENTS

FORUM AGENDA
11 APRIL

START	END	PROGRAMME ITEM	PRESENTERS
8.30	9.00	Coffee and registration Main Hall	
9.00	9.15	Welcome and opening remarks The Schutterszaal	Niklas Hedberg, EUnetHTA (TLV)
WHAT CONSTITUTES UNMET MEDICAL NEED? Views and perspectives from different stakeholders			
9.15	10.30	Part **A** The Schutterszaal	**Moderator** Giovanni Tafuri, ZIN **Panelists** - Chantal Bélorgey, HAS - Jordi Llinares Garcia, European Medicines Agency - Ansgar Hebborn, EFPIA (Roche) - Valentina Strammiello, European Patients' Forum
10.30	11.00	Coffee break Foyer	
11.00	12.00	Part **B** The Schutterszaal	**Moderator** Giovanni Tafuri, ZIN **Panelists** - Flora Giorgio, DG SANTE, European Commission - Anna Lefevre Skjöldebrand, Swedish Medtech - Christine Dawson, European Social Insurance Platform - Elena Petelos, European Forum of Primary Care/European Public Health Association
12.00	13.00	Lunch Stuyvesant Brasserie	

START	END	PROGRAMME ITEM	PRESENTERS
BREAKOUT SESSIONS			
13.00	13.05	Introduction The Schutterszaal	Giovanni Tafuri, ZIN
13.05	14.30	Uptake of EUnetHTA Joint Assessments for Pharmaceuticals at a national level The Schutterszaal	**Facilitators** - Edith Frénoy, European Federation of Pharmaceutical Industries - Anne Willemsen, ZIN
		Impact of EUnetHTA Joint Assessments for Other Technologies at a national level The Admiraalszaal	**Facilitators** - Ingivil Saterdal, NIPHNO - Pascale Brasseur, Medtronic
14.30	15.00	Coffee break Foyer	
15.00	16.30	Lessons learned and avenues for the improvement of patient involvement in EUnetHTA processes The Schutterszaal	**Facilitators** - Stephanie Said, G-BA - François Houÿez, EURORDIS
		Challenges in the interaction between EUnetHTA and payers The Admiraalszaal	**Facilitators** - Marcus Guardian, EUnetHTA (ZIN) - Ad Schuurman, ZIN
		Bridging EUnetHTA and Healthcare Providers The Compagnieszaal	**Facilitators** - Giovanni Tafuri, ZIN - Daniel Widmer, European Union of Family Doctors - Denis Lacombe, EORTC
16.30	17.20	**Plenary** Debriefing from breakout sessions and action points for discussion paper The Schutterszaal	Various
17.20	17.30	Closing remarks The Schutterszaal	- Niklas Hedberg, EUnetHTA (TLV) - Marcus Guardian, EUnetHTA (ZIN)

EUNETHTA SECRETARIAT

Lead Partner: Zorginstituut Nederland (ZIN)

Objectives

- Provide scientific and technical coordination support for European collaboration activities on HTA to the integration of 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 to ensure re-use in regional and national HTA reports and activities, in order, notably, to avoid duplication of assessments.
- Ensure dialogue with EUnetHTA stakeholders through coordinated communication and interaction.

The coordination of several key governance groups and events forms a major part of the Secretariat's activities:

THE EXECUTIVE BOARD

The Executive Board elects its own Chair and 2 supporting Vice Chairs from its voting members. It is comprised of organisations representing the Work Package Lead and Co-Lead Partners (13 Consortium Partners), elected member organisations of the EUnetHTA Assembly (5 Consortium Partners) and non-voting observers (DG SANTE, CHAFEA, Chair and Vice-Chair of the Assembly). The Secretariat manages F2F and virtual ExB meetings throughout the calendar year.

HEADS OF AGENCIES MEETING

This event pulls together all HTA agency heads from Member States represented in the Executive Board (voting & non-voting members) to discuss high-level strategy on both Pharmaceuticals (1st day) and Other Technologies (2nd day), and also supports the ExB in providing strategic guidance.

TASK GROUPS

Active governance elements of the Executive Board, composed of Consortium Partners only, with a strong focus on specific transversal issues.

PROJECT MANAGEMENT GROUP

Supports the coordination of project management tasks both at Work Package and Cross Work Package level.

EUNETHA ASSEMBLY

Representing body of the Consortium, comprised of one representative from each Consortium Partner. The Assembly elects its Chair from members of the Assembly.

EUNETHA FORUM

Assembly and collaborating stakeholders, providing a platform for networking, scientific discussions, and exchange of experience.

YEAR 3 ACHIEVEMENTS

- At the invitation of the Austrian and Romanian Presidency of the Council of the European Union, the Secretariat coordinated technical expertise on European HTA collaboration during the meetings of the Council's Working Party on Pharmaceuticals and Medical Devices.

- Based on the EMA/EUnetHTA Work Plan 2017-2020, collaboration activities have been carried out with the objective of ensuring mutual understanding and dialogue on evidence needs. The collaboration covers several activities, ranging from Early Dialogues and post-licensing data generation plans, to information exchange, discussion on methodologies, and mutual sharing of experiences on patient and clinician engagement. These activities are also topics for discussion and update during the bi-annual EUnetHTA – EMA meetings, two of which were organised in Year 3, in July and December 2018 respectively, both concluding the importance of active and continued collaboration between HTA and regulatory bodies.

- The Secretariat also organises annual technical meetings with EFPIA with the objective of exchanging views and promoting dialogue on topics of common interest. In December 2018, a new technical meeting was organised which covered topics such as mutual learnings from the experience of REAs and their implementation at the national level, updates on methodological guidelines, Early Dialogues, and post-launch evidence generation plans.

- The Secretariat also leads four Cross Work Package task groups:

1. CONFLICT OF INTEREST AND CONFIDENTIALITY UNDERTAKING IN EUNETHTA TASK GROUP (COI TG)
   - The objective of COI TG is to ensure consistent understanding and application of the EUnetHTA Declaration of Interest and Confidentiality Undertaking (DOICU) procedure, identifying also any limitations of the current procedure and recommendations for improvements.
   - In Year 3, the task group produced a EUnetHTA procedure guidance for handling declarations of interest and confidentiality issues. This document was developed for transparent description of EUnetHTA JA3 processes in handling potential conflict of interest, through a procedure that applies equally for individuals representing HTA bodies.

   To view the latest DOICU Form, visit www.eunethta.eu/doicu.

2. PATIENT AND CONSUMER/HEALTHCARE PROVIDER INVOLVEMENT IN EUNETHTA TASK GROUP (P&C/HCP TG)

- The objective of P&C/HCP TG is to explore opportunities for stakeholder engagement in EUnetHTA-specific tasks, particularly in WP4 and 5 activities.
- In Year 3, a paper on 'Patient Input in Relative Effectiveness Assessments' was produced by the task group with the aim to report the development of a plan for patient involvement in the EUnetHTA REA process. Key features of the paper are the description of possible methods and time frames for patient input.

3. FUTURE MODEL OF COOPERATION ON HTA TASK GROUP (FMC-HTA TG)

- The objective of the task group is to develop a complete blueprint for future European collaboration on HTA post-EUnetHTA JA3. The focus of this blueprint will be primarily at the technical level, emphasising elements of HTA products and coordination of European level efforts.
- In Year 3, the task group was established and a thorough analysis of the elements that should be part of the future model of HTA cooperation was launched.

4. EUNETHTA COMMON PHRASES TASK GROUP (ECP TG)

The objectives of the group are:

- To avoid the use of sentences/words in an assessment report which may unintentionally imply or predetermine reimbursement decisions in some jurisdictions.
- To recommend on the use or non-use of GRADE or other internationally adopted rating systems in Joint Assessments.
- To provide a scenario-based set of standardised formulations regarding the textual presentation of results and conclusions in PT & OT Joint Assessments for increased consistency.
- The task group was recently set up and is currently in the kick-off phase.

