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European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3

JA2015 - GPSD [705038]

| START DATE:          | 01/06/2016          |
| END DATE:            | 31/05/2021          |
| DURATION:            | 48 month(s)         |
| CURRENT STATUS:      | Ongoing             |
| PROGRAMME TITLE:     | 3rd Health Programme (2014-2020) |
| PROGRAMME PRIORITY:  | -                   |
| CALL:                | Health Programme Adhoc Call for invited (named) beneficiaries |
| TOPIC:               | Health Technology Assessment cooperation |
| EC CONTRIBUTION:     | 11999798.74 EUR     |
| KEYWORDS:            | Early Dialouges, Eunetha, European Network On Heath Technology Assessment, Health Technology Assessment, Hta, Hta |
| PORTFOLIO:           | Health technology assessment |
Project abstract

The general objective for EUnetHTA JA3 is to 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 notably to avoid duplication of assessments. An overarching objective is to develop a general strategy, principles and proposal for a scientific and technical mechanism of permanent sustainable European Collaboration on HTA in the light of the Directive on CBHC. During the JA3 the collaborative production of structured HTA core information, including rapid HTAs will be structurally implemented and the methodologies and production related information and communication technology infrastructure will be finalised as to stand alone from 2020 onwards. EUnetHTA JA3 will also aim to increase the alignment between HTA reports used for reimbursement decisions and clinical practice guidelines that are used by physicians in daily practice. Additionally, EUnetHTA JA3 will also support more alignment of different processes in the lifecycle of health technologies. For instance, processes on market authorization and HTA of pharmaceuticals could be organised in a more closely aligned fashion which may lead to a timelier and more efficient process promoting earlier patient access to products that have a real added value. EUnetHTA JA3 will also contribute to the discussion on the assessment of the effectiveness and safety of new medical devices as is currently taken place as part of the debate on new European legislation for medical devices. Finally, all these outcomes will contribute to the dissemination of health information and knowledge, thus improving policy-and decision-making in the health systems, which turns into protection of citizens against unsafe or ineffective technologies and improves access to high value health technologies. Ultimately this contributes to the development of

Summary of context, overall objectives, strategic relevance and contribution of the action

Health Technology Assessment (HTA) aims at responding to decision-makers’ information needs regarding the introduction, coverage, use or disinvestment of health technologies. Information needs often arise simultaneously across Member States (MS), and multiple HTA agencies address these needs concurrently. Despite concurrent need for HTA information to support decision makers, differences in decision making structures, timing, information requirements and level of HTA implementation vary across the MS. Without a sustainable mechanism for cross European collaboration in HTA to support timely and transparent transfer of information, frequent duplication of efforts in HTA can occur. A sustainable mechanism of cooperation within Europe in meeting these information needs would decrease the duplication of efforts and result in increased efficiency and support at national HTA agencies and across
MS. This European collaboration is focused on the technical and scientific assessment; appraisal, the societal valuation of the assessment results, that supports national or regional decision-making on reimbursement of health technologies, will remain within the remit of the Member States. EUnetHTA has always been very explicit in stating that the evidence should be global (and therefore be assessed globally) while the decision making (appraisal) should be local.

Previous European projects have demonstrated that collaboration and information sharing is facilitated with an organisational structure and common tools for HTA production. The EUnetHTA Joint Action (JA1) 2010-2012 refined the collaboration structure and tools with attention to global developments in the field. EUnetHTA Joint Action 2 (2012-2015) extended this by strengthening the practical application of tools and approaches to cross-border HTA collaboration, further supporting and refining a system of collaboration in HTA. These experiences have proven the ability of national HTA organisations to work together and produce valuable products.

The Directive on cross-border healthcare (CBHC, 2013) requires the establishment of a permanent network on HTA in Europe. The Council of the European Union has pointed out the need to strengthen activities aiming at ensuring financial sustainability of health systems while ensuring universal, equitable access to quality care. HTA is under the same financial pressure as the health systems and thus itself is required to use its resources efficiently. The need to enhance the use of HTA has also been pointed out by the European Commission and the HTA-scientific community. Participation in collaborative projects in JA1 and JA2 has been shown to foster HTA in countries lacking an established HTA structure or capacity. JA3 will now proceed with the final step of establishing this permanent sustainable network on HTA in Europe.

