EUnetHTA Joint Action 2 on HTA 2012-2015

3-year Work Plan

May 1, 2013

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Introduction of EUnetHTA 3 year work plan

Purpose of the document

The purpose of this document is to lay out the details of the work plans of each of the 8 Work Packages (WP) in the EUnetHTA Joint Action 2 in implementing the Technical Annex of the EUnetHTA JA2 Grant Agreement (2011 23 01) with the Executive Agency for Health and Consumers (EAHC).

Each individual WP Work Plan includes detailed description of the partners, methods, specific activities, processes and their timeframe.

The document will be prospectively amended (if and where necessary) after each project year.

EUnetHTA JA2 general Objective

The general objective of the Joint Action on Health Technology Assessment (JA2) is to strengthen the practical application of tools and approaches to cross-border HTA collaboration. The JA2 aims at bringing collaboration to a higher level, resulting in better understanding for the Commission and Member States of the way to establish a sustainable structure for HTA in EU. Specifically, the JA2 will develop a general strategy, principles and an implementation proposal for a sustainable European HTA collaboration according to the requirements of Article 15 of the Directive for cross-border healthcare.

The JA2 will have two interrelated streams of activity. The 'production' stream (WP4 and WP5) and the structure and methodological consolidation stream (WP 2, WP6, WP7 and WP8). The JA2 especially builds upon the activities of the EUnetHTA Joint Action on HTA (JA1).

EUnetHTA JA2 Specific Objectives and Indicators

Specific objective 1: **Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of on costs and overall efficiency of the production in the network)**	
Output indicators	**Outcome indicators**
Production of HTA structured information: at least 3 full Core HTAs. At least 14 rapid assessments (10 for drugs and 4 for non-drug technology) At least 40 national HTA reports with use of tools and information from JA2	N/A
Specific objective 2: **Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function**	
Output indicators	**Outcome indicators**
Guidelines for collaboration, including identification of partners and clusters of organisations for specific topics, issued	N/A
Specific objective 3: **Produce recommendations on the design and running of the EU HTA cooperation process based on analysis of various coordination capacities for the permanent secretariat function and further testing of involvement of stakeholders in network activities**	

Output indicators	Outcome indicators
Recommendations produced	Approved by the JA2 Plenary Assembly
Specific objective 4: **Provide a conceptual and information management infrastructure and related services to support the piloting of collaborative production of HTAs by partner agencies, and facilitate the tasks and team working of the other WPs**	
Output indicators	**Outcome indicators**
IMIS implemented	At least 90% of JA2 participants using it (i.e., having access and having contributed at least one piece of information Core HTA Models and online tool updated Core HTA Database has information on at least 17 commonly produced Core HTAs (including rapid HTAs)
Specific objective 5: **Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders.**	
Output indicators	**Outcome indicators**
At least 3 trainings to JA2 participants and stakeholders are provided.	Attendance at the EUnetHTA conference is 80% of its targeted capacity
N/A	At least 80% of the national medicines agencies and reimbursement authorities in the EU are aware of EUnetHTA JA2 and its objectives.
Specific objective 6: **Develop and test a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues and quality improvement of evidence generation for HTA.**	
Output indicators	**Outcome indicators**
Guidelines for pertinent HTA issues produced: At least one guideline including specificities for drugs and other technologies. At least one guideline for evidence generation. Template for submissions from technology sponsors available and tested for at least two technologies	N/A

EUnetHTA JA2 Deliverables

#	Title	Description	Confidentiality level	Month of delivery
1 **WP 1**	Recommendations on the implementation of a sustainable European network for HTA	Recommendations for the relevant policy- and decision-makers committed with the transposition of the Directive on CBHC	Public	Mar ´16
2 **WP 1**	Final report from the JA2	Final reporting to the Commission	Public	Mar ‘16
3 **WP 2**	Report on yearly training courses on EUnetHTA tools and methodology	Three face-to-face training workshops on EUnetHTA tools and methodology, 3 training courses in Core HTA Model online tool for JA2 partners attendance only by JA2 partners and a limited number of stakeholders (training workshop)	Public	Sep ‘15
4 **WP 3**	Report on evaluation of project completion including assessment of impact on secondary users of HTA information	Document and implement ongoing monitoring, evaluation, feedback and vigilance processes and systems (to include, interviews with LPs, annual evaluation reports, technical support information gathering and metrics)	Public	Mar ‘16
5 **WP 4**	Full Core HTAs	Full Core HTAs to be used by a cluster of agencies for at least 20 national HTA reports in relation to applicability by partners	Public	Sep ´15
6 **WP 5**	Pilot rapid assessments	A total of 14 pilot assessments (10 on drugs and 4 on other medical technologies such as medical devices, surgical interventions or diagnostics) containing rapid HTA information based on structured core information from the HTA Model	Public	Sep ‘15
7 **WP 6**	Report on Information Management Infrastructure and Services	Information Management environment and the related services, documentation, processes and policies (IMIS). Areas with both public and restricted access	Confidential	Sep ‘15
8 **WP 7**	Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation	(1) Early dialog: (a) overview (b) piloting (2) Additional evidence: (a) questions for additional data collection (b) guidelines on appropriate study design (c) pilot common protocol for collection of additional data for a technology of interest	Public	Sep ‘15
9 **WP 7**	Methodological guidelines and Templates to support production of core HTA information and rapid assessment	Process for regular updating of methodological guidelines. Update of selected JA1 guidelines (according to the needs of JA2 WP4, 5 & 8), data templates for rapid assessments and for manufacturer’s submissions	Public	Sep ‘15
10 **WP 8**	Upgraded and updated application package of HTA Core Model	Includes updated applications on medical / surgical interventions, diagnostic and screening technologies and pharmaceuticals (first versions developed within EUnetHTA project 2006-8/JA1), upgraded version of application for pharmaceutical evaluation	Confidential	Sep ‘15

EUnetHTA JA2 Work Packages

WP	Title	Lead Partner / *Co-Lead Partner*	Country
1	**Coordination of the joint action**	DMHA	Denmark
2	**Dissemination of the joint action**	NOKC *KCE*	Norway *Belgium*
3	**Evaluation of the joint action**	HVB	Austria
4	**Testing collaborative production of HTA information for national adaptation and reporting**	AGE.NA.S	Italy
5	**Applying the HTA Core Model for Rapid Assessment for national adaptation and reporting**	CVZ *LBI-HTA*	Netherlands *Austria*
6	**Information Management Infrastructure and Services (IMIS)**	KCE *DIMDI*	Belgium *Germany*
7	**Methodology development and evidence generation: Guidelines and pilots production**	HAS *IQWIG*	France *Germany*
8	**Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information**	THL	Finland

EUnetHTA JA2 Partnership

Associated Partners (organisations nominated by Ministry of Health to participate in EUnetHTA JA2)

#	Country	Organisation	Work Package
1	Austria	Hauptverband der Österreichishen Sozialversicherungsträger, HVB	WP1, WP3 (LP), WP4, WP5
2	Austria	Gesundheit Österreich GmbH/Geschäftsbereich, BIQG/GÖG	WP4, WP5
3	Austria	Ludwig Boltzmann Institut für Health Technology Assessment, LBI	WP1, WP5 (co-LP), WP6
4	Belgium	Belgian Health Care Knowledge Center, KCE	WP1, WP2 (co-LP), WP5, WP6 (LP), WP7, WP8
5	Bulgaria	National Centre of Public Health Protection, NCPH	WP2, WP4
6	Croatia	Agency for Quality and Accrediation in Health Care and Social Welfare AAZ	WP2, WP4, WP5
7	Cyprus	Ministry of Health, Department of Pharmaceutical Services, Ministry of Health Cyprus	WP5
8	Czech Republic	Ministry of Health of the Czech Republic MoH Cz Rep	WP5, WP7
9	Denmark	Danish Health and Medicines Authority, DHMA	WP1 (LP), WP2, WP4
10	Denmark	HTA and Health Services Research, Public Health and Quality Improvement, Central Denmark Region, CR.DK	WP5, WP8
11	Estonia	Tartu University Department for Public Health, UTA	WP4, WP8
12	Finland	National institute for health and welfare, THL	WP1, WP2, WP4, WP5, WP6, WP8 (LP)

13	Finland	Finnish Medicines Agency Assessment of Pharmacotherapies Process, FIMEA	WP5
14	France	Direction générale de Santé/ Haute Autorité de Santé, HAS	WP1, WP2, WP3, WP4, WP5, WP6, WP7 (LP), WP8
15	Germany	Deutsches Institut für Medizinische Dokumentation und Information, DIMDI	WP1, WP4, WP6 (co-LP)
16	Germany	Institute for Quality and Efficiency in Health Care, IQWIG	WP1, WP5, WP7 (co-LP)
17	Greece	National School of Public Health, NSPH	WP2, WP4
18	Hungary	National Institute for Quality- and Organizational Development in Healthcare and Medicines, GYEMSZI	WP3, WP5, WP7
19	Ireland	Health Information and Quality Authority, HIQA	WP1, WP5, WP7
20	Italy	Agenzia Nazionale per i Servizi Sanitari Regionali, AGENAS	WP1, WP4 (LP), WP5, WP7
21	Italy	Agenzia Italiana Del Farmaco, AIFA	WP5, WP7
22	Italy	Regional Agency for health and social care – Emilia Romagna, ASSR	WP4, WP7
23	Italy	Regione Veneto	WP4, WP5A, WP7
24	Latvia	National Health Service, NHS	WP5
25	Lithuania	State Health Care Accreditation Agency, VASPVT	WP2, WP5 A/B, WP7
26	Luxembourg	Ministère de la sécurité socialeInspection générale de la securité sociale Cellule d'expertise médicale, CEM	WP2, WP4
27	Malta	Directorate for Pharmaceutical Affairs, Ministry for Health, the Elderly and Community Care, DPA/MHEC	WP2, WP5
28	Netherlands	College voor zorgverzekeringen, CVZ	WP1, WP2, WP5 (LP), WP7, WP8
29	Norway	Norwegian Knowledge Centre for the Health Services, NOKC	WP1, WP2 (LP), WP5, WP7
30	Poland	Agency for HTA in Poland, AHTAPol	WP5, WP7
31	Portugal	National Authority of Medicines and Health Products, INFARMED	WP4, WP5, WP7
32	Romania	National School of Public Health, Management and Professional Development, NSPH MPD	WP2, WP4, WP8
33	Slovakia	Nadacia Zrak, SLOVAHTA (Foundation)	WP5
34	Slovenia	National Institute of public health, NIPH	WP2, WP4, WP5
35	Slovenia	Institute of Economic Research, IER	WP4, WP7
36	Spain	Instituto de Salud Carlos III, ISCIII	WP2, WP4, WP5, WP7
37	Sweden	Swedish Council on Health Technology Assessment, SBU	WP4, WP7, WP8
38	United Kingdom	National Institute for Health and Clinical Excellence, NICE	WP7
39	United Kingdom	NIHR Health Technology Assessment Programme, NETSCC	WP3, WP7

Collaborating partners

#	Country	Organisation	Work Package
1	Austria	University for Health Sciences, Medical Informatics and Technology, UMIT	WP2, WP7, WP8
2	Austria	Donau Universität Krems	WP5
3	Belgium	Rijksinstituut voor Ziekteen Invaliditeitsverzekering, RIZIV	WP5
4	Bulgaria	Medical University of Sofia, MU Sofia	WP2, WP4, WP5
5	Denmark	Danish Institute for Local and Regional Government Research, KORA	WP5, WP7
6	Germany	National Cluster of Excellence, Health Technologies - Medical Valley EMN, University of Erlangen-Nuremberg, Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health, Medical Valley EMN	WP5B, WP7
7	Germany	Gemeinsamer Bundesausschuss, GBA	WP5, WP7
8	Italy	Centre for Economic and International Studies. University of Roma Tor Vergata), CEIS	WP3, WP4
9	Italy	Laziosanità – Agenzia di Sanità Pubblica, Regione Lazio	WP4, WP5
10	Italy	University Hospital 'A. Gemelli'	WP4, WP5, WP8
11	Italy	Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency), ARESS	WP5
12	Russia	National Center for Health Technology Assessment, NC HTA	WP5, WP8
13	Scotland	Healthcare Improvement Scotland, HIS	WP5, WP7
14	Spain	AVALIA-t, Galician Agency for HTA Assessment	WP2, WP4, WP7
15	Spain	The Andalusian Agency for Health Technology Assessment, AETSA	WP4, WP5, WP7
16	Spain	Spanish Ministry of Health, Social Services and Equality, MSSSI	WP2
17	Spain	Directorate General for Pharmacy and Health Care Products (Spanish Ministry of Health, Social Policy and Equality), DGFPS MSPSI	WP5
18	Spain	Basque Office for HTA, Osteba	WP2, WP4, WP5, WP7
19	Spain	Catalan Agency for Health Information, Assessment and Quality, CAHIAQ	WP5
20	Spain	Health Technology Assessments Unit. Subdirección General de Tecnología e Innovación Sanitarias. Consejería de Sanidad, UETS	WP6
21	Sweden	Dental and Pharmaceutical Benefits Agency ,TLV	WP7
22	Switzerland	Swiss Federal Office for Public Health, SNHTA	WP2, WP3, WP4, WP5, WP7
23	Turkey	Turkish Evidence Based Medicine Association, KDTD	WP2, WP3, WP4, WP5

Abbreviated terminology used in EUnetHTA JA2

ADC	Additional Data Collection
AEG	Additional evidence generation
EAHC	Executive Agency for Health and Consumers
AP	Associated Partner (terminology used in the EUnetHTA Grant Agreement (2011 23 01 EUnetHTA JA2) with the Executive Agency for Health and Consumer
CBHC Directive	Cross Boarder Health Care Directive
CMHP	Committee for Medicinal Products for Human Use
ColMod	Collaborative Model
Co-LP	Co-Lead Partner
CoP	Community of Practice
CP	Collaborating Partner (terminology used in the EUnetHTA Grant Agreement (2011 23 01 EUnetHTA JA2) with the Executive Agency for Health and Consumer
CUR	Current use of the technology
DB	Database
DG SANCO	Directorate General Health and Consumers Protection of the European Commission
ECO	Costs, economic evaluation of the technology
ED	Early Dialogue
EMA (formerly EMEA)	European Medicines Agency
ENCePP	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance
EPAR	European Public Assessment Report
ETH	Ethical aspects of the technology
EUnetHTA / EUnetHTA Collaboration	European network for Health Technology Assessment
EUnetHTA JA	European network for Health Technology Assessment Joint Action
EVIDENT	The Evidence database on new technologies
F-t-F meeting	Face to Face meeting
FP	Founding Partner
HTA	Health Technology Assessment
HTAi	Health Technology Assessment International
IMIS	Information Management Infrastructure and Services
IMS / EUnetHTA IMS	EUnetHTA Information Management System

JA	Joint Action
LEG	Legal aspects of the technology
LP	Lead Partner
MAH	Market Authorisation Holder
MSP	Methodological Standards and Procedures
M1-M36	Month 1 – Month 35 (M1= October 2012)
ORG	Organizational aspects of the technology
PI	Primary Investigator
POP	Planned and On-going Projects
R	Reviewer
REA	Relative Effectiveness Assessment
RE	Relative Effectiveness
RSS	Rich Site Summary
SAF	Safety of the technology
SAG	Stakeholder Advisory Group
SF / EUnetHTA SF	EUnetHTA Stakeholder Forum
SG	Sub Group
SOP	Standard Operating Procedures
STK	Stakeholder
WG	Working Group
TEC	Description and technical characteristics of technology
TOR	Terms of Reference
WP	Work Package (terminology used in the EUnetHTA Grant Agreement (2011 23 01 EUnetHTA JA2) with the Executive Agency for Health and Consumer

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 2 on HTA 2012-2015

Work Package 1

Coordination and sustainable network implementation

3-year Work Plan

Sundhedsstyrelsen

Danish Health and Medicines Authority

May 1, 2013

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1. WP title

Work Package 1 - Coordination and sustainable network implementation.

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
• Lead Partner: Danish Health and Medicines Authority (DHMA), Denmark	• DHMA will be the primary responsible organisation for the general coordination of the Joint Action 2 (according to the 2011 23 01 EUnetHTA JA2 Grant Agreement). • Hosting and managing the EUnetHTA Secretariat. • Member of EUnetHTA Executive Committee. • Preparation of the WP1 interim and final technical reports. • Preparation of the EUnetHTA JA2 interim and final technical and financial reports. • Will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
• Co-Lead Partner: N/A	N/A
Associated partners – AP (10)	
1. KCE (Belgium) 2. DIMDI (Germany) 3. THL (Finland) 4. HAS (France) 5. AGENAS (Italy) 6. CVZ (Netherlands) 7. LBI-HTA (Austria) 8. HVB (Austria) 9. NOKC (Norway) 10. IQWIG (Germany)	• APs will participate in the tasks of WP1. Provide regular progress updates from their respective WPs. • Attend Face-to-Face and e-meetings. • Contribute to the preparation of the interim and final technical reports. • Contribute to the preparation and update of the EUnetHTA JA2 3-year work plan and SOP manual. • Actively implement the EUnetHTA JA2 3-year work plan. • Follow the AP's responsibilities as described in the EUnetHTA JA 2 SOP, EUnetHTA JA2 Consortium Agreement, and 2011 23 01 EUnetHTA JA2 Grant Agreement.
Collaborating partners – CP	
N/A	N/A
Other Parties	
All EUnetHTA partners	• EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA 2 SOP, EUnetHTA JA2 Consortium Agreement, and 2011 23 01 EUnetHTA JA2 Grant Agreement.

	• Participate in the common EUnetHTA activities as agreed per the specific activity content and schedule preparation requirements.
EUnetHTA Stakeholder Forum members	• EUnetHTA Stakeholder Forum members will give feedback and comments on the EUnetHTA JA2 3-year work plan.

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: www.eunethta.eu

3. Objectives

Title	Description	Indicators
Produce recommendations on the design and running of the EU HTA cooperation process based on analysis of various coordination capacities for the permanent Secretariat function and further testing of involvement of stakeholders in network activities	Analysis of new data on the JA2 collaboration across WPs and cooperation with various relevant European and national bodies. Development of recommendations based on further testing and development of stakeholder involvement in the HTA collaboration (following process and structure of JA1).	Recommendation on design of the permanent EU HTA cooperation produced and approved by the JA PA
Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders	Dissemination and communication of the knowledge and results of the JA2 to various internal and external target groups including the provision of training in EUnetHTA tools and methodologies to JA2 partners and stakeholders	Attendance at the EUnetHTA conference is 80% of its targeted capacity
		At least 80% of the national Medicines Agencies and reimbursement authorities in the EU are aware of EUnetHTA JA2 and its objectives

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
SOP and 3-year JA Work Plan approved by the Plenary Assembly (1st PA meeting, place – Zagreb, Croatia).	M6 Mar '13
Coordination meeting with the four FP7-sponsored projects on HTA (Advance_HTA, Integrate-HHTA, AdHopHTA and MedTecHTA) .[1]	M8 May '13
Draft considerations for implementation of the sustainable European network for HTA circulated to Plenary Assembly.	M17 Feb '14
EUnetHTA Symposium (up-to-date results and discussions on European network implementation).	M25 Oct '14
Recommendations delivered	M33 Jun '15

[1] The initial milestone 'Executive Committee exploratory meeting with relevant parties (stakeholder representatives, EU-bodies etc.) regarding implementation of Article 15 of the directive 2011/24/EU' has been replaced with the current one as the four FP7 Projects on HTA are more relevant and appropriate for the work of WP1/EUnetHTA JA2 at the current stage.

Deliverables	Deadline
Final report from the JA.	M38(42) Mar '16
Recommendations[2] on the implementation of a sustainable European network for HTA.	M33 Jun '15

4.2 Methods

Various methods to support the work of WP1 will be used in relation to the 5 strands of activities:

Project management
Daily assistance and guidance by the EUnetHTA Secretariat via internet-based coordination, phone and email correspondence.

Use of intranet and WP work rooms to share relevant and important information and documents.

Use of project management tool / Gantt chart on the intranet for all WPs.

E-meetings and face-to-face meetings.

Site visits targeting specific work packages when needed.

Communication
Internet-based communication on public site and intranet in order to share news feeds and Newsletters.

Use of social media (LinkedIn and Twitter) to keep EUnetHTA members and interested followers updated on the work of WP1 and EUnetHTA in general.

Organising a EUnetHTA Conference, to share up-to-date results and discussions on European network implementation and HTA.

Identification of and participation in the relevant scientific conferences on a yearly basis (at least 1 conference per year) to present work in progress and results.

Identification of and provision of information for publication in one of the relevant printed media channel.

Stakeholder involvement
Public consultations on JA2 deliverables. The consultations will be announced in the news section on the website.

Stakeholder Forum. The EUnetHTA Secretariat will facilitate interaction between the SF and the Exec Comm as well as wider EUnetHTA partnership.

SAG management. The EUnetHTA Secretariat will assist the WP LP/Co-LP with managing contact information and confidentiality undertakings.

Expert meetings. The EUnetHTA Secretariat will assist clarifying which WPs will hold the expert meetings with stakeholder participation and assist with meeting content and organization management,

Stakeholder participation in the EUnetHTA JA2 Conference and in the planning of the conference.

External collaborations
Biannual meetings with relevant parties and ongoing collaboration and strategic information sharing.

Recommendations

Based on results from WP activities, the draft Recommendations on the implementation of a sustainable European network for HTA will be circulated among and discussed in the Executive Committee, Plenary Assembly and in the Stakeholder Forum.

Wherever and whenever relevant and as appropriate, provide input to the ongoing process of implementing Article 15 of the CBHC Directive

[2] Referred to as "The Recommendations" further in the text

4.3 Meetings
Meetings 2012/13

Date	Location	Duration (nights)	Participants	Purpose
3-4 Oct '12	Diemen	2 days (1 night)	WP1 partners and Executive Committee members	Discussion of the format and content of the JA2 3-year work plan Regular coordination issues
28 Nov '12	E-meeting		WP1 partners and Executive Committee members	Regular coordination issues (SH applications, 3-year work plan, WP updates)
23-24 Jan '13	Copenhagen	2 days (1 night)	WP1 partners and Executive Committee members	Coordination of the content of the final drafts of 3-year work plans Regular coordination issues
5 Feb '13	Brussels	1 day	**Stakeholder Forum (SF)** and Executive Committee members	Presentation of the JA2 3-year work plan and solicitation of input from the SF
20 Feb '13	E-meeting		WP1 partners and Executive Committee members	Preparation for the Plenary Assembly meeting. Regular coordination issues
21-22 Mar ´13	Zagreb	2 days (2 nights)	Plenary Assembly Meeting	JA2 3-year work plan and SOP endorsement, scientific coordination and networking
9 Apr ´13	E-meeting		**SF** and Executive Committee members	Regular coordination issues and as per proposed agenda
24 Apr '13	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
May '13	London	1 day	EMA-EUnetHTA	To be specified
29 May '13	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
4 Jun '13	E-meeting		**SF** and Executive Committee members	To be specified
26 Jun '13	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
4 Sep '13	E-meeting		WP1 partners and Executive Committee members	Preparation for F-t-F meeting in Dublin, Considerations of the EUnetHTA Conference Programme (topics, potential speakers); Regular coordination issues
17 Sep '13	E-meeting		**SF** and Executive Committee members	Themes/speakers for the EUnetHTA Conference
25-26 Sep '13	Dublin	2 days (1 night)	WP1 partners and Executive Committee members	Preparation for the 1st interim report to EAHC; Draft Conference Programme Regular coordination issues
Meeting dates can be subject for change, so please see current information on www.eunethta.eu				

Meetings 2013/14

Date	Location	Duration (nights)	Participants	Purpose
27 Nov '13	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Nov '13	to be determined	1 day	EMA-EUnetHTA	To be specified
11-12 Dec '13	Paris	2 days (1 night)	WP1 partners, Executive Committee members	Preliminary considerations for implementation of the sustainable European Network for HTA. Endorsing next-to-final programme of the EUnetHTA Conference, Speakers list
Jan '14	Brussels	2 days (1 night)	**SF** and Executive Committee members *To be coordinated with WP2 training course to be held in connection to this meeting!*	Recommendations for implementation of the sustainable European Network for HTA; final input into the EUnetHTA Conference Programme
Feb '14	E-meeting		WP1 partners and Executive Committee members	Final version of the EUnetHTA Conference agreed, other issues to be specified Regular coordination issues
Mar '14	E-meeting		**SF** and Executive Committee members	To be specified
Apr '14	E-meeting		WP1 partners and Executive Committee members	Preparations for the Plenary Assembly Meeting Regular coordination issues
10-11 Apr '14	Madrid	2 days (2 nights)	Plenary Assembly Meeting	EUnetHTA elections, promotion of the EUnetHTA Conference; JA2 work in progress discussions, etc
Apr '14	To be determined	1 day	EMA-EUnetHTA	To be specified
Jun '14	E-meeting		**SF** and Executive Committee members	To be specified
Jun '14	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Sep '14	E-meeting		**SF** and Executive Committee members	To be specified
Sep '14	E-meeting		WP1 partners and Executive Committee members	Preparations for F-t-F in Copenhagen Regular coordination issues
Sep '14	Copenhagen	2 days (1 night)	WP1 partners and Executive Committee members	Preparation for the 2nd interim report to EAHC; final preparation and coordination before the EUnetHTA Conference in Rome
Meeting dates can be subject for change, so please see current information on www.eunethta.eu				

Meetings 2014/15

Date	Location	Duration (nights)	Participants	Purpose
Oct '14	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Oct '14	Rome	2 days (1 night)	EUnetHTA members, SF, Commission, invited guests (to be specified), scientific community, policy makers, etc	EUnetHTA Conference (conference's theme to be identified)
Oct '14	E-meeting		**SF** and Executive Committee members	To be specified
Nov '14	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Nov '14	To be determined	1 day	EMA-EUnetHTA	To be specified
Jan '15	Vienna	2 days (1 night)	WP1 partners, Executive Committee members	To be specified
Feb '15	(Brussels)	2 days (1 night)	**SF** and Executive Committee members	To be specified
Feb '15	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Apr '15	E-meeting		WP1 partners and Executive Committee members	To be specified Regular coordination issues
Apr '15	E-meeting		**SF** and Executive Committee members	To be specified
Apr '15	To be determined	1 day	EMA-EUnetHTA	To be specified
May '15	E-meeting		WP1 partners, Executive Committee members	Preparations for the Plenary Assembly Meeting. Regular coordination issues
May '15	Copenhagen	2 days (2 nights)	Plenary Assembly Meeting	Plenary Assembly To be specified
Jun '15	E-meeting		**SF** and Executive Committee members	To be specified
Sep '15	E-meeting		WP1 partners and Executive Committee members	Preparation for final report to EAHC Regular coordination issues
Sep '15	Helsinki	2 days (1 night)	WP1 partners and Executive Committee members	Preparation for final report to EAHC Regular coordination issues
Sep '15	E-meeting		**SF** and Executive Committee members	To be specified
Meeting dates can be subject for change, so please see current information on www.eunethta.eu				

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Activity: Project management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M3 Dec '12	**M6 Mar '13**	**EUnetHTA JA2 3 year work plan**	All EUnetHTA partners	WP1 partners, EUnetHTA Secretariat, all EUnetHTA partners
M3 Dec '12	M5 Feb '13	First draft development by LP/Co-LPs		
M5 Feb '13		Second draft development – including presentation to and comments from stakeholders		
M6 Mar '13		Final JA2 3 year work plan (including Gantt Chart) approved and endorsed by the Plenary Assembly		
M4 Jan '13	**M6 Mar '13**	**EUnetHTA JA2 SOP**	All EUnetHTA partners	WP1 partners, EUnetHTA Secretariat, all EUnetHTA partners
M4 Jan '12		EUnetHTA Secretariat send draft SOP to LP/Co-LPs for comments. Draft discussed at WP1 Face-to-Face meeting in Copenhagen		
M5 Feb '13		LP/Co-LP to send final comments to EUnetHTA Secretariat		
M8 May '13		Final SOP approved and endorsed by the Plenary Assembly		
M3 Dec '12	**M6 Mar '13**	**EUnetHTA JA2 Consortium Agreement and Conflict of interest declaration**	All EUnetHTA partners	WP1 partners, EUnetHTA Secretariat, all EUnetHTA partners
M3 Dec '12	M5 Feb'13	Draft development by EUnetHTA Secretariat		
M 6 Mar '12		Draft shared for comments and approval by the Plenary Assembly		
M3 Dec'12	**M13 Oct'13**	**Management of EAHC reporting – preparation of 1st interim report**	All EUnetHTA partners JA2 APs EAHC	WP1 partners JA2 APs EUnetHTA Secretariat
M3 Dec '12		EUnetHTA Secretariat distributes the 30% pre-financing of the EU-grant		
M1 Dec '12	M9 Jun '13	EUnetHTA Secretariat clarifies specific requirements of the format for the report		
M9 Jun '13		Format of the report available to the LPs (Technical report) and the APs (Financial report)		
M10 Jul '13	M12 Sep '13	Preparing the content of the interim report		
M 13 Oct '13		Delivery of the final report to the EUnetHTA Secretariat (deadline 15 October 2013)		
M1 Oct '12	**M12 Sep '13**	**Site visits with LPs and assistance to WP activities** (to be defined)	LP/Co-LPs	EUnetHTA Secretariat, LPs/Co-LPs
M3 Dec '12	**M7 Apr '13**	**Preparation of the 1st Plenary Assembly meeting**	All EUnetHTA partners	WP1 partners AZZ
M3 Dec '12		EUnetHTA Secretariat (in cooperation with AAZ) logistics of the meeting – venue, catering, social programme, transportation, registration for the meeting etc.		