Regarding stakeholder engagement, the Secretariat developed a schedule of regular meetings with all stakeholder categories to ensure continuous interaction between all parties and to look into possible ways of engaging stakeholders in EUnetHTA activities. The schedule is currently in implementation.

- The first amendment to the Grant Agreement was developed to update the document with a large number of changes that took place at the Consortium Partner level (termination of participation for two beneficiaries, addition of a new affiliated entity, etc.) to Work Package level (budget transfers, changes regarding deliverables and milestones, update of the text of the Grant Agreement, etc.). The amendment is currently under review with CHAFEA.

- The Secretariat updates the EUnetHTA Work Plan on an annual basis, covering work plans of the 7 Work Packages in implementing the Grant Agreement. In Year 3, the corresponding EUnetHTA Work Plan was updated, outlining the activities carried out in Year 1 and 2, the planned timeframe for Year 3, and the general planned activities for Year 4.

- An IT infrastructure (Sharepoint/Intranet) was created in Year 1 to provide a platform for collaboration and support to Consortium Partners. In Year 3, a series of improvements were made to improve the sites. For example, the Address Book was created to function as a single contact point for partners.

YEAR 4 HIGHLIGHTS

The preparation of the 2nd EUnetHTA JA3 Interim Report, comprising Technical and Financial Reports, represents an important activity and is planned for the period April – July 2019.

The Technical Report presents the progress and the achievements of JA3, while the Financial Report provides information regarding partner costs, both for the period between December 2017-May 2019. The Work Package Lead and Co-Lead Partners will provide input to the Technical Report, while all Consortium Partners will submit financial data for the Financial Report. The Interim Report represents the basis for the reimbursement of partner costs.

In January 2019, the Executive Board tasked the Secretariat with exploring a possible prolongation to EUnetHTA Joint Action 3. This request was reiterated by the heads of agencies in their annual meeting. The Secretariat is currently taking steps to explore the financial and technical implications of a prolongation to the Joint Action. It is important to note that any prolongation will not result in additional funding. Under the terms of the Grant Agreement, a prolongation would allow existing funds to be spread over a longer period.

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

DISSEMINATION

WP2 PARTNERS*
AETS-ISCIII
SU
NICE
AQUAS
UCSC GEMELLI
LBI
HAS
SNHTA

Objectives

- Supports EUnetHTA in the dissemination of Joint Action 3 information.
- Collaborates in identifying and improving engagement of stakeholders.
- Overviews and coordinates the training strategy for Joint Action 3.
- Participates in the development of the post-2020 European HTA Model.
- Explores and improves strategies for promoting EUnetHTA activities.

ACTIVITIES & PRODUCTS

Dissemination (WP2) activities and products are based in three main topics: Communication, Training, and Stakeholder Engagement.

COMMUNICATION

PRODUCTS AND PUBLICATIONS SUPPORTING THE SECRETARIAT

- EUnetHTA Communication Strategy.
- EUnetHTA Graphical Guide.
- EUnetHA Welcome Package.
- EUnetHTA Magazine (external audiences).
- Newsletter (internal audiences).
- ARCI - Instructions on Authoring Rules and Copyright Issues (collaboration between WP2, WP4, and WP6).

THE DISSEMINATION REGISTRY

- Record of publications, events attendance and other dissemination activities. The data of the Dissemination Registry is used to analyse and evaluate the dissemination activities in EUnetHTA, identifying gaps and making recommendations to improve the dissemination process. The analysis of the two first years of the JA showed that 69 records were related to events (e.g. congresses, workshops, communications). In addition, 16 records were published scientific articles.

* Dissemination partners: AETS-ISCIII: Agencia de Evaluación de Tecnologías Sanitarias-Instituto de Salud Carlos III, Lead partner, Spain; SU:Semmelweis University, Hungary; NICE: National Institute for Health & Care Excellence, UK; AQuAS: Agencia de Qualitat i Avaluació Sanitaries, Spain; UCSC Gemelli: Universita' Cattolica Del Sacro Cuore, Italy; LBI-HTA: Ludwig Boltzmann Institute, Austria; HAS: Haute Autorité de Santé, France; SNHTA: Swiss Network of HTA, Switzerland

INTERNATIONAL CONTRIBUTIONS

- EUnetHTA contribution to international definition of HTA and Glossary composition.

TRAINING

PRODUCTS

- JA3 Training Strategy summarising needs, methods, and procedures for training actions.

CHANNELS

- Virtual Classroom (intranet): Webinars and electronic materials on guidelines, methodological tools, and standard operating procedures developed by WP6 and maintained by WP2. Accessible for partners.

STAKEHOLDER ENGAGEMENT

ACTIVITIES

- 'Stakeholder Analysis' in July 2018. Analysis of the definition, collaboration modes, and involvement policies related to EUnetHTA Collaborating Stakeholder activity (Deliverable 2.1.).
- The Stakeholder Registry: Compiles the historical and current data on modes of stakeholder involvement in EUnetHTA since 2006. The data sources are EUnetHTA publications, archives and WP documents, from the EUnetHTA Project (2006), Joint Action (JA) 1, 2 and current JA 3. This data helps to evaluate modes of engagement, roles of stakeholders, and trends in collaboration.
- Task groups: Patients, Consumers, and Healthcare Provider Involvement Task Group (WP1, WP4, WP5 and WP6). This group explores how to improve the engagement of patients, consumers, and healthcare providers in assessments and Early Dialogues.

WHAT NEXT?

- Reviewing dissemination rules, tools, and activities in the search for improvement.
- Updating dissemination registry results to make recommendations on dissemination activities, helping build a permanent model of HTA cooperation after 2020.
- Updating the training strategy, reviewing methods in-depth, identifying strategy needs reflecting sustainability, and consideration of training requirements post-2020 to support the development and implementation of a permanent model of HTA cooperation.
- Updating historical analysis of stakeholder engagement in EUnetHTA to discern trends and compile all results in a single document.
- Ongoing collaboration within task groups:
  - WP2 will continue supporting the Patients & Consumers/Healthcare Provider Task Group as they look for ways of improvement in stakeholder engagement.
  - WP2 also participates in the Future Model of Cooperation on HTA Task Group, the aim of which is to present strategic plans and lines of action to help the development of the post-2020 European HTA Model.

EVALUATING OUR WORK

Lead Partner: Dental and Pharmaceutical Benefits Agency (TLV, Sweden).
Partners: Hauptverband der Österreichischen Sozialversicherungsträger (HVB, Austria), Higienos Institutas (HI, Lithuania), National and Kapodistrian University of Athens (NKUA, Greece), Swiss Network Health Technology Assessment (SNHTA, Switzerland), Zorginstituut Nederland (ZIN, Netherlands).

Objectives

The objective 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 – WHAT WE PRODUCE

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.

CORE ACTIVITIES - YEAR 3 SUMMARY

During the third project year, WP3 finalised Bi-annual Reports IV and V and the Second Yearly Interim Evaluation Report. The general outline of the bi-annual reports means they contain a description of the scope of the individual report, the methods and financial resources used, the deliverables fulfilled, and a section with conclusions. This is where the evaluation team presents their positive findings and recommendations for Executive Board consideration. 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 IV, JUNE 2018

In the fourth bi-annual report, the evaluation team presented an analysis of the responses from new partners, meaning a selection of the ones for which the JA3 is the first experience of EU collaboration of HTA bodies. The analysis showed that the new partners were in many ways satisfied with their experience so far and that being a new partner in JA3 did not seem to have been an obstacle when it came to getting involved, contributing, or finding the cooperation useful. In order to deliver on the main evaluation objective concerning uptake, this report also had a summary and a reflection from the first implementation report by WP7.