The objective of EUnetHTA JA3 is to support voluntary cooperation at scientific and technical level between Health Technology Assessment Bodies to validate the model for joint work to be continued after EU funding under the Health Programme ends. The cooperation between national and regional HTA Bodies is essential to meet the provisions set out by Article 15 of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare and to create synergy with the strategic HTA Network set up under this Directive.

An overarching objective is to develop a general strategy, principles and proposal for a scientific and technical mechanism of permanent sustainable European Collaboration on HTA in the light of the Directive on CBHC, which states that a voluntary HTA network should support cooperation between national HTA institutions and support MS in the provision of objective, reliable, timely and comparable information. During the JA3 the collaborative production of structured HTA core information, including rapid HTAs will be decentralised and the methodologies and production related information and commun
Methods and means

The JA3 will have two interrelated streams of activity. The implementation stream (WP4, WP5 and WP7) and the structure and methodological consolidation stream to ensure scientific quality (WP6).

In the implementation stream HTA information for priority technologies will be produced collaboratively based on the methods and recommendations generated so far by EUnetHTA. This output will be then implemented on a national level (WP7), in a way also to closely relate to additional evidence needed for the decision making process in that country (WP5).

In the second stream the information and knowledge management tools developed during JA2 will be refined and finalised and additional methodologies, guidelines and models developed. Experiences from the implementation stream will be accounted for.

More fundamentally, the work builds on the scientific background of relevant international research. Joined assessments will be conducted in a collaborative manner based on the methodological developments and recommendations generated in the JA1 and JA2. These methodologies are firmly based on international methodology developed by Cochrane and GRADE. To ensure collaboration, all partners have committed to actively contribute to one of the implementation WPs. In later phases of this JA3 coordination of the joint assessment may be decentralized for some types of technologies, in order to create a stand-alone structure from 2020 onwards. For specific types of technologies, such as pharmaceuticals it may be more obvious to have a centralized approach because of the submission based form of assessment and the needed alignment with EMA procedures and timing.

In the structure and methodological consolidation stream the information and knowledge management tools which were developed in the JA2 will be refined and finalized, methodologies, guidelines and models new developed and further refined (WP6). Also, there will be maintenance, revision, and development of tools and methodologies and training according to needs. The governance structure and the approach to involve stakeholders will be continued, and even extended.

Work performed during the reporting period
The most important activities carried by each WP during the reporting period are presented below.

Work Package 1 - Coordination:
• EUnetHTA JA3 4-year work plan was developed together with WP Lead Partners and Co-Lead Partners, being updated for each project year;
• A joint work plan describing the collaborative activities between EMA and EUnetHTA was developed;
• A network infrastructure was created to provide partners a platform for collaboration and support in their project activities.

Work Package 2 - Dissemination:
• A leaflet was created and made available at main EUnetHTA JA3 events that were organised during the reporting period;
• A Training Strategy including training materials was developed;
• A Communication Strategy including dissemination actions, communication tools and communication channels was delivered.

Work Package 3 - Evaluation:
• Three evaluation reports, two bi-annual short reports and one yearly interim report were finalised.

Work Package 4 - Joint Production:
• Two joint assessments for pharmaceutical technologies and three collaborative assessments for other technologies were published.

Work Package 5 - Life cycle approach to improve Evidence Generation:
• Seven early dialogues were completed based on the organisational framework and procedure specially created;
• Two collaborative disease/registry specific PLEG pilots on drugs were launched.

Work Package 6 - Quality Management, Scientific Guidance and Tools:
• A quality management concept paper was developed which describes the fundamental aspects as well as EUnetHTA specific means of quality management in the context of joint work;
• Process flows for Rapid REA for pharmaceutical technologies and Rapid REA for other technologies were elaborated and required SOPs for each process step were defined. Initial quality management SOP was finalized;
• A prototype of the EUnetHTA Companion Guide was developed and presented to partners to ensure timely consideration of feedback from potential future users;
• A roadmap for the orientation of the development of the EUnetHTA scientific guidance and tools was created and delivered.