M3 Dec '12	M5 Feb'13	Agenda and material preparation	All EUnetHTA partners	Executive Committee EUnetHTA Secretariat
M4 Jan '13		Launching of the nomination process (3 electable members of the Exec Comm)		
M 6 Mar '13		Final agenda and material distributed to the partners (2 weeks in advance)		
21/22 Mar '13		1st Plenary Assembly meeting in Zagreb		
M7 Apr '13		Report from the meeting		
M9 Jun '13		**A survey to review availability of formal conflict of interest policies and policies for handling confidentiality issues at the individual EUnetHTA Partner and Associate organisation**	WP1 partners	EUnetHTA Secretariat WP1 partners WP3
M9 Jun '13		Development of survey and sharing with EUnetHTA partners - in coordination with WP3 general surveys, if possible		
M7 Apr '13		**Coordinate overview of WP Surveys to WP3** Development of overview of JA2 WP surveys	EUnetHTA partners External Parties	WP1 WP3

Activity: Communications				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	**M12 Sep '13**	**Coordination and update on WP activities for public website and intranet**	All EUnetHTA partners	EUnetHTA Secretariat WP6
M1 Oct '12	**M12 Sep '13**	**Publishing Internal and external newsletters and newsfeeds online**	All EUnetHTA partners and external parties	EUnetHTA Secretariat WP1 partners
M7 Apr '13 M10 Jul '13		Regular news updates to EUnetHTA partners (EUnetHTA LinK) and external audience (EUnetHTA Newsletter) on the progress and results of the EUnetHTA JA2		
M1 Oct '12	**M12 Sep '13**	**Development and update of content for use in social media (LinkedIn & Twitter), printed materials and in other public presentations**	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M5 Feb '13	**M7 Apr '13**	**Review and update of the EUnetHTA Communication Strategy**	All EUnetHTA partners	EUnetHTA Secretariat WP2
M5 Feb '13		Review of current strategy and draft development		
M7 Apr '13		Share draft with WP1 and WP2 for comments		
M8 May '13		Final draft shared with Exec committee for approval		

M4 Jan '13	**M12 Sep '13**	**Identification of relevant Scientific Conferences for EUnetHTA to be present in (HTAi, ISPOR, DIA, Forum Gastein and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M4 Jan '13	**M12 Sep '13**	**Identification of relevant scientific journals (printed/online) where EUnetHTA information should be disseminated (European Voice and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M5 Feb '13	**M12 Sep '13**	**Preparation for EUnetHTA Conference in Rome Oct 2014**	All EUnetHTA partners European HTA community	EUnetHTA Secretariat Agenas WP1 partners Stakeholder Forum
M5 Feb '13	M 9 June '13	EUnetHTA Secretariat (in cooperation with AGENAS) identifies Conference Bureau and sign contract. Date and venue for conference agreed.		
M5 Feb '13	M12 Sep '13	Planning promotion of the Conference		
M9 Jun '13		Announcing the date, place and theme of the conference		
M9 Jun '13	M12 Sep '13	Development and agreement of the Conference programme (continues until M15 Dec'13)		
M9 Jun '13	M12 Sep '13	Development of Conference brochure (continues until M15 Dec'13)		
M9 Jun '13	M12 Sep '13	Clarifying (with conference bureau) logistics around the conference i.e. registration, accommodation, speakers management, invited guests management, transportation, social programme, branding etc. (continues until M15 Dec'13)		

Activity: Stakeholder involvement				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M5 Feb13		**JA2 3 Year work plan presented orally for SH comments at Face-to-Face meeting in Brussels**	JA2 Stakeholder Forum	EUnetHTA Secretariat WP1 partners
M1 Oct '12	**M12 Sep '13**	**SAG management**. The EUnetHTA Secretariat will assist the WP LP/Co-LP with managing contact information and confidentiality undertakings.	JA2 Stakeholder Forum	EUnetHTA Secretariat WP1 partners
M1 Oct '12	**M12 Sep '13**	**Clarification of expert involvement in JA2 activities** EUnetHTA Secretariat to coordinate which WP will plan and hold the Expert meetings (at least 2 per Year).	Stakeholder Forum	EUnetHTA Secretariat WP1, 4,5,7 (8) Stakeholder Forum

Activity: External collaborations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	**M12 Sep '13**	**Collaboration with EMA, EUCERD, HTAi, IMI, GP collaborative, PARENT, EUPATI, FP7 Projects** (To be specified further) Follow-up individually via the assigned EUnetHTA responsible contact. Regular updates at the Exec Comm meetings.	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP1 partners
M2 Nov '12 M7 May '13		Biannual meetings with EMA	All EUnetHTA partners External Parties	EUnetHTA Secretariat EMA WP5 WP7
M5 Feb '13	**M8 May '13**	**Coordination meeting with the four FP7-sponsored projects on HTA (Advance_HTA, Integrate-HAT, AdHopHTA and Med TecHTA)**	EUnetHTA partners DG SANCO DG Research	EUnetHTA Secretariat WP1 partners LBI-HTA
M5 Feb '13	M7 Apr '13	EUnetHTA Secretariat (in cooperation with LBI-HTA, DG SANCO and DG research) logistics of the meeting – venue, catering, transportation, registration for the meeting etc.		
M7 Apr '13		Agenda and material preparation		
M8 May '13		Coordination meeting with the four FP7-sponsored projects on HTA		
M9 Jun '13		Report from meeting		

Activity: Recommendations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan '13	**M9 Jun '13**	**Follow up the developments in the HTA Expert Group of the Directive Committee, etc**	Exec Comm Plenary Assembly	EUnetHTA Secretariat, Exec Comm

Year 2 (Oct 2013-Sep 2014)

Activity: Project management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	**M24 Sep '14**	**EUnetHTA JA2 3 year work plan and SOP – On-going follow up**	All EUnetHTA partners	WP1 partners, EUnetHTA Secretariat
M14 Nov'13	**M25 Oct' 14**	**Management of EAHC reporting – preparation of 2nd interim report**	All EUnetHTA partners JA2 APs EAHC All	WP1 partners JA2 APs EUnetHTA Secretariat WP1
M14 Nov '13		EUnetHTA Secretariat delivers 1st interim report to EAHC, request for next pre-financing instalment (depending on expenditure in 2012)		
M15 Dec '13	M16 Jan '14	EUnetHTA Secretariat clarifies if necessary the details of the 1st interim report with EAHC		

M17 Feb '14	M18 Mar '14	If next pre-financing approved by and received from the EACH – distribution of the grant (20%) to the APs	EUnetHTA partners JA2 APs EAHC	partners JA2 APs EUnetHTA Secretariat
M22 Jul '14	M24 Sep '14	Preparing the content of the 2nd interim report		
M25 Oct '14		Delivery of the final report to EUnetHTA Secretariat (deadline 15 October 2014)		
M13 Oct '13	**M24 Sep '14**	**Site visits with LPs and assistance to WP activities** (to be defined)	LP/Co-LPs	EUnetHTA Secretariat, LPs
M13 Oct '13	**M20 May '13**	**Preparation of the 2nd Plenary Assembly meeting**	All EUnetHTA partners	WP1 partners ISCII Executive Committee
M14 Nov'13	M15 Dec '13	EUnetHTA Secretariat (in cooperation with ISCIII) logistics of the meeting – venue, catering, social programme, transportation, registration for the meeting etc.		
M16 Oct '13	M18 Dec '13	Agenda and material preparation		
M16 Jan '14		Launching of the nomination process (3 electable members of the Exec Comm and Chair/Deputy Chair of the Plenary Assembly)		
M18 Mar '14		Final agenda and material distributed to the partners (2 weeks in advance)		
10-11 Apr '14		2nd Plenary Assembly meeting in Madrid		
M20 May 13		Report from the meeting		
M19 Apr '13		**Coordinate overview of WP Surveys to WP3** Development of overview of JA2 WP surveys	EUnetHTA partners External Parties	WP1 WP3

Activity: Communications				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	**M24 Sep '14**	**Coordination and update on WP activities for public website and intranet**	All EUnetHTA partners	EUnetHTA Secretariat WP6
M13 Oct '13	**M24 Sep '14**	**Publishing Internal and external newsletters and newsfeeds online**	All EUnetHTA partners	EUnetHTA Secretariat WP1 partners
M13 Oct '13 M16 Jan '14 M19 Apr '14 M22 Jul '14		Regular news updates to EUnetHTA partners (EUnetHTA LinK) and external audience (EUnetHTA Newsletter) on the progress and results of the EUnetHTA JA2		
M13 Oct '13	**M24 Sep '14**	**Development and update of content for use in social media (LinkedIn & Twitter), printed materials and in other public presentations**	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners

M13 Oct '13	**M24 Sep '14**	**Identification of relevant Scientific Conferences for EUnetHTA to be present in (HTAi, ISPOR, DIA, Forum Gastein and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M13 Oct '13	**M24 Sep '14**	**Identification of relevant scientific journals (printed/online) where EUnetHTA information should be disseminated (European Voice and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M13 Oct '13	**M24 Sep '14**	**Preparation for EUnetHTA Conference in Rome Oct 2014**	All EUnetHTA partners European HTA community	EUnetHTA Secretariat Agenas WP1 partners Stakeholder Forum
M13 Oct '13	M15 Dec '13	Continuing development and agreement of the Conference programme		
M13 Oct '13	M15 Dec '13	Continuing development of Conference brochure		
M13 Oct '13	M24 Sep '14	Continuing clarifying (with conference bureau) logistics around the conference i.e. registration, accommodation, speakers management, invited guests management, transportation, social programme, branding etc.		
M16 Jan '14	M18 Mar '14	Development and launch of the Conference Website		
M18 Mar '14		Registration open		
		Further organisational details and timing to be specified when the Conference Bureau is identified (and contract is signed) and date for the conference is set up.		

Activity: Stakeholder involvement				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	**M24 Sep '14**	**SAG management**. The EUnetHTA Secretariat will assist the WP LP/Co-LP with managing contact information and confidentiality undertakings.	JA2 stakeholder forum	EUnetHTA Secretariat WP1 partners
M13 Oct '13	**M24 Sep '14**	**Clarification of expert involvement in JA2 activities** EUnetHTA Secretariat to coordinate which WP will plan and hold the Expert meetings.	Stakeholder Forum Research community	EUnetHTA Secretariat WP1, 4,5,7 (8) Stakeholder Forum

Activity: External collaborations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	**M24 Sep '14**	**Collaboration with EMA, EUCERD, HTAi, IMI, GP collaborative, PARENT, EUPATI, FP7 Project**	All EUnetHTA	EUnetHTA Secretariat

		(To be specified further) Follow-up individually via the assigned EUnetHTA responsible contact Regular updates at the Exec Comm meetings.	partners External Parties	WP1 partners
M14 Nov '13 M19 Apr '14		Biannual meeting with EMA	All EUnetHTA partners External Parties	EUnetHTA Secretariat EMA WP5 WP7

Activity: Recommendations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13	**M18 Mar '14**	**Draft considerations for implementation of the sustainable European Network for HTA circulated to PA**	All EUnetHTA partners EAHC	EUnetHTA Secretariat WP3 WP1 partners
M13 Oct '13		Implementing Act is published		
M13	M15	Review of the Act and identification of sections for recommendations (align with the format and development procedures of the Rule of Procedure as per DG SANCO)		
M15		Paris meeting of Exec Comm – discussion of the Recommendations		
M18 Mar '14		Sharing the 1st draft with the PA (as background document for the PA meeting in Madrid)		
M19 Apr '14		Discussion of the draft by the PA		
M19 Apr '14	M25 Oct '14	Developing the 1st public draft of the Recommendations		

Year 3 (Oct 2014-Sep 2015)

Activity: Project management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	**M36 Sep '15**	**EUnetHTA JA2 3 year work plan and JA2 SOP – on-going follow up**	WP1 LP/CoLP	EUnetHTA Secretariat
M26 Nov'14	**M38 Nov '15**	**Management of EACH reporting – preparation of final report**	All EUnetHTA partners JA2 APs EAHC	WP1 partners JA2 APs EUnetHTA Secretariat
M26 Nov '14		EUnetHTA Secretariat delivers 2nd interim report to EAHC, request for next pre-financing instalment (depending on expenditure in 2014)		
M26 Nov '14	M28 Jan '15	Adjustment of the global budget: APs send the request on movement of funds between the cost categories		
M28 Jan '15	M31 Apr '15	Secretariat adjusts the global budget and submits to EAHC		
M32 May'15	M34 Jul '15	EAHC reviews new budget for approval		
M27 Dec '15	M28 Jan '15	EUnetHTA Secretariat clarifies if necessary the details of the 2nd interim report with the EAHC		
M29 Feb '15	M30 Mar '15	If the next pre-financing approved by and received from EAHC – distribution of grant (20%) to APs		

M34 Jul '15	M36 Sep '15	Preparing the content of the final report	All EUnetHTA partners JA2 APs EAHC	WP1 partners JA2 APs EUnetHTA Secretariat
M 37 Oct '15		Delivery of the final report to EUnetHTA Secretariat (deadline 15 October)		
M38 Nov		EUnetHTA Secretariat deliver the final report to EAHC (deadline 1 December)		
M25 Oct '14	**M36 Sep '15**	**Site visits with LPs and assistance to WP activities** (to be specified)	WP1 LP/CoLP	EUnetHTA Secretariat WP1 partners
M25 Oct '14	**M31 Apr '15**	**Preparation of the 3rd Plenary Assembly meeting**	All EUnetHTA partners	WP1 partners Executive Committee
M25 Oct '14	M26 Nov'14	EUnetHTA Secretariat: logistics of the meeting – venue, catering, social programme, transportation, registration for the meeting etc.		
M26 Nov'14	M27 Dec'14	Agenda and material preparation		
M29 Feb '15		Final agenda and material distributed to the partners (2 weeks in advance)		
M30 Mar '15		2nd Plenary Assembly meeting in Madrid		
M31 Apr '15		Report from the meeting		
M31 Apr '15		**Coordinate overview of WP Surveys to WP3** Development of overview of JA2 WP surveys	EUnetHTA partners External Parties	WP1 WP3

Activity: Communications				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	**M36 Sep '15**	**Coordination and update on WP activities for public website and intranet**	All EUnetHTA partners	EUnetHTA Secretariat WP6
M25 Oct '14	**M36 Sep '15**	**Publishing Internal and external newsletters and newsfeeds online**	All EUnetHTA partners	EUnetHTA Secretariat WP1 partners
M25 Oct '14 M28 Jan '15 M31 Apr '15 M34 Jul '15 M36 Sep '15		Regular news updates to EUnetHTA partners (EUnetHTA LinK) and external audience (EUnetHTA Newsletter) on the progress and results of the EUnetHTA JA2		
M25 Oct'14		**Final preparations for EUnetHTA Conference in Rome**	All EUnetHTA partners European HTA community	EUnetHTA Secretariat WP1 partners Stakeholder Forum
M25 Oct'14		EUnetHTA Conference in Rome		

M25 Oct '14	**M36 Sep '15**	**Development and update of content for use in social media (LinkedIn & Twitter), printed materials and in other public presentations**	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M25 Oct '14	**M36 Sep '15**	**Identification of relevant Scientific Conferences for EUnetHTA to be present in (HTAi, ISPOR, DIA, Forum Gastein and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners
M25 Oct '13	**M36 Sep '15**	**Identification of relevant scientific journals (printed/online) where EUnetHTA information should be disseminated (European Voice and others)** (To be specified further)	All EUnetHTA partners External Parties	EUnetHTA Secretariat WP2 WP1 partners

Activity: Stakeholder involvement				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	**M36 Sep '15**	**SAG management**. The EUnetHTA Secretariat will assist the WP LP/Co-LP with managing contact information and confidentiality undertakings.	JA2 Stakeholder Forum	EUnetHTA Secretariat WP1 partners
M25 Oct '14	**M36 Sep '15**	**Clarification of expert involvement in JA2 activities** EUnetHTA Secretariat to coordinate which WP will plan and hold the Expert meetings. (To be specified)	JA2 Stakeholder Forum	EUnetHTA Secretariat WP1, 4,5,7 (8) Stakeholder Forum

Activity: External collaborations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	**M36 Sep '15**	**Collaboration with EMA, EUCERD, HTAi, IMI, GP collaborative, PARENT, EUPATI, FP7 Project** (To be specified further) Follow-up individually via the assigned EUnetHTA responsible contact Regular updates at the Exec Comm meetings.	All EUnetHTA partners External Parties	EUnetHTA Secretariat EMA WP5 WP7
M26 Nov '14 M31 Apr '15		Biannual meeting with EMA (to be specified)		

Activity: Recommendations				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	**M33 Jun '15**	**Recommendations for implementation of the sustainable European Network for HTA delivered to EAHC**	All EUnetHTA partners EAHC	EUnetHTA Secretariat WP3
M25 Oct '14		Finalizing developing the 1st public draft of the Recommendations		
M26 Nov '14		Approval of the 1st public draft by the PA		
M28 Jan '15		**Stakeholder Forum Consultation on recommendations for implementation of the sustainable European Network for HTA**	Stakeholder Forum	EUnetHTA Secretariat WP1 partners Plenary Assembly
M29 Feb '15		Comments from Stakeholder Consultation collected and processed		
M30 Mar'15		**Public Consultation[3] on recommendations for implementation of the sustainable European Network for HTA**	Stakeholder Forum EUnetHTA followers	EUnetHTA Secretariat WP1 partners Plenary Assembly
M30 Mar'15		Comments from Public Consultation collected and processed		
M31 Apr '15		Comments from Stakeholder and Public Consultation shared as background document for Plenary Assembly		
M32 May'15		Comments from Stakeholder and Public Consultation discussed and agreed upon at the Plenary Assembly in Copenhagen		
M33 Jun'15		**Recommendations delivered to the Commission**	EAHC	EUnetHTA Secretariat WP1 partners
M32 May'15	M33 Jun '15	Finalization of Recommendations		
M33 Jun '15		Recommendations delivered to the Commission		

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery** (i.e. online or e-mail)	**Coordination with other WPs** (Yes/No – if yes which WP)
M9 Jun '13	A survey to review availability of formal conflict of interest policies and policies for handling confidentiality issues at the individual EUnetHTA Partner and Associate organisation	EUnetHTA Partners	e-mail	WP3

[3] To be further considered if necessary for implementation

4.4.1 Stakeholder involvement

Stakeholders will be involved in the work of WP1 in 5 different ways:

JA2 3 year work plan
The 2nd draft of the JA2 3 year work plan will be presented at the stakeholder forum Face-to-Face meeting in Brussels February 5, 2013 and stakeholders will be invited to comment on the work plan.

Stakeholder Forum.
Stakeholder Forum will provide stakeholders with the opportunity for participate as representatives in the EUnetHTA JA2, observe and comment on the EUnetHTA JA2 work, provide advice to overarching governance questions and to bring forward themes and concerns considered relevant and in line with the aims of EUnetHTA Joint Action.

Three stakeholder E-meetings and 1 stakeholder Face-to-Face meeting will be held each year.

Stakeholder advisory Group (SAG).
The Stakeholder Forum participants will appoint relevant representatives with specific expertise into the SAGs. The SAGs will be consulted and be able to provide advice in relation to e.g. the pilots in JA2. Each person participating in the SAGs will have a clear mandate from the Forum participant, and the mandate will be agreed between the Forum participant and the Secretariat and communicated to the relevant WPs LP and Co-LP.

EUnetHTA Conference.
Stakeholders will be involved as participants in the EUnetHTA Conference in Rome in October 2014 and will also be part of planning the program and suggesting and providing speakers.

Expert meetings
The EUnetHTA Secretariat will assist clarifying which WPs will host the expert meetings. There will be one meeting per year where relevant methodologies and challenges in relation to e.g., REA and HTA Core Model will be discussed. Stakeholders will participate in the meetings, be consulted and provide advice and expertise where relevant.

Finally the EUnetHTA Executive Committee coordinates the stakeholder involvement in EUnetHTA Joint Action 2 on an ongoing basis lead by the Secretariat.

4.4.2 Public Consultation

WP1 will solicit inputs into the development of recommendations for the implementation of the European HTA network from a wide audience of JA2 target groups.

4.4.3 Conflict of interest

No specific projects are anticipated in WP1 that will require a separate declaration of conflict of interest for the participating partners. WP1 refers to the EUnetHTA JA2 Conflict of Interest policy at the network level.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP1 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP1 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP1.

4.4.5 Quality assurance procedures

Different quality assurance procedures will be used in WP1 for the different strands of activities:

Project management
Extensive review of the 3 year work plan by the Secretariat, Stakeholder Forum and by the Plenary Assembly. Review of SOP and Consortium Agreement by WP1 Partners and the Plenary Assembly.
Regular WP1 / Executive e-meetings to share and follow up on activities.
Site visits by the Secretariat to LP/Co LPs to assist when needed.

Communication
All external communication and publications will be reviewed by members of the Secretariat and relevant WP Lead and Co-Lead Partners.

Stakeholder Involvement
Stakeholder Forum will be involved in the work and activities of EUnetHTA and SAGs will be developed for Stakeholders to provide advice and expertise.

Recommendations
The recommendations for the implementation of the sustainable European Network for HTA will undergo review by EUnetHTA Partners and Stakeholder Forum.

4.4.6 National HTA Report Production

In Coordination with WP 4 and 5 monitor and encourage the use of tools and information coming out of EUnetHTA in national reporting following the efforts and timing of the relevant WP.

4.4.7 Cooperation with other WPs / LPs

WP2 LP and Co-LP
Close cooperation on development of the content of the dissemination / communication materials and establishing contact with external parties.

WP3
Close cooperation with WP3 in order to ensure the best planning and use of the evaluation process and results, especially in relations to the development of recommendations on the implementation of a sustainable European network for HTA.

WP5 and WP7
Coordination of collaboration with EMA and meeting preparations.

WP6
Collaborating on the development and maintenance of EUnetHTA JA2 Website and Intranet. Support in communication and information sharing with partners on the EUnetHTA Intranet issues.

WP4, WP5, WP7, and WP8
Collaboration on facilitation of the use of tools and information coming out of EUnetHTA in national reporting following the efforts and timing of the relevant WPs.

5. Dissemination plan

Output	Format	Time
Recommendations	Final report to the Commission	Nov 2015-Mar 2016
JA2 Progress Reports / information	Web	Ongoing
	Newsletters internal and external	Quarterly
	EUnetHTA Conference	October 2014
	Interim reports	Oct 2013, Oct 2014

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 2 on HTA 2012-2015

Work Package 2

Dissemination and capacity building

3-year Work Plan

kunnskapssenteret

Norwegian Knowledge Centre for the Health Services

KCE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

May 1, 2013

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1. WP title

Work Package 2 – Dissemination and capacity building

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
• Lead Partner: Norwegian Knowledge Centre for the Health Services (NOKC)	LP and Co-LP work closely on all tasks. LP will take the main responsibility for the capacity building and training tasks including coordination and organisation of the training activities and learning material. LP will provide support for creation of the learning material including the e-learning material. LP will provide support for the organization of trainings. Will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement.
• Co-Lead Partner: Belgian Health care Knowledge Centre (KCE) **WP6 LP**	Co-LP will take the main responsibility for the networking tasks. Co-LP will take the main responsibility for the coordination of the support by WP2 to WP1 / EUnetHTA Secretariat on its tasks related to communication. Co-LP will provide support for the dissemination of training material. Will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement.
Associated partners – AP (13 partners)	
1. Danish Health and Medicines Authority (DHMA) (Denmark) **WP1 LP, JA2 Coordinator** 2. National Centre of Public Health Protection (NCPHP) (Bulgaria) 3. Agency for Quality and Accreditation in Health care and Social Welfare (AAZ) (Croatia) 4. National institute for health and welfare (THL) (Finland) **WP8 LP** 5. Direction générale de Santé/ Haute Autorité de Santé (HAS) (France) **WP7 LP** 6. National School of Public Health (NSPH) (Greece) 7. Health Information and Quality Authority (HIQA) (Ireland)	WP1 LP will be responsible for the communication strategy and its implementation (day to day communication about EUnetHTA; a communication officer is a staff member of the EUnetHTA Secretariat). WP4, 5, 6, 7 and 8 and will provide learning material and training activities. APs that are not WP LPs are responsible for evaluating the learning material. All APs are responsible for providing feedback on further training and capacity building requirements that they detect in their institution and country. All APs will participate in e-meetings and face-to-face meetings. APs are responsible for recruiting candidates with relevant backgrounds for participation in a community of practice (CoP) to be developed during JA2. The CoP aims to exchange experience on monitoring and enhancing the impact of HTA reports, and will produce

8. State Health Care Accreditation Agency (VASPVT) (Lithuania) 9. Ministry for health, the elderly and community care (SSD/MHEC) (Malta) 10. College voor zorgverzekeringen (CVZ) (The Netherlands) **WP5 LP** 11.National School of Public Health, Management and Professional Development (NSPH MPD) (Romania) 12. National Institute of public health, NIPH (Slovenia) 13. Instituto de Salud Carlos III, ISCIII (Spain)	best practices on that topic. All APs will collect and provide information on national HTA reports based on the Core Model. All APs will serve as a point of contact for their institutions and country and ensure communication about the different activities within WP2. They will transmit specific requests and feedback to WP2. Will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement.
Collaborating partners – CP (8 partners)	
1. Private Universität für Gesundheitswissenschaften, Medizinishe Informatik und Technik (Austria) 2. Medical University of Sofia (Bulgaria) 3. Ministère de la sécurité sociale Inspection générale de la securité sociale Cellule d'expertise médicale, CEM (Luxemburg) 4. Spanish Ministry of Health, Social services and Equality, MSSSI (Spain) 5. Basque Office for HTA Osteba (Spain) 6. AVALIA-t, Galician Agency for HTA Assessment (Spain) 7. Swiss Federal Office for Public Health - will be several institutions (Switzerland) 8. Turkish Evidence Based Medicine Association - KDTD (Turkey)	CP will be invited to the face-to-face meetings in order to evaluate the learning material and training courses. CP will also be invited to provide feedback on further training and capacity building requirements. CPs will be asked to communicate and provide members for the community of practice. CPs will collect and provide information on national HTA reports based on the Core Model. CP will be asked to support communication about the activities within WP2 in their own institutions and on a national level. CP will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement.
Other Parties	
All EUnetHTA partners	EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement EUnetHTA partners will be invited to the training courses. Communicate about the activities within EUnetHTA to their own institutions and on a national level.
EUnetHTA Stakeholders	EUnetHTA stakeholders will be invited to participate in the training courses. They will also be asked to evaluate and give input to the training courses and learning material. EUnetHTA stakeholders will be encouraged to communicate about the activities within EUnetHTA to their constituencies.

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: www.eunethta.eu

3. Objectives

Title	Description	Indicators
Increase awareness and understanding of the usefulness of the EUnetHTA tools, methods and results among EUnetHTA partners and stakeholders	Dissemination and communication of the knowledge and results of the JA2 to various internal and external target groups including the provision of training in EUnetHTA tools and methodologies to JA2 partners and stakeholders.	**Output indicators** At least 3 trainings to JA2 participants and stakeholders are provided. **Outcomes Indicators** Attendance at the EUnetHTA conference is 80% of its targeted capacity. At least 80% of the national medicines agencies and reimbursement authorities in the EU are aware of EUnetHTA JA2 and its objectives.

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
Training course in tools (core HTA and Adaptation Toolkit) developed	M12 Sep ’13 (1 month delay from the GA date)
Training course in methods developed	M13 Oct ’13 (1 month delay from the GA date)
First face-to-face training course for EUnetHTA partners	M16 Jan ’14 (3 months delay from the GA date)*
First face-to-face training course for EUnetHTA stakeholders	M16 Jan ’14 (2 month delay from the GA date*)
E-learning material for the EUnetHTA tools** developed	M25*** Oct ‘14

*We will run the training courses as parallel sessions for the partners and stakeholders at the same event. The first training courses will be held in connection with the scheduled Stakeholder forum face-to-face meeting in Jan ’14 in Brussels.
We will identify which tools that will be selected for preparing e-learning material based on input from AP’s and CP’s and the WP8 JA1 report “Report of HTA training and capacity building line of activities, July 2011**”.
***The deadline for this milestone is delayed (if compared to the Grant Agreement indicative date) in order not to develop the e-learning material before the tools are fully developed.

Deliverables	Deadline
Report on yearly training courses on EUnetHTA tools and methodology.	M36 Oct ‘ 15

4.2 Methods

For all the tasks, we will seek active involvement of all WP2 members through e-meetings, face-to-face meetings and e-mail communication.