SUMMARY OF FINDINGS

- EUnetHTA has made a number of changes in its governance structure and increased the involvement of the heads of agencies (from Executive Board partners). Through this, EUnetHTA has improved internal work and increased the degree of proactivity, especially with respect to industry contact.
- The Early Dialogues for pharmaceuticals are a continuing success and the inflow of letters of intent is high. However, for Joint Assessments the situation was still challenging (status in June 2018).
- The first implementation report showed a positive trend for implementation compared to EUnetHTA JA2. There is a need for further analysis and discussion about the hurdles for implementation identified in the report.

SECOND YEARLY INTERIM REPORT, OCTOBER 2018

The Second Yearly Interim Report contained a further analysis of the partner survey conducted in 2017 and first analysed in the Third Bi-annual Evaluation Report. The deeper analysis could not detect any clear differences in how the JA was perceived between answers from new and more experienced partners. This report also contained the first financial evaluation report for JA3. The resources used were divided by Work Package, by deliverable, and separated for management and production. However, since data was only available for the time until November 2017, no firm conclusions should be made from this. Further analysis is needed.

BI-ANNUAL EVALUATION REPORT V DELAYED UNTIL MARCH 2019

The Fifth Bi-annual Evaluation Report was delayed from December 2018 to March 2019. The report contains a section analysing the answers from a stakeholder survey that was conducted among industry stakeholders between January and February 2019.

STAKEHOLDER ENGAGEMENT

Evaluation has continuously reached out to stakeholders. In the second year there was a round of interviews with a selection of key stakeholders, while during year 3 Evaluation has specifically reached out with a survey to industry, both pharma and non-pharma, to investigate their view of EUnetHTA's relationship with the industry and to channel possible suggestions for improvement.

WHERE NEXT?

BI-ANNUAL EVALUATION REPORT VI

The Sixth Bi-annual Evaluation Report is planned to be published in June 2019, with the ambition to conduct interviews with a selection of partners for a section in the report concerning the sustainable (future) model of a continued EU collaboration between HTA bodies.

BI-ANNUAL EVALUATION REPORT VII

The Seventh Bi-annual Evaluation Report is planned for publication in December 2019, with a section of the report about end users.

INTERIM YEARLY REPORT 3

The Third Yearly Interim Report is scheduled for publication in August 2019, the plan being to have a better basis for analysis of the resources used. This can be useful both for the remaining JA3 and for any form of future work on joint HTA.

JOINT PRODUCTION

WP4 Lead Partner: Norwegian Institute of Public Health.
WP4 Co-Lead Partners: Zorginstituut Nederland (Pharmaceuticals), Norwegian Medicines Agency (Pharmaceuticals), Ludwig Boltzmann Institute for Health Technology Assessment (Other Technologies).

Joint Production consists of around 60 partner organisations, all non-profit, that produce or contribute to HTA.

Objectives

- Production of Joint and Collaborative Assessments.
- Refine the production processes of jointly produced assessments based on lessons learned and experiences from Joint Action 2 and 3.
- Develop a system of horizon scanning, topic identification, selection and prioritisation.
- Facilitate the implementation of jointly produced assessments.
- Provide input to a sustainable model of European collaboration on Joint Assessments after 2020.

UPDATE ON ACTIVITIES

PRODUCTION OF ASSESSMENTS

Pharmaceuticals	Other Technologies
3 assessments published 5 assessments ongoing	11 assessments published 8 assessments ongoing

Access all ongoing and published EUnetHTA assessments on the EUnetHTA website.

EUnetHTA values engagement with patient organisations and clinical experts during the production of assessments highly. This helps to ensure EUnetHTA assessments are fit for purpose and reflect clinical practice.

It is a priority for EUnetHTA to define suitable engagement methods for patients, patient representatives, and healthcare professionals. Therefore, a dedicated EUnetHTA Task Group was established for this. Patients and patient representatives have been involved in various ways until now, as indicated in the following data. Recommendations for patient involvement in EUnetHTA assessments have been finalised. Recommendations for the involvement of healthcare professionals are under development.

RECOMMENDATIONS FOR PATIENT INVOLVEMENT IN EUNETHTA ASSESSMENTS

Recommendations on how to involve patients and patient representatives in EUnetHTA assessments have been finalised. The primary audience for the recommendations are those who design and carry out EUnetHTA assessments, but it should also be informative for multiple stakeholders. During the development of these recommendations, relevant stakeholders were consulted and kept informed. EUnetHTA deems patient involvement very important in the production of assessment reports, and recognises that patients and those who support them have unique knowledge about what it is like to live with a specific disease or medical condition. Patient input is, therefore, considered essential to inform the scope (research question) of the assessment.

The goals for patient contribution in assessments are to gain better insight into the disease/condition, current available treatments, and the outcomes that are important from the patient perspective. Patients can also describe expectations with respect to new treatments (e.g. fewer side effects), identify subgroups and possible effect modifiers, while describing quality of life issues. For patients, involvement in the assessments may also provide insight into the HTA method. In total, patient involvement can improve the relevance of assessments.

While efforts have been made by EUnetHTA to include patients or patient representatives in the majority of assessments, to date they have been involved in 13 out of 27 assessments.

PILOTED METHODS FOR EXPERT ENGAGEMENT

Patients/patient representatives

Pharmaceuticals
- 2/8: interview
- 5/8: patient input template
- 1/8: unsuccessful

Other Technologies
- 3/18: interview
- 2/18: focus group
- 4/18: patient input template
- 3/18: other
- 4/18: unsuccessful

Healthcare professionals

Pharmaceuticals
- 2/8: reviewing report
- 2/8: Q&A approach
- 3/8: ongoing identification
- 1/8: unsuccessful

Other Technologies
- 5/18 participation in scoping (e)meeting
- 18/18 reviewing project plan/PICO
- 18/18 reviewing report
- Q&A approach

RECOMMENDATIONS FOR HEALTHCARE PROVIDER INVOLVEMENT IN EUNETHTA ASSESSMENTS

EUnetHTA is now developing recommendations on how to engage with healthcare professionals in EUnetHTA assessments. Input of healthcare professionals is deemed essential when developing the scope of the assessment, to ensure that key factors relevant for clinical practice are considered during the assessment process. In addition, healthcare professionals play an important role during the production of the EUnetHTA assessment by helping the EUnetHTA team understand the clinical practice and answer questions they may have, for example on clinical pathways and procedures.

EUnetHTA is also testing different methods of engagement for healthcare professionals. Currently, this engagement can be either by reviewing the scope of the assessment (research question), answering specific clinical questions to define the scope, reviewing the draft assessment report and/or answering specific clinical questions during the production of the assessment.

CONTINUOUS UPDATES ON THE PRODUCTION PROCESS OF ASSESSMENTS

The production process of assessments is being continuously improved based on feedback from the assessment teams on previous EUnetHTA assessments, together with input from WP4 partners. WP4 also collects feedback from manufacturers who have been involved in the process. This valuable information is also used to further improve processes and templates.

ONGOING ACTIVITIES IN THE TWO BRANCHES

Pharmaceuticals
- Procedural revisions to ensure timely publication after Market Authorisation
- Revisions of templates to ensure better readability and usability in national appraisal process

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

Joint Production works closely with Quality Management (WP6) to produce Standard Operating Procedures (SOPs) which will be integrated in the Companion Guide. The tools, templates, and guidelines that support production of assessments will also be available there (see the Quality Management section for more information about the Companion Guide and SOPs).