Work Package 7 - National implementation and impact:
• A report, presenting key implementation challenges in 59 agencies in 31 countries and how agencies could engage in HTA cooperation and use EUnetHTA assessments, was made available;
Nine case studies were completed covering nine countries and involving 21 agencies;
A metric tool to monitor uptake and implementation of joint products was developed in collaboration with WP3 and WP1 and incorporated into the feedback survey.

The main output achieved so far and their potential impact and use by target group (including benefits)

From the perspective of the specific objectives of EUnetHTA JA3, two joint assessments for pharmaceutical technologies and three collaborative assessments were produced. These assessments were produced based on a standardised methodology and process and by using tools that can be incorporated in the working processes of HTA national producers. Also, the collaboration between partners involved in the joint work was further strengthened.

As the produced assessments were recently published, it is too early to provide an accurate insight of the implementation at national, local or regional level of these assessments. According to the current surveys performed, 23 partners have worked or are working on the topic areas related to the finalised assessments and 13 partners expect to be working on the topic area in the future so more intake is expected. The first set of implementation data for these assessments will be published in May 2018.

Achieved outcomes compared to the expected outcomes

During the reporting period, two joint assessments for pharmaceutical technologies and three collaborative assessments were produced. According to the Grant Agreement, fifty joint products are expected to be produced per year by the end of JA3. Nevertheless, during the reporting period, the production of joint assessments encountered a series of challenges that are described in the first technical report. Corrective actions were taken or are planned to be taken to improve the production process and to determine the increase of joint products.
Dissemination and evaluation activities carried out so far and their major results

Two EUnetHTA JA3 Forums, organised during the reporting period, offered a platform for networking, scientific discussions and exchange of experience between EUnetHTA partners and HTA stakeholders. Also, several partners showed strong commitment by representing EUnetHTA JA3 in more than sixty conferences around Europe and promoting the EUnetHTA JA3 activities in fourteen published articles. As a result, part of this representation strengthened the collaboration with other scientific organisations that deal with HTA such as HTAi and ISPOR.

Three evaluation reports were finalised during the reporting period: two bi-annual short reports and one yearly interim report. The aim of these reports was to evaluate EUnetHTA JA3 activities in accordance with the Grant Agreement.
Work Package 1: Coordination
Start month: 1
End month: 48
Work Package Leader: ZIN

Coordinator (Coor) answering to the EUnetHTA Assembly (EA) (consisting of the partner organisations who have signed the consortium agreement, main policy setting body) and being a member of the Executive Board (EB) (Consisting of Lead and Co-Lead Partners (LPs and CLPs), 5 elected beneficiaries; and is the main executive body, strategic leadership) will act as the JA3 operational contact for CHAFEA and Beneficiaries for technical, administrative, financial matters & monitoring (operational leadership). WP LPs will be responsible for coordination of activities in the WPs and assist Coor with timely reporting and providing information on request. WP LPs will be responsible for providing input into the development of a model for a sustainable mechanism for the European cooperation on HTA.

Defining a model for a sustainable mechanism for the European cooperation on HTA will be coordinated by the Coor and the EB and developed for sustainable HTA network implementation set out by Article 15 of Directive 2011/24/EU. The defined model for a sustainable collaboration mechanism in HTA will be delivered at the end of JA3. Reports to the CHAFEA will be prepared to ensure rigorous quality assurance of JA3. The JA2 SOP manual (with details on management/governance, procedures & forms) will be adjusted and a 4-year JA3 Work Plan will be developed and updated as needed in collaboration with WP6 (Quality Assurance) and the EB.