Communication

WP2 will support WP1 (EUnetHTA Secretariat) in the revision process of the communication and dissemination plan prepared during JA1 by participating to brainstorming/interviews regarding the current document, reviewing the new draft and evaluating the implemented strategy.

The EUnetHTA public site will list the HTA reports making use of the EUnetHTA Core Model™, or done collaboratively thanks to EUnetHTA tools.

Training in EUnetHTA tools and methods

Experience gained in WP8 during JA1 and their survey on "HTA capacity building and training needs" and the evaluation of the training courses held in October 2011 and June 2012 will be applied in JA2.

An overview of the EUnetHTA tools and methods (methodological guidelines) and suggestions for proper teaching form and learning material will be created, presented for and discussed with the WP2 members. Learning objectives will be defined.

WP2 will identify teaching personnel in member organisations.

WP2 will provide training both through webinars (presentations or lectures transmitted through the EUnetHTA website or intranet), e-learning (delivery of text, audio, images and/or, animation through the EUnetHTA web site or intranet) and face-to-face courses (yearly training courses).

HTA capacity building and networking

Capacity building plan based on the HTA capacity building handbook from 2008 will be developed and implemented in the joint action.

A learning path (step by step process) that includes HTA methodology, the methodological guidelines developed through EUnetHTA and the EUnetHTA tools will be created. The aim will be to to enhance both EUnetHTA members' and 'stakeholders' understanding of HTA, its implications and how HTA can contribute in the resource allocation process within each member state.

Courses on HTA methodology in Europe are planned to be mapped (collaboration with HTAi vortal http://vortal.htai.org is envisioned in this respect).

Contact with, and involvement in the training courses of the academic institutions that are currently providing education and research in HTA is planned.

"Train the trainers" approach is planned to be applied and be essential (future trainers will transfer knowledge to their member organisations and stakeholders on a national level)

A Community of Practice (CoP) aiming to exchange experience on monitoring and enhancing the impact of HTA reports to favour actual implementation by decision makers, and producing best practices on that topic is to be established among EUnetHTA members. Collaboration with the INAHTA working group on Impact of HTA is foreseen (http://inahta.episerverhotell.net/HTA/).

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
14 Nov 2012 (M2)	KCE, Brussels	1	KCE and NOKC	Discuss the 3-year work plan. Identify tasks and delegate responsibility
20 Mar 2013 (M6)	E-meeting	10^{00} - 11^{30}	LP, Co-LP, APs and CPs	Present the 3-year work plan. Plan the work forward.
25-26 Apr 2013 (M7)	NOKC, Oslo Face-to-face meeting	1	LP, Co-LP, APs and CPs	First kick of face-to-face meeting. Discuss production of learning material and training activities.
May 2013 (M8)	NOKC, Oslo	1	KCE and NOKC	Discuss progress on production of learning material, training activities, capacity building plan, the communication strategy and communication channels
11 Sep 2013 (M12)	E-meeting	10^{00} - 11^{30}	LP, Co-LP, APs and CPs	Finalize and discuss the learning material for the first training courses.
Jan 2014 (M16)	Brussels		APs, CPs, EUnetHTA members and stakeholders	F-t-f training course for EUnetHTA members and stakeholders
Mar 2014 (M18)	E-meeting	10^{00} - 11^{30}	LP, Co-LP, APs and CPs	Evaluate the training courses. Discuss further need for training.
Sep 2014 (M24)	E-meeting	10^{00} - 11^{30}	LP, Co-LP, APs and CPs	Evaluate the training courses. Discuss further need for training.
Oct 2014 (M25)	Rome	1	APs, CPs, EUnetHTA members and stakeholders	F-t-f training course EUnetHTA members and stakeholders
Oct 2014 (M25)	Rome	1	EUnetHTA partners	Workshop for the community of practice.
Mar 2015 (M30)	KCE, Brussels Face-to-face meeting	1	LP, Co-LP, APs and CPs	Evaluate training courses and learning material.
April or May 2015 (M31 or M32)	Madrid	1	APs, CPs, EUnetHTA members and stakeholders	F-t-f training course for EUnetHTA members and stakeholders
June 2015 (M33)	E-meeting	10^{00} - 11^{30}	LP, Co-LP, APs and CPs	Evaluate the training courses. Plan the final report

4.4 Specific activities per year

Year 1 (Oct 2012 – Sep 2013)

Activity: 3-year work plan				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M3 Dec '12	Draft creation and revision	EUnetHTA partners, stakeholder forum and WP2 members	WP2 LP, Co-LP and the secretariat
M3 Dec '12	M3 Dec '12	First version delivered to the secretariat, WP2 Co-LP, APs and CPs	EUnetHTA partners, stakeholder forum and WP2 members	WP2 LP
M4 Jan '13	M4 Jan '13	Implement feedback from the secretariat, WP APs and CPs	EUnetHTA partners, stakeholder forum and WP2 members	WP2 LP and Co-LP
M5 Feb '13	M5 Feb '13	Implement feedback from stakeholders	Stakeholder Forum	WP2 LP, Co-LP, Stakeholder Forum and the Secretariat
M6 Mar '13	M6 Mar '13	Final endorsement at the Plenary Assembly meeting on the 21st/22nd of March	EUnetHTA partners	WP2 LP, Co-LP and the Secretariat

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M9 Jun '13	M12 Sep '13	Draft and revise the 1st interim report	WP1	WP2 LP and Co-LP, APs and CPs

Activity: Production (include coordination, support, delivering and evaluation) of learning material for the EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan '13	M7 Apr '13	Identify training needs	EUnetHTA partners and stakeholders	WP2 LP, WP2 Co-LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs. Stakeholders.
M6 Mar '13	M7 Apr '13	Identify training needs among Stakeholders by e-mail	EUnetHTA	WP1 LP,

		questionnaire.	Stakeholders	WP2 LP and Co-LP
M5 Feb '13	M9 Jun '13	Identify proper training activities	EUnetHTA partners and Stakeholders	WP2 LP, WP2 Co-LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs.
M9 Jun '13	M16 Jan '14	Develop and implement learning material both for the EUnetHTA tools and methods • Plan content of learning material • Produce learning material • Input on learning material from Stakeholders	EUnetHTA partners and stakeholders	WP2 LP, WP2 Co-LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs. Stakeholders

Activity: Communication strategy				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M5 Feb '13	M8 May '13	Participating to input provision to WP1 in order to ameliorate the current Communication strategy, including social media	EUnetHTA partners and Stakeholders	WP1 LP, and WP2 partners (task force "Communication strategy")
M7 Apr '13	M7 Apr '13	Commenting on the reviewed communication strategy	EUnetHTA partners and Stakeholders	WP1 LP, and WP2 members
M8 May '13	M8 May '13	The secretariat will share the final draft with Exec committee for approval	EUnetHTA partners and Stakeholders	WP1 LP, WP2 Co-LP and LP

Activity: Promotion of national HTA reports based on Core HTAs or resulting from collaboration initiated thanks to the POP database through the EUnetHTA website				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan '13	M5 Feb '13	Create space on EUnetHTA website for the list of national HTA reports that are prepared using Core HTAs or resulting from collaboration initiated thanks to the POP database	Not applicable	WP 2 Co-LP, WP6 LP
M6 Mar '13	M36 Oct '15	Describe such HTA reports on the EUnetHTA website	EUnetHTA partners and stakeholders	WP 2 Co-LP and EUnetHTA partners

Activity: Prepare and publish e-learning about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan '13	M8 May '13	Decide for which of the EUnetHTA tools and methods we will create e-learning	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs
M4 Jan '13	M8 May '13	Identify e-learning platforms	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP6 LP, WP1 LP
M8 May '13	M20 Oct '13	Prepare content to the e-learning	EUnetHTA partners and Stakeholders	WP1 LP, WP2 LP and Co-LP (facilitate), Tools developers

Activity: Organise face-to-face training courses about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M5 Feb '13	M11 Sep '13	• Work on practical issues regarding the organization in collaboration with the host of the training courses	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs
M7 Apr '13	M7 Apr '13	Discussions at face-to-face meeting in Oslo	WP2 members	WP2 LP and Co-LP, WP2 APs and CPs
M5 Feb '13	M12 Sep '13	Develop training course in tools • Plan content of training course • Plan format of training course • Identify personnel to provide trainings • Include the learning material developed within EUnetHTA in the course	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs
M5 Feb '13	M13 Oct '13	Develop training course in methods • Plan content of training course • Plan format of training course • Identify personnel to provide trainings • Include the learning material developed within EUnetHTA in the course	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs

Activity: Support HTA capacity building and HTA education for EUnetHTA members and stakeholders (focus on health care consumers and providers) by providing a learning path.				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M6 Mar '13	M7 Apr '13	Identify training needs on HTA capacity building among Stakeholders	EUnetHTA Stakeholders	WP1 LP, WP2 LP and Co-LP
M7 Apr '13	M9 Jun '13	Identify training needs on HTA capacity building among EUnetHTA members based on the survey "HTA capacity building and training needs" from EUnetHTA JA1.	EUnetHTA members	WP2 LP and Co-LP
M7 Apr '13	M7 Apr '13	Discuss the learning path on the WP2 face-to-face meeting	WP2 members	WP2 LP, Co-LP, APs and CPs
M9 June'13	M17 Feb '14	Identify steps in the learning path (step by step process) on HTA capacity building and education .	EUnetHTA partners and Stakeholders	WP2 LP, WP2 APs and CPs, Stakeholders Potential collaboration with HTAi vortal

Year 2 (Oct 2013 – Sep 2014)

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	M13 Oct '13	Finalization of the 1st interim report	WP1	WP2 LP and Co-LP
M21 Jun '14	M24 Sep '14	Draft and revise the 2nd interim report	WP1	WP2 LP and Co-LP, APs and CPs

Activity: Production (include coordination, support, delivering and validation) of learning material for the EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M9 Jun '13	M16 Jan '14	Develop and implement learning material both for the EUnetHTA tools and methods • Plan content of learning material • Produce learning material • Input on learning material from Stakeholders	EUnetHTA partners and Stakeholders	AP WP1, WP2 LP, WP2 Co-LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs. Stakeholders
M16 Jan '14	M34 Aug '15	Evaluation and further development of learning material	EUnetHTA partners and Stakeholders	AP WP1, WP2 LP, WP2 Co-

				LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs. Stakeholders

Activity: Promotion of national HTA reports based on Core HTAs or resulting from collaboration initiated thanks to the POP database through the EUnetHTA website				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M6 Mar '13	M36 Oct '15	Enter titles on HTA reports on the EUnetHTA website	EUnetHTA partners and stakeholders	WP 2 Co-LP and EUnetHTA partners

Activity: Prepare and publish e-learning about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M8 May '13	M20 Oct '13	Prepare content to the e-learning	EUnetHTA partners and stakeholders	WP1 LP, WP2 LP and Co-LP (facilitate), Tools developers
M13 Oct '13	M24 Sep '14	Prepare the e-learning material for the selected e-learning platform	EUnetHTA partners and stakeholders	WP1 LP, WP2 LP, Co- LP, WP2 APs and CPs

Activity: Organise face-to-face training courses about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M5 Feb '13	M13 Oct '13	Develop training course in methods • Plan content of training course • Plan format of training course • Identify personnel to provide trainings • Include the learning material developed within EUnetHTA in the course	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs
M16 Jan '14	M16 Jan '14	Organise first face-to-face training course about EUnetHTA tools and methods	EUnetHTA partners and Stakeholders	WP2 LP, WP 1, 4, 5, 6, 7 and 8 LP.
M17 Feb '14	M18 Mar '14	Evaluate training course, define need for improvement	EUnetHTA partners and Stakeholders	WP2 LP + Co-LP, WP2 APs + CPs, WP 1, 4, 5, 6, 7 and 8 LP. Stakeholders

Activity: Organise webinars about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M17 Feb '14	M19 Apr '14	Decide for which of the EUnetHTA tools and methods we will give webinars	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs
M17 Feb '14	M19 Apr '14	Identify webinar platforms	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP6 LP, AP WP1
M19 Apr '14	M21 Jun '14	Provide content to the webinars	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP (facilitate), WP 4, 5, 7 and 8 LP
M23 Aug '14	M25 Oct '14	Prepare the webinar material for the selected platform	EUnetHTA partners and Stakeholders	WP2 LP, Co- LP, WP2 APs and CPs

Activity: Organise one workshop for the Community of Practice				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M18 Mar '14	M36 Oct '15	Establish a Community of Practice (CoP) aiming to exchange experience on monitoring and enhancing the impact of HTA reports, and producing best practices on that topic	EUnetHTA partners	WP2 Co-LP and voluntary EUnetHTA partners
M18 Mar '14	M26 Nov '14	Prepare content of workshop and identify host organization	EUnetHTA partners	WP2 Co-LP and LP, voluntary WP2 APs and CPs
M23 Aug '14	M25 Oct '14	Identify members for the CoP	EUnetHTA partners	WP2 Co-LP
M20 May '14	M24 Nov '14	Work on practical issues related to the workshop	EUnetHTA partners	WP2 Co-LP and host organizatio n

Activity: Support HTA capacity building and HTA education for EUnetHTA members and stakeholders (focus on health care consumers and providers) by providing a learning path.				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M9 June'13	M17 Feb '14	Identify steps in the learning path (step by step process) on HTA capacity building and education	EUnetHTA partners and stakeholders	WP2 LP, WP2 APs and CPs

				Potential collaboration with HTAi vortal
M21 June ‘14	M29 Feb ‘15	Identify and/or produce learning material tailored to the learning path. Developed by EUnetHTA or outside (by academic or other institutions	EUnetHTA partners and Stakeholders	WP2 LP, WP2 APs and CPs. Stakeholders Potential collaboration with HTAi vortal

Year 3 (Oct 2014 – Sep 2015)

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct ‘14	M25 Oct ’14	Finalization of the 2nd interim report	WP1	WP2 LP and Co-LP
M32 Jun ‘15	M35 Sep ‘15	Draft and revise the final report	WP1	WP2 LP and Co-LP, APs and CPs
M36 Oct ‘15	M36 Oct ’15	Finalization of the final report	WP1	WP2 LP and Co-LP

Activity: Production (include coordination, support, delivering and validation) of learning material for the EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M16 Jan ‘14	M34 Aug ‘15	Evaluation and further development of learning material		AP WP1, WP2 LP, WP2 Co-LP, WP 4, 5, 6, 7 and 8 LP. APs and CPs. Stakeholders

Activity: Promotion of national HTA reports based on Core HTAs or resulting from collaboration initiated thanks to the POP database through the EUnetHTA website				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M6 Mar ‘13	M36 Oct ‘15	Enter titles on HTA reports on the EUnetHTA website	EUnetHTA partners and stakeholders	WP 2 Co-LP and EUnetHTA partners

Activity: Prepare and publish e-learning about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct ‘14	M25 Oct ‘14	Launch e-learning	EUnetHTA partners and Stakeholders	WP1 LP, WP2 LP and Co- LP.
M26 Nov ‘14	M29 Feb ‘15	Evaluate e-learning, define need for improvement	EUnetHTA partners and Stakeholders	WP1 LP, WP2 LP, Co- LP, WP2 APs and CPs
M30 Mar ‘15	M32 May ‘15	Improve and launch e-learning	EUnetHTA partners and Stakeholders	WP1 LP, WP2 LP, Co- LP, WP2 APs and CPs

Activity: Organise face-to-face training courses about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct ‘14	M25 Oct ‘14	Organise second face-to-face training course about EUnetHTA tools and methods	EUnetHTA partners and Stakeholders	WP2 LP, WP 1, 4, 5, 6, 7 and 8 LP.
M26 Nov ‘14	M28 Jan ‘15	Evaluate training courses, define need for improvement	EUnetHTA partners and Stakeholders	WP2 LP and Co-LP, WP2 APs and CPs, WP 1, 4, 5, 6, 7 and 8 LP. Stakeholders
April or May 2015 (M31 or M32)	April or May 2015 (M31 or M32)	Organise third face-to-face training course about EUnetHTA tools and methods	EUnetHTA partners and Stakeholders	WP2 LP, WP 1, 4, 5, 6, 7 and 8 LP.

Activity: Organise webinars about EUnetHTA tools and methods				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M23 Aug ‘14	M25 Oct ‘14	Prepare the webinar material for the selected platform	EUnetHTA partners and Stakeholders	WP2 LP, Co- LP, WP2 APs and CPs
M26 Nov ‘14	M35 Sep ‘15	Present the webinars (not decided yet if it will be one or more webinars during this timeframe)	EUnetHTA partners and Stakeholders	WP2 LP, WP2 Co-LP, APs or CPs involved in the training

Activity: Organise one workshop for the Community of Practice				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M18 Mar ‘14	M36 Oct ‘15	Establish a Community of Practice (CoP) aiming to exchange experience on monitoring and enhancing the impact of HTA reports, and producing best practices on that topic	EUnetHTA partners	WP2 Co-LP and voluntary EUnetHTA partners
M18 Mar ‘14	M26 Nov ‘14	Prepare content of workshop and identify host organization	EUnetHTA partners	WP2 Co-LP and LP, voluntaryWP 2 APs and CPs
M23 Aug ‘14	M25 Oct ‘14	Identify members for the network	EUnetHTA partners	WP2 Co-LP
M25 Oct ‘14	M25 Oct ‘14	The workshop for the community of practice will take place	EUnetHTA partners	WP 2 Co-LP, one AP (for hosting the meeting)
M25 Oct ‘14	M36 Oct ‘15	Produce best practices for monitoring and enhancing the impact of HTA reports	EUnetHTA partners	WP2 Co-LP and voluntary EUnetHTA partners

Activity: Support HTA capacity building and HTA education for EUnetHTA members and stakeholders (focus on health care consumers and providers) by providing a learning path.				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M21 June ‘14	M29 Feb ‘15	Identify and/or produce learning material tailored to the learning path. Developed by EUnetHTA or outside (by academic or other institutions	EUnetHTA partners and Stakeholders	WP2 LP, WP2 APs and CPs. Stakeholders Potential collaboration with HTAi vortal
M30 Mar ‘15	M30 Mar’15	Present learning path	EUnetHTA partners and Stakeholders	WP2 LP, WP2 APs and CPs

4.4.1 Stakeholder involvement

WP2 will assess the need for training (topic, format) among the stakeholders by an e-mail questionnaire. We will provide separate training courses for stakeholders. We will aim at having a particular focus on patients and health care professionals. We will also aim at including academic institutions that are currently providing education and research in HTA when preparing the learning material and providing the courses.

We will establish a stakeholder advisory group (SAG) consisting of primarily patient and healthcare consumers and healthcare providers. The SAG will be asked to evaluate the learning material, webinars, e-learning material and the format and content (topics) of the face-to-face training courses.

SAG involvement			
Timing	**Purpose**	**Type of input from SAG**	**Info from SAG to be used for…**
Before using the material at the training courses or provided on the EUnetHTA website or intranet (Oct/Nov 2013, Aug/Sep 2014, Feb/Mar 2015	Improve the learning material	Feedback on learning material (make sure the material is understandable and suited for the target groups)	Further improvement of the learning material
After each training course (Jan 2014, Oct 2014, Apr or May 2015)	Improve the training courses	Feedback on the training courses. Both on the content and format	Further improvement of the training courses
Mar 2014 to Oct 2014	Improve the Community of Practice	Feedback on best practices	Contributing to the Community of Practice reaching its aims.

4.4.2 Public Consultation

No public consultations are planned.

4.4.3 Conflict of interest

All WP2 partners will fill in a “Declaration of interes” form to declare any conflict of interest within the work of WP2. If any inappropriate interest in any of the tasks or activities of WP2 is discovered, those agencies or persons will be excluded from important decisions related to those tasks or activities. LP will judge what is defined by “inappropriate interest” together with their Co-LP on a case-by-case manner. All decisions made will be communicated to the APs and CPs of WP2 and to the Secretariat.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP2 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP2 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP2.

4.4.5 Quality assurance procedures

Quality assurance will be implemented by assessing the indicators for the WP2 objectives.

The quality of the learning material, e-learning material and training courses will be evaluated by the WP2 partners and Stakeholders in order to make improvements and further develop the material and courses.

4.4.6 National HTA Report Production

Plan for facilitating national application/implementation of WP outputs:

WP2 will provide proper educational training both on the HTA Core Model and Online Tool and Service so that members will be able to use the tools when preparing their national or local HTA reports. We will also provide training on all the EUnetHTA tools and methods (including guidelines (methodological standards and the HTA Core Model). We will encourage the implementation and use of EUnetHTA tools and methodology.

WP2 will facilitate the access to national HTA reports based on Core HTA information or resulting from collaboration initiated by the POP database by publishing description of such reports on the EUnetHTA website.

4.4.7 Cooperation with other WPs / LPs

WP2 will collaborate closely with the EUnetHTA Secretariat on all communication and administrative issues.

WP2 will collaborate with WP6 regarding the tools to deliver learning materials and training courses (e-learning platform, webinars, ...).

WP2 will collaborate (WP2 will coordinate the production) with WP 4, 5, 6, 7 and 8 regarding learning material for the HTA core model, other EUnetHTA tools and guidelines (methodological standards). The collaboration will also include active participation by these WPs in the face-to-face training courses.

5. Dissemination plan

Output	Format	Time
3-year work plan	Document, on the website	May 2013
Communication strategy	Document, on the website or intranet	June 2013
Learning material	Various format, on the website or intranet and/or e-learning site	Jan 2014 to Sep 2015
Face-to-face training courses	Presentations, workshops, group work	Jan 2014, Oct 2014, Apr/May 2015
E-learning material	On the e-learning site	Oct 2014/May 2015
Webinars	On the intranet	Nov 2014 to Sep 2015
Interim WP2 reports, Final WP2 report	Document, on the website	Sep 2014, Sep 2014, Oct 2015

Joint Action 2 on HTA 2012-2015

Work Package 3

Evaluation and data collection on costs and efficiency

3-year Work Plan

Hauptverband der
österreichischen
Sozialversicherungsträger

May 1, 2013

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1. WP title

Work Package 3 – Evaluation of the joint action and data collection on costs and efficiency

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
Lead Partner: HVB Hauptverband der Österreichischen Sozialversicherungsträger Kundmanngasse 21 A 1031 Wien Tel: +431 71132 3615 Fax: +431 71132 3786 Contact: Gottfried.Endel@hvb.sozvers.at	- Coordination, communication and dissemination of the evaluation process and its results; - work package coordination with APs and CPs; - final responsibility for the WP3 deliverables and time schedule - Will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA Grant Agreement.
• Co-Lead Partner	n/a
Associated partners – AP (2 partners)	
1. NETSCC NIHR Evaluation, Trials and Studies Coordinating Centre Alpha House, Enterprise Road, University of Southampton Science Park, Chilworth, Southampton SO16 7NS Tel.: +44 (0) 23 8059 5586 Fax.: +44 (0)8059 5639 Contact: E.Guegan@soton.ac.uk 2. GYEMSZI National Institute for Quality and Organizational Development in Healthcare and Medicines Tel.: +36 1 354 5353/ext. 5307 Fax.: Contact: nemeth.bertalan@gyemszi.hu	• NETSCC: a)provide input in developing JA2 evaluation process - specifically in devloping surveys of EUnetHTA JA2 participants (ie, EUnetHTA APs and CPs as well as EUnetHTA Stakeholders), b) monitor HVB (internal control) • GYEMSZI : Calculation of the resource use and added value • Follow the AP's responsibilities as described in the EUnetHTA JA 2 SOP, EUnetHTA JA2 Consortium Agreement, and 2011 23 01 EUnetHTA JA2 Grant Agreement.
Collaborating partners – CP (1partner)	
BAG (Ch) Swiss Federal Office for Public Health Scharzenburgstrasse 165 CH-3003 Berne Tel.: +41 31 322 1586 Contact: christoph.kuenzli@bag.admin.ch	Internal evaluation process for WP3 - CP will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 S SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement
Other Parties	
All EUnetHTA partners	- Provision of information (to the EUnetHTA Secretariat via time registration sheets) on the usage of resources (staff time) for participation in the WP activities, WP pilots (WP4 and 5) and production of national/local HTA reports (where EUnetHTA Core HTAs and/or rapid HTAs were used). - The EUnetHTA Secretariat facilitates collection of the necessary data and its provision in an aggregated form EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim

	and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
EUnetHTA Stakeholders	- Answer WP3 surveys of the EUnetHTA Stakeholder Forum - Comment on transparency and easy reading of correct details in the WP3 documents submitted to the Stakeholder Forum review

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: www.eunethta.eu

3. Objectives

There are no specific objectives directly assigned to WP3 (horizontal Work Package).

Actions undertaken in WP3 aim to verify if the project is being implemented as planned and reaches its objectives.

WP3 will contribute to the EUnetHTA JA2 Specific Objective 1

Title	Description	Indicators
Test the capacity of national HTA bodies to produce core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network)	A number of core HTAs and rapid HTA information based on the core model structure and its abridged version for rapid assessments (i.e. the first 4 domains) will be produced. The assessments produced will be used for local (i.e. national, regional) reports fo inform decision-making. Data will be collected on costs and overall efficiency.	*As proposed by the WP3 (not specified in the Grant Agreement):* - mean personal costs/agency according to the financial statements (1x yearly); - costs per HTA in WP4 and in WP5 as mean of person days per assessment (according to the financial/ time statements); - usage of POP and EVIDENT (Nr. of cooperative HTAs); - Estimate effects of collaboration after each Core HTA done in JA2 - N of reached info Core HTAs (products in JA2) - N national HTA/ N info Core HTA (details see in graph 1) - N of exchange (homepage use of network tools, common deliverables, support) (WP6, WP8) - N of POP database overlappings monitored as a trend (decrease?) (WP6)

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
Deliver an evaluation plan including baseline evaluation*, success criteria, indicators, metrics**, timings and responsibilities. Pilot plan of resource use measurement***. (*official Grant Agreement milestone*) **The main components of baseline evaluation are clarified in graph 1 in appendix. The results of our evaluation will be presented in the interim and final reports.* ***The criteria, indicators and metrics are adressed in the method section.* ****The plan how we will evaluate resource use and calculate the efficiency is explained in Graph 2 in the appendix*	M3 December 2012 (Pilot plan sent to the secretariat in December 2012; Final Project plan January 2013 after correction of comments and reviewing)
Ongoing monitoring and evaluation processes and systems (to include publishing, technical support, information gathering, efficiency gains and metrics) (*official Grant Agreement milestone*)	M12 September 2013 M24 September 2014
Reports after each core HTA information project summarised; A **report on efficiency gains** will be prepared and a simple calculation model to estimate effects of collaboration will be provided.	M14 November 2013 M25 October 2014 M36 September 2015
Final evaluation reporting and recommendations for the evaluation function for a sustainable EUnetHTA network from 2015 onwards.	M36 September 2015

Deliverables	Deadline
Report on evaluation of project completion including assessment of impact on secondary users of HTA information (*official deliverable as per the Grant Agreement*)	M36 (42*) Sept'15 (Mar'16*) ** Only if an extension of the grant agreement is necessary and requested during the JA2*
Deliverables as further specified by the WP3:	
o Evaluation plan in detail draft	M3 Dec'12
o Evaluation plan in detail final	M6 M12 Sep'13
o Interview evaluation reports with LPs	Mar'13
o First interim report	M13 Oct'13
o Second interim report	M25 Oct'14
o Third final report	M36 Oct'15

4.2 Methods

- Data recording out of routine documentation (costs, efficiency, success)
- Surveys and interviews (problems, lessons learned, cooperation etc.)
- Observation (support, early reaction, securing data) with a calendar of milestones

WP3 will be collecting data to fulfill their tasks in the WP's 4 lines of activities:

1. **Calculation of efficiency gains**
   - Data linked to a) the level of pilot projects (WP4 and 5) and b) WP level (WP1,2,3,6,7,8).
   - Calculation of efficiency gains will be directed to the national institutions and to argue added value at the European level

- Data will be collected (via case by case surveys or interviews) on the use of the core information in production of local reports
- The EUnetHTA Secretariat will adjust the financial statement forms to include reporting on
    a. number of person days per individual (besides the costs expressed in relevant currency)
    b. affiliation to the WP4/WP5 pilots (specific pilot project identifier will be agreed with WP4 and WP5 LPs and included in the financial and tech reports).
- WP3 will use the financial and tech report data collected by the Secretariat via annual interim reporting process (see Graph 2 in the appendix)
    a. The Secretariat will have to provide an aggregated financial data (level and details of how such aggregation to be done will be specified by HVB further during the first six months of the JA2 (ie, by the end of March 2013)

2. **Auditing of the progress in implementation of JA2 as per the JA agreement and verifying if it is on course to achieve its objectives**
    - Surveys and process developed by NETSCC for JA1 will be utilized (after adjustment to the needs of JA2) – please see Section 4.4 Specific activities per year for a concrete timeline and specification of activities under this activity line

3. **Capturing cross-border collaboration activities of the "spin-offs/add-ons" in the network as the outcome of the EUnetHTA activities**
    - Data will be gathered via focused interviews/surveys of EUnetHTA partners and via analysis of utilization of EUnetHTA tools (POP database, EVIDENT, Core HTA information database, etc).