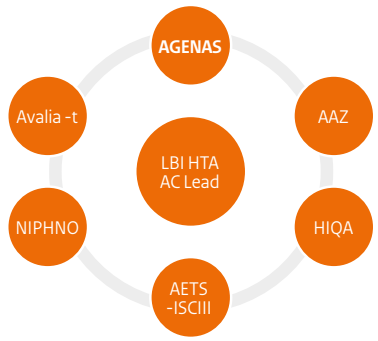
TOPIC IDENTIFICATION, SELECTION, AND PRIORITISATION

The Joint Production Lead Partner and a working group consisting of members from several WP4 partners have developed draft recommendations for horizon scanning and topic prioritisation in the European context. These recommendations were made on a stakeholder consultation including patient organisations, payers/decision makers, healthcare providers, regulators, and industry. A pilot is currently ongoing for a workflow for Topic Identification, Selection and Prioritisation (TISP). As part of the pilot, stakeholders were invited to suggest topics for EUnetHTA assessments. The results of the pilot will inform the final recommendations for horizon scanning and TISP for European cooperation on HTA beyond 2020, and are planned to be made publicly available by November 2019.

In the Pharmaceutical branch in 2018, there was a need to strengthen the production of Pharmaceutical Joint Assessments. Therefore, the EUnetHTA Prioritisation List (EPL) was published in October 2018. The EPL may be accessed on the EUnetHTA website. The EPL consists of individual compounds that are of significant interest to national HTA agencies. The EPL stands complementary to the already well-established mechanism for voluntary submission of new compounds. The EPL has been incorporated into the ongoing TISP pilot.

DECENTRALISED PROJECT MANAGEMENT OF COLLABORATIVE ASSESSMENTS: ACTIVITY CENTRE DEPARTMENT LEADS IN OTHER TECHNOLOGIES

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



ROADMAP FOR COORDINATED ACTIVITIES ON HTA AND MEDICAL DEVICE AUTHORITIES

A second workshop of the EUnetHTA Task Force on HTA and Medical Devices will take place on May 28th, 2019, in Vienna. The aim of the workshop is to explore the synergies between EUnetHTA (Early Dialogue (ED)/ Scientific Advice (SA)/ Post-Launch Evidence Generation (PLEG)/ Post Market Clinical Follow-up (PMCF)) and Competent Authorities (Regulators) responsible for medical devices, and will welcome stakeholders to participate and contribute.

Aim of Roadmap
To develop coordinated activities between the Competent Authorities, Notified Bodies, and EUnetHTA (supported by the EU Commission and in cooperation with stakeholders).

Final aim
To reduce the evidence gap between market approval (CE marking) and market access (reimbursement and coverage decisions).

An alignment of requirements for evidence generation between regulation and HTA - as far as possible - can contribute to provide early market access of safe and effective medical devices for patients, contain costs for healthcare systems, and ease the burden of manufacturers to comply with different requirements across European countries.

PROCESS FOR IMPLEMENTATION OF EUNETHTA ASSESSMENTS IN NATIONAL AND REGIONAL PRACTICE

Joint Production works to ensure the usability and timely availability of assessments. The collaboration with National Implementation and Impact (WP7) is essential as they collect data about 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.

WHERE NEXT?

In year four of Joint Action 3, Joint Production will seek to continue the increase of jointly produced assessments and support the use of these in national contexts. Involvement of healthcare professionals will also have priority and such recommendations will be developed.

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

LIFE CYCLE APPROACH TO IMPROVE EVIDENCE GENERATION

EARLY DIALOGUES

Lead Partner: Haute Autorité de Santé (HAS, France).
Co-Lead Partner: Federal Joint Committee (GBA, Germany).

EARLY DIALOGUES IN 2018

The core focus of 2018 was the continuation of the EUnetHTA Early Dialogues (ED) programme and its expansion to include not only pharmaceutical products, but medical devices as well.

During 2018, the EUnetHTA ED Secretariat received and processed 31 requests for EDs. Of these, 25 were requests for pharmaceutical parallel consultations with 9 following the Consolidated Parallel Consultation (PCC) pathway and 16 following the Individual Parallel Consultation (PCI) pathway (one of which was later withdrawn by the Applicant). Four pharmaceutical Multi-HTA requests were recieved, for which two were accepted and completed, one was withdrawn by the applicant and the last is awaiting initial applicant feedback. Two requests were received for Medical Devices, one of which was accepted and completed. Almost 52% of requests included questions on the economic model. Orphan drugs comprised only 9 of the 31 requests, with 7 being accepted for multi-HTA or PCC procedures. Table 1 below provides an overview of all requests received since the beginning of EUnetHTA JA3.

The activities carried out to date have allowed us to identify areas of the procedure that could be revised and simplified. The ED Secretariat (with input from the EDWP, EMA, and stakeholders where appropriate) will revise the procedures for Parallel Consultations and for multi-HTA EDs in 2019. These revisions will not only take into account feedback received from participating companies, but also that which has been received from stakeholders during the public consultation for the EDMD procedure.

Finally, the ED Secretariat is also working on several projects, notably the writing of detailed quantitative and qualitative analysis of EDs thus far that will be published in 2019. Further guidance documents and tools for assisting the HTA bodies participating in an Early Dialogue and facilitating the roles of the Scientific Coordinator and Rapporteur.

TABLE 1: EARLY DIALOGUES SINCE THE BEGINNING OF EUNETHTA JA3

54 TOTAL REQUESTS FOR EARLY DIALOGUES

	EUnetHTA Early Dialogues				**Non-EUnetHTA**
	MULTI-HTA EARLY DIALOGUES		PARALLEL CONSULTATIONS		
Therapeutic Field *(indication)*	**Pharmaceutical Products** *(4 requests)*	**Medical Devices** *(3 requests)*	**PCC** *(20 requests)*	**PCI** *(26 requests)*	
	Refused: 1 *(pharmaceutical: did not meet selection criteria)*		**Refused: 1** *(did not follow procedure)*		
Auto-immune disease/ dysfunction				2 *(completed)* 1 *(on-going)*	
Cancer	1 *(completed)*	1 *(completed)*	4 *(completed)* 2 *(on-going)* 1 *(withdrawn by Applicant)*	9 *(completed)* 1 *(on-going)*	
Diabetes		1 *(awaiting applicant decision)*		1 *(completed)*	
Neuro-degenerative Disorder	1 *(completed)*		1 *(completed)* 1 *(on-going)*	2 *(completed)*	
Viral Disease			1 *(completed)*	1 *(completed)* 2 *withdrawn by the applicant)*	
Other	1 *(completed)*	1 *(withdrawn by applicant)*	7 *(completed)* 3 *(on-going*	5 *(completed)* 2 *(withdrawn by the applicant)*	

ENLARGEMENT OF THE WORKING PARTY FOR PHARMACEUTICALS AND CREATION OF A WORKING PARTY FOR MEDICAL DEVICES

The past year also saw the renewal and expansion of the EUnetHTA Early Dialogues Working Party for Pharmaceutical Products (EDWP). The ED Secretariat is pleased to report that all existing members were renewed and 3 new members were added. The EDWP is now composed of the following HTA bodies: AEMPS, AIFA/RER, G-BA, HAS, NICE, NIPN, NOMA/TLV, RIZIV-INAMI/ZIN. The expansion of the EDWP has allowed more partners to take on the roles of Scientific Coordinator and Rapporteur for EUnetHTA EDs and provided official membership to AEMPS, NOMA, and TLV after more than a year of undertaking EDWP duties in an unofficial standing.

In 2019, the group will collaborate with the ED Secretariat and EMA to revise the Guidance document for Parallel Consultations.