WP1 is responsible for organising 2 annual EUnetHTA Assembly (EA), 2 EUnetHTA Forum, and 8 WP1 meetings in different MS. Representatives of DG SANTE, CHAFEA, and other relevant EU-bodies (e.g., EMA) and representatives of the JA3 Stakeholder Registry will be invited to the EUnetHTA forum/symposium meeting. The JA3 EB and Coordinator will lead the sustainable network implementation work including responsibility for stakeholder involvement to ensure coherence with the processes and achievements in and across the JA3 WPs. Continuous dialogue with DG SANTE (and other relevant EU institutions) will be ensured through regular communication (e-mail/phone/e-meeting).

The EUnetHTA Assembly will decide the JA’s working and management plan, elect representatives of the EA to serve on the EB, and provide opportunity for JA participants to meet and strengthen JA dynamics. JA3 EB will be responsible for potential conflict resolutions between the partners and stakeholder involvement activities. The Governance Guiding Principles and the Stakeholder Involvement Policy adopted for JA2 will continue to apply in JA3.

Work Package 2: Dissemination
WP2 will support EUnetHTA in the dissemination to general public and the
stakeholders of high quality information on EUnetHTA deliverables and progress
through a wide range of means to contribute to the development of a sustainable
mechanism of HTA cooperation in Europe. WP2 promotes dissemination and
communication activities that will be linked to the production of the different WPs of
EUnetHTA JA3 to ensure that results of the project (tools, methods and products)
will be made available for partners and target groups. For this purpose, WP2 will
work in close collaboration with all WPs, but very especially with WP1 and WP7.
WP2 will actively identify and engage stakeholders throughout the course of the
project in order to ensure that the results of the project are applicable and
appropriate to stakeholders. WP2 will perform a stakeholder analysis and
continuously update of it through the project. WP2, in collaboration with WP1 will
create a database of stakeholder registry. To facilitate dissemination, WP2 will
develop a dissemination strategy, as well as update the communication strategy of
JA2 with particular focus in a communication strategy that supports the sustainable
model of collaboration. WP2 will increase capacity and know-how in HTA-bodies by
development and provision of training for Quality Management and methodologies
and tools in the context of EUnetHTA.

Work Package 3: Evaluation
Start month: 1
End month: 48
Work Package Leader: TLV

WP3 will consist of evaluation activities to verify if the JA3 is being implemented as
planned and reaches the objectives. WP3 will develop an evaluation strategy, which
corresponds to the needs and activities of the other WPs, most notably the core
WPs. In particular, WP3 will monitor and facilitate the evaluation as part of the
development of a metrics tool coordinated by WP1 and in collaboration with WP6,
and WP7. Such a metrics tool will be important in monitoring the impact and uptake
of EUnetHTA joint work at the national, local, and regional level. WP3 will take the
final evaluation report of JA 2 into account and the WPs should follow-up on the
calculations on efficiency gains as was done in the evaluation of JA2. The evaluation
of the added value of the JA3 joint work is of paramount interest to the member
states. WP3 will therefore evaluate and include in the final reports, both
calculations and analyses on efficiency gains and added value as well as costs
related to the work. At the end of the JA3 a final report including the efficiency
gains, the added value calculation and the project progress will be provided.

Work Package 4: Joint Production
This WP focusses on the production of joint health technology assessments. The joint assessments should be fit for purpose, of high quality, of timely availability, and cover the whole range of health technologies. Along the way, the production processes of these joint assessments will be improved and updated and probe a stepped roll-out of additional collaborative assessments yielding timely information. Next to this, a system of horizon scanning, topic selection and prioritisation will be developed, and a process that facilitates the implementation of the joint assessment in the national/regional practice.

Work Package 5: Life cycle approach to improve Evidence Generation

This WP will support developers of medical technologies (pharmaceuticals, medical devices and diagnostics) by providing a collaborative approach between a wide range of European HTA agencies on their product development plans. By integrating structures that facilitate the exchange of different perspectives, learning, efficiency, and consistency throughout Early dialogues they will optimize the interaction with regulators for pharmaceuticals and medical devices. Next to this, pilots regarding post-launch evidence generation will be developed conducted. A number of pilots will be using data from registries, others will be using data from sources other than registries. A wide range of stakeholders should be involved in the pilots in order to catch all the relevant aspects. This will lead to the development of a tool to support permanent collaboration on post-launch evidence generation.