4. **Quality assessment process:**
    - Evaluating the project progress and its timely attainment of the milestones, deliverables, etc – The interim/final tech reports will be used for this task
    - Pilot projects – quality of the output will be assessed via
        a. Qualitative assessment of the review process utilized in each pilot project
        b. Assessment of the ensuing transfer of the core HTA information into the national/regional report
            - The issue of the Adaptation Toolkit usage for this process is to be clarified with WP8 (ie, if (and how if yes) the current Adaptation Toolkit will be developed further to fit the needs/process of the core HTA information transfer to the local report)
        c. Conflict of interest process review, ie, how the conflict of interest was handled in the pilot
    - Handling of conflict of interest issues on the WP level
        a. The Secretariat is to produce the conflict of interest handling guidelines for JA2

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
2012-12-11	London	6 hrs	Gottfried Endel, Ingrid Wilbacher, Eleanor Guegan, Andrew Cook	Fix the evaluation plan including details for surveys and data processing (using tools from JA1) Distribute the evaluation tool (database) for testing internally (Quality check)
2013-01-11	Copenhagen	6hrs	Gottfried Endel, Ingrid Wilbacher Julia Chamova Anne Raahauge Finn Børlum Kristensen	Coordinate he evaluation plan including details from routine data processing (using test data from JA1) Declarations of conflict of interest - agreement for routine data usage and personalized surveys
no further meetings planned for WP3 until now (Collaborative partners do not get paid); General Assembly or WP1 meetings maybe used but not stated for WP3 e-meetings and intensive cooperation (instead of face-to-face meetings) accordingly				

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Activity: Calculation of efficiency gains				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M11 Aug' 13	M12 Sept' 13	collection of available information on pilots from WP4 and 5, interviews about cases of local pilot-transformation	WP4 and WP5	WP4 LP, WP5 LP WP3 LP/AP/CP
M12 Sept' 13	M12 Sept' 13	calculation and preparing report of results out of the information collection from WPs 4,5 according to the prepared formula	WP3	WP3 LP/AP/CP

Activity: Auditing of the progress in implementation of JA2 as per the JA agreement and verifying if it is on course to achieve its objectives				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M7 Apr' 13	M8 May 13	conception and coordination of first WP3 yearly survey for EUnetHTA Partners and Associates	WP1 (survey needs of other WPs); WP3	WP1, WP3 LP/AP
M8 May 13	M8 May 13	preparing and announcing first WP3 yearly survey for EUnetHTA Partners and Associates		WP3 LP/AP
M9 Jun' 13	M9 Jun' 13	start first WP3 yearly survey for EUnetHTA Partners and Associates and reminder after 2 weeks	EUnetHTA Partners and Associates	WP3 LP
M10 Jul' 13	M12 Sept' 13	analysis of results of the first WP 3 yearly survey for EUnetHTA Partners and Associates and preparation of reporting	WP3 LP/AP	WP3 LP/AP
M7 Apr' 13	M8 May 13	conception and coordination of first WP3 yearly survey for stakeholders	WP3 LP/AP	WP3 LP/AP
M8 May 13	M8 May 13	preparing and announcing first WP3 yearly survey for stakeholders	stakeholder /WP3 LP/AP	WP3 LP/AP
M9 Jun' 13	M9 Jun' 13	start first WP3 yearly survey for stakeholders and reminder after 2 weeks	stakeholder	WP3 LP/AP
M10 Jul' 13	M12 Sept' 13	analysis of results of the first WP3 yearly survey for stakeholders and preparation of reporting	WP3 LP/AP	WP3 LP/AP
M12 Sept' 13	M13 Oct' 13	writing the interim report (status - for Commission, feedback for all WPs), relevant information will be prepared for the Stakeholder meeting	WP1, Commission, EUnetHTA Partners and Associates	WP3 LP/AP

Activity: Capturing cross-border collaboration activities of the "spin-offs/add-ons" in the network as the outcome of the EUnetHTA activities				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M12 Sep' 13	M12 Sep' 13	capture the utilization of EUnetHTA tools and included in	WP5 (?)	WP3

		the report at yearly level (from the second year on the trend of usage will be added) - POP database - regularly report - EVIDENT- regularly report - Core HTA information database - Adaptation toolkit		LP/AP
M11 Aug' 13	M12 Sep' 13	collection of available information on collaboration in the context of EUnetHTA, interviews about cases of collaboration	EUnetHTA Partners and Associates	WP3 LP/AP/CP
M12 Sep' 13	M12 Sep' 13	preparation of reporting the results	WP3 LP/AP/CP	WP3 LP/AP/CP

Activity: Quality assessment process				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M12 Sep' 13	M12 Sep' 13	Evaluating the project progress and its timely attainment of the milestones, deliverables, etc. Findings will be included in the interim report	WP LP	WP3 LP/AP
M12 Sep' 13	M12 Sep' 13	The interim/final reports will be used (addtional interviews if needed) for - Qualitative assessment of the review process utilized in each pilot project - Assessment of the transfer of the core HTA information into the national/regional report - Conflict of interest process review, ie, how the conflict of interest was handled in the pilot-- Findings will be included in the interim report	WP LP	WP3 LP/AP

Year 2 (Oct 2013-Sep 2014)

Activity: Calculation of efficiency gains				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct' 13	M13 Oct' 13	data collection: number of person days per individual (besides the costs expressed in relevant currency) (WP3 will use the financial and tech report data collected by the Secretariat via annual interim reporting process of all EUnetHTA partners) The Secretariat will provide an aggregated financial data	all EUnetHTA partners	WP1(data providing)/ WP3 LP/AP/CP
M14 Nov' 13	M14 Nov' 13	data quality assurance (including re-assurance)	WP3	WP3 LP/AP/CP
M14 Nov' 13	M14 Nov' 13	Calculation of the efficiency gain and reporting (this preliminary report will - after review and adjustment - be included in the second interim report. Key findings could be included in the newsletter)	WP1	WP3 LP/AP/CP
M23 Aug' 14	M24 Sep' 14	collection of available information on pilots from WP4 and 5, interviews about cases of local pilot-transformation	WP4 and WP5	WP4 LP, WP5 LP WP3 LP/AP/CP
M24 Sep' 14	M24 Sep' 14	calculation and preparing report of results out of the	WP3	WP3

		information collection from WPs 4,5 according to the prepared formula		LP/AP/CP

Activity: Auditing of the progress in implementation of JA2 as per the JA agreement and verifying if it is on course to achieve its objectives				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M19 Apr' 14	M20 May 14	conception and coordination of 2nd WP3 yearly survey for EUnetHTA Partners and Associates	WP1 (survey needs of other WPs); WP3	WP1, WP3 LP/AP
M20 May 14	M20 May 14	preparing and announcing 2nd WP3 yearly survey for EUnetHTA Partners and Associates		WP3 LP/AP
M21Jun' 14	M21Jun' 14	start 2nd WP3 yearly survey for EUnetHTA Partners and Associates and reminder after 2 weeks	EUnetHTA Partners and Associates	WP3 LP
M22 Jul' 14	M24 Sept' 14	analysis of results of the 2nd WP3 yearly survey for EUnetHTA Partners and Associates and preparation of reporting	WP3 LP/AP	WP3 LP/AP
M19 Apr' 14	M19 Apr' 14	conception and coordination of 2nd WP3 yearly survey for stakeholders	WP3 LP/AP	WP3 LP/AP
M19 Apr' 14	M20 May 14	preparing and announcing 2nd WP3 yearly survey for stakeholders	stakeholder /WP3 LP/AP	WP3 LP/AP
M21 Jun' 14	M21 Jun' 14	start 2nd WP3 yearly survey for stakeholders and reminder after 2 weeks	stakeholder	WP3 LP/AP
M22 Jul' 14	M24 Sep' 14	analysis of results of the 2nd WP3 yearly survey for stakeholders and preparation of reporting	WP3 LP/AP	WP3 LP/AP
M22 Jul' 14	M24 Sept' 14	writing the 2nd interim report (status - for Commission, feedback for all WPs), relevant information will be prepared for the Stakeholder meeting	WP1, Commission, EUnetHTA Partners and Associates	WP3 LP/AP

Activity: Capturing cross-border collaboration activities of the "spin-offs/add-ons" in the network as the outcome of the EUnetHTA activities				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M24 Sep' 14	M25 Oct' 14	capture the utilization of EUnetHTA tools and included in the report at yearly level (from the second year on the trend of usage will be added) - POP database - regularly report - EVIDENT- regularly report - Core HTA information database - Adaptation toolkit	WP5 (?)	WP3 LP/AP
M24 Sep' 14	M25 Oct' 14	collection of available information on collaboration in the context of EUnetHTA, interviews about cases of collaboration	EUnetHTA Partners and Associates	WP3 LP/AP/CP
M24 Sep' 14	M25 Oct' 14	preparation of reporting the results	WP3 LP/AP/CP	WP3 LP/AP/CP

Activity: Quality assessment process				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M24 Sep' 14	M25 Oct' 14	Evaluating the project progress and its timely attainment of the milestones, deliverables, etc. Findings will be included in the interim report	WP LP	WP3 LP/AP
M24 Sep' 14	M25 Oct' 14	The interim/final reports will be used (addtional interviews if needed) for - Qualitative assessment of the review process utilized in each pilot project - Assessment of the transfer of the core HTA information into the national/regional report - Conflict of interest process review, ie, how the conflict of interest was handled in the pilot-- Findings will be included in the interim report	WP LP	WP3 LP/AP

Year 3 (Oct 2014-Sep 2015)

Activity: Calculation of efficiency gains				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M36 Sep' 15	M36 Sep' 15	data collection: number of person days per individual (besides the costs expressed in relevant currency) (WP3 will use the financial and tech report data collected by the Secretariat via annual interim reporting process of all EUnetHTA partners) The Secretariat will provide an aggregated financial data	all EUnetHTA partners	WP1(data providing)/ WP3 LP/AP/CP
M36 Sep' 15	M36 Sep' 15	data quality assurance (including re-assurance)	WP3	WP3 LP/AP/CP
M36 Sep' 15	M36 Sep' 15	Calculation of the efficiency gain and reporting (this preliminary report will - after review and adjustment - be included in the second interim report. Key findings could be included in the newsletter)	WP1	WP3 LP/AP/CP
M36 Sep' 15	M36 Sep' 15	collection of available information on pilots from WP4 and 5, interviews about cases of local pilot-transformation	WP4 and WP5	WP4 LP, WP5 LP WP3 LP/AP/CP
M36 Sep' 15	M36 Sep' 15	writing the final report - will include the different reports of all activities of WP3	WP3	WP3 LP/AP/CP

Activity: Auditing of the progress in implementation of JA2 as per the JA agreement and verifying if it is on course to achieve its objectives				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M31 Apr' 15	M32 May 15	conception and coordination of 3rd WP3 yearly survey for EUnetHTA Partners and Associates	WP1 (survey needs of other WPs); WP3	WP1, WP3 LP/AP
M32 May 15	M32 May 15	preparing and announcing 3rd WP3 yearly survey for EUnetHTA Partners and Associates		WP3 LP/AP
M33 Jun' 15	M33 Jun' 15	start 3rd WP3 yearly survey for EUnetHTA Partners and	EUnetHTA	WP3 LP

		Associates and reminder after 2 weeks	Partners and Associates	
M34 Jul' 15	M35 Aug' 15	analysis of results of the 3rd WP3 yearly survey for EUnetHTA Partners and Associates and reporting	WP3 LP/AP	WP3 LP/AP
M31 Apr' 15	M32 May 15	conception and coordination of 3rd WP3 yearly survey for stakeholders	WP3 LP/AP	WP3 LP/AP
M32 May 15	M32 May 15	preparing and announcing 3rd WP3 yearly survey for stakeholders	stakeholder /WP3 LP/AP	WP3 LP/AP
M33 Jun' 15	M33 Jun 15	start 3rd WP3 yearly survey for stakeholders and reminder after 2 weeks	stakeholder	WP3 LP/AP
M34 Jul' 15	M33 Aug' 15	analysis of results of the 3rd WP3 yearly survey for stakeholders and preparation of reporting	WP3 LP/AP	WP3 LP/AP
M34 Jul' 15	M35 Aug' 15	start of writing the final report (for Commission, feedback for all WPs)	WP1, Commission, EUnetHTA Partners and Associates	WP3 LP/AP

Activity: Capturing cross-border collaboration activities of the "spin-offs/add-ons" in the network as the outcome of the EUnetHTA activities

Start	End	Activity steps	Target group	Parties involved
M35 Aug' 15	M36 Sept' 15	capture the utilization of EUnetHTA tools and included in the report at yearly level (from the second year on the trend of usage will be added) - POP database - regularly report - EVIDENT- regularly report - Core HTA information database - Adaptation toolkit	WP5 (?)	WP3 LP/AP
M35 Aug' 15	M36 Sept' 15	collection of available information on collaboration in the context of EUnetHTA, interviews about cases of collaboration	EUnetHTA Partners and Associates	WP3 LP/AP/CP
M35 Aug' 15	M36 Sept' 15	preparation of reporting the results	WP3 LP/AP/CP	WP3 LP/AP/CP

Activity: Quality assessment process

Start	End	Activity steps	Target group	Parties involved
M35 Aug' 15	M36 Sept' 15	Evaluating the project progress and its timely attainment of the milestones, deliverables, etc. Findings will be included in the final report	WP LP	WP3 LP/AP
M35 Aug' 15	M36 Sept' 15	The interim/final reports will be used (additional interviews if needed) for - Qualitative assessment of the review process utilized in each pilot project - Assessment of the transfer of the core HTA information into the national/regional report - Conflict of interest process review, ie, how the conflict of interest was handled in the pilot-- Findings will be included in the final report	WP LP	WP3 LP/AP

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery** (i.e. online or e-mail)	**Coordination with other WPs** (Yes/No – if yes which WP)
June 2013 (M9)	WP3 first yearly survey for EUnetHTA Partners and Associates on effectiveness of internal communication/cooperation, needs, requirements, user satisfaction and lessons learned	EUnetHTA Partners and Associates	online	WP1, WP6
June 2013 (M9)	WP3 first yearly stakeholder survey on perception, awareness and lessons learned	Stakeholder	online	WP1, WP6
June 2014 (M21)	WP3 second yearly survey for EUnetHTA Partners and Associates on effectiveness of internal communication/cooperation, needs, requirements, user satisfaction and lessons learned	EUnetHTA Partners and Associates	online	WP1, WP6
June 2014 (M21)	WP3 second yearly stakeholder survey on perception, awareness and lessons learned	Stakeholder	online	WP1, WP6
June 2015 (M33)	WP3 third yearly survey for EUnetHTA Partners and Associates on effectiveness of internal communication/cooperation, needs, requirements, user satisfaction and lessons learned	EUnetHTA Partners and Associates	online	WP1, WP6
June 2015 (M33)	WP3 third yearly stakeholder survey on perception, awareness and lessons learned	Stakeholder	online	WP1, WP6

4.4.1 Stakeholder involvement

- distribute the evaluation plan and the deliverables to the Stakeholder Forum members for review and comments
- collect inputs in the WP3 stakeholder surveys
- we do not install and run a SAG (reason: not in budget, no persons)

4.4.2 Public Consultation

Not planned for the internal evaluation.

4.4.3 Conflict of interest

For WP3 members the Declaration of Interest will be collected using the standard of EUnetHTA JA2 Conflict of Interest Policy. The COIs will be stated in the reports of WP3. We will collect them once including a statement for renewing-duty if contents changed.

Handling of conflict of interest will be reported based on the activity (quality assessment).

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP3 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP3 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP3.

4.4.5 Quality assurance procedures

- Peer review inside WP3: results produced by one member will be reviewed by one member of another agency and have to be committed by all WP3 participants

- Communication of delays, lessons learned and best practice: we will produce some kind of newsletter to all WP leaders including short information of our yearly results (especially for trends of tools usage, trends of JA2 benefit anaylsis in the current status, and interesting lessons learned out of the survey answers to be included in the work process)

- Problem communication: delivery of the data in time; other problems (what and to whom is to be specified by the problem - if none occurs - we will not do it)

4.4.6 National HTA Report Production

WP3 will not directly contribute to the national HTA report production, but will monitor and count

- national HTAs using POP, EVIDENT or parts of the network results

- network HTAs (via surveys)

4.4.7 Cooperation with other WPs / LPs

- cooperation with all WP LPs for interviews/surveys

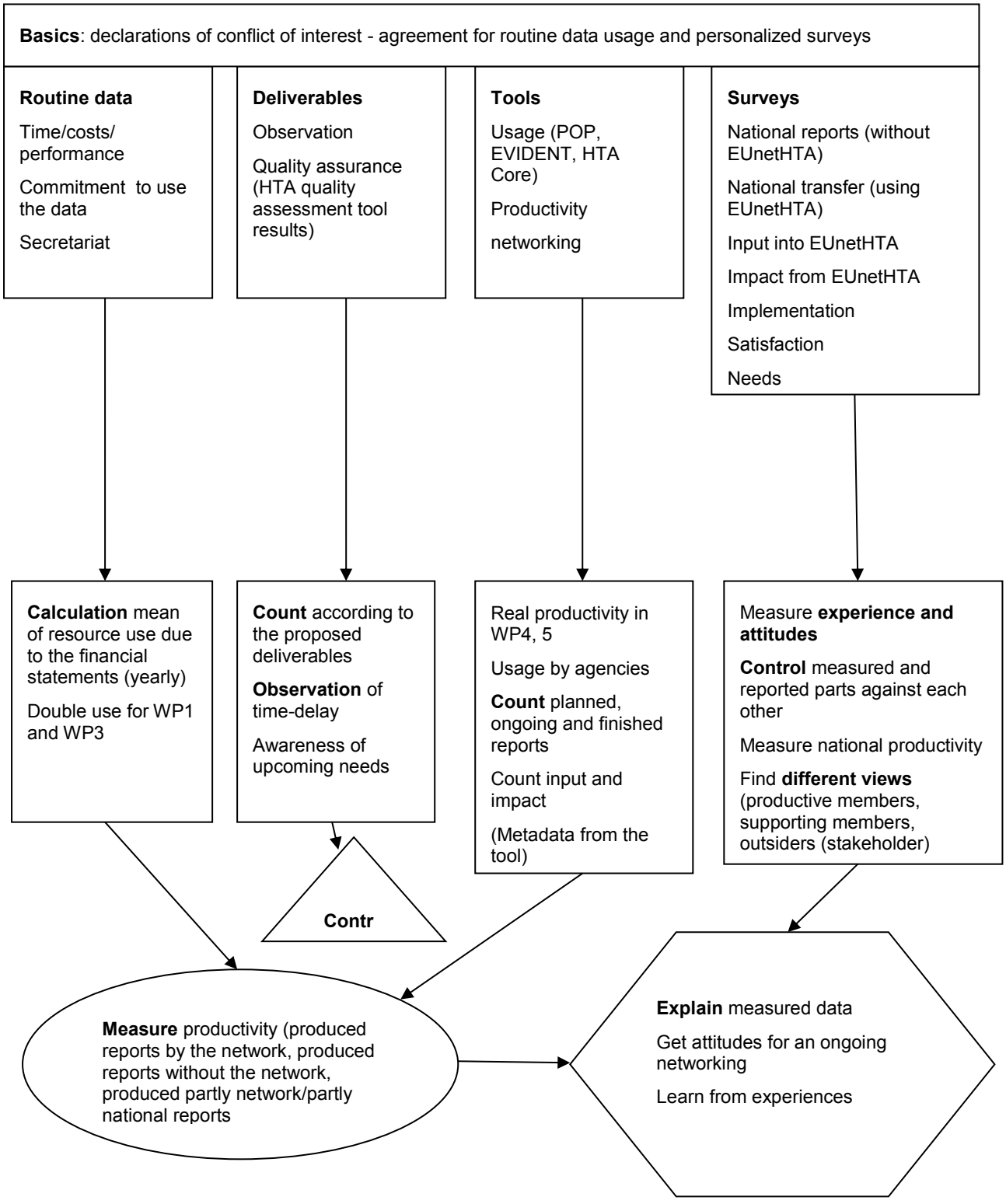
5. Dissemination plan

We will not disseminate our results directly to external partners.

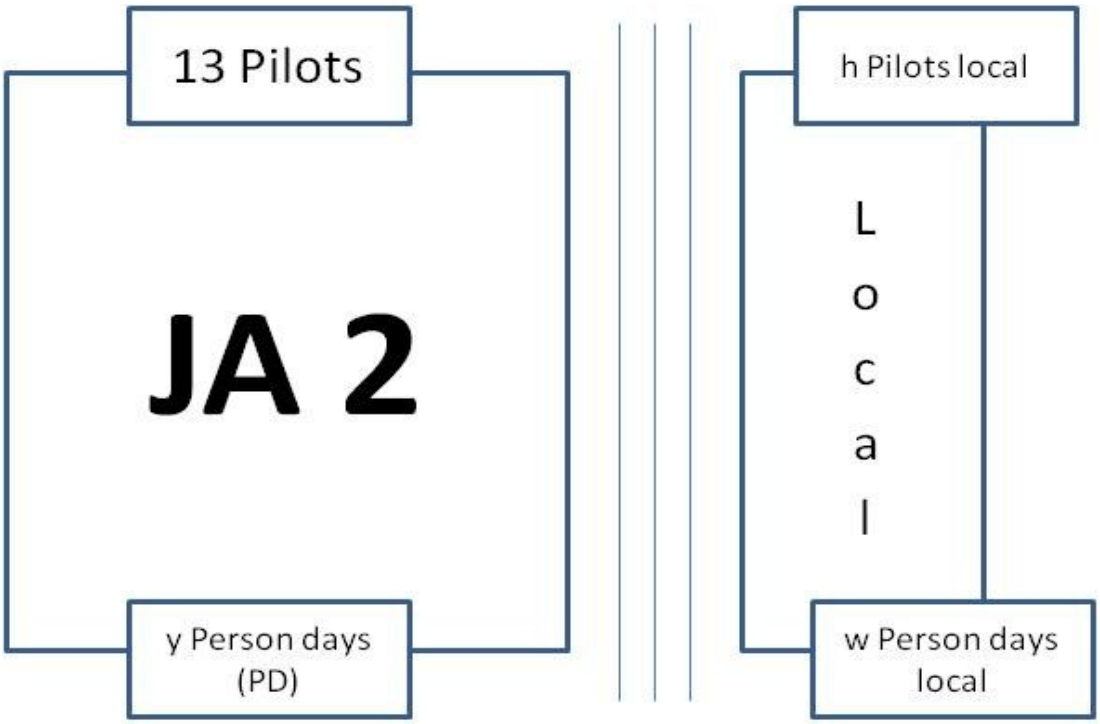
Our results/ reports are provided via WP1.

6. Appendices

Graph 1 – Detailed plan of action(s)



Graph 2 – Calculation method



Pilot x = n PD
„Localisation"/Pilot = m PD

Time used Member State (MS) 1 = €/PD
.
.
.
MS n

Total cost of local HTA = cost of JA2 pilot + cost for localisation
Added value (saving) = ∑s local HTAs – (s-1)*JA2 pilot

h,y,w,x,n,m,s – variables counted

Joint Action 2 on HTA 2012-2015

Work Package 4

Core HTA

3-year Work Plan

May 1, 2013

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1. WP title

Work Package 4 – Testing collaborative production of HTA information for national adaptation and reporting

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	**Description of responsibilities and input**
• Lead Partner Agenas (Agenzia Nazionale per I Servizi Sanitari Regionali)	General WP coordination Member of the EUnetHTA Executive Committee; preparation of the WP interim and final technical reports; LP follows the LP's responsibilities as described in the EUnetHTA JA Methodological Standards and Procedures Will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
• Co-Lead Partner: N/A	N/A
Associated partners – AP (18 partners)	
1. Gesundheit Österreich GmbH/Geschäftsbereich BIQG/GÖG (Austria) 2. Hauptverband der Österreichishen Sozialversicherungsträger, HVB (Austria) 3. National Center of Public Health and Analyses, NCPHA (Bulgaria) 4. Agency for Quality and Accreditation in Health Care and Social Welfare, AAZ (Croatia) 5. Danish Health and Medicines Authority, DHMA (Denmark) 6. Tartu University Department for Public Health UTA (Estonia) 7. National institute for health and welfare, THL (Finland) 8. Direction générale de Santé/ Haute Autorité de Santé, HAS (France) 9. Deutsches Institut für Medizinische Dokumentation und Information, DIMDI (Germany) 10. National School of Public Health NSPH (Greece) 11. Regional Agency for health and social care – Emilia Romagna (Italy) 12. Regione Veneto (Italy) 13. Ministère de la sécurité sociale Inspection générale de la securité sociale Cellule d'expertise médicale, CEM (Luxembourg) 14. National Authority of Medicines and Health Products, INFARMED (Portugal) 15. National School of Public Health, Management and Professional Development NSPH MPD (Romania) 16. Institute of Economic Research, IER (Slovenia) 17. National Institute of public health, NIPH (Slovenia) 18. Instituto de Salud Carlos III, ISCIII (Spain)	Associated partners are expected to collaborate in all tasks of WP4 including: • Drafting a "Methodological Standards e Procedures" for collaborative Core HTA information production • Topic selection process • Core HTA information production • Production of national/local HTA report using Core HTA information Involvement in each task will be agreed with LP according to the level of activity (less active or more active partner), to the expertise of each partner and their internal resources and to the amount of person/days for Work Package 4 in the Grant Agreement Will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement

19. Swedish Council on Health Technology Assessment, SBU (Sweden)	
Collaborating partners – CP (8 partners)	
1. Medical University of Sofia (Bulgaria) 2. Centre for Economic and International Studies. University of Roma Tor Vergata (Italy) 3. Laziosanità – Agenzia di Sanità Pubblica, Regione Lazio (Italy) 4. University Hospital "A. Gemelli" (Italy) 5. Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, AETSA (Spain) 6. AVALIA-t, Galician Agency for HTA Assessment (Spain) 7. Basque Office for HTA, Osteba (Spain) 8. Swiss Federal Office for Public Health (Switzerland)	Collaborating partners are expected to participate actively in all the tasks of WP4 and in the production of three new Core HTAs. According to their expertise Collaborating partners will be involved also in piloting national adaptation of core HTA information and reporting. CPs will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 S SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement
Other Parties	
All EUnetHTA partners	Participation in validation surveys Participation in the topic selection process Participation in implementing the use of core HTA information for national reporting EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
EUnetHTA Stakeholders	Participation in public feedback mechanisms Participation in Stakeholder Advisory Groups (SAG) Participation in Topic Selection procedures (call for interest)

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: www.eunethta.eu

3. Objectives

Title	Description	Indicators
Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network).	A number of core HTAs and rapid HTA information based on the core model structure and its abridged version for rapid assessments (i.e. the first 4 domains) will be produced. The assessments produced will be used for local (i.e. national, regional) reports fo inform decision-making. Data will be collected on costs and overall efficiency.	Production of HTA structured information: at least 3 full Core HTAs, at least 14 rapid assessments[4] (10 for drugs and 4 for non-drug technology), at least 20 national HTA reports with use of tools and information from Joint Action 2 (JA2).

[4] Please note that rapid assessments will be performed by WP5

Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function	To provide guidance and testing in identifying and organising collaborations between partners for setting up a specific collaboration (i.e. around an assessment topic).Coordinating function of various activity clusters and overall partnership coordination will be further developed and streamlined.	Methodological Standards and Procedure for collaboration, including identification of partners and clusters of organisations for specific topics, issued.

4. Organization of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
First draft of Methodological Standards and Procedures for partners' collaboration	M08 (May 2013)
1st core HTA	M14 (Nov 2013)
Final version of Methodological Standards and Procedures for partners' collaboration	M15 (Dec 2013)
2nd core HTA	M23 (Sep 2014)
3th core HTA	M34 (Jul 2015)

Deliverables	Deadline
Full Core HTAs • 1st Core HTA A new Core HTA on topic chosen with a specific and shared procedure; the Core HTA production involves different HTA Agencies (APs & CPs) with different roles and duties (Primary Investigator, Investigator, Reviewer) • 2nd Core HTA A new Core HTA on topic chosen with a specific and shared procedure; the Core HTA production involves different HTA Agencies (APs & CPs) with different roles and duties (Primary Investigator, Investigator, Reviewer) • 3rd Core HTA A new Core HTA on topic chosen with a specific and shared procedure; the Core HTA production involves different HTA Agencies (APs & CPs) with different roles and duties (Primary Investigator, Investigator, Reviewer)	M14 M23 M34

4.2 Methods

Preparatory Activities

As some activities have to be completed before the effective start of the Core HTA production, members of Work Package 4 will be divided in 3 working groups basing on their interest and expertise; all WP4 partners can join the one (or more) group on a volunteer basis.