In preparation for the official launch of EDs for Medical Devices (EDMD) and as a way to ensure continuity, a call for participation was sent out for the creation of an EDMD Working Party (EDMD WP). This group, like its pharmaceutical counterpart, will be renewed after two years and is composed of: HAS, NICE, RER, Avalia-T.

Both the EDWP and the EDMD WP are responsible for applying the EUnetHTA selection criteria to all requests received and thereby deciding on the acceptance or pathway of each request.

LAUNCH OF EARLY DIALOGUES FOR MEDICAL DEVICES

Spring 2018 saw the drafting of the procedure and briefing book template for EDMD. Once the documents were finalised, they were posted on the EUnetHTA website for public consultation by stakeholder groups. Comments were received from +10 organisations, including several EUnetHTA partners and 6 stakeholder organisations (patients and professional organisations). The feedback received primarily related to transparency regarding the process, inclusion criteria for external stakeholders, how stakeholders are recruited, and the iteration of advice. These comments were reviewed and taken into account in the revised Guidance for EUnetHTA Early Dialogues for Medical Devices. Furthermore, the comments received from this public consultation have nourished our reflection on the revision of the pharmaceutical procedures (both parallel and multi-HTA) that will be undertaken in 2019.

By December 2018, the first pilot EDMD had been successfully completed. Not only did this mark the first ED for a medical device, but it also marked the first EUnetHTA ED to officially involve healthcare practitioners as external experts. In total, four experts were consulted by four of the participating HTA bodies, one of whom participated in the pre-F2F meeting with the HTA bodies.

On the basis of the feedback received during the public consultation and the pilot EDMD, the procedure and briefing book template have been revised and published on the EUnetHTA website in March 2019.

INVOLVEMENT OF EXTERNAL EXPERTS

To date, patients have been involved in over 75% of EUnetHTA EDs. We are currently using a graduated approach to expert involvement and have developed three different approaches as explained in Table 1.

The EUnetHTA ED Secretariat is actively providing and collecting feedback to/from each participant following the completion of each procedure in order to explain how their contribution was used, to continually improve the process and to identify areas for further development. Based on the feedback we have received, the EUnetHTA ED Secretariat will produce a handbook for external experts (patients, healthcare professionals) aimed at better informing them about what to expect from their participation in a EUnetHTA ED. The objective is to explain the process of an ED and to help participants understand what they can expect from their involvement, regardless of the approach used. In addition, the ED Secretariat will produce a guidance document for interviewing patients and for chairing a F2F meeting – with a specific section on integrating patient feedback and ensuring that the patient is heard (when present) during the F2F.

As stated in the EUnetHTA JA3 Grant Agreement, the second half of ED activities should be financed by a fee-for-service model. This will be instituted in 2019. Further information regarding the model will be available as soon as possible.

TABLE 1: APPROACHES TO EXTERNAL EXPERT IN EUNETHTA EARLY DIALOGUES

Expert contribution deliverables	Healthcare Professional (HCP) contribution deliverables
Approach 1: Individual patient/HCP - interviewed regarding the disease and their experience	
- Minutes of the interview - Patient contribution visible in final EUnetHTA recommendations - Feedback questionnaire	- Minutes of the interview - Feedback questionnaire
Approach 2: Approach 1 + discussion with local HTA bodies regarding submission file (without applicant)	
- Minutes of the interview - Patient contribution visible in final EUnetHTA recommendations - Feedback questionnaire	- Minutes of the interview - Feedback questionnaire
Approach 3: Expert; Approach 1 + discussion with all participating HTA bodies regarding the submission file and participation in the F2F meeting with the applicant	
- Minutes of the interview - Share final EUnetHTA recommendations - Feedback questionnaire	- Minutes of the interview - Feedback questionnaire

For more information on EUnetHTA Early Dialogues, including Guidance documents and templates, please visit https://www.eunethta.eu/services/early-dialogues/.

LIFE CYCLE APPROACH TO IMPROVE EVIDENCE GENERATION

POST-LAUNCH EVIDENCE GENERATION AND REGISTRIES

Lead Partner: This activity is being led by HAS (France) with specific involvement of AIFA (Italy), avalia-t (Spain), NICE (UK), and TLV (Sweden).

Objectives

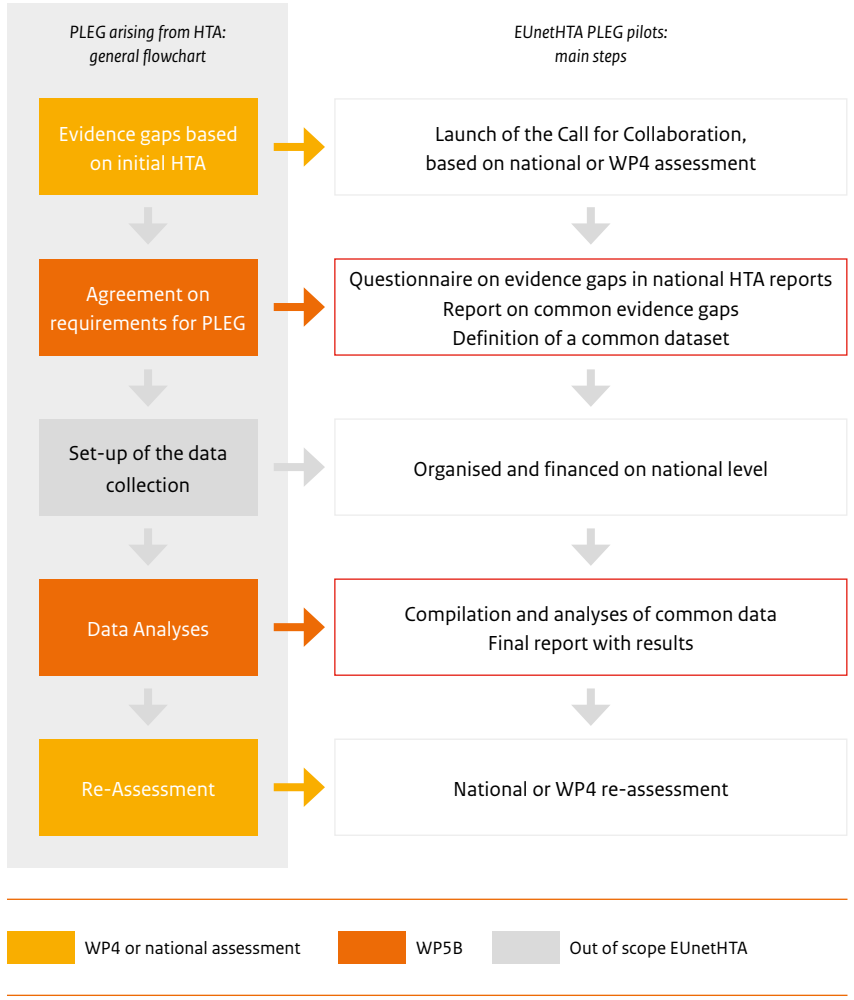
- Pilot joint work on defining requirements for post-launch evidence generation (PLEG), for specific products or diseases (PLEG pilots).
- Develop a tool aiming to support HTA organisations in guiding and evaluating registries towards effective usage in HTA (REQueST®).

PRODUCT-SPECIFIC PLEG PILOTS ARISING FROM HTA

Three product specific PLEG pilots are currently being carried out by WP5B, two on drugs and one on a medical device. The indications covered are a rare disease (first drug pilot), oncology (second drug pilot), and cardiology (medical device pilot). All three ongoing pilots are based on proposals made by WP5B agencies and arise from evidence gaps identified in respective national assessments.

They all consist in agreeing, among participating agencies, on the dataset for real world evidence generation and, whenever possible, gathering generated data from different jurisdictions. While the pilots are confidential in the beginning, their intermediary and final reports are made public. Expected publication dates for on-going pilots will be updated on the EUnetHTA website shortly.