Work Package 6: Quality Management, Scientific Guidance and Tools

Actions undertaken to develop and establish quality management for the HTA collaboration at European level systematically based on the results of EUnetHTA Joint Action 2 in order to improve efficiency and quality of joint work, favour its adaptation at national and on EU level and its scientific up-to-dateness and
acceptance. This will be done by e.g. maintaining Standard Operating Procedures (SOP) in the context of joint work, and by provision and development of necessary tools and methodologies for joint work – in particular production of HTA information - at EU level. This will increase capacity and know-how in HTA-bodies by development and provision of training for Quality Management and methodologies and tools in the context of EUnetHTA.

Work Package 7: National implementation and impact
Start month: 1
End month: 48
Work Package Leader: NICE

Actions undertaken to support the development of a sustainable mechanism of HTA cooperation in Europe through supporting production of a model that successfully takes the implementation issues at national, regional and local (hospital) levels into account to inform an implementation mechanism which facilitates uptake and implementation in national, regional and local settings of EUnetHTA tools and jointly produced HTA information in EUnetHTA or by member states.
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FEDERAAL KENNISCENTRUM VOOR DE GEZONDHEIDSZORG  
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City: 93218 SAINT DENIS LA PLAINE CEDEX
Country: France
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<td>WEGELYSTRASSE 8</td>
<td>10623 BERLIN</td>
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<td>DEUTSCHES INSTITUT FUR MEDIZINISCHE DOKUMENTATION UND INFORMATION (DIMDI)</td>
<td>WAISENHAUSGASSE 36-38A</td>
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Country: Greece
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Country: Greece
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Country: Greece
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Country: Hungary
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<td>City: 00187 Roma</td>
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<td>Street: Via Giorgio Ribotta 5</td>
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<td>City: 00144 ROMA</td>
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<tr>
<td>Street: Palazzo molin, San Polo 2514</td>
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<tr>
<td>City: 30152 VENEZIA</td>
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<td>Country: Italy</td>
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<td>Website: <a href="http://www.zorginstituutnederland.nl">http://www.zorginstituutnederland.nl</a></td>
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</table>
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<td>AGENCIA ESPANOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS</td>
<td>Street: c/ Campezo Edificio 8, edif 1</td>
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EUSKO JAURLARITZA-GOBIERNO VASCO
Street: c/Donostia-San Sebastian, 1
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Country: Spain
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Country: Spain
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Country: Sweden
Website: http://www.zorginstituutnederland.nl

Medical Products Agency
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Country: Sweden
Website: http://www.zorginstituutnederland.nl
Final report WP2
ISCIII
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Final report. Including description of JA3 dissemination activities, strategies to support the development of a sustainable network in terms of communication, and recommendations for the establishment of final training strategy for post-JA3 phase

Yearly reports
TLV
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Yearly interim reports on efficiency gains and added value. These will provide feedback for resource use, good examples etc. – 4 reports in 4 years

Bi-annual report
TLV
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/01/2020
Bi-annual (=2x/year) short-reports and update of project progress (expected/observed results) and resource use – 7 reports in 4 years

Final report WP3
TLV
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
1 final report (including findings from the project and analysis of how to bring the knowledge forward after 2020)

Evaluation report on outcomes of piloting
model
NICE
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Evaluation report with outcomes of the piloting of the model of HTA cooperation in Europe against adoption metrics and including the Member States’ experience – month 48 relating to activities 2 and 4 (public)

Final report WP1
ZIN
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Final technical and financial report WP1, due in Month 50

Sustainable model for European cooperation
ZIN
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
A Sustainable model for the scientific and technical mechanism of a permanent European cooperation on HTA (including criteria/requirements for the coordination hosting function post-2020)

Work plan interaction with EMA
ZIN
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Work plan for continued interaction between regulators (EMA) and the European scientific and technical cooperation (JA3)

SOP manual and Work plan
ZIN
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
The JA2 SOP manual (with details on management/governance, procedures &
forms) will be adjusted and a 4-year JA3 Work Plan will be developed and updated as needed in collaboration with WP6 (Quality Assurance) and the EB, due in month 50.