- **WG1 – Topic selection process**
  This group will focus on drafting the methodological process of topic identification, prioritisation and selection for Core HTA information production. This guide will be part of the WP4- Methodological Standards and Procedures (MSP) for collaboration (please see the WG2)

- **WG2 – Methodological Standards and Procedures (MSP) for collaboration**
  Members of this group will be identified among researchers participating in Work Package 4 with the aim of crafting methods and procedures for Core HTA information production.
  There will be regular meeting or e-meeting just after the start of the JA2; the group will be composed of at least 5 researchers with an active role and experience in Core HTA production in Joint Action 1 (JA1) Work Package 4, participating in JA2, plus 2 members from the WP4 Lead Partner ("co-opted members");
  Basing on the previous experiences from EUnetHTA Joint Action 1 Work Package 4, the working group will develop a first draft of the MSP that will include:

  - Methods for identification of Domain teams through a call of interest among WP4 partners
  - Methodological guidance for domains EFF, SAF, ECO based on current international best practice and empirical evidence of bias containment or minimisation
  - Methodological guidance for other domains (e.g. CUR, TEC, LEG) will be crafted with the collaboration of Primary Investigators (PIs) of the previous project (JA1).
  - Methods for a common search of references and use of reference manager software.
  - Regular MSP updating rules

  Please see Appendix 1 for the **Methodological Standards and Procedures (MSP)** Outline Draft Index.

  The document will be created during the first months of the EUnetHTA Joint Action 2 before and simultaneously with the production of the first Core HTA (M14); feedback and comments from active partners involved in the Core HTA production during JA1 will be included in the MSP and shared in cross-WPs collaboration.

  A review process of the MSP will be developed for updating and amending the guidance basing on the experiences of Core HTA producers.

- **WG3 – Local/National report piloting**

  This group will deal with the methodological issues related to the piloting of local/national report using and producing Core HTA information ("Any information on a technology that has been produced through using the HTA Core Model and published through the HTA Core Model Online. This information is very likely to be useful in the European context (i.e. also in another country) due to its importance and/or transferability"). For more detailed information please see "HTA Core Model online handbook: https://fio.stakes.fi/htacore/ViewHandbook.aspx).

  Using collections of Core HTA information combined with locally produced information, at least 20 local/national reports by members of Work Package 4 will be piloted. Partners will be actively involved in producing national reports using available EUnetHTA tools.

  To this aim the use of available EUnetHTA tools (Online Tools & Service, Adaptation toolkit, etc.) will also be supported by training activities by WP2 and WP8. Such tools will help EUnetHTA partners to avoid duplication of work and thus to save money and time in production of local HTA information.

WG1 and WG2 will remain active till the final draft of MSP will be released (M15), WG3 will continue its activity giving support to national reporting (see par 4.4.5).

Methodological documents available from JA1 will be used as basis for MSP development.

HTA information production - Project Management

As scheduled in this Work plan, a complete set of three Core HTA will be produced by WP4 Partners; each core HTA will be produced individually. The 1st core HTA will be produced mainly using the previous experiences in the Joint Action1 as the MSP will be under development; a topic selection call will be made and feedback collected from WP4 partners, Stakeholders and other interested institution (DG Sanco), considering also results from the POP database.

The last version of POP database will be explored as source for topic selection in collaboration with WP6.

In addition, a prioritisation procedure will be used to improve the relevance of topics selected.

After the topic selection process, a call for Domain Teams will be carried out through WP4 Partners and then a related domain team composition will be made. A Collaborative Model (ColMod) will be chosen considering the experiences in the

Joint Action 1 so that each core HTA could be produced using Collaborative Model 1 (ColMod 1) (each Domain team is composed of researchers from different WP4 Partner) or ColMod2 (each domain will be carried on by a single Agency).Considering the different impact on workload of participant institutions, the collaborative model will be chosen according to the interest on the prioritized topic, expertise and manpower availability of partners for specific domains.

Each domain team will be formed taking into account the preferences, expertise and availability of researchers from WP4 members; a Primary Investigator (PI) will be identified within each Domain Team and she/he will have the responsibility for coordinating the works in the domain. Other tasks for PI include: regular feedback to LP for working progress, planning of co-operation with other investigators, leading the Domain protocol definition (i.e.: specific domain scope and framing, assessment elements selection, etc.).

Each team will include also at least 1 more Investigator (I), but preferably at least 2 more researchers should be involved. This is especially important for EFF and SAF Domains, which 3rd systematic reviewer should be involved in case of uncertainty during the Systematic Review process. Investigator and researchers should work in coordination with PI, taking an active role in the production of each result card.

For each Domain at least 1 Reviewer (R), but preferably 2 or more, will be identified; Reviewers will give feedback and comments to PI and I(s) on protocol definition, domain scope and frame, result cards production.

In the case that ColMod1 will be chosen, Primary investigator and Investigator(s) will be from different WP4 member Agency, in this case, it will be essential a regular communication among researchers for a reliable and effective working and to avoid wasting of time and duplication of work. On the contrary, if ColMod2 will be chosen, PI and I(s) will be from the same Agency so it will be essential the communication with other domains for production of homogeneous information.

Procedures and working organization will be shared with the 9 Domain Teams, as well a working programme that will also include regular e-meeting within each Domain Team.

An Editorial Team will be organized for each Core HTA, composed by PIs and chaired by LP organisation.

The Editorial Team will deal with major decisions on basic principles and solutions related to the content of core HTA.

Core HTA 1-2-3 Domain teams		**ColMod 1 One domain/more Agencies**	**ColMod 2 One Agency/one domain**
Domain teams 1-9	**1 PI**	**2 or more Investigators**	**2 or more Reviewers**
Editorial teams	**9 PIs+LP**		

Documents will be shared through the facilities available at EUnetHTA website.

It could be foreseen to carry out 3 surveys related to the topics under assessment during the core HTA production phases, in order to gather information (if needed) on the current use and the spreading of the technologies. Surveys will be carried out through EUnetHTA available tools (i.e. website) or external on-line resources already used during JA1 (i.e.: Survey Gizmo).

Another survey will be carried out to map local procedures for HTA activities in order to pilot national reporting.

Piloting of local/national reports using Core HTA information will be carried out simultaneously with the Core HTAs production according to a predefined work plan (see par.4.4.5). The WG3 above mentioned will facilitate the activities.

On-line Tool and Service (www.corehta.info) will be used for production and finalization of the 3 Core HTAs that will be delivered accordingly to the 3-year Work Plan, feedback on the Tool will be delivered to WP8.

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
1st week March 2013	Rome	1	30 researchers divided among participating APs + CPs + 4LP	WP4 F-t-F Meeting 1 will focus on • 1st draft of MSP • Topic selection procedures • 1st Core HTA production
October 2013	Zagreb	1	30 researchers divided among participating APs + CPs + 4LP	WP4 F-t-F Meeting 2
April 2014	Vienna	1	30 researchers divided among participating APs + CPs + 4LP	WP4 F-t-F Meeting 3
May 2015	Rome	1	30 researchers divided among participating APs + CPs + 4LP	WP4 F-t-F Meeting 4

Regular e-meeting will be held for each Sub-group. At least 1 e-meeting each 6 months for general updates but up-to 1 e-meeting each month during more active periods (i.e.: core HTA production)

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Activity: Core HTA Production and management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M8 May '13	Development of a draft of MSP to give methodological guidance for European cooperation on HTA through the use of Core Model in HTA collaborative production and related methodological issues for partner collaboration	Core HTA producers	WP Members
M4 Jan '13	M5 Feb '13	Topic selection procedure for the **1st Core HTA** and following topic selection	WP4 members	WP Members SAG DG Sanco
M5 Feb '13	M6 Mar '13	Organisation of cluster of agencies for Core HTA Production (**1st Core HTA**)	WP4 members	WP Members
M6 Mar '13	M12 Sep '13	**1st Core HTA** Starting production: protocol, 1st draft,	WP4 members	WP Members
M8 May '13	M8 May '13	First draft of MSP for collaborative Core HTA production	EUnetHTA members	WP Members
M11 Aug '13	M12 Sep '13	Topic selection procedure for the **2nd Core HTA** and following topic selection	WP4 members	WP Members SAG DG Sanco
M12 Sep '13	M12 Sep '13	Organisation of cluster of agencies for Core HTA Production (**2nd Core HTA**)	WP4 members	WP Members
M6 Mar '13	M12 Sep '13	Pilot production of national HTAs : analysis of local procedures, facilitation to produce core HTA structured information, national HTA reports (from Core HTAs)	EUnetHTA members	WP Members

Year 2 (Oct 2013-Sep 2014)

Activity: Core HTA Production and management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct '13	M14 Nov '13	**1st Core HTA** validation	Core HTA producers	WP Members SAG
M13 Oct '13	M14 Nov '13	Organisation of cluster of agencies for Core HTA Production (**2nd Core HTA**)	WP4 members	WP Members
M13 Oct '13	M13 Oct '13	1st year Interim report	EUnetHTA members	LP
M15 Dec '13	M15 Dec '13	Final version of MSP for collaborative Core HTA production	EUnetHTA members	WP Members
M15 Dec '13	M21 Jun' 14	**2nd Core HTA** Production: protocol, 1st draft,	WP4 members	WP Members
M22 Jul '14	M22 Jul '14	**2nd Core HTA** validation	Core HTA producers	WP Members SAG
M13 Oct '13	M24 Sep '14	Pilot production of national HTAs : analysis of local procedures, facilitation to produce core HTA structured information, national HTA reports (from Core HTAs)	EUnetHTA members	WP Members
M22 Jul '14	M23 Aug '14	Topic selection procedure for the **3rd Core HTA** and following topic selection	WP4 members	WP Members SAG DG Sanco
M23 Aug '13	M24 Sep '14	Organisation of cluster of agencies for Core HTA Production (**3rd Core HTA**)	WP4 members	WP Members

Year 3 (Oct 2014-Sep 2015)

Activity: Core HTA Production and management				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	M25 Oct '14	2nd year Interim report	EUnetHTA members	LP
M26 Nov '14	M32 May '15	**3rd Core HTA** Production: protocol, 1st draft,	WP4 members	WP Members
M33 Jun '15	M33 Jun '15	**3rd Core HTA** validation	Core HTA producers	WP Members SAG
M25 Oct '14	M35 Aug '15	Pilot production of national HTAs : analysis of local procedures, facilitation to produce core HTA structured information, national HTA reports (from Core HTAs)	EUnetHTA members	WP Members
M35 Aug '15	M36 Sep '15	Final reporting	EUnetHTA members	

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery** (i.e. online or e-mail)	**Coordination with other WPs** (Yes/No – if yes which WP)
M6	Survey on HTA national procedures	WP partners	online	NO
M7-M8	Core HTA 1 – Technology	SAG/SF EUnetHTA partners Manufacturers	online	WP1
M16-M17	Core HTA 2 – Technology	SAG/SF EUnetHTA partners Manufacturers	online	WP1
M27-M28	Core HTA 3 – Technology	SAG/SF EUnetHTA partners Manufacturers	online	WP1

4.4.1 Stakeholder (STK) involvement

Stakeholders will be involved in different ways, steps of work and time in WP4 activities, as shown in the following table, according to EUnetHTA Stakeholder Involvement Policy, Methodological Standards and Procedure (MSP) and needs expressed by domain teams.

Four different ways of Stakeholders involvement will be through:

1. Stakeholder advisory group (SAG)
2. Specific product assessments
3. Public consultation

After the 1st full Core HTA pilot has been conducted, if needed, it may be organized an 1 day expert meeting with STKs and experts to discuss and share the experience/lessons learned from the first pilot assessments; this meeting may be organized during one of the already scheduled meeting in JA2 whit STKs presence.

Timing (preliminary)	**Purpose**	**Type of input from SAG**	**Input from SAG to be used for…**
2013 Jan-Feb	Topic selection and prioritization procedures draft (Core HTA 1)	List of technologies of interest and prioritization	Creation of a consolidated list of technologies to be selected for Core HTA production
2013 Apr-May	1st core HTA protocol validation	Comments and Feedback on the Core HTA 1 protocol	Feedback will be used to improve protocol
2013 Oct-Nov	1st draft of 1st core HTA validation	Comments and feedback on draft of the 1st Core HTA	Feedback will be used to improve document .Experts from STK groups can be invited during activities according to the needs
2013 Aug-Sep	Topic selection procedure for the **2nd Core HTA** and following topic selection	List of technologies of interest and prioritization	Creation of a consolidated list of technologies to be selected for Core HTA production
2014 Jan	2nd core HTA protocol validation	Comments and Feedback on the Core HTA 1 protocol	Feedback will be used to improve protocol

2014 Jul -Aug	1st draft of 2nd core HTA validation	Comments and feedback on draft of the 2nd Core HTA	Feedback will be used to improve document .Experts from STK groups can be invited during activities according to the needs
2014Jul	Topic selection procedure for the **3rd Core HTA** and following topic selection	List of technologies of interest and prioritization	Creation of a consolidated list of technologies to be selected for Core HTA production
2014 Nov-Dec	3rd core HTA protocol validation	Comments and Feedback on the Core HTA 1 protocol	Feedback will be used to improve protocol
2015 Jun	1st draft of 3rd core HTA validation	Comments and feedback on draft of the 3rd Core HTA	Feedback will be used to improve document .Experts from STK groups can be invited during activities according to the needs
2013-2015	Updates on on-going activities	Suggestion to improve processes	Feedback will be used to improve and optimize production

4.4.2 Public Consultation

3 Core HTAs will be validated through a Public Consultation.

Comments and feedback from public consultation (as for the ones from Stakeholders) will be implemented in the final products.

Timing	Purpose	Target group	Info used for
2013 Nov	1st core HTA Public Consultation	Public	Comments and feedback will be implemented in the final deliverables (if relevant)
2014 Aug	2nd core HTA Public Consultation	Public	Comments and feedback will be implemented in the final deliverables (if relevant)
2015 Jul	3rd core HTA Public Consultation	Public	Comments and feedback will be implemented in the final deliverables (if relevant)

4.4.3 Conflict of interest

Conflict of interest will be managed as per the EUnetHTA JA2 Conflict of Interest Policy at the network and project level. Each Work Package member, as EUnetHTA partner (AP or CP) has the responsibility of declaring any possible conflict of interest in relation to the topics at stake. Partners should use common EUnetHTA JA2 Declaration of Interest form.

In case of use of external contributors during the Core HTA production, conflicts of interests related to the topics at stake will be recorded for each contributor (Manufacturer, external experts, patients, etc.) by LP.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP4 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities and pilots. Individual WP4 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP4.

4.4.5 Quality assurance procedures

A continuous quality assurance process will be set-up with a special regard to the Core HTA production phase through:

- MSP for collaborative HTA information production
- Validation process for Core HTA related products (Core HTA, collections, result cards, etc.)

WG2 will develop specific procedures that will be included into the MSP, systematic quality assurance procedures will be further developed in collaboration with WP 1,3,5,7,8.

4.4.6 National HTA Report Production

All WP4 Partners will be asked for availability to produce HTA national reports using EUnetHTA tools (Core Model Applications).The WG3 above mentioned will develop a plan for production of HTA national reports, using and producing core HTA information. The plan will be based on the available EUnetHTA tools and guidance.

Specific projects will be developed to facilitate partner :

- to produce both core HTA information and local information on prioritized topics, for national reporting.

- to produce both core HTA information and local information on topics of interest for national reporting

- to integrate core HTA information already available into national reports.

All the national pilots initiatives will be notified to LP and will be monitored and supported by the Working group.

Partners involved in national production will gather also data for WP3 evaluation.

4.4.7 Cooperation with other WPs / LPs

WP4 collaborates actively with WPs 5 (Testing partners' capacity to apply(ing) the HTA Core Model for Rapid Assessment in collaborative production of HTA information for national adaptation and reporting) to avoid duplication.

The use of on-line tool and service for full and rapid assessments should represent a base for piloting national reporting.

Methodological issues on core model applications use will be shared, to ensure consistency.

Feedback on the use of EUnetHTA tools will be provided to WP8 and WP6 for developments and to WP2 for training needs.

Data for evaluation by WP3 will be recorded.

A Coordination Working Group of WP4, WP5 and WP8 will be set up with the aim of producing feedback on the use of the development of Online Tool & Service for future development.

Work Package	Cooperation tasks
WP1	Coordination with other WPs Communication of piloting of national/local reports using Core HTA available information and tools
WP2	Feedback on the use of EUnetHTA tools from WP4 members for training needs definition, training material provision
WP3	Collaboration for evaluation procedure of Core HTA production phases and feedback from Core HTA producers on the use of Core HTA available tools
WP5	Coordination in Core HTA production to avoid duplications (with WP5 strand B).
WP6	Feedback on the use of IMS from WP4 members for future development
WP7	Feedback on guidelines topics Feedback on evidence generation needs (possible)
WP8	Feedback on the use of On-line tool & service from WP4 members for future development

5. Dissemination plan

Output	Format	Time
1st Draft of MSP for Core HTA information production	internal document	2013 (M08)
Final MSP for Core HTA information production	internal document	2014 (M15)
HTA information joint production: experiences from a collaborative network	presentation (EUnetHTA Conference)	2014
Report on WP4 activities	Presentation at HTAi meeting	2014
Report on WP4 activities	Presentation at HTAi meeting	2015
Scientific articles		2015

APPENDIX 1

EUnetHTA JA2 WP4

First draft of Methodological Standards and Procedures (MSP) for partners' collaboration

This document issues guidance on:

- topic selection
- research methods
- updating for JA2 WP4 researchers involved in Core HTA information production

The general objective of this document is primarily to promote high quality, efficient and effective scientific collaboration among the partners of JA2 WP4 (and secondarily among the wider group of all EUnetHTA Partners) sharing relevant methodological aspects.

Outline of content

Introduction

The story so far. [Background to the project with history, aims and evolution]

JA2 WP4 aims and production outputs [summary of why and what WP4 will produce]

Why produce guidance now [rationale for producing guidance on how to do things]

Description of the content and use of the JA1 feed-back. [how the JA1 feed back was incorporated in the guidance]

The overall objective is to issue guidance on four macro-areas that need to be addressed to carry out the task of WP4 during the JA2 with a view to the whole EUnetHTA

Aim 1

To agree and systematize the methodological principles to identify and select core HTA topics. ("topic selection guidance") [this may be a topic for the whole EUnetHTA]

Methods addressed

1. General issues: identifying topics [how to identify topics]
2. General issues: prioritizing topics [how to prioritise topics]
3. General issues: selecting topics [how to select topics]

Aim 2

To agree and issue guidance on the principles for an efficient and effective collaboration in developing and producing core HTA information within JA2 WP4

Methods

4. Composition and TORs of working subgroups [role and membership]
5. General issues: order of domain work [how to approach domain work and how to communicate across domains]
6. General issues: handling the electronic environment [how to use EUNeHTA electronic tools, training needs]
7. General issues: project management and forming teams [how to form teams]
8. General issues: Stakeholder consultation and validation [methods to involve stakeholders and carry out validation]
9. General issues: Dissemination [methods to disseminate content]
10. General issues: Updating [methods to update content]

11. General issues: national production [how to promote the use of core HTA information]
12. General issues: Feed back to and from other WPs and co-development of methods (e.g. WP5 on Rapid Core on REA of pharmaceuticals and devices).
13. constructing a scoping document and writing a core HTA protocol

General issues: Format of reporting, Conflict of interest disclosures and rules (Format for disclosure will be at project level to be developed by Secretariat and WP1/Executive Committee), Authorship rules, Acknowledgments, Glossary, Role of professional copy editors in the preparation of the documents and general editorial support.

Aim 3

To agree and systematize the methodological principles to produce core HTA information within JA2 WP4 ("methodological guidance"). [Domains for which reasonably robust and accepted methods exist] with a view to the whole EUnetHTA

Methods

14. General issues: carrying out evidence searches [how to construct, run, store and update searches]
15. Domain specific issues: Current use of the technology(CUR) [methods to produce domain content]
16. Domain specific issues: Description and technical characteristics of technology (TECH) [methods to produce domain content]
17. Domain specific issues: Safety of the technology (SAF) [methods to produce domain content]
18. Domain specific issues: Effectiveness of the technology (EFF) [methods to produce domain content]
19. Domain specific issues: Costs, economic evaluation of the technology (ECO) [methods to produce domain content]

Aim 4

To develop, test and validate methodological principles to develop core HTA content within JA2 WP4 ("methodological guidance"). [Domains for which reasonably robust and accepted methods are in development]

20. Domain specific issues: Ethical aspects of the technology (ETH) [methods to produce domain content]
21. Domain specific issues: Organisational aspects of the technology (ORG) [methods to produce domain content]
22. Domain specific issues: Social aspects of the technology (SOC) [methods to produce domain content]
23. Domain specific issues: Legal aspects of the technology (LEG) [methods to produce domain content]

Several topics would require wider input and decision than those of WP4 members, to ensure adequate expertise input from EUnetHTA Partners will be pursued, primarily through cross-WPs coordination.

Joint Action 2 on HTA 2012-2015

Work Package 5

Apply(ing) the HTA Core Model for Rapid Assessment for national adaptation and reporting

3-year Work Plan

May 1, 2013

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1. WP title

Work Package 5 – Apply(ing) the HTA Core Model for Rapid Assessment for national adaptation and reporting

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
• Lead Partner: College voor zorgverzekeringen (CVZ) • Co-Lead Partner: Ludwig Boltzmann Institut – Health Technology Assessment (LBI-HTA)	CVZ and LBI-HTA will be the primary responsible organisations for the preparation of the proposal for this function in EUnetHTA JA2. The operational secretariat/project group will exist of eight persons (four from LBI-HTA and four from CVZ). The primary contact person will be the project coordinator at CVZ. CVZ will coordinate strand A. LBI will coordinate strand B. Lead Partner: Member of the EUnetHTA JA2 Executive Committee; preparation of the WP interim and final technical reports; LP will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement Co-Lead Partner: Member of the EUnetHTA JA2 Executive Committee with conditional voting rights (when the rights are delegated by LP); facilitates preparation of the WP interim and final technical reports; Co-LP will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
Associated partners – AP (27 partners)	
1. CVZ (Netherlands) 2. LBI-HTA (Austria) 3. HVB (Austria) 4. BIQG/GÖG (Austria) 5. KCE (Belgium) 6. MoH (Cyprus) 7. MoH (Czech Republic) 8. AAZ (Croatia) 9. CR.DK (Denmark) 10. FIMEA (Finland) 11. THL (Finland) 12. HAS (France) 13. IQWIG (Germany) 14. GYEMSZI (Hungary) 15. HIQA (Ireland) 16. Agenas (Italy) 17. Regione Veneto (Italy) 18. AIFA (Italy) 19. NHS (Latvia) 20. VASPVT (Lithuania) 21. MoH (Malta) 22. NOKC (Norway) 23. AHTAPol (Poland) 24. INFARMED (Portugal) 25. SLOVAHTA (Slovakia) 26. NIPH (Slovenia) 27. ISCIII (Spain)	AP will participate in face to face meetings and (co-) produce pilot rapid assessments, review pilot rapid assessments, and adapt pilot assessments into national/local reports. They will support communication about the information system in their own institution and transmit specific requests. AP will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement There will be close collaboration with WP7 which will be further developing guidelines and a submission file template and with WP8 which will be further developing the online tool and service and an HTA Core Model for pharmaceuticals. In order to reduce duplication in production of manuals, guidelines, evaluation forms etc., there will be collaboration with WP4 and other WPs. Collaboration with WP3 is planned in terms of evaluation of WP5 products.

Collaborating partners – CP (15 partners)	
1. Donau Universität Krems (Austria) 2. RIZIV (Belgium) 3. Medical University of Sofia (Bulgaria) 4. KORA (Denmark) 5. Interdisciplinary Centre for Health Technology Assessment (HTA) and Public Health, University of Erlangen-Nuremberg, National BMBF-Cluster of Excellence ‚Medical Technologies - Medical Valley EMN' (Germany) 6. Laziosanità (Italy) 7. University Hospital "A. Gemelli (Italy) 8. NCHTA (Russia) 9. Healthcare Improvement Scotland (Scotland) 10. AETSA (Spain) 11. DGCF MSSSI (Spain) 12. Basque Office for HTA (Spain) 13. CAHIAQ (Spain) 14. Swiss Federal Office for Public Health (Switzerland) 15. KDTD (Turkey)	CP will participate in face to face meetings and (co-) produce pilot rapid assessments and/or review pilot rapid assessments, and/or adapt pilot assessments into national/local reports. CP will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 S SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement
Other Parties	
All EUnetHTA partners	EUnetHTA partners will be informed on the progress and results of the WP5 work and encouraged to apply the outcomes in the relevant national/local processes and inform WP5/ EUnetHTA Secretariat on the experience. EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
EUnetHTA Stakeholders	The input of EUnetHTA Stakeholders will be in the form of public consultations on the final versions of HTA Core Models for Rapid REA (pharmaceuticals and other health technologies). Stakeholder Advisory Group (SAG) will be consulted on the draft of the HTA Core Model for Rapid Relative Effectiveness Assessment (REA) and procedure manuals. For Strand A pharmaceutical companies will participate in the pilots by providing submission files and will be invited to a scoping meeting. For Strand B there will be an inquiry to respective medical device manufacturers on information (e.g. C/E mark, on-going studies, and completed studies). In addition, the SAG, the manufacturer(s) and public will be invited to comment on the draft Project Plans for every pilot rapid assessment which will be made accessible on the EUnetHTA website for a period of 10 days. Further, the manufacturer(s) will also be involved in the consultation phase.

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: www.eunethta.eu

3. Objectives

Title	Description	WP5 specific deliverables
Test the capacity of national HTA bodies to produce structured core HTA information (full core/rapid HTAs) together and apply it in national context (including collection of data on costs and overall efficiency of the production in the network).	A number of core HTAs and rapid HTA information based on the core model structure and its abridged version for rapid assessments (i.e. the first 4 domains) will be produced. These assessments will address a range of technologies (e.g. drugs, devices, interventions, procedures). The assessments produced will be used for national/local reports to inform decision-making. Data will be collected on costs and overall efficiency.	The specific deliverables of WP5 are pilot rapid assessments: a total of 14 pilot assessments (10 on drugs and 4 on other medical devices, surgical interventions or diagnostics) containing rapid HTA information based on structured core information from the HTA core Model

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
Coordinating and supporting the joint pilots of rapid assessments of pharmaceuticals (strand A) and non-pharmaceuticals (strand B): • Start of development of procedure manual for pilot rapid (strand A & B) • Start of first pilot rapid assessment, including selection of topic (strand A & B)	M3: Dec '12
Coordinating and supporting the joint pilots of rapid assessments of pharmaceuticals (strand A) and non-pharmaceuticals (strand B) • Start of pilot rapid assessments 2-10 including selection of topic (strand A) • Start of pilot rapid assessments 2-4 including selection of topic (strand B)	M6: Mar '13
Coordinating and supporting the joint pilots of rapid assessments of pharmaceuticals (strand A) and non-pharmaceuticals (strand B) • Discussion and evaluation of on-going pilots at f-t-f meeting in Vienna	M9: Jun '13
Coordinating and supporting the joint pilots of rapid assessments of pharmaceuticals (strand A) and non-pharmaceuticals (strand B) • Discussion and evaluation of on-going pilots at f-t-f meeting in Helsinki	M21[5]: Jun '14
Final rapid model for relative effectiveness of pharmaceuticals and rapid core model for non-pharmaceuticals (in cooperation with WP7)	M35: Aug '15

[5] This milestone was changed from M13 to M21 as the latter is the timing of the 3rd f-t-t meeting of WP5 JA2 in which the accumulated experience with pilots will be discussed resulting in further adaptation and/or refinement of the process and templates for doing these pilots.

Deliverables	Deadline
Pilot rapid assessments: • A total of 14 pilot assessments (10 on drugs and 4 on other medical devices, surgical interventions or diagnostics) containing rapid HTA information based on structured core information from the HTA core Model.	M1-M36

4.2 Methods

Introduction

WP5 is an output (products) oriented work package in order to prove the capacity of cooperation for increased efficiency of European HTA-production and avoid duplications.

Pilot rapid assessments will be produced in order to critically review the applicability of the work already accomplished by JA1 WP5 and WP7B in 2010-2012.

The work package will be divided into two major subgroups:

1. STRAND A: assessments on pharmaceuticals (10 pilot assessments);
2. STRAND B: assessments on other health technologies such as medical devices, surgical interventions or diagnostics (4 pilot assessments).

APs will further be split according to workload/tasks/budget into active groups and less active groups. The participation into active and less active groups will influence the level of involvement of each partner. Active partners will operate as authors and co-authors of the pilot assessments. Less active partners will operate as dedicated reviewers of the pilot assessments.

The production of the pilot rapid assessments in JA2 will be built upon the experiences with the HTA Core Model for Rapid REA of pharmaceuticals in WP5 of JA1 and on other hands-on experiences with a number of assessments on pharmaceuticals and medical devices that were produced as a spin-off of the work on the POP database.

Tasks

Within WP5, the capacity of national/local HTA bodies to collaboratively produce structured rapid core HTA information on pharmaceuticals (strand A) and other health technologies, such as medical devices, surgical interventions or diagnostics (strand B) will be tested. In addition, the application (transportation) of those collaboratively produced HTAs in the national/local context will be tested.