FIGURE 1: PLEG FLOWCHART AND PILOT MAIN STEPS



In parallel with the conduct of pilots, in year 3 WP5B has been updating general pilot templates and procedures.

Finally, topics for year 4 pilots are currently being considered.

STANDARDS TOOL TO EVALUATE THE QUALITY OF REGISTRIES

Year 3 has been dedicated to further developments of the Registry Quality Standards tool[1] (REQueST®) and its Vision paper[2]. Firstly, the draft tool's use has been tested by three EUnetHTA partners in their everyday work during 2018. Secondly, global WP5 partners and EUnetHTA stakeholder consultation has been organised at the end of 2018, in order to consult on the latest draft of the tool and the Vision paper.

Thanks to the feedback gathered through these two activities, upgraded versions of the tool and the Vision paper are currently being produced. They will be shared for a public consultation in May 2019.

The final versions of both the tool and the Vision paper are expected in September 2019.

STAKEHOLDER ENGAGEMENT

WP5B is continuously exploring possibilities to perform collaborative pilots with other projects/initiatives from various stakeholders. Similarly, WP5B is involving stakeholders in the development of the REQueST® tool and its Vision paper. Seven organisations have responded to the consultation organised at the end of 2018 and have provided valuable feedback that has been of great help in refining the outputs to near-final versions.

WP5B will be happy to welcome stakeholder feedback once again, during the public consultation on the near-final versions of both the tool and the Vision paper in May 2019.

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

[1] *Tool aiming to support HTA organisations in guiding and evaluating registries towards effective usage in HTA.*

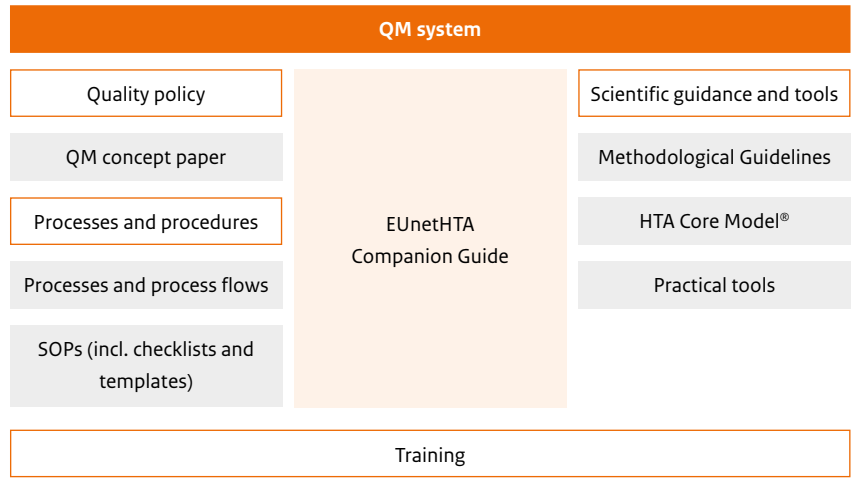
[2] *Paper accompanying the tool and setting out proposed options for the long-term delivery, use and sustainability of the tool beyond Joint Action 3*

QUALITY MANAGEMENT, SCIENTIFIC GUIDANCE AND TOOLS

Objectives

Activities aim at developing and establishing quality management for HTA collaboration at a European level in order to improve the efficiency and quality of joint work, favour its adaptation at national and EU level, and secure robust scientific relevance and acceptance.

The quality management (QM) system for EUnetHTA includes the quality policy, processes, and procedures, as well as an organisational structure provided by the EUnetHTA Companion Guide. Methodological guidance, tools, and QM-related training modules complement those aspects.



YEAR 3 ACHIEVEMENTS…

- The EUnetHTA Companion Guide, EUnetHTA's new and comprehensive online repository, is in use by the assessment teams and project managers of WP4 since autumn 2018. It provides support and guidance during the production of the reports and enables easy access to all SOPs, templates, methodological guidelines, and tools developed and updated in WP6.

- 26 out of around 40 standard operating procedures (SOPs) describing all process steps of Rapid REA Pharma and Rapid REA Other Technologies (OT) are now available in the Companion Guide. In addition, Process Flows for Pharma and OT that visualise the overall assessment processes were implemented.

- Templates relating to the Rapid REA Pharma Process have been updated by a team composed of WP4 and WP6 (Co-) Leads and national experts on the Rapid REA Pharma Process. The aims of the revisions are to facilitate the provision of required data by manufacturers and to improve the structure and readability of the assessment reports.

- 2 new methodological guidelines on the critical assessment of clinical and economic evidence are currently under development. Updates for the methodological guidelines 'Process of Information Retrieval for Systematic Reviews and Health Technology Assessments on Clinical Effectiveness' and 'Comparators & Comparisons: Direct and Indirect Comparisons' are underway. Requests for the update of other methodological guidelines have been collected.

- The activity HTA Core Model® has been restarted in November 2018 with a new activity leader and a 'Core Model Working Party' composed of EUnetHTA partners experienced in the development and application of the HTA Core Model®.

- Project descriptions and statuses are continually being updated in the Planned and Ongoing Projects (POP) database. It currently holds approximately 750 project descriptions from 21 countries.

- The Evidence Database on New Technologies (EVIDENT Database) is currently offline for a technical upgrade. Relaunch is planned in 2019 Q2.

- A new online tool has been developed to facilitate the management of the unique identifier for the different EUnetHTA tools: the EUnetHTA ID.

- Training modules on the development of SOPs and the EUnetHTA Quality Management Concept and the use of the Companion Guide have been created and made available to all EUnetHTA partners.

…AND YEAR 4 PLANS

- All SOPs, templates, methodological guidelines and tools are subject to a continuous evaluation through the 'WP4 Survey for Assessment Teams and Project Managers' and other feedback sources. Based on the change suggestions received, the required updates and new developments will be implemented in WP6 in order to have a sustainable quality management for the European HTA Collaboration available at the end of Joint Action 3.
- The methodological guidelines currently in development or under major revision will go to public consultation in 2019.

PARTIES INVOLVED

Quality Management, Scientific Guidance and Tools comprises 25 EUnetHTA partners from 16 different countries.
The teams of WP6 closely collaborate with WP4 in the development and update of all quality management products and processes.

Other cross work package collaborations of WP6 include:

- Participation in different task groups (Authoring and Copyright Issues Task Group, Core Model Working Party, Pool of Information Specialists, Patient & Consumers and Health Care Providers Task Group, Task Group on Common Phrases, Post-2020 Model of Cooperation Task Group, Joint Group on the Rapid REA Pharma Process).
- Implementation of training activities in cooperation with WP2.
- Cooperation with WP3 to reflect WP6 activities in the project evaluations.
- Joint development of an Early Dialogue Tool with WP5.
- A collaborative project with WP7 that aims at evaluating how EUnetHTA methodological guidelines and tools are being used in national HTA work and their potential to support implementation of EUnetHTA joint work.

Additionally, all interested parties – both within and outside of EUnetHTA – are invited to provide their input within the development and major update of methodological guidelines (public consultation).

NATIONAL IMPLEMENTATION & IMPACT

Objectives

- Provide technical support about implementation issues to enable the development of an HTA cooperation mechanism that successfully takes implementation issues at national, regional, and local (hospital) levels into account.
- Facilitate uptake and implementation in national, regional and local settings of EUnetHTA tools and jointly produced HTA information in EUnetHTA (from previous joint actions as well as in Joint Action 3), and the reuse of HTA reports produced by Member States.

PARTNERS INVOLVED IN OUR ACTIVITIES

The National Institute for Health and Care Excellence (NICE) is the Lead Partner for WP7. The Italian National Agency for Regional Health Services (Agenas) is the Co-Lead Partner. In total there are 57 WP7 partners.