Quarterly reports on usage and requests
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Quarterly reports on usage and requests

Proposals regarding technical requirements
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Proposals regarding technical requirements on request of WP6 (M21, M36, M50)

Completion of interim technical report
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/08/2019
Completion of interim technical report, due in month M14, M26, M38

Final JA3 WP4 technical report
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Final JA3 WP4 technical report M48

Joint assessments Year 3
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2019
Joint assessments Year 4
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
6 finalised joint pharmaceutical assessments and 7 initiated pharmaceutical joint assessments (to be published in either year 4 or year 5) and 10 joint/collaborative assessments of other technologies M48

Final recommendations for topic selection
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/08/2019
Final recommendations for horizon scanning, topic selection and prioritization; (in collaboration with Liaison committee and WP7) M38

Final recommendations for production process
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Final recommendations for a sustainable production process of European joint assessments as part of a sustainable model for coordination of future European joint assessment collaboration after 2020.

Definition of system for structural uptake
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2019
The definition of a system that facilitates the structural uptake of the joint assessments in the national and regional practice for piloting. In this process a collaboration between the assessors, the national HTA organisations, EMA (for pharmaceuticals), technology producers and other stakeholders will take place. This will also include the funding of specific stakeholders, such as patients and clinicians, through subcontracting funds. M36
Results first testing process for implementation
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2018
Results from the first testing of a structural process for the implementation of joint assessments in national practice will be further developed and adapted for a larger number of single technology assessments in collaboration with WP7. M24

Draft recommendations for production process after 2020
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2019
Draft of recommendations for a sustainable production process of European joint assessments as part of a sustainable model for coordination of future European joint assessment collaboration after 2020. M36

Final recommendations for production process after 2020
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Final recommendations for a sustainable production process of European joint assessments as part of a sustainable model for coordination of future European joint assessment collaboration after 2020. M48

Deliver EDs
HAS
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Deliver the EDs: carry out at least 15 EDs in the first 2,5 years. More EDs will be carried out if possible given budgetary constraints.
System for EDs post-2020
HAS
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Develop and implement a financially sustainable system for delivering EDs: contracts and related administrative documents to be signed by relevant parties by M40 at latest. Testing of the platform through Month 48.

Pilots Post-Launch Evidence generation and registries
HAS
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/02/2020
Conducting pilots on post-launch evidence registration (PLEG)

Revised QM system for joint work
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/10/2019
Revised QM system for joint work in sustainable network after 2020 (status report M40).

Status report on tools management
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/02/2020
Tools management (content management, user management, user support including training, maintenance and development) (status report - M44).

Recommendations and tools for post-launch evidence generation
HAS
Roadmap for coordinated activities on HTA and medical device authorities
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Expected on: 01/06/2020
Development of a roadmap for coordinated activities the competent authorities, notified bodies and EUnetHTA, supported by the European Commission and in cooperation with stakeholders.

Interim report
ZIN
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 03/09/2019
Technical and financial interim reports, due in month 14, 26 and 38

Second draft recommendations for topic selection
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 03/09/2019
Second draft recommendations for horizon scanning, topic selection and prioritization; (in collaboration with Liaison committee and WP7) M30

Proposal to optimize and adapt the infrastructure
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Proposal to optimize and adapt the infrastructure
New version of technical services
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
New version of technical services (including updates required by WP6)

Joint assessments Year 2
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
6 joint technology assessments and 1 collaborative assessment of a pharmaceutical technology and 4 joint assessments of other technologies and 6 collaborative assessments of other technologies M24

Draft recommendations for topic selection
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Draft recommendations for horizon scanning, topic selection and prioritization; (in collaboration with the Liaison committee and WP7) M14

Determine number of joint STA
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Determine a sustainable number of joint single technology assessments for pharmaceuticals and joint assessments for other technologies to be completed in JA3. M12

First testing of structural process for implementation
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint
Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Results from the first testing of a structural process for the implementation of joint assessments in national practice will be further developed and adapted for a larger number of single technology assessments in collaboration with WP7. M24

Testing of framework for alignment with EMA
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Testing of the framework for alignment of joint single technology assessments for pharmaceuticals with EMA processes including early access to data during the assessments of the CHMP will be tested. M24

Process definitions and SOPs
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
- Process definitions and SOPs (including checklists and document templates) for joint work (based on inventory, identification and prioritisation upon consultation with WP4); status report M12; M24; M36).