This includes:

- Testing and piloting collaborative production
- Transferring those rapid HTA or parts of the information into national/local HTA reports,
- Models and tools as well as production processes to support collaborative and national/local production

A total of 14 pilot assessments (10 on drugs and 4 on other health technologies such as medical devices, surgical interventions or diagnostics) containing rapid HTA information based on structured core information from the HTA Core Model for Rapid REA will be collaboratively produced. In addition about 30 national/local reports will be produced based on the pilot REAs.

Strand A: Rapid assessments of pharmaceuticals

1) **Specific deliverables:**
    - 10 pilot assessments (i.e. REAs)
    - Approximately 20 national/local reports based on pilot REAs

- Update of the 'HTA Core Model for Rapid Relative Effectiveness Assessment (REA) of pharmaceuticals'
- Testing of the submission file template for marketing authorisation holders developed by WP7

2) Documentation and tools

Each pilot assessment of pharmaceutical will be produced using the following documentation:

- HTA Core Model for Rapid Relative Effectiveness Assessment (REA) (version 3) & guidelines on methodological issues (version 5) produced within Joint Action 1 (JA1) WP5
- Procedure manual and templates for doing the assessments (to be developed in WP5 JA2)
- A detailed Project Plan for each pilot rapid assessment will be generated during the scoping phase
- European Public Assessment Report (EPAR) or the draft EPAR (if possible)
- Submission file of marketing authorisation holder (if possible)
- Whenever possible, the HTA Core Model online tool will be used for the pilot assessments.

3) Work-Organisation

A schematic overview of the organisation of the process of the pilots is included in Figure 1. However, it should be read as an ideal picture due to the high possibility of divergence (e.g. doing pilots with products that are already on the market). In addition, the goal is to begin the scoping phase (as seen in Figure 1.) by the 121st day of the EMA procedure. However, as the timelines remain uncertain, this may not be possible in all cases, and must remain the 'ideal' picture.

A procedure manual and templates for doing assessments will be produced during WP5 JA2 to serve as guidance for pilot teams. The procedure manual will be developed based on discussion with WP5 members and manufacturer(s) organisations. The manual will be subject to consultation of WP5 members and the SAG.

Collaboration model per rapid assessment
1 organisation as author + 1 organisation as co-author
A pool of dedicated reviewers (± 5 organisations)

If appropriate and feasible other collaboration models may be tested during production of the pilot assessments.

Identification of the pilot topics:
Topics (pharmaceuticals) can be proposed based on 1) an expression of interest by a WP5 partner or 2) an expression of interest by a pharmaceutical company to have a specific pharmaceutical assessed.

As WP5 also has to facilitate the generation of national/local reports, the relevance of the topic to the authoring organisations or institutions will be taken into account during the identification of topics. Per authoring organisation or institution, Step1 should be a pilot rapid assessment based on HTA Core Model for Rapid REA. Step 2 should be the adaptation of the pilot rapid assessment into a national/local HTA report. In order to maximise the utility of the pilot rapid assessment produced in step 1 for as many countries as possible, it should be explored whether the assessments can be conducted as close to the time of market authorisation as possible. For this purpose, identification of possible topics will include the development of the list of possible pharmaceuticals that will get market authorisation between 2012 and 2014, based on information from the European Medicines Agency (EMA). To optimise the process, there will be discussions with EMA that will provide WP5 with information about possible timing when the Committee for Medicinal Products for Human Use (CMHP) will finalise decisions on certain pharmaceuticals. In addition, a list will be developed of pharmaceutical companies that are willing to participate in a pilot (by providing a submission file) based on their pipeline and the assumption that a product from their pipeline will receive market authorisation between 2012 and 2014.

In order to gain diverse experience with the methods/tools and developed procedures WP5 Strand A will strive to select also some pharmaceuticals that are on the market for a longer period. In addition, topics for diverse therapeutic areas will be preferred. Finally, we would like to select at least two orphan drugs in order to test methods/tools and developed procedures.

Consultations and involvement of stakeholders in pilots:
The consultation (period) per pilot rapid assessment has to be practical (should not add a lot of time to the process). The rounds of consultation should be limited per pilot rapid assessment to at least the marketing authorisation holder and WP5 members. It may be discussed during the development of these pilots whether other stakeholders such as relevant clinical specialties and patient organisations can be included in the consultation phase. In addition, the timelines for responses should be short (e.g. max of 2 weeks). The latter means that the consultations need to be well planned in advance so the parties to be consulted can schedule the work.
The marketing authorisation holder will be involved in the scoping of the assessment including a meeting on a pre-submission file that will be discussed with the organisations or institutions that are the authors for the pilot.

Submission file template
The submission file template for marketing authorisation holders developed by WP7 will be tested during pilot assessments.

National/local reports:
See section 4.4.6 National HTA Report Production page 98-99.

4) Scheduling the pilots
The first pilot should start in 2012. CVZ will be the author of this pilot. Along with this pilot, the procedure documents (such as a manual, templates and evaluation forms) for the other pilots will be drafted. The other 9 pilots can start as considered appropriate by the authoring institution or organisation, bearing in mind that all pilots should be started in time in order to guarantee appropriate wrap up by M36.

5) Evaluation
After each pilot, there will be an evaluation of the pilot that aims at further developing the HTA Core Model for Rapid REA of pharmaceuticals. The survey will be spread among pilot participants and will include a standardised set of questions about:

a. The use of the model/templates and guidelines
b. Procedure manual and templates for doing the assessments
c. Data regarding the time invested in the assessment. The data should be used to report back to WP3 which evaluates efficiency gains or losses by collaboration

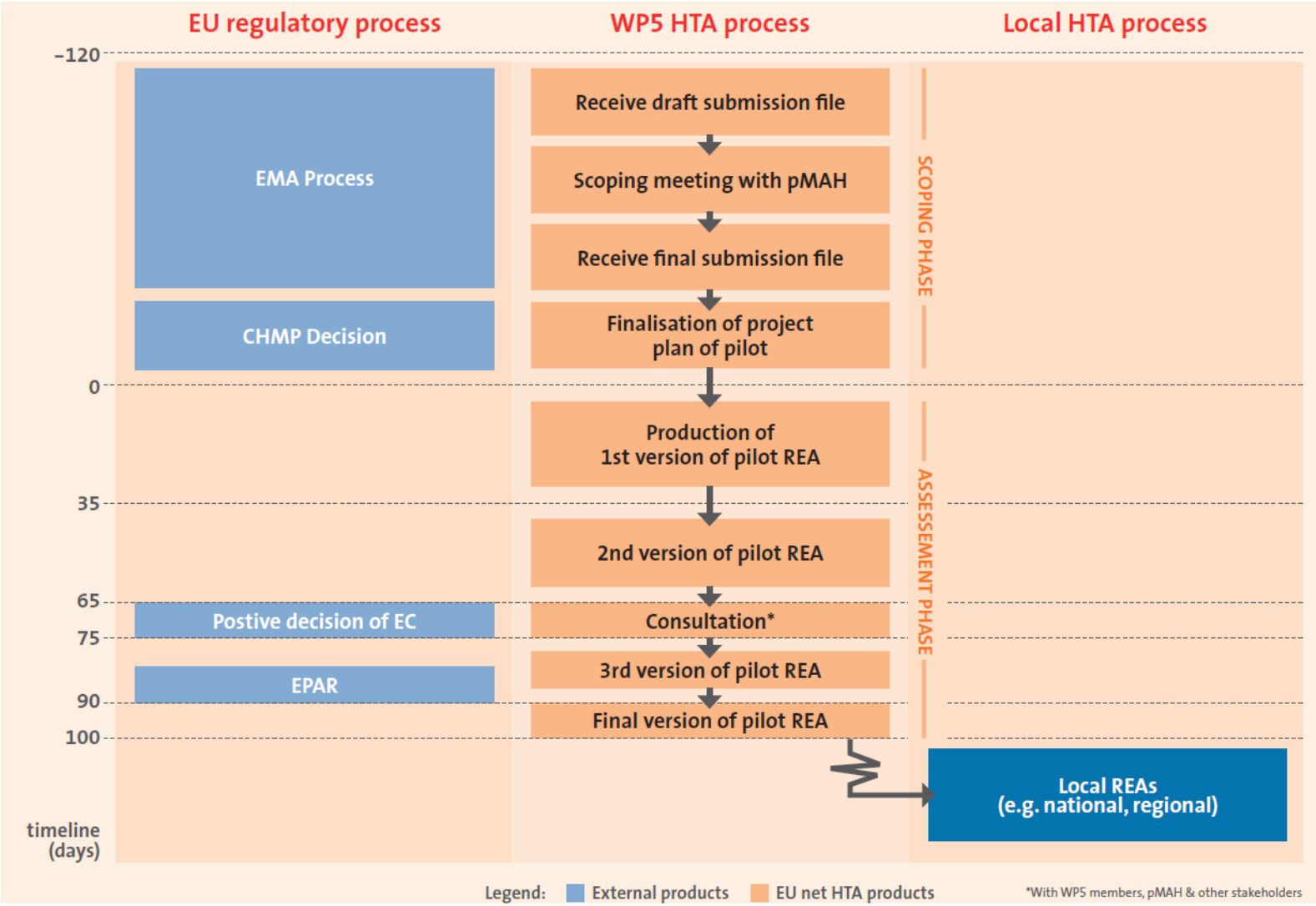
In addition, these data will be used for the final evaluation of applicability and usability of REA model, as a part of the WP5 final technical report. Coordination with WP3 is also needed to avoid potential duplication.

6) Further development of the HTA Core Model for Rapid REA and procedure manual and templates for doing the assessments
Based on the experience with the pilot assessments, the HTA Core Model for Rapid REA should be improved. As the final model for Rapid REA should be delivered in M35, the draft version should be ready by M29 to ensure sufficient time for the consultations (1st WP5/SAG consultation, 2nd public consultation). In addition, these data should provide input for the final WP5 evaluation report.

The procedure manual and templates for doing the assessments will also be improved based on the experience gained in the pilots.

7) Collaboration with other organisations and/or initiatives
Information from EMA is needed for the identification of possible topics for the pilots (See 'Identification of the pilot topics').
There will be close collaboration with the Innovative Medicines Initiative (IMI) 'GetReal' (Incorporating real-life clinical data into drug development) on methodology of relative effectiveness in which there is also interaction between regulators, industry and EUnetHTA partners.

Figure 1. Schematic overview of the organisation of the process of the pilots –general overview
It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific pilots



Abbreviations: CHMP - Committee for medicinal products for human use; EC – European Commision; EMA – European Medicines Agency; EPAR- European Public Assessment Report; EUnetHTA – European network of Health Technology Assessment; HTA – Health technology assessment; pMAH- prospective marketing authorisation holder; REA – Relative effectiveness assessment; WP5 – work package 5

Strand B: Assessments of other health technologies (such as devices and medical interventions)

1) Specific deliverables:

- ≥ 4 pilot rapid assessments
- +/- 10 national/local HTA reports based on pilot assessments
- Adaptation of the "HTA Core Model for Rapid REA" for other technologies (such as devices and medical interventions)
- Assisting WP7 with adaptation of the "REA guidelines on methodological issue" for other technologies (such as devices and medical interventions)

2) Documentation and Tools

Each pilot assessment will be produced using the following documentation:

- The HTA Core Model for Rapid Relative Effectiveness Assessment (REA) (version 3): adaptations will be necessary because some items in the HTA Core Model for Rapid REA may be specific for pharmaceuticals and additionally, further issues (from other Applications of the HTA Core Model e.g. medical and surgical interventions, diagnostics) may be added to the model.
- Guidelines on methodological issues (version 5).
- Procedure manuals, evaluation forms (to be developed in WP5 JA2)
- A detailed Project Plan for each pilot rapid assessment will be generated during the scoping phase
- Whenever possible, the HTA Core Model online tool will be used for the pilot assessments.

3) Work-Organisation

The guiding principle is not to create additional work because of participation within EUnetHTA JA2, but to stay within the work-programs of the national/local HTA-agencies.

Identification of potential topics and collaborating partners using two different collaboration models:

Two models for identifying collaborating partners are possible:

- Model 1: "Call for collaboration" (active brokering) to find partners:

  Authoring organisations or institutions submit their topics/indications as well as suggested time-frames to the LBI-HTA. The LBI-HTA will send out these calls to the members participating in Strand B in order to identify co-authors and reviewers.

- Model 2: individually contacting partners with similar work programs based on POP

  Topics for collaboration could be identified, either by Strand B members or by the LBI-HTA, via POP or based on spontaneous reactions to POP-alerts on similar work-programs between several agencies (see principle above: intention to collaborate with this model within the 3 years).

  Proposition for identified topics beforehand (based on analysis of POP during last months)

  - Physio- and Ergotherapy: collaboration in indication groups/ epidemiology, in definition of endpoints/outcomes independent of delivery mode or intensity of interventions,
  - Pre-reimbursement or pre-purchase decision-support: e.g. High Tech in Hospitals etc.

Project management/ work-division:

Strict project management:

- 1 organisation as author: general project management, compilation of rapid pilot assessment

- At least 1 organisation as co-author/author: active contribution to compilation of rapid pilot assessments (including e.g. control of data extraction, study selection)

- Pool of dedicated reviewers (±5 organisations): dedicated reviewers consisting of 3-5 methodological experts out of Strand B members will be involved at the beginning of collaboration (e.g. scoping, defining the research question). These dedicated reviewers and at least 1 external clinical expert will also review the first draft of the pilot rapid assessment.

Other forms of topic selection/collaboration may be tested during the production of pilot assessments. For example, topics submitted by manufacturers (the "Topic Notification and Selection Procedure Form" should be used) will be distributed

amongst authoring agencies within Strand B who will be asked to express their interest on conducting a pilot rapid assessment on the topic proposed.

The LBI-HTA will send out the calls actively and will give support in project-management/ process/ timelines. The LBI-HTA will also follow and assist collaborations arising from individual initiatives (see Model 2 above) and gather the experiences concerning modes of project-management and work-organisation.

A procedure manual and templates for doing assessments will be produced during WP5 JA2 to serve as guidance for the pilot team.

National/local reports
See section 4.4.6 National HTA Report Production page 98-99.

4) Scheduling the pilots

The first pilot should start in 2012. The LBI-HTA will be the author of this first pilot. Along with this pilot, the procedure documents (such as a manual, templates and evaluation forms) for the other pilots will be drafted and will be sent to Strand B members.

The other 3 pilots can start as is considered appropriate by the authoring organisation or institution, bearing in mind that all pilots should be started in time in order to guarantee appropriate wrap up by M36. In order to facilitate organisation, authoring organisations or institutions will be asked to indicate when they are planning on conducting their pilot rapid assessments.

5) Evaluation

After each pilot there will be an evaluation which aims at improving the applicability of the HTA Core Model for Rapid REA for other technologies. The survey will be spread among pilot participants and will include a standardised set of questions about:

- The use of the HTA Core Model for Rapid REA and guidelines
- Procedure manual and templates for doing the rapid pilot assessments
- Data regarding the time invested in the assessment according to a common evaluation form. The data should be used for reporting to WP2 efficiency gains/losses by collaborating

In addition, these data will be used for the final WP5 evaluation report.

6) Further development of the HTA Core Model for Rapid REA, procedure manual and templates and adaption of Guidelines for technologies other than pharmaceuticals

- HTA Core Model for Rapid REA: The applicability of the HTA Core Model for Rapid REA for other technologies will be elicited. As the final HTA Core Model for Rapid REA should be delivered in M35, the draft version should be ready by M29 to ensure sufficient time for the consultations (1st WP5/SAG consultation, 2nd public consultation). In addition, these data should provide input for the final WP5 evaluation report.
- Procedure Manual, etc.: The procedure manual and templates for doing the assessments will also be improved based on the experience gained in the pilots.
- Guidelines for REA: the applicability of the guidelines for REAs (e.g. on safety, clinical endpoints) for other technologies (such as devices and medical interventions) will be tested to assist WP7 with adapting the guidelines.

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
14 Feb 2013 (12.00 – 18.00) 15 Feb 2013 (9.00 – 14.00)	Diemen (NL), CVZ office	1 day	Leads, APs and CPs	Finalisation of working plan, discussion on procedure STRAND A: manual, selection procedure STRAND B: selection procedure, discussion on applicability of HTA Core Model for Rapid REA for other technologies (such as devices and medical interventions), manual
21 Nov 2013 (12.00 – 18.00) 22 Nov 2013 (9.00 – 14.00)	Vienna (AU), conference centre	1 day	Leads, APs and CPs	STRAND A: discussion on on-going and future pilots STRAND B: discussion on on-going and future pilots
June 2014	Helsinki	1 day	Leads, APs and CPs	STRAND A: discussion on on-going and future pilots STRAND B: discussion on on-going and future pilots
June 2015	Dublin	1 day	Leads, APs and CPs	STRAND A: discussion on on-going and future pilots; discussion of final version of HTA Core Model for Rapid REA STRAND B: discussion on on-going and future pilots; discussion of final version of HTA Core Model for Rapid REA
2014 or 2015	To be determined	1 day	WP5: Leads, and voluntary presence from APs and CPs involved in Strand A and Strand B. External groups: Stakeholders and other experts	Expert meeting on lessons learned from first five pilots in Strand A Expert meeting on lessons learned from pilots in Strand B.

Note: several e-meetings will be arranged to support the work

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Activity: Work Plan				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1: Oct '12	M2: Nov '12	First version	WP5 members	CVZ, LBI
M3: Dec '12	M4: Jan '13	Second version	SAG Members	WP5 members
M4: Jan '13	M5: Feb '13	Finalisation of work plan	General public	CVZ, LBI

Activity: Procedure manual including evaluation forms (Strand A & Strand B)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M2: Nov '12	M3: Dec '12	Writing first draft	WP5 members	CVZ, LBI
M4: Jan '13	M5: Feb '13	Review by WP5 members	CVZ, LBI	WP5 members
M5: Feb '13	M5: Feb '13	Discussion at Diemen meeting	WP5 members	WP5 members
M6: Mar '13	M6: Mar '13	WP5/SAG consultation	CVZ, LBI	SAG members
M7: Apr '13	M7: Apr '13	Finalisation of the manual	General public	CVZ, LBI

Activity: First pilot (Strand A)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M3: Dec '12		Receive expression of interest from pharmaceuticals company for participation in pilot with specific topic	CVZ	Pharmaceutical company, authors,
	M5: Feb '13	Receive draft submission file from MAH/ Scoping with company	Authors, co-authors, Coordination Team (CVZ)	Pharmaceutical company, authors, co-authors, Coordination Team (CVZ)
M5: Feb '13	M6: Mar' 13	Written comments on draft submission file	Pharmaceutical company	Authors, co-authors, (reviewers?), Coordination Team (CVZ)
M6: Mar '13	M7: Apr' 13	Receive draft submission file from MAH	Authors, co-authors	Pharmaceutical company
M7: Apr '13	M8: May '13	Writing first draft pilot rapid assessment by authors/review by second author (35 days total)	Reviewers	Authors, co-authors
M8: May '13	M8/M9: May-Jun '13	Review by dedicated pool of review organisations (15 days)	Authors, co-authors	Reviewers

M9: Jun '13	M9: Jun '13	Writing second version (15 days)	MAH, WP5 Strand A members	Authors
M9: Jun '13	M9: Jun '13	Review by WP5 members, MAH and other possible stakeholders (10 days)	Authors, co-authors	MAH, WP5 Strand A members
M10: Jul '13	M10: Jul '13	Editorial version of pilot rapid assessment	General public	Coordination Team (CVZ), editorial reviewer
MXX	MXX	Adaption of pilot rapid assessments into national/local reports	national/local HTA organisations or institutions	WP5 Strand A members and EUnetHTA members in general

Activity: Pilots 2-10 (Strand A)*
On-going

* See time schedules of pilots in Strand A (pilot 2-10) below

Activity: First pilot (Strand B)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M2: Nov '12	M3: Dec '13	Receive themes of the Austrian MoH, call for collaboration	WP5 Strand B members	LBI-HTA
M7: Apr' 13	M7: Apr' 13	Consultation of the draft Project Plan	Authors, co-authors, dedicated reviewers	Stakeholder Forum (SAG), Manufacturer, public
M4: Jan '13	M8: May 13	Writing first draft of pilot rapid assessment by authors/review by second author (45 days)	dedicated reviewers	authors
M8: May 13	M8: May 13	Review by dedicated pool of several (3-5) review organisations (strand B members) (10 days)	authors	reviewers
M8: May 13	M8: May 13	Writing second version of pilot rapid assessment (10 days)	Strand B members, at least 1 clinical expert, the manufacturer(s), other potential stakeholders	authors
M8: May 13	M8: May 13	Review by WP5 members, by≥1 clinical expert, the manufacturer(s) and other possible stakeholders (10 days)	authors	at least 1 clinical expert, WP5 Strand B members, manufacturer(s), other potential stakeholders
M9: June13	M9: June 13	Final version of pilot rapid assessment (5 days)	WP5 members	authors
M9: June '13	M9: June 13	Final version of national/local report	General Public	LBI HTA
MXX	MXX	Adaptation of pilot rapid assessment to national/local reports	national/local HTA organisations or institutions	WP5 Strand B members, EUnetHTA members in general

Activity: Pilots 2-4 (Strand B)*
On-going

* See time schedules of pilots in Strand B (pilot 2-10) below

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M9: Jun '13	M10: Jul '13	First version of the 1st interim report	Not applicable	CVZ/LBI
M11: Aug '13	M12: Sep '13	Second version of the 1st interim report	Not applicable	CVZ/LBI
M12: Sep '13	M13: Oct '13	Finalisation of the 1st interim report	WP1	CVZ/LBI

Year 2 (Oct 2013-Sep 2014)

Activity: Reporting				
Start	**End**	**Activity**	**Target group**	**Parties involved**
M21: Jun '14	M22: Jul '14	First version of the 2nd interim report	Not applicable	CVZ/LBI
M23: Aug '14	M24: Sep '14	Second version of the 2nd interim report	Not applicable	CVZ/LBI
M24: Sep '14	M25: Oct '14	Finalisation of the 2nd interim report	WP1	CVZ/LBI

Activity: Pilots 2-10 (Strand A)*
On-going

Activity: Pilots 2-4 (Strand B)*
On-going

* See time schedules of pilots in Strand A and B below

Year 3 (Oct 2014-Sep 2015)

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M33: Jun '15	M34: Jul '15	First version of the final report	Not applicable	CVZ/LBI
M35: Aug '15	M36: Sep '15	Second version of the final report	Not applicable	CVZ/LBI
M36: Sep '15	M37: Oct '15	Finalisation of the final report	WP1	CVZ/LBI

Activity: HTA Core Model for Rapid REA				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M28: Jan '15	M29: Feb '15	Draft final version of HTA Core Model for Rapid REA	WP5	CVZ

			Strand A members	
M28: Jan ‘15	M29: Feb ‘15	Draft adapted version of HTA Core Model for other technologies	WP5 Strand B members	LBI
M29: Feb ‘15	M30: Mar ‘15	WPs/SAG consultation	Not applicable	WP5 members, SAG members
M31: Apr ‘15	M32: May ‘15	Process comments of WP5/SAG	WP5 members, SAG members	CVZ, LBI
M32: May ‘15	M33: Jun ‘15	Public consultation	CVZ, LBI	General public
M34: Jul ‘15	M35: Aug ‘15	Finalisation of HTA Core Model for Rapid REA	General public	CVZ, LBI

Activity: Reporting / Publication				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M:XX	M:XX	Publication based on HTA Core Model for Rapid REA	General public	CVZ

Activity: Pilot 2-10 (Strand A)
On-going

Activity: Pilot 2-4 (Strand B)
On-going

Time schedules of other pilots Strand A (pilot 2-10)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
MXX		Receive submission file from company that applies for MA/ Scoping with company	CVZ, authors	Pharmaceutical company,
MXX+1		Writing first drafts of pilot rapid assessments by authors/review by second author (30 days total)	reviewers	authors
MXX+2		Review by dedicated pool of 5 review organisations (15 days)	authors	reviewers
MXX+2		Writing second version (10 days)	MAH, WP5 members	authors
MXX+2		Review by WP5 members, MAH and other possible stakeholders (10 days)	authors	MAH, WP5 members
MXX+3		Writing editorial version of the pilot rapid assessments	Not applicable	editor
MXX+3		Final version of pilot rapid assessments	General public	authors
MXX		Adaptation of pilot rapid assessments to the national/local reports	national/local HTA organisations or institutions	WP5 Strand A members and EUnetHTA members in general

Time schedules of other pilots Strand B (pilot 2-4)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
MXX		Identification of relevant topics, call for collaboration	co-authors, dedicated reviewers	authors
MXX		Consultation of Project Plan draft	authors	Stakeholder Forum (SAG), Manufacturer, public
MXX+2		Writing first draft pilot rapid assessment by authors/review by second author (45 days)	dedicated reviewers	authors
MXX+2		Review by pool of several (3-5) dedicated review organisations (strand B members) (10 days)	authors	Dedicated reviewers
MXX+3		Writing second version of pilot rapid assessment (10 days)	WP5 members, at least 1 clinical expert, the manufacturer(s), other potential stakeholders	authors
MXX+3		Review by WP5 members, by ≥1 clinical expert, manufacturer(s) and other possible stakeholders (10 days)	authors	at least 1 clinical expert, Strand B members, manufacturer(s), other potential stakeholders
MXX+4		Final version of pilot rapid assessment (5 days)	General public	authors
MXX		Adaptation of pilot rapid assessment to the national/local reports	national/local HTA organisations or	WP5 Strand B members and EUnetHTA

			institutions	members in general

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery**	**Coordination with other WPs**
During each pilot assessment	Data collection on time invested	Author(s), Co-author(s), reviewers	e-mail	WP3
After each pilot assessment	Applicability and usability of rapid REA model/guidelines for pharmaceuticals (Strand A) Applicability of HTA Core Model for rapid REA/guidelines to other technologies (strand B) Usefulness of templates for pilot rapid assessments/Procedure Manual, Project Plan Usability/readability of pilot rapid assessments	Author(s), Co-author(s), reviewers, WP5 members	e-mail or online	WP7
M4-M36	On-going surveillance of translation of pilot rapid assessments into national/local reports	WP5 members, other WP members of EUnetHTA	e-mail	No

4.4.1 Stakeholder involvement

Strand A. Assessments of pharmaceuticals

Stakeholders will be involved in Strand A in four different ways:
1. Public consultation
2. Stakeholder advisory group (SAG)[6]
3. Specific product assessments
4. Expert meeting on lessons learned from first five pilots

1) Public consultation (including the timing):
Final version of HTA Core Model for Rapid REA (M32-33);

2) Stakeholder advisory group (SAG)

Strand A invites Stakeholder Forum participants to appoint representatives with specific expertise into a WP5 Stakeholder Advisory Group (SAG). Each person participating in this group should have a clear mandate from the Forum participant. The mandate should be agreed upon between the Forum participant and the Secretariat and communicated to WP5 LP and Co-LP by the Secretariat. To ensure effective communication between the partners of WP5 and the SAG, the following feedback method should be used: if there is more than one representative from any given Forum participant, their feedback should be collated into one response, resulting in one response per Forum participant. The feedback of the SAG is requested for the following activities (including timing):
- Procedure manual for pilot rapid assessment (M6)
- Draft version of HTA Core Model for Rapid REA (M29-30);

3) Specific product assessments (pilot rapid assessment)

Strand A will consult the companies that apply for marketing authorisation for the specific products that will be part of the pilot rapid assessments. The companies will be involved in the scoping phase. In addition, the companies will be consulted before the report will be made publicly available.

[6] Stakeholder Advisory Group (SAG) is a group of experts appointed by various stakeholders that comment on (some) product of a specific work package in an early phase (before public consultation).

It is to be explored whether other stakeholders such as clinical specialities and patient organisations can be included in the scoping and/or consultation phase of the pilots. This will be developed in more detail during the three year period.

4) Expert meeting on lessons learned from first five pilots
An expert meeting will be organised with stakeholders and experts after the first five pilots have been conducted. The aim of the expert meeting is to discuss and share the experience/lessons learned from the first five pilot assessments.

Strand B: Assessments of other medical technologies

Stakeholders will be involved in Strand B in three different ways:
4. Public consultation
5. Stakeholder advisory group (SAG)
6. Specific product assessments

1) Public consultation (including the timing):
- Final version of the adapted HTA Core Model for rapid REA of other technologies (M32-33)
- Individual draft Project plans for each pilot rapid assessment (will be available on the EUnetHTA website for a period of 10 days)

2) Stakeholder advisory group (SAG)

Strand B invites Stakeholder Forum participants to appoint representatives with specific expertise in the assessment of medical devices, procedures and diagnostics into a WP5 Stakeholder Advisory Group (SAG). Each person participating in this group should have a clear mandate from the Forum participant. The mandate should be agreed upon between the Forum participant and the Secretariat and communicated to WP5 LP and Co-LP by the Secretariat. To ensure effective communication between the partners of WP5 and the SAG, the following feedback method should be used: if there is more than one representative from any given Forum participant, their feedback should be collated into one response, resulting in one response per Forum participant. The feedback of the SAG is requested for the following activities (including timing):
- Procedure manual for pilot rapid assessment (M6)
- Draft version of the adapted HTA Core Model for rapid REA of other technologies (M29-30);

3) Specific product assessments (pilot rapid assessment reports)

Mandatory stakeholder involvement includes:

- The respective manufacturer will be contacted at the beginning of pilots inquiring further information (e.g. C/E mark, on-going studies, available evidence). Whenever possible, the submission file for other technologies shall be used as developed by WP7. In addition, the draft Project Plan will be sent to the manufacturer and the manufacturer(s) will be consulted before the pilot rapid assessment will be made publicly available.
- The Stakeholder Advisory Group will be invited to comment on the draft Project Plans for every pilot rapid assessment which will also be made accessible on the EUnetHTA website for a period of 10 days.
- At least 1 clinical expert will review the second draft of the pilot rapid assessment.

Further stakeholders who may be involved are:
- Contact of respective providers/clinicians of technology (surgeons, etc.) at beginning of pilots for scoping
- Contact of the respective patient group (e.g. for support on patient-relevant endpoints) at the beginning of the pilots and/or for reviewing

SAG involvement			
Timing	**Purpose**	**Type of input from SAG**	**Info from SAG to be used for…**
M6: Mar ‘13	Receive input on draft procedure manual of Strand A and Strand B	Expertise for optimal drafting of procedure for rapid assessments	Updating/developing Procedure manual including evaluation forms
M29: Feb ‘15 M30: Mar ‘15	Receive input on HTA Core Model for Rapid REA for Pharmaceuticals (Strand A) and other technologies (Strand B)	Expertise on methodology for rapid assessments	Updating/editing HTA Core Model for Rapid REA for Pharmaceuticals (Strand A) and other technologies (Strand B)

4.4.2 Public Consultation

Public Consultations			
Timing	**Purpose**	**Target group** (EUnetHTA Web/other)	**Info used for**
M32-M33	Receive input from members of the public on the final version of the HTA core model	EUnetHTA website	Updating/editing final version of HTA Core Model for Rapid REA for Pharmaceuticals (Strand A) and other technologies (Strand B)

4.4.3 Conflict of interest

Conflicts of interest will be managed as per the EUnetHTA JA2 Conflict of Interest Policy at the network and project level. As conflict of interest may be topic dependent, conflict of interest declarations will be collected from authors and reviewers involved in a specific pilot assessments. Authors and reviewers with a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.

If external experts are involved in WP5 a conflict of interest declarations will be collected from them regarding the topic. External experts with a conflict of interest will be excluded from parts of, or the whole work under this specific topic. However, they may still be included in other pilots.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP5 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in pilots. Individual WP5 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in pilots.

4.4.5 Quality assurance procedures

The following activities will be applied in order to assure the quality of the pilot assessments:

- Authorship of the pilots by two WP5 partners (one author and one co-author) ;
- Review by WP5 partners (dedicated reviewers): an additional checklist will be developed so dedicated reviewers can review the pilots systematically;
- Consultations with Market Authorisation Holders (MAHs);
- Consultations with other partners of WP5;
- Coordination by CVZ & LBI-HTA
- Technical review by professional editorial reviewer (subcontracting)

4.4.6 National HTA Report Production

Strand A:

Based on the pilot rapid REA, about 20 national/local reports should be produced at least by the organisations or institutions involved in work package 5, Strand A. It is anticipated that authoring organisations or institutions as well as co-authoring organisations or institutions have a strong interest in the topic assessed and are thus likely to translate the pilot assessments into national/local reports. Furthermore, organisations or institutions acting as dedicated reviewers for pilot assessments are also encouraged to translate pilot assessments into national/local reports. The timing may depend on the availability of the partners and the exact involvement of the marketing authorisation holder. So, this cannot be defined beforehand.

Whenever possible, APs and CPs of WP5 and other EUnetHTA members will also adapt pilot assessments into national/local reports. The production of national/local reports will be facilitated by WP5 by sending out notifications and reminders to EUnetHTA members regarding the availability of pilot assessments. Survey-based data on the usability of

WP5 rapid assessments for national/local reporting will be collected per pilot report and evaluated at the end of the project.

Using pilot assessments for national/local reports may take two forms: either the whole pilot rapid assessment can be used as a national/local report when referenced accordingly or only parts of the pilot assessment can used for national/local reports (e.g. conclusions/discussion are reformulated). In both cases, the Strand A lead has to be informed.

Stand B:

Based on the pilot rapid assessments about 10 national/local reports should be produced by organisations or institutions involved in Strand B. It is anticipated that authoring organisations or institutions as well as co-authoring organisations or institutions have a strong interest in the topic assessed and are thus likely to translate the pilot assessments into national/local reports. Furthermore, organisations or institutions acting as dedicated reviewers for pilot assessments are also encouraged to translate pilot assessments into national/local reports.

Whenever possible, APs and CPs of WP5 and other EUnetHTA members will also adapt pilot assessments into national/local) reports. The production of national/local reports will be facilitated by WP5 by sending out notifications and reminders to EUnetHTA members regarding the availability of pilot assessments. Survey-based data on the usability of WP5 rapid assessments for national/local reporting will be collected per pilot report and evaluated at the end of the project.

Using pilot assessments for national/local reports may take two forms: either the whole pilot rapid assessment can be used as a local report when referenced accordingly, or only parts of the pilot assessment can used for national/local reports (e.g. conclusions/discussion are reformulated). In both cases, Strand B lead has to be informed.

4.4.7 Cooperation with other WPs / LPs

There will be a close collaboration with WP7 who will be further developing guidelines and a submission file template and with WP8 who will be further developing the online tool and service and an HTA Core Model for Rapid REA of pharmaceuticals.

In order to reduce duplication in production of manuals, guidelines, evaluation forms etc., there will be collaboration with WP4 and other WPs.

Collaboration with WP3 is planned in terms of evaluating WP5 products. To elicit efficiency gains and losses, detailed time sheets of hours spent on individual tasks for compiling rapid assessments will be collected from all participating agencies

5. Dissemination plan

Output	Format	Time
WP5 deliverables, key milestones and results, progress, achievements, current considerations for the future	Presentations at conferences including HTAi meeting, European ISPOR meeting and EUnetHTA Conference (Oct 2014)	Jun 13, Nov ’13, Jun ’14, Oct ’14, Nov ’14, Jun ’15, Nov ‘15
Pilot assessments	Publication of the experience with the pilot assessments in a scientific journal	2016
14 rapid assessment reports	Publication on the EUnetHTA website	
HTA Core Model for Rapid REA	Publication in the online Tool & Service	

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 2 on HTA 2012-2015

Work Package 6
Information Management Infrastructure and Services

3-year Work Plan

KCE

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

40 Jahre medizinwissen
Deutsches Institut für Medizinische Dokumentation und Information

May 1, 2013

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1. WP title

Work Package 6 – Information Management Infrastructure and Services (IMIS)

2. Participants

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
Lead Partner: KCE (Belgium)	WP6 LP will coordinate the development and implementation of a new public website and intranet, based on JA1 WP6 recommendations. LP will provide technical support and training materials regarding management of the sites and its content, and deliver communication about related tools and procedures. LP will ensure the provision of maintenance and act as a 2nd line helpdesk for both sites. LP will provide a tool allowing the management of Newsletters for both public site and intranet LP will provide, through the Intranet, a tool allowing electronic discussion with e-mail notification. LP will maintain and further develop the EUnetHTA Aggregator tool, the EUnetHTA complementary documents repository, and the EUnetHTA Toolbar for Web browsers. LP will create and disseminate an “aggregated newsletter” summarizing information from the HTA community to be released on a regular basis during the JA2. Under coordination of WP2, LP will coordinate the development and implementation of an “e-learning” platform available for other WPs wishing to create and disseminate online courses. LP will coordinate the maintenance of the common standards for EUnetHTA tools, including those hosted by other WPs; and promote interoperability with HTA tools outside EUnetHTA where possible LP will coordinate the attendance of a WP6 representative at the other WP’s meeting to present and obtain feed-back regarding the on-going work at WP6. LP will provide training material and sessions related to the use of the website and the Intranet. LP is member of the EUnetHTA Executive Committee; will prepare the WP interim and final technical reports; follows the AP’s responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
Co-Lead Partner: DIMDI (Germany)	WP6 Co-LP will handle hosting, maintenance and further development of the following tools: - Centralized authentication system (EUnetHTA ID), - the planned and ongoing projects database (POP db), Co-LP will collaborate with LP regarding the development and hosting of some other WP6 tools. Co-LP facilitates preparation of the WP interim and final technical reports; Co-LP will follow the AP’s responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement

Associated partners – AP (4 partners)	
1. HAS (France), LP WP7 2. HVB (Austria), LP WP3 3. LBI-HTA (Austria), Co-LP WP5 4. THL (Finland), LP WP8	LBI-HTA will be responsible for the active brokering for collaboration on identical topics identified through the POP database, and for the administration, maintenance and moderation of the POP database. HVB will manage the surveys of users HAS and THL develop tools under their own WP; they will participate to the discussions related to-, will agree on – and implement standards that ensure interoperability. All AP will participate to the planned (e-)meetings All AP (and LP and Co-LP) will participate to the preparation of the surveys, and take care of their analysis. All AP will serve as point of contact for their country and ensure communication about the WP6 activities. They will transmit specific requests and feedback to WP6 LP and Co-LP. Will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
Collaborating partners – CP (0 partners)	
N/A	Due to the particular nature of this Work Package, no CP is foreseen.
Other Parties	
EUnetHTA Secretariat	Secretariat is responsible for the management of the users of both Intranet and Public Site. Secretariat will provide feed-back on user needs or problems, including the Secretariat itself. Secretariat is responsible for the provision of content on the public site, and on the intranet "general group" and WP1 group Secretariat is responsible of the provision and management of the e-meeting facility.
EUnetHTA Stakeholders	Stakeholders Forum members will make use of the SF area on the public site. Stakeholder forum members will be invited to participate to survey related to Public site
ALL EUnetHTA Lead Partners	Lead partners are responsible for the management (members and content) of their group(s) in the Intranet.
All EUnetHTA partners	All partners will serve as point of contact for their country and ensure communication about the WP6 activities. They will transmit specific requests and feedback to WP6 LP and Co-LP. All partners will respond to the requests regarding the POP database All partners will make use of the IMIS. - They will participate to the surveys related to the IMIS - Out of the surveys, they will transmit their comments and proposal to WP6 LP and Co-LP. - They will follow the related Policy and security rules, and inform EUnetHTA Secretariat if any infringement is identified EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement.

Consultants	Consultants will provide development of IT tools (e.g. website design and infrastructure), supervised by LP

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: ***www.eunethta.eu***

3. Objectives

Title	Description	Indicators
Information Management Infrastructure and Services (IMIS)	Provision of an information management infrastructure and the related services to support the piloting of collaborative production of HTAs by partner agencies, and facilitate the tasks and team working of the other WPs.	90% of JA2 Participants use the IMIS and have provided at least one piece of information. ***** Results of the surveys will show a reduction of technical limitations related to the Intranet and the "work rooms" (at least 90% of respondents do not express such a limitation) * The POP db will, in average, contain the description of 1000 current projects from at least 40 partners from 22 countries (in average).

*Additional Indicator developed by the Work Package.

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
New website, intranet and workrooms	M4
Information Management environment	M36

Deliverables	Deadline
Report on Information Management Infrastructure and Services	M36

4.2 Methods

General methodology

- Development of common standards will happen by group discussion through (e-)meeting, and document creation / revision. Documents will be exchanged through the intranet group, discussion facilities provided will be used to reduce the e-mail traffic.
- Development of tools will occur internally (LP, Co-LP), or will be sub contracted following the National tender rules.
- Surveys will be conducted through online surveys systems
- POP db brokering will happen by monitoring of the database using build in tools, and regular e-mail notifications (requests and reminders) to the Partners and Associates in order to ensure the provision of updated information. Additionally the list of alert topics will be sent to the partners who entered information to the database.
- For all actions, best practices of the field will be identified, selected, adapted and applied.

Risk analysis

Risk description	Response (Success factors)
Other WPs tools do not implement common standards	Include other WP tools developers in the process (identification selection and definition of common standard), and creation of common standard based on consensus
New websites do not meet user needs.	Involvement of Secretariat, EUnetHTA websites task force, other stakeholders in the description of needs. List of "user cases"
Time/ sub-contractors: Dependent on subcontractors meeting deadlines.	Agreement on planning, contract specifications.
Partners reduce commitment due to internal priorities	Have reasonable expectations (3 year Work Plan), provide regular monitoring and appropriate communication (e.g. POP db: raise awareness about the advantages of using the db, encourage partners to include the search in the db as a first step when staring a new project: to include it in their protocol), provide training and support, escalate to the Executive Committee
Change in the leading team, unexpected human problems (people leaving agency, changing roles, sick leave)	Good project management and continuity policy (including documentation of tasks)
Unexpected technical problems	Contract specifications
Cost evolution not sustainable	Revision of the objectives
External projects (dependencies) do not collaborate	Revision of the objectives

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
M6 (Mar'13)	Face to face meeting Copenhagen	1	LP, secretariat	Coordination WP6 Training websites
M7 (Apr'13)	e-meeting(s)	0	All WP6 Partners(*)	Presentation of the 3 year Work plan (final) Preparation of the 1st survey New LDAP Common standards & Interoperability e-learning platform
M7 (Apr'13)	e-meeting	0	LP, Co-LP, AP LBI-HTA	POP database development (release 2)
M12 (Sep'13)	e-meeting	0	All WP6 partners	Analysis of the 1st survey and discussion Preparation of the interim report 2013
Date to be determined following WP4 agenda	Face to face meeting	1	LBI-HTA	Participation to WP4 face to face meeting
Date to be determined following WP5 agenda	Face to face meeting	1	LBI-HTA	Participation to WP5 face to face meeting

Date to be determined following WP7 agenda	Face to face meeting	1	LBI-HTA	Participation to WP7 face to face meeting
M17 (Feb'14)	Face to face meeting Oslo	1	LP, WP2 LP	e-learning preparation
M18 (Mar'14)	Face to face meeting Brussels	1	All WP6 partners(*)	e-learning preparation Common standards and interoperability
M20 (May'14)	Face to face meeting	1	LBI-HTA	Participation to meeting at HAS
M24 (Sep'14)	e-meeting	0	All WP6 partners	Preparation of the interim report 2014
M30 (Mar'15)	e-meeting(s)	0	All WP6 partners	Preparation of the 2nd survey Common standards e-learning
M32 (May'15)	Face to face meeting	1	LBI-HTA	Participation to meeting at HAS
M36 (Sep'15)	e-meeting	0	All WP6 partners	Analysis of the 2nd survey and discussion Preparation of recommendations Preparation of the interim report 2013

(*) HVB depending on travel budget

4.4 Specific activities per year

Year 1 (Oct 2012 – Sep 2013)

Activity: 3 Year work plan				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct'12	M2 Nov'12	Preparation	EUnetHTA Secretariat	WP6 LP All partners
M4 Jan '13	M4 Jan '13	Implement feedback from the secretariat, WP APs and CPs	EUnetHTA Secretariat, WP6 APs and CPs	WP2 LP and Co-LP
M5 Feb '13	M5 Feb '13	Implement feedback from stakeholders	Stakeholder Forum	WP2 LP, Co-LP, Stakeholder Forum and the Secretariat
M6 Mar '13	M6 Mar'13	Final endorsement at the Plenary Assembly meeting on the 21st/22nd of March	EUnetHTA partners	WP2 LP, Co-LP and the Secretariat

Activity: Implementation of a new Public site				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M1 Oct '12	Evaluation of the assessment done by JA WP6 with support of the JA Task Force "JA2	EUnetHTA Secretariat	WP6 LP

		Websites" (evaluation of needs, identification of technical options), selection of the technical option and the provider	WP2	Secretariat WP2 CLP Sub-contractor
M2 Nov '12	M6 Mar '13	Development and implementation	EUnetHTA Secretariat WP2	WP6 LP Secretariat WP2 CLP Sub-contractor
M3 Dec '12	M6 Mar '13	User manual will be provided to secretariat	EUnetHTA Secretariat WP2 EUnetHTA Stakeholder Forum	WP6 LP Sub-contractor
M3 Dec'12	M3 Dec'12	Training for secretariat	EUnetHTA Secretariat WP2 EUnetHTA Stakeholder Forum	WP6 LP Sub-contractor
M6 Mar '13	M6 Mar '13	Training for secretariat	EUnetHTA Secretariat WP2 EUnetHTA Stakeholder Forum	WP6 LP Sub-contractor
M4 Jan'13	M36 Sep'15	Hosting, maintenance, and support	EUnetHTA Secretariat WP2 EUnetHTA Stakeholder Forum	WP6 LP Sub-contractor

Activity: Implementation of a new intranet (including "work rooms")				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct'12	M1 Oct'12	Evaluation of the assessment done by JA WP6 with support of the JA Task Force "JA2 Websites" (evaluation of needs, identification of technical options), selection of the technical option and the provider	EUnetHTA Secretariat	WP6 LP Secretariat Sub-contractor
M2 Nov'12	M6 Mar'13	Development and implementation	EUnetHTA Secretariat WP2	WP6 LP Secretariat Sub-contractor
M3 Dec'12	M6 Mar'13	User manual will be provided to secretariat, lead partners and partners.	All individuals from EUnetHTA Partners and Associates	WP6 LP Sub-contractor
M3 Dec'12	M3 Dec'12	Training will be organised for secretariat through face to face training and webinars.	Secretariat	WP6 LP Sub-contractor
M6 Mar'13	M6 Mar'13	Training will be organised for secretariat through face to face training and webinars.	Secretariat	WP6 LP Sub-contractor
M4 Jan'13	M6 Mar'13	Training will be organised for Lead partners through webinars. Supplemental sessions will be	Lead partners	WP6 LP

		organised on demand (taking into account staff changes at LPs)		
M5 Feb'13	M8 May'13	Webcasts will be provided to all partners & associates. Demonstration will be provided when opportunities happen (e.g. when participating to other WPs face to face meeting, workshops,...)	All individuals from EUnetHTA Partners and Associates	WP6 LP
M4 Jan'13	M36 Sep'15	Hosting, maintenance and support	All individuals from EUnetHTA Partners and Associates	WP6 LP Sub-contractor

Activity: Implementation of a Newsletters diffusion tool				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan'13	M6 Mar'13	Development and implementation	EUnetHTA Secretariat WP2	WP6 LP Secretariat WP2 CLP Sub-contractor
M4 Jan'13	M6 Mar'13	User manual	EUnetHTA Secretariat WP2 EUnetHTA Stakeholder Forum	WP6 LP WP2 CLP Sub-contractor
M6 Mar'13	M6 Mar'13	Training for secretariat (face to face or webinar)	EUnetHTA Secretariat	WP6 LP Sub-contractor
M6 Mar'13	M36Sep'15	Hosting, maintenance and support	EUnetHTA Secretariat All EUnetHTA partners	WP6 LP Sub-contractor

Activity: Planned and On-going Projects database operation				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan'13	M36 Sep'15	Hosting, technical maintenance and further development	AP LBI-HTA All EUnetHTA Partners and Associates	WP6 Co-LP & LP WP6 AP LBI-HTA
M4 Jan'13	M36 Sept'15	Users administration & support	All EUnetHTA Partners and Associates	WP6 AP LBI-HTA
M4 Jan'13	M36 Sep'15	Training material will be provided to WP2, which is responsible for organizing trainings in EUnetHTA JA2. LBI-HTA is willing to provide the POP database trainings (face to face or through webinars), which is intended to facilitate the initiation of active brokering for collaboration.	All EUnetHTA Partners and Associates	WP6 AP LBI-HTA WP2 LP
M4 Jan'13	M10 Jul'13	User manual update	All EUnetHTA Partners and Associates	WP6 AP LBI-HTA WP2 LP
M4 Jan'13	M36 Sep'15	Content administration, maintenance & moderation	All EUnetHTA Partners and Associates	WP6 AP LBI-HTA

M4Jan'13	M36 Sep'15	Active brokering for collaboration on identical topics identified through the POP database	All EUnetHTA Partners and Associates	WP6 AP LBI-HTA

Activity: Centralized authentication system (EUnetHTA ID)				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan'13	M36 Sep'15	Hosting, technical maintenance and any needed further development	All EUnetHTA Partners and Associates	WP6 Co-LP & LP
M4 Jan'13	M36 Sep'15	Provision of the necessary information to EUnetHTA tools developers in order for them to implement the EUnetHTA ID in their tool	WP6 LP WP6 AP HAS WP6 AP THL Other developers	WP6 Co-LP

Activity: EUnetHTA Aggregator				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan'13	M36 Sep'15	Hosting, technical maintenance and any needed further development	All EUnetHTA interested parties	WP6 LP
M4 Jan'13	M36 Sep'15	Any opportunities of communication and demonstration of the Aggregator will be taken in order to support the implementation of interoperability standards at Partners (RSS, OAI)	All EUnetHTA Partners	WP6 LP

Activity: EUnetHTA Toolbar				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M4 Jan'13	M36 Sep'15	Technical maintenance and further development, provision of updated documentation	All EUnetHTA Partners	WP6 LP

Activity: "e-learning " platform				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M7 Apr'13	M9 Jun'13	Needs assessment, identification of technical options	WP2 (including training material providers)	WP6 LP, Co-LP, APs WP2 LP & APs
M10 Jul'13	M14 Nov'13	Development and implementation	WP2 LP	WP6 LP & Co-LP Sub-contractor
M15 Nov'13	M36 Sep'15	Technical maintenance	WP2	WP6 LP Sub-contractor WP2 Co-LP

Activity: Surveys of users				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M6 Mar'13	M8 May'13	Preparation of the 1st survey (user needs)	WP6 partners	WP6 partners
M9 Jun'13	M9 Jun'13	Conduction of the 1st survey	All EUnetHTA partners	WP6 AP HVB

M12 Oct'13	M12 Oct'13	Analysis of the 1st survey	WP6 partners	WP6 AP HVB WP6 LP
M29 Feb'15	M31 Apr'15	Preparation of the 2nd survey (user satisfaction)	WP6 partners	WP6 partners
M32 May'15	M32 May'15	Conduction of the 2nd survey	All EUnetHTA partners	WP6 AP HVB
M35 Aug'15	M35 Aug'15	Analysis of the 2nd survey	WP6 partners	WP6 AP HVB WP6 LP

Activity: Common standards & interoperability				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M7 Apr'13	M36 Sep'15	Update of Common standards	WP6 partners	WP6 partners
M7 Apr'13	M36 Sep'15	Maintenance of existing collaboration related to HTA tools developed outside EUnetHTA (HTA glossary, HTAi vortal)	ALL EUnetHTA Partner	WP6 LP HTAi / INAHTA HTAi IRG
M7 Apr'13	M36 Sep'15	Evaluate feasibility of projects aiming at implement interoperability between EUnetHTA tools and HTA tools outside EUnetHTA	ALL EUnetHTA Partner	WP6 LP WP6 Partners CRD INAHTA

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct'12	M36 Sep'15	Participation to WP1 (e-)meetings	Executive Committee	WP6 LP & Co-LP
M6 Mar'13	M36 Sep'15	Provision of news related to WP6 activities for the Partners newsletter	All EUnetHTA Partners	WP6 LP
M11 Sep'13	M12 Sep'13	Preparation and provision of intermediate technical and financial report year 1	EU	WP6 LP & Co-LP
M23 Sep'14	M24 Sep'14	Preparation and provision of intermediate technical and financial report year 2	EU	WP6 LP & Co-LP
M34 Sep'15	M36-M38 Sept'15/Nov' 15	Preparation and provision of final technical and financial report	EU	WP6 LP & Co-LP

Year 2 (Oct 2013 – Sep 2014)

Activity: "Aggregated" Newsletter[7]				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct'13	M16 Jan'14	Needs assessment, identification of technical options, selection of sources (Partners sites, websites of interest, journals, ...)	WP2 Secretariat	WP6 LP WP2
M16 Jan'14	M18 Mar'14	Development and implementation	WP2	WP6 LP

[7] The aggregated newsletter is the provision in the form of a newsletter of nest hat are automatically gathered from selected resources of interest like partners websites, other websites of interest, journals etc.

			Secretariat	WP2 Co-LP
M19 Apr'14	M36 Sep'15	Regular delivery of the "Aggregated" Newsletter	All EUnetHTA Partners	WP6 LP WP2 Co-LP

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M23 Sep'14	M24 Sep'14	Preparation and provision of intermediate technical and financial report year 2	EU	WP6 LP & Co-LP
M34 Sep'15	M36-M38 Sept'15/Nov' 15	Preparation and provision of final technical and financial report	EU	WP6 LP & Co-LP

Year 3 (Oct 2014 – Sep 2015)

Activity: Reporting				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M34 Sep'15	M36-M38 Sept'15/Nov' 15	Preparation and provision of final technical and financial report	EU	WP6 LP & Co-LP

Surveys				
Timing	**Type of survey/topic**	**Target groups**	**Method of delivery (i.e. online or e-mail)**	**Coordination with other WPs (Yes/No – if yes which WP)**
M12	User needs	All partners	Online (+ e-mail invitation)	Yes, WP3 (AP)
M32	User satisfaction	All servers	Online (+ e-mail invitation)	Yes, WP3 (AP)

4.4.1 Stakeholder involvement

Stakeholders Forum members will make use of the SF area on the public site, dedicated persons of from the Stakeholder forum will make use of the SAG groups areas.

4.4.2 Public Consultation

No public consultation is planned

4.4.3 Conflict of interest

No specific projects are anticipated in WP6 that will require a separate declaration of conflict of interest for the participating partners. WP6 will refer to the EUnetHTA JA2 Conflict of Interest Policy at the network level.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP6 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP6 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP6.

4.4.5 Quality assurance procedures

The quality assurance will be managed based on the Plan – Do – Check - Act (PDCA) approach:

- Responsibilities, Indicators, Meeting schedule and risk analysis have been detailed in the 3 year work plan = Plan, those will be evaluated yearly at WP6's plenary meetings (e-meeting or face to face) = Check, necessary action will be agreed and implemented = Act
- All activities are detailed in steps, Milestones have been identified and Deliverable also: those will be described on a Gantt chart = Plan; the Gantt chart will be reviewed yearly at WP6's plenary meetings (e-meeting or face to face) = Check, necessary adaptation will be agreed and implemented = Act & Plan
- Survey" (WP6 activity) are planned to assess user satisfaction = Check, results will be used for amelioration = Act. Supplemental survey will be conducted when necessary to assess user needs for new tools / upgrade of existing tools = Plan
- For critical activities (Website, Intranet): a specific project description will be created at the beginning to provide detailed analysis (AS IS / TO BE + SWOT analysis: Strengths, Weaknesses, Opportunities and Threats) = Plan; After Action Review (AAR) will be used to draw lessons learned = Check
- Communication with Intranet's provider will happen through a Ticketing system, allowing to assess performance = Plan & Check.

4.4.6 National HTA Report Production

WP6 will not produce HTA reports.

By providing work areas and communication facilities for pilots (Intranet), active brokering of the potential collaboration (AP LBI-HTA), development of common standard for the different EUnetHTA tools, WP6 will contribute to the dissemination / implementation of EUnetHTA outputs, including the HTA reports based on Core/Rapid HTA.

The public site will contain a "library" of outputs that will host references of reports based on core/rapid HTA (managed by WP2).

4.4.7 Cooperation with other WPs / LPs

WP6 will support WP1/WP2 regarding the communication through the website and intranet.

WP6 will closely collaborate with WP2/Capacity building and training for the technical aspects related to the "e-learning"

5. Dissemination plan

Output	Format	Time
HTAi Conference	Poster	2014
EUnetHTA Conference	Poster	2014
HTAi Conference	Poster	2015
IJTAHC	Article (proposal)	2015

eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 2 on HTA 2012-2015

Work Package 7

METHODOLOGY DEVELOPMENT AND EVIDENCE GENERATION: GUIDELINES AND PILOTS PRODUCTION

3-year Work Plan

HAS

HAUTE AUTORITÉ DE SANTÉ

IQWiG

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

May 1, 2013

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1. WP title

Work Package 7 - Methodology development and evidence generation: guidelines and pilots production

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
• Lead Partner: HAS (France)	WP7 LP (HAS) will be responsible for the coordination of all WP7 activities. In addition to these tasks, HAS will be directly responsible for the subgroups 1 and 2: **SG 1:** Pilots and guidelines to improve quality and adequacy of initial evidence generation : Early Dialogue and Disease specific guidelines **SG2:** Guidelines and pilots to improve quality and adequacy of additional evidence generation **SG4** Templates for manufacturers' submissions to support production of core HTA information and rapid assessments. Leading of SG4 activities is agreed to be taken care of by NICE (Active Partner, see section on Active Partners below) HAS is responsible for WP coordination and management as well as the preparation of the WP interim and final technical reports. HAS is member of the EUnetHTA Executive Committee. LP will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
• Co-Lead Partner: IQWIG (Germany)	WP7 Co-LP (IQWIG) will be responsible for the subgroup 3 on general methodology guidelines: **SG3:** Guidelines on distinct methodological issues, all health technologies (continued and expanded from JA1 WP5) Co-LP facilitates preparation of the WP interim and final technical reports; Co-LP will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement and Co-LP is a member of Exec Comm with conditional voting rights (when the rights are delegated by the LP)
Associated partners – AP 19	
28. National Institute for Health and Clinical Excellence, NICE-UK Nice is leading the operational management of SG4 29. Hauptverband der Österreichischen Sozialversicherungsträger, HVB (Austria) 30. Belgian Health Care Knowledge Center, KCE – Belgium	AP will participate to WP7 face to face meetings in order to select standards and provide feedback and further orientation for the development of the deliverables. The difference between "active" and "less active" partners is that all are asked to share work and information (respond to surveys, review the first drafts and final versions of deliverables), but the "active" APs are asked to actively support collaboration: authors/co-

31. Ministry of Health of the Czech Republic, MoH Cz Rep - Czech Republic 32. GYEMSZI (National Institute for Quality- and Organizational Development in Healthcare and Medicines) – Hungary 33. Health Information and Quality Authority, HIQA – Ireland 34. Agenzia Nazionale per i Servizi Sanitari Regionali, AGENAS – Italy 35. Regional Agency for health and social care – Emilia Romagna– Italy 36. Agenzia Italiana Del Farmaco, AIFA – Italy 37. Regione Veneto– Italy 38. State Health Care Accreditation Agency, VASPVT – Lithuania 39. College voor zorgverzekeringen, CVZ – Netherlands 40. Norwegian Knowledge Centre for the Health Services, NOKC - Norway 41. Agency for HTA in Poland, AHTAPol – Poland 42. National Authority of Medicines and Health Products, INFARMED - Portugal 43. Institute of Economic Research, IER – Slovenia 44. Instituto de Salud Carlos III, ISCIII – Spain 45. Swedish Council on Health Technology Assessment, SBU – Sweden 46. NIHR Health Technology Assessment Programme, NETSCC– UK	authors/members of a drafting group ; actively participate to specific meetings etc. AP will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement In addition to these common tasks, AP will participate to the following specific activities of the subgroup(s) they have chosen: **SG1:** **Early Dialogue (ED)** AP will actively participate in ED pilots i.e. teleconference, written answers to companies' questions, face to face meeting and minutes review in order to select standards and provide feedback and further orientation for the development of the deliverables. **Disease specific guidelines** AP will participate in the choice of the condition(s), drafting of the concept paper(s) and the guideline(s) **SG2:** • actively filling-in the EVIDENT database and providing information on uncertainties identified in their HTA reports, the related research question and the additional evidence required - participation in the study (survey) on the possibilities and the conditions for performing harmonised Additional Data Collection (ADC) in different countries • participation in the development of guidelines/position paper to improve additional evidence generation (on how to best formulate research question and on how to decide on the appropriate trial design for additional data collection (or other if identified so in the survey)), • participation in the setting-up of a common core protocol for additional data collection (for one technology of common interest) • reviewing the intermediate and final results of all productions • contribution to the activities of the ENCePP working group on HTA (level of participation TBD) **SG3:** 1. Drafting of templates and of a process for developing guidelines 2. Identification of needs/topics of interest for new methodological guidelines (referring to <u>all</u> health technologies) 3. Prioritisation, focusing on 'uncovered areas', choice and production of new methodological guidelines 4. Monitoring of the use of existing guidelines (from JA1) in CORE-HTA production, identification of the guidelines needing an update, conduct of the update process

	SG4: **NICE will be the operational leader of this subgroup** 1. Establish submission templates/ evidence requirements: • Collect and analyse submission templates or evidence requirements from HTA agencies in EU MS and EEA countries • Produce a report on similarities and differences 2. Create a draft submission template in a modular structure reflecting the HTA Core Model 3. Piloting of draft template in WP5 4. Targeted consultation on report and draft submission template with WP4 and WP5, agencies receiving submissions and industry via SF 5. Further piloting in WP5 6. Develop final template This SG is closely linked to Joint Action 2 WP5 activities, most participants should be active partners of JA2 WP5
Collaborating partners – CP (8 partners)	
1. UMIT (Austria) 2. RIZIV-INAMI (Belgium) 3. EMN (Germany) 4. G-BA (Germany) 5. University Hospital "A. Gemelli" (Italy) 6. AVALIA-t (Spain) 7. OSTEBA (Spain) 8. SNHTA (Switzerland) 9. HIS (Scotland) 10. TLV (Sweden)	CP will participate to face to face meetings on a voluntary basis in order to select standards and provide feedback and further orientation for the development of the deliverables. CP will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 S SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement
Other Parties	
All EUnetHTA partners	**SG1:** The input of all EUnetHTA partners will be in the form of consultations on the consolidated procedure for the early dialogues on pharmaceuticals and other technologies as well as on the concept paper/disease specific guideline that will be produced according to the pre-defined process **SG2:** all EUnetHTA partners will have access to the EVIDENT database and should provide information on uncertainties identified in their HTA reports, the related research question and the additional evidence required. **SG3:** EUnetHTA partners – especially those in the JA2 work packages 4 and 5 – are recommended to base their Core HTA activities on the methodological guidelines updated, supplemented and created in this subgroup. In addition they should give a continuous and detailed feedback to SG 3 concerning the applicability of the methodological guidelines in their HTA routine work and comment on the revised framework for guideline elaboration. The articulated needs of WP 4 and WP 5 for methodological support of their work will be the most relevant input for the choice of guideline topics in SG 3. **SG4:** EUnetHTA partners in JA2 work package 5 are expected to pilot the draft template; EUnetHTA partners that are receivers of manufacturers submissions, and EUnetHTA partners active in WP4 will be asked to comment on the proposed draft template

EUnetHTA Stakeholders	In addition to exchanges taking place at the general level of the Stakeholder Forum, stakeholders will be involved in WP7 in two different ways: - WP7 Stakeholder advisory group (SAG) - Public consultation. Specific webinars might also be organised (please see 4.4.1.). Stakeholder involvement per subgroup: **SG1:** Stakeholders are expected to participate in the planned SAG and public consultation processes of non-confidential deliverables, i.e. on the draft procedure for early dialogues and on the concept paper and draft version of disease specific guideline(s) that will be produced. **SG2:** Stakeholders are expected to participate in the planned SAG and public consultation processes of non-confidential deliverables. They are also expected to contribute to the choice of a common technology of interest (for the pilot core protocol). **SG3:** Stakeholders are expected to participate in the planned public consultation processes of the new and updated methodological guidelines. Their proposals for topics of new guidelines or updates of existing guidelines from JA1 – WP5 are taken into consideration during the initial and repeated prioritization of themes in SG3. **SG4:** Industry stakeholders are expected to contribute to the development of, and participate in the consultation on the draft template; agencies receiving manufacturers submissions who are not EUnetHTA partners of WP7 will be asked to comment on the completeness of the draft template. Involvement of the WP5 SAG will be considered if appropriate.

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: ***www.eunethta.eu***

3. Objectives

Different types of actions are included in JA2 WP7 and the work is divided into 4 subgroups, as follows:

- SG 1: Pilots and guidelines to improve quality and adequacy of initial evidence generation: Early Dialogue and Disease specific guidelines (new activity)
- SG2: Guidelines/position paper and pilots to improve quality and adequacy of additional evidence generation (continued and expanded from JA1 WP7)
- SG3: Guidelines on methodological issues, all health technologies (continued and expanded from JA1 WP5)
- SG4: Templates for manufacturers' submissions to support production of core HTA information and rapid assessments (new activity, closely related to JA2 WP5).

Title	Description	Indicators
2. Implement, pilot and further develop models and tools as well as production processes to support collaborative production of core HTA information with reinforced secretariat and coordination function.	To provide guidance and testing in identifying and organizing collaborations between partners for setting up a specific collaboration (i.e. around an assessment topic). Coordinating function of various activity clusters and overall partnership coordination will be further developed and streamlined.	Guidelines for collaboration, including identification of partners and clusters of organisations for specific topics, issued. Specific indicators per subgroup: **SG1:** **Early Dialogue (ED)** - Conduct of pilot EDs for 3 drugs and at least 1 medical device or procedure - One survey to be performed by participating HTA bodies, EMA, manufacturers and other stakeholders at the end of 2013 - Consolidated procedure based on survey analysis Production of at least one guideline on the type of data to be produced during the development of technologies in a given condition: choice of the condition, drafting of concept paper and guideline, public consultation.
6. Develop and test a methodological basis for European cooperation on HTA including guidelines for distinct methodological issues and quality improvement of evidence generation for HTA.	To develop a) methodological guidelines on pertinent issues of assessment (e.g. for devices) or update existing guidelines according to needs and resources or b) guidelines for improving evidence generation in early dialog with manufacturers or c) a uniform data template for submissions enabling sound, common rapid assessments and national adaptation	Guidelines for pertinent HTA issues produced: at least one guideline including specificities for drugs another technologies, at least one guideline for evidence generation, template for submissions from technology sponsors available and tested for at least two technologies Specific indicators per subgroup: **SG2:** - Guidelines/position paper to improve additional evidence generation developed and published - Common core protocol for Additional Data Collection (for a technology of common interest) developed **SG3:** - Revised concept for the elaboration of guidelines incl. templates [topic prioritisation/selection; elaboration, maintenance] - New methodological guidelines, updated methodological guidelines **SG4:** a modular template for evidence submissions that includes the evidence requirements from European HTA organisations and reflects the HTA Core Model

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
Reviews and surveys of HTA bodies practices	M 12 – Sep 2013
Draft versions of templates and first guidelines	M 15 – Dec 2013
Results of first templates, guidelines and pilots	M26 – Nov 2014
Final Report	M36 – Sep 2015

Deliverables	Deadline
Guidelines and pilots to improve quality and adequacy of initial and additional evidence generation	M36 – Sep 2015
Specific deliverables per SG:	
SG1:	
Early dialogues	
- 3 pilots early dialogue on drugs	M9- June 2013
- 1 pilot early dialogue on medical device or procedure	M 13 – Oct. 2013
- Survey to participating HTA bodies, EMA, manufacturers and other stakeholders on ED process	M 13 – Oct. 2013
- Consolidated procedure on drug and non-drug early dialogues	M 22 – Dec 2014
Disease specific guidelines	
- Choice of condition(s)	M8 – May 2013
- Development of template for concept paper and guideline	*M8 – May 2013*
- Concept paper	*M9 – June 2013*
- 1st draft guideline	M17 – Feb 2014
- Public consultation	M31 – April 2015
- Final version(s) of disease specific guideline(s)	M36 – Sept 2015
SG2:	
- Guidelines/position paper to improve additional evidence generation	M30 – March 2015
- Common core protocol for Additional Data Collection (for a technology of common interest)	M34 – July 2015
SG3: Methodological guidelines and templates to support the production on core HTA information and rapid assessments	
- Stepwise developed concept for EUnetHTA´s elaboration process of methodol. guidelines incl. new templates for guidelines, containing also a description of procedures to identify and prioritise new methodological topics and to systematically maintain existing guidelines (continuous quality assurance, defining criteria for revision / updating)	M15 – Dec 2013
- New methodol. guidelines / methodol. papers (N ≥ 2) produced in two waves	M26 – Nov2014
- Updated or supplemented guidelines from the JA1-WP5-Guideline-Pool (N ≥ 2) produced in two waves	M36 – Sep2015
Methodological guidelines and templates to support the production on core HTA information and rapid assessments	M36 – Sept 2015
Specific deliverables per SG:	
SG4: Templates to support the production on core HTA information and rapid assessments	

• Collect and analyse submission templates or evidence requirements from EU agencies • Produce a report on similarities and differences, expert meeting • Create a draft submission template for piloting in WP5 • Piloting in WP5 • Develop updated template based on feedback • Targeted consultation on report and draft submission template with agencies receiving submissions and industry via SF • 2nd round piloting in WP5 • Develop final template	M12 – Sept 2013 M12 – Sept 2013 M19 – April 2014 M26 – Nov 2014 M32 – May15 M36 – Sept 2015

4.2 Methods

SG1:

Early dialogues (ED):

Three early dialogue pilots for drugs and one for a medical device are planned in the framework of JA2 WP7. They will be conducted based on a draft procedure and on the experience gained from 2 preparatory pilots early dialogues on pharmaceuticals conducted in 2012.

With the experience gained from these 4 pilots, the process and draft procedure for early dialogues will be reviewed, improved and refined towards a final consolidated procedure for early dialogues. This will be achieved based on a survey performed in October 2013 by the LP with the involved parties, i.e. participating HTA bodies, manufacturers, the EMA (invited as observer for drug ED pilots), and the SAG. An expert meeting or e-meeting with interested parties will be organised beginning of 2014 if necessary.

Ten additional EDs will be organised with the financial support of the European Commission that is expected in September 2013.

Scope of early dialogue pilots: pilot early dialogues with HTA organization representatives may be requested for a new technology for questions pertaining to relative effectiveness, economic and other aspects of development of a pharmaceutical (new chemical entity or new biological product) or a non-drug technology (e.g. medical device, diagnostic, procedure) with supposed added benefit for patients. Each pilot early dialogues **is** restricted to one indication and/or one line of treatment. ED are prospective in nature (advice on ongoing trials is out of scope) and **confidential**

Current draft process:

DAYS (calendar days)	**ACTION**
D -60: Start of procedure	• Submission by the company of the early dialogue request validated by HAS to all participating HTA bodies
D -45	• A teleconference or e-meeting with HTA bodies is organized by HAS to identify possible missing information related to the application file and to the proposed development plan (list of main issues that should be addressed by the company either in writing or at the next face-to-face meeting). • The company is informed of the outcome of the teleconference/e-meeting and additional data or clarifications requested if needed
D -30	The company provides additional information or clarification as needed
D -7:	Short written answers to company's questions are sent by each HTA participant to the coordinator
D -3:	Individual HTA positions are released to participating HTA organisations in the format of a compiled document
D 0: Early Dialogue Meeting	• Preliminary discussion among HTA organizations (without the company) • Face-to-Face meeting with the company and HTA organizations • Conclusions among HTA organizations (without the company)

D +7	The draft detailed minutes of the meeting relating general and individual HTA bodies positions for each question is provided by the company
D +20: End of procedure	The detailed minutes are reviewed and corrected in writing by HAS and participating HTA organisations. In case of remaining uncertainties, a teleconference or e-meeting with HTA bodies may organized by coordinator.

The timelines indicated here may be subject to change based on the input from interested parties.

Disease specific guidelines:

At least one disease-specific guideline will be produced by the volunteering SG1 members (one main author, one co-author, with the support of ED SG1 partners) on the type of data to be produced during the development of technologies (initial evidence generation) to support relative effectiveness and cost-effectiveness assessment in a given condition:

- Choice of condition(s) based on the input from the early dialogues pilots and from the SAG
- Development of templates for concept paper and guideline (LP)
- Drafting of concept paper(s) identifying the scope, problem statement, the specific points to be addressed, the timetable for release of draft and final guidelines and main references;. the concept paper will be released for comments (WP7 partners and SAG) before publication on EUnetHTA website: June 2013
- Drafting of the disease specific guideline(s) to be released for comments to all WP7 partners, SAG and EMA before public consultation targeted in January 2015. If needed an expert meeting to discuss critical issues before public consultation will be conducted.
- Finalization of disease specific guideline(s): collection of comments, WP7 partner review, adoption and release of final guideline on the EUnetHTA website: September 2015

SG2:

Subgroup 2 will be dedicated to the development of guidelines/position paper to improve the quality of additional evidence generation, as well as to setting-up possibilities for collaboration on AEG (ideally through a pilot common core protocol).

First, an analysis of uncertainties identified in European HTA reports, related research questions and the nature of additional evidence required will be carried out by LP thanks to the records in EVIDENT database.

This analysis will be followed and completed with the Survey on the possibilities and conditions for performing harmonized ADC that will be carried out among WP7 partners. This survey should enable understanding HTA bodies' practices in the domain of additional evidence generation and their specific needs and requirements in terms of methods, as well as to explore the possibilities for collaboration.

The results will allow defining the final orientation of SG's deliverables.

The development of the deliverables will consist of:

- literature review of existing guidelines, study protocols checklists etc (by LP)
- Delphi rounds to select a technology of common interest (for the Common core protocol pilot) among WP7 partners
- Development of the first drafts of the guidelines/position paper (by LP) and the common core protocol (by volunteering partners)
- Review of first drafts by WP7 partners and Stakeholders
- Public consultation on the final proposals of guidelines/position paper (and protocol, if not confidential)
- Development of final versions of the deliverables

Other SG2 activities will include further development of the EVIDENT database, and collaboration with other organizations that deal with additional evidence generation, especially ENCePP and EMA:

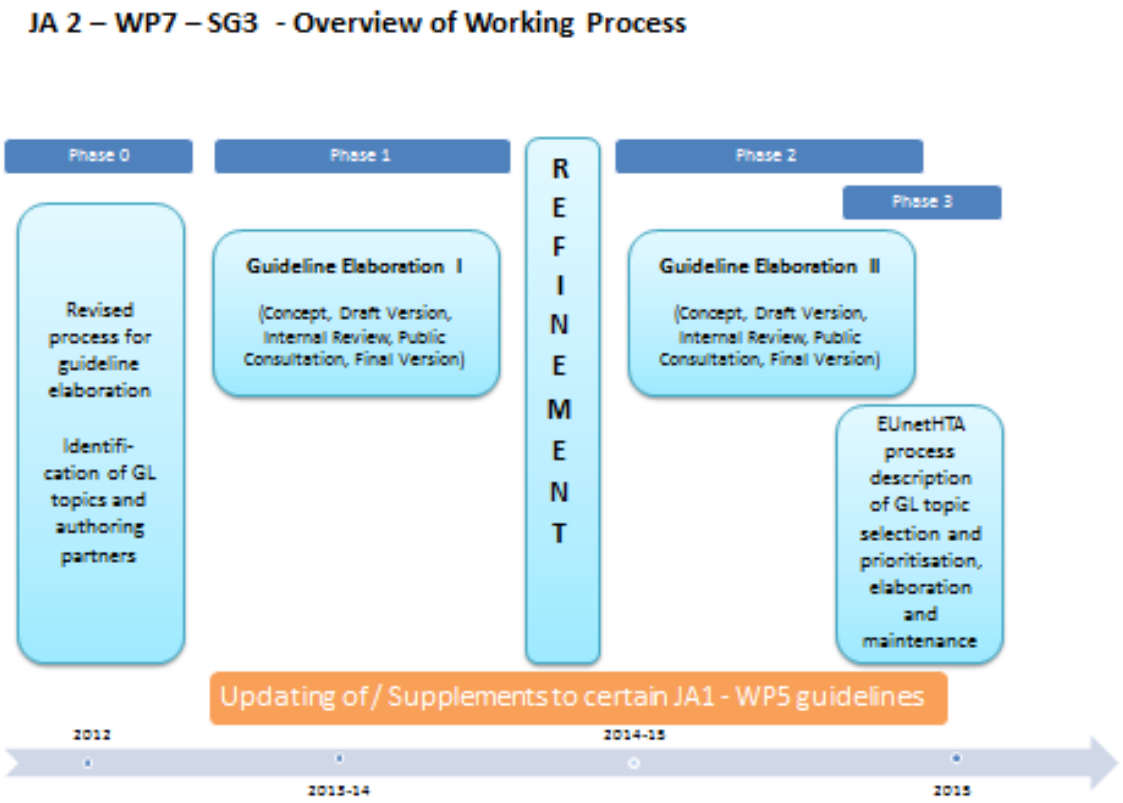
- HAS will continue to upgrade EVIDENT database, according to the user's feedback. Opening at least partially the database to the public will be envisaged. The active use of the database should be promoted

- Collaboration with EMA in order to develop and agree on a methodology for studies in the post licensing phase has already been initiated and will continue during JA2 (limited on drugs)

- Collaboration with ENCePP Working group on HTA will be also put in place (specific actions TBD). Possibilities for other external collaborations will be explored.

SG3:

- Concept revision of guideline elaboration process together with WP7 partners, agreement on a new working model for JA2
- Drafting of a new working manual and of templates for methodological guideline development
- Choice of guideline topics for new generation or updating (together with WP4,5,7 partners) and identification of authoring agencies
- Development of guidelines within the new framework (including internal reviews and public consultations) in two consecutive waves (Co-Lead and other WP7 partners), intermediate phase of revision and process refinement
    - Cooperating with other WPs (i.e. 2,4,5,8) in the dissemination, implementation and use of existing and new methodological guidelines
- Drafting of a final concept version for methodological guideline production at the end of project based on practical experience, finally approved by EUnetHTA



SG4:

- Collection of evidence requirements/ submission templates from individual national agencies in Europe
- Analysis of evidence requirements (taking also into account the Assessment templates from EMA) and development of an outline draft template for discussion at expert group meeting
- Developing a 1st draft submission template for piloting in WP5 (REA)

- Using feedback from piloting to develop 2nd draft template ready for consultation with industry stakeholders and EUnetHTA partners (and national agencies that receive submission templates but are not EUnetHTA partners), and further piloting in WP5

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
2013-01-30	Paris	One day meeting	WP 7 LP + CLP WP 7 AP + CP	Kick-off meeting (discussions on the Workplan, confirmation of participation to SGs) + specific activities per subgroup: SG2: Training on EVIDENT database SG3: Discussion of alternative models for the guideline elaboration process choice of guideline topics identification of authoring agencies
January 22-23th 2014	Cologne	Two days meeting (one night)	WP 7 LP + CLP WP 7 AP + CP	Update on deliverables + specific activities per subgroup: SG1: presentation of survey results for EDs and concept paper of disease specific guideline(s) SG2: presentation of the first drafts SG3: presentation of the first methodol. guideline drafts (new or updated/supplemented) discussion of the experiences with the revised process of guideline elaboration/updating SG4: present and discuss the analyses of evidence requirements and draft template
Week of November 17th 2014	To be decided	One day meeting	WP 7 LP + CLP WP 7 AP + CP	Update on deliverables + specific activities per subgroup: SG1: presentation of consolidated procedure on drug and non-drug early dialogues and 3rd draft of disease specific guideline(s) SG2: Presentation of the results of the public consultation on guidelines/position paper, discussion on the final version Presentation of the first results of the common core protocol SG3: presentation of finalised guidelines (phase 1) presentation of the first drafts or concepts of methodological guidelines (phase 2) SG4: present and discuss the consultation responses and the template for piloting

Additionally, several e-meetings will be arranged to support practical work within subgroups. Specific webinars might be organised with SAG if needed (for example to clarify responses received during SAG consultation).

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Strand of activities: SG1 - Pilots and guidelines to improve quality and adequacy of initial evidence generation				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M9 Jul´13	3 pilot early dialogues on drugs	WP7 partners, EMA, companies	LP, WP members, EMA industry,
M1 Oct '12	M12 Sep´13	Draft procedure for early dialogues to be adapted to non drugs	WP7 partners, manufacturers	LP
M5 Feb'13	M8 May´13	Choice of condition(s) and development of template for concept paper and disease specific guideline	WP7 partners, companies	LP, Volunteering SG1 WP members
M9 Jun´13	M9 Jun´13	Development of concept paper(s) for disease specific guideline(s)	WP7 partners	LP, Volunteering SG1 WP members
M10 Jul´13	M10 Jul´13	Review of the concept paper(s) for disease specific guideline(s)	WP7 partners, SAG members	WP and SAG members
M11 Aug´13	M11 Sept´13	Validation of concept paper(s) for disease specific guideline(s)	WP7 partners	LP, WP members
M12 Sep'13	M12 Sep'13	Publication on EUnetHTA website of concept paper for disease specific guideline(s)	EUnetHTA, External parties	
M12 Sep'13	M12 Sep'13	Development of 1st draft for disease specific guideline(s) (ctd year 2)	WP7 partners, EMA, companies	LP, Volunteering SG1 WP members

Strand of activities: SG 2 - Guidelines and pilots to improve quality and adequacy of additional evidence generation				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M5 Fev´13	Work plan development	WP members	WP members
M1 Oct '12	M12 Sep '13	Maintaining EVIDENT database, identification of needs for further development according to users' feedback; trainings if needed	EUnetHTA partners	LP
M5 Feb '13	M9 June '13	Literature review of existing guidelines on evidence generation and study protocols	EUnetHTA partners	LP and volunteering WP members
M7 Apr '13	M7 Apr '13	Preparatory activities for the First survey	WP members	LP
M8 May '13 (end of the	M10 July '13	First survey on the possibilities and conditions for performing harmonised ADC	WP members	WP members

month)				
M12 Sep'13	M12 Sep'13	Development of the first draft of guidelines/position paper for AEG (ctd in year 2)	EUnetHTA, partners, SAG	LP/ volunteering WP members
M12 Sep´13	M12 Sep´13	Preparing SG 2 special part for JA2-WP7 Interim Report	EUnetHTA	LP, Co-LP

Strand of activities SG3: "General methodology guidelines"				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct '12	M3 Dec´12	Work plan development (WP7 Lead / Co-Lead)	WP7 partners, WP1,4,5	WP7 partners, WP1,4,5
M4 Jan ´13	M6 Mar´13	Drafting + approval of a revised concept for metholog. guideline elaboration; choice of guideline issues (new ones, to be updated) and identifying authoring agencies by Co-Lead	WP7 partners, WP1,4,5	WP7 partners, WP1,4,5
M4 Jan ´13	M6 Mar´13	Drafting of a new working manual and of templates for methodological guideline elaboration by Co-Lead	WP7 partners, WP1,4,5	WP7 partners, WP1,4,5
M7 Apr´13	M12 Sep´13	1st guideline production wave following the chosen model of elaboration (new guidelines)	WP7 partners,	WP7 partners,
M7 Apr´13	M12 Sep´13	Updating / supplementing existing EUnetHTA methodolog. guidelines	WP7 partners,	WP7 partners,
M12 Sep´13	M12 Sep´13	Preparing SG 3 special part for JA2-WP7 Interim Report	WP7 Co-Lead, WP7 Lead	WP1, WP7 partners

Strand of activities SG4: Templates for manufacturers files' submissions to support production of core HTA information and rapid assessments				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M1 Oct 12	M3 Dec12	Work plan development (WP7 Lead / Co-Lead/ NICE)	WP7 partners, WP1,4,5	WP7 partners, WP1,4,5
M4 Jan 13	M6 Mar 13	Request submission templates or evidence requirements with translation if needed - by EUnetHTA partners' translators Call to industry stakeholders for collaboration	WP7 partners, WP5, industry	WP7 SG4
M6 Apr 13	M7 Jun 13	Clarify evidence requirements with individual agencies, analyse submission templates for similarities and differences, report Compile/ combine/ merge evidence requirements into a modular structure format for outline draft template for REA	WP7 SG4	WP7 SG4
M8 Jun 13	M13 Sep 13	Hold a expert meeting/ workshop with industry stakeholders and WP7 SG4 Partners Develop 1st draft template for piloting	WP7 partners, WP5, industry	WP7 SG4

Year 2 (Oct 2013-Sep 2014)

Strand of activities: SG1 - Pilots and guidelines to improve quality and adequacy of initial evidence generation

Start	End	Activity steps	Target group	Parties involved
M13 Oct´13	M13 Oct´13	1 pilot early dialogue on medical device or procedure (ctd from year 1)	WP7 partners, company	LP, WP members, industry
M13 Oct´13	M13 Oct´13	Survey to participating HTA bodies, EMA, manufacturers and other stakeholders on ED process (drug and non drug)	WP7 partners, companies, EMA	LP, Co-LP , WP members, industry, EMA
M13 Oct'13	M17 Feb'14	Development of first draft of disease specific guideline(s) (ctd from year 1)	EUnetHTA partners, EMA, companies	Author and volunteering WP members
M16 Jan´14	M16 Jan´14	Presentation of the concept paper/1st draft on disease specific guideline(s) and survey results (and draft consolidated procedure) for EDs at the FtF meetings	WP7 SG1 partners, WP7 partners	LP, WP partners
M16 Jan´14	M16 Jan´14	An expert meeting or e-meeting with interested parties will be organised on the process of pilots of early dialogue	SAG industry	SAG industry
M18 Mar´14	M19 Apr'14	Review of draft consolidated procedure for ED for drugs and non drugs	WP7 partners, companies, EMA (drugs)	LP, WP members,
M20 May'14	M21 Jun'14	Review of 1st draft of disease specific guideline (s)	WP7 partners, companies, EMA (drugs)	SAG, EMA
M17 Feb'14	M17 Feb'14	Validation of first draft of disease specific guideline(s)	WP7 members	WP members,
M22 Jul' '14	M24 Sep'14	2nd draft of disease specific guideline(s) (cont. year 3)	WP7 partners	Author and volunteering WP members (drafting group)
M19 Apr'14	M21 Jun'14	Review of consolidated procedure for ED for drugs and non drugs	WP7 partners, companies, EMA (drugs)	SAG and EMA
M22 Jul'14	M24 Sep'14	Public consultation of consolidated procedure for ED for drugs and non drugs	External parties	External parties
M24 Sep'14	M24 Sep '14	Interim report	EUnetHTA	LP, Co-LP

Strand of activities: SG 2 - Guidelines and pilots to improve quality and adequacy of additional evidence generation

Start	End	Activity steps	Target group	Parties involved
M13 Oct '13	M24 Sep