CORE ACTIVITIES – UPDATE

ACTIVITY 1: RESEARCH AND ANALYSIS

This activity is complete. A report on HTA and reimbursement procedures in EUnetHTA partner countries was published in November 2017, based on analysis of pharmaceutical and non-pharmaceutical HTA processes from 59 agencies in 31 countries.

Publically Available Documents

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

ACTIVITY 2: CASE STUDIES

Case studies are being undertaken to support implementation of Joint Assessments. In year 3 of the Joint Action, WP7 completed a case study on the use of EUnetHTA Joint REAs to inform economic evaluation. Interviews were undertaken with 9 agencies that use health economics as part of their procedures. Results were analysed thematically and incorporated into the 2nd Implementation Report published in November 2018, together with a supporting appendix of case study interview summaries. An abstract of the case study has been selected for presentation at the HTAi Conference 2019.

National Implementation & Impact is currently working with Science Guidance & Tools (WP6b) to undertake a case study on the use of EUnetHTA tools and guidelines in agency procedures and the effect of choosing different tools and methods on uptake of joint REAs. The case study is being undertaken through an online survey sent to all WP7 partners and follow-up interviews undertaken with selected cases. The findings of the case study will be incorporated into the next Implementation Report (for publication May 2019).

Publically Available Documents

Year 3 case study on REA to inform economic evaluation: Interview summaries.
https://www.eunethta.eu/wp-content/uploads/2018/12/Appendix-Case-Study-interview-summaries-final-without-cover.pdf

Year 2 Analysis of HTA and reimbursement procedures: Case studies.
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

National Implementation & Impact is supporting the Secretariat to develop the scientific and technical mechanism for sustainable HTA cooperation. In March 2019, a report on Technical Support to Develop a Model of HTA Cooperation was finalised. This outlines, from a user perspective, the key elements of a permanent model of HTA cooperation that supports uptake of joint HTA outputs.

This report informs work being undertaken by the Secretariat in years 3 and 4 of JA3 which will form final recommendations about implementing the scientific and technical aspects of a sustainable model of HTA cooperation after EUnetHTA JA3 (post-2020).

ACTIVITY 4: IMPLEMENTATION NETWORK

A total of 14 Joint or Collaborative Assessments have been published to date under JA3, of which 3 are for Pharmaceuticals and 11 are for Other Technologies. WP7 implementation data (correct as of March 2019) indicates:

- There have been 144 reported uses of assessments in total, 48 for Pharmaceutical Technologies and 96 for Other Technologies.
- 84 of the 144 uses were in assessment procedures and 60 were examples of dissemination to raise awareness of EUnetHTA assessments.
- An increase in the use of assessments between May 2018 and March 2019.
- An increasing number of countries using JA3 assessments.
- The use of Pharmaceutical Technologies assessments under JA3 is higher than under JA2.
- The use of Other Technologies assessments under JA3 is comparable with JA2.

We are now working on our 3rd implementation report to be published May 2019.

Publically Available Documents

2nd Implementation Report (November 2018):
https://www.eunethta.eu/wp-content/uploads/2018/12/Implementation-Report-November-2018-Final-without-cover.pdf

1st Implementation Report (May 2018):
https://www.eunethta.eu/wp-content/uploads/2018/06/May-2018-Implementation-report_website_FINAL.pdf

ADDITIONAL ACTIVITY: IMPLEMENTATION STRATEGY

We are currently developing an Implementation Strategy which will include a shared set of principles, responsibilities, and activities that have been identified by partners as being important to supporting implementation in JA3 and post-2020.

The finalised Implementation Strategy will be incorporated into the next Implementation Report, to be published May 2019.

STAKEHOLDER ENGAGEMENT

National Implementation and Impact is working with EFPIA to collect data from Industry partners about the use of Pharmaceutical Assessments published in JA3. Data will be collected by an online survey and interviews with selected cases. Results will be published in the 3rd Implementation Report and future reports thereafter.
We are also in discussions with MedTech Europe about collecting data from Industry partners about the use of Other Technologies assessments.

Through the implementation network, we continue to reach out to HTA users and producers who are not part of EUnetHTA to support awareness of EUnetHTA and the more widespread use of EUnetHTA assessments and tools.

PLANS AND NEXT STEPS

- Complete case study on use of EUnetHTA tools and guidelines (April 2019) and undertake further case studies in year 4 of JA3 (2019/2020).
- Finalise and publish EUnetHTA Implementation Strategy (May 2019).
- Finalise and publish 3rd Implementation Report (May 2019), with further (4th) Implementation Report to follow in November 2019.
- Collect and analyse industry implementation data (ongoing).
- Continue to provide technical support to the Secretariat for a model of HTA cooperation.
- Produce a final evaluation report with implementation outcomes from EUnetHTA JA3 and recommendations for developing a permanent model of HTA cooperation (May 2020).

AN OVERVIEW OF TASK GROUPS IN EUNETHTA

FUTURE MODEL OF COOPERATION ON HTA (FMC-HTA)

Chaired by Marcus Guardian, ZIN

- Develop a complete blueprint for future European collaboration on HTA post-EUnetHTA JA3.
- The focus of this model and related recommendations will be primarily at a technical level, emphasising elements of HTA products and coordination of European-level efforts. The orientation of these efforts will be output-driven along the products and services HTA bodies are expected to provide.
- Such a model will take into consideration achievements of current and former Joint Actions as well as the legislative proposal on a European HTA framework currently under discussion before Parliament and Council.

CONFLICT OF INTEREST (COI)

Chaired by Giovanni Tafuri, ZIN

- Ensure consistent understanding and application of the EUnetHTA DOICU procedure.
- Check in: What is working well? What needs to be clarified/improved?
- Identify limitations of the DOICU procedure and tools (i.e. the template).
- Develop a new adapted procedure and tools.

PATIENTS, CONSUMERS, AND HEALTHCARE PROVIDERS (P&C/HCP)

Chaired by Giovanni Tafuri, ZIN

- To define a common/consistent strategy for P&HCP contribution to EunetHTA WP4&5 activities, and to facilitate the deliverables, namely of WP4 and WP5, with respect to how patients/consumers (P&C) and healthcare providers (HCP) will be involved at the project level.

TF HTA AND MDR/IVDR - MEDICAL DEVICES

Chaired by Claudia Wild, LBI-HTA

- Explore the possible synergies between EUnetHTA activities on medical devices and in-vitro diagnostics and the regulators (Competent Authorities supported by EU-Commission (DG Grow) in implementing the MDR/ IVDR) – similar to EMA-EUnetHTA collaboration in the area of medicinal products.

AUTHORING RULES AND COPYRIGHT ISSUES (ARCI)

Chaired by Iñaki Imaz, ISCIII

- Propose and agree authorship and copyright rules for EUnetHTA products. The proposals are only applicable to EUnetHTA Joint Action 3 and aim to support dissemination and reuse of EUnetHTA documents and other EUnetHTA outputs.

EUNETHTA COMMON PHRASES (ECP)

Chaired by Rudy Dupree, ZIN

- To avoid the use of sentences/words in an assessment report which may unintentionally imply or predetermine reimbursement decisions in some jurisdictions.
- To recommend on the use or non-use of GRADE or other internationally adopted rating systems in Joint Assessments.
- To provide a scenario-based set of standardised formulations regarding the textual presentation of results and conclusions in PT & OT Joint Assessments for increased consistency.

HTA CORE MODEL

Chaired by IQWiG

- The main objective of the group is the revision of the Core Model to provide a clear and easy way to handle structure, provide scientific guidance which can easily fit new scientific results, and to provide support for scientists working on Joint Assessments through the integration of the HTA Core Model into the EUnetHTA Companion Guide.
- The first aim is to adapt the reporting structure of the HTA Core Model by developing a set of templates for the project plan and for the assessment reports of different applications of the HTA Core Model.
- The second aim is to outsource methodological guidance from the HTA Core Model into separate Methodological Guidelines and identify additional guidelines.

TASK IDENTIFICATION AND PRIORITISATION GROUP (TISP)

Chaired by Vigdis Lauvrak, NIPHNO

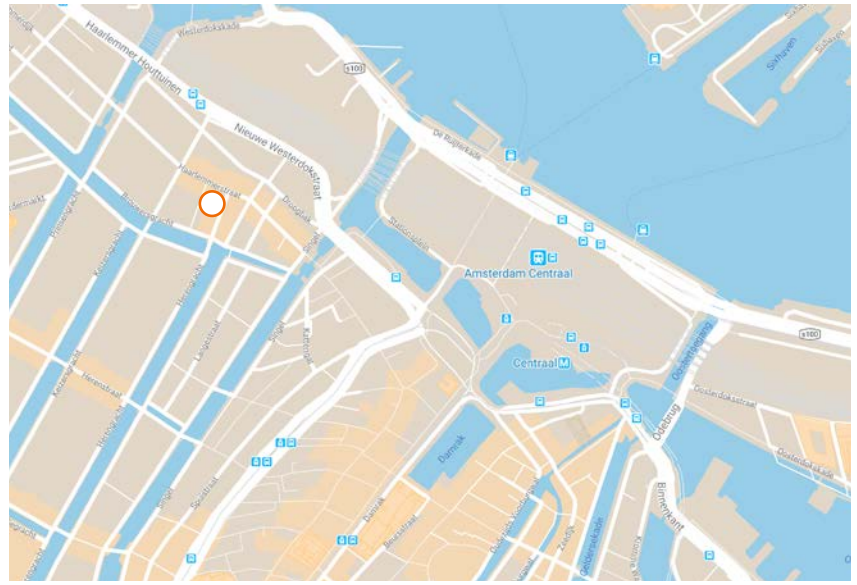
- To develop and refine a system of horizon scanning, topic selection, and prioritisation in close collaboration with relevant Work Packages.

USEFUL INFORMATION

ADDRESS

The West-Indisch Huis
Herenmarkt 99
Amsterdam 1013 EC
Netherlands

TRAVEL



WALKING

The West-Indisch Huis is a 9-minute (750m) walk from Amsterdam Centraal Station.

- Head west on Stationsplein (22 m)
- Turn right to stay on Stationsplein (160 m)
- Turn right to stay on Stationsplein (150 m)
- Turn left toward Nieuwendijk (56 m)
- Turn right toward Nieuwendijk (100 m)
- Turn right onto Nieuwendijk (19 m)
- Continue onto Haarlemmerstraat (190 m)
- Turn left onto Herenmarkt and your destination will be on the right (41 m)

Data provided by Google Maps. Use with caution – walking directions may not always reflect real-world conditions.

DRIVING

Parking garage P1 'Amsterdam Centraal' is located 8 minutes away from Amsterdam Centraal Station. Users must consult the vendors website to reserve parking at least one day in advance at a cost of €10.00 per day.

Parking garage IJ Dock is located 850 meters (10-minute walk) from the House. Users must consult the vendor website to reserve parking at least one day in advance at a cost of €10.00 per day.

PUBLIC TRANSPORT

To plan your journey using other forms of transport, please visit 9292.nl. This free site provides up-to-date, daily travel information throughout the Netherlands.

NEARBY

Amsterdam Centraal Station (1.5 km)
Amsterdam Schiphol Airport (18.6 km)
Anne Frank House (1.2 km)
Dam Square (4.8 km)
Rijksmuseum (2.8 km)
Van Gogh Museum (3.7 km)
Royal Palace (4.9 km)
Oude Kerk (4.3 km)
Vondelpark (2.5 km)
Leidseplein (2.9 km)
Bloemenmarkt (2.3 km)
Rembrandt Square (3.8 km)

Distances are approximate and are measured in driving time.


Rijksmuseum


Van Gogh museum


Vondelpark


Bloemenmarkt

ON THE DAY

GET INVOLVED

Be part of this year's Assembly & Forum by posting your questions, comments and pictures of the day on social media using #eunethta19.

Throughout the event, you will also have the opportunity to interact with us via live polling. Questions will be posed throughout presentations and you will be able to submit your responses via the Poll Everywhere app or by texting in.

Download the app so you will be ready to participate on the day.

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

INTERACTING WITH EUNETHTA

The Assembly and Forum will also provide you with an opportunity to pose your questions to the Leads and Co-Leads of our Work Packages. Members of staff will be identifiable by an orange EUnetHTA lanyard and will be available during the breaks in designated areas in the foyers.

Look out for signposts on the day to guide you to specific work package areas.

WIFI

To access WiFi on the day, connect to 'Taste' and enter the password 'WelcomeAtTaste'.

SMOKING

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

ACCESSIBILITY

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

SECURITY

To ensure the safety and security of our personnel, guests, and venue staff, it is essential guests wear their name badges at all times. If you have lost your name badge, please contact a member of the Secretariat who will arrange a replacement.

CONTACT

If you require assistance or need further information on the day, please contact our general event helpline on +31 612 502681.

PHOTOGRAPHY AND VIDEO

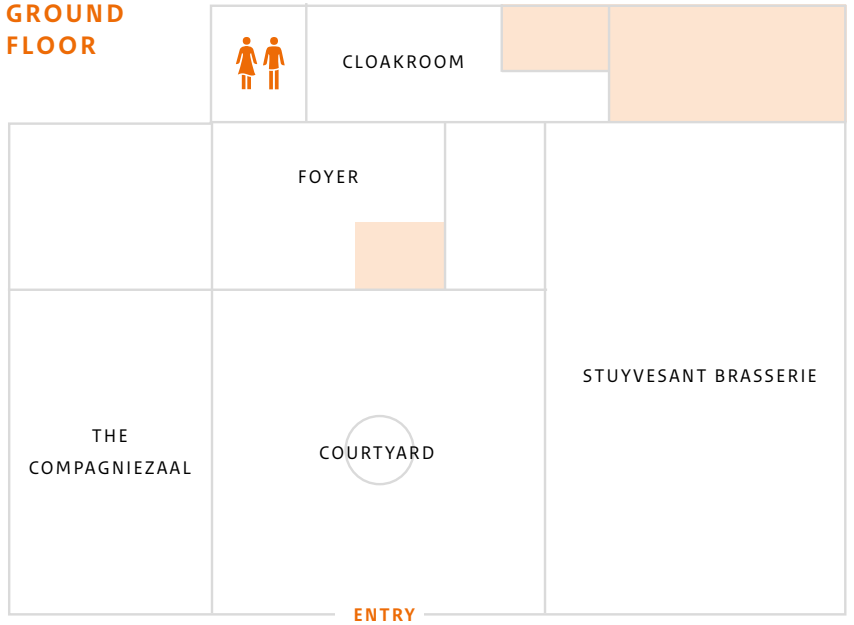
EUnetHTA reserves the right to use any photography/video taken at the event, without the expressed permission of those included within the photography/video. EUnetHTA may use the photography/video in publications or other media produced or contracted by EUnetHTA.

To ensure the privacy of individuals, images will not be identified using full names or personal identifying information without written approval from the photographed subject.

By participating in a EUnetHTA event or by failing to notify EUnetHTA, in writing, your desire to not have your photograph taken, you agree to having images used for the purposes as stated above.

FLOOR PLAN

GROUND FLOOR



FIRST FLOOR