Evaluation of whole established QM system
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Evaluation of whole established QM system (report M33).

Companioni guide for HTA doers
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 12/06/2019
Implementation of manuals and practical tools to the EUnetHTA Companion Guide for the HTA doers (M12).
Input for recommendations for production process after 2020
NIPHNO
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 08/11/2018
Provide input to recommendations for a sustainable production process of European joint assessments as part of a sustainable model for coordination of future European joint assessment collaboration after 2020. M15

Stakeholder analysis
ISCIII
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 05/09/2018
Stakeholder analysis

Training report
ISCIII
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Report including: Overall training strategy and EUnetHTA training portfolio

Dissemination plan
ISCIII
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Dissemination plan

Final report on mechanisms
NICE
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Final report on mechanisms to support and encourage the reuse of jointly
produced HTA reports and reuse of national and regional HTA information from Member States’ reports – month 18 relating to activities 1 and 2 (public)

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<tr>
<th>Production of 4-year work plan for WP4</th>
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<td>European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)</td>
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<td>Production of 4-year work plan for WP4</td>
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<th>Joint assessments Year 1</th>
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<td>Published on: 14/06/2018</td>
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<td>2 joint technology assessments and 3 collaborative assessment of a pharmaceutical technology and 2 joint assessments of other technologies and 3 collaborative assessments of other technologies M12</td>
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<th>Development system alignment with EMA</th>
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<td>Published on: 14/06/2018</td>
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<td>Development of a system of closer alignment of joint single technology assessments for pharmaceuticals with EMA processes including early access to data during the assessments of the CHMP. M12</td>
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<tr>
<th>Organisational framework for EDs</th>
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<td>Published on: 14/06/2018</td>
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<tr>
<td>Develop and establish an organizational structure for EDs based on the experiences from the JA2 Early Dialogues (EDs) and related Shaping European Early Dialogues (SEED) initiative: nominate an organizational secretariat (for administrative and organisational purposes) and a scientific secretariat (for preparation of documents), define criteria for and constitute a standing committee (voluntarily, permanently participating organisations), define criteria for rapporteur selection, nominate rotating chairs, expert involvement</td>
</tr>
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Evaluate fee-for-service options
HAS
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
After legal counselling, evaluate how the collection of fees from industry and the redistribution among partners could best be implemented. Furthermore, evaluate how the actual agreement between industry and EUnetHTA partners could be set up: templates/proposals for contracts, consortium agreement and related documents to be made available by M12. All this needs to be compatible with European and national legal contexts.

QM concept paper
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Concept paper for quality management (QM) for practical implementation in EUnetHTA (M6).

Concept training activities
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Online and face-to-face training activities (concept M12).

Inventory guidelines and tools
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
Inventory, evaluation and prioritisation of methodological guidelines, tools and HTA Core Model® available at the start of JA3 with a cross-WP panel (WP1-4-5-6-7) (status report - M6).
New guidelines and tools
IQWIG
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 14/06/2018
New methodological guidelines or tools (max 3) based on prioritisation (M12).

Temporary network infrastructure
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 31/01/2018
Intra and internet

First final working area
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 31/01/2018
First final working area

The continuous service with technical infrastructure
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 31/01/2018
The continuous service with technical infrastructure

First services including online help functions
DIMDI
European Network for Health Technology Assessment (EUnetHTA) - Joint Action 3 (EUnetHTA JA3)
Published on: 31/01/2018
First services including online help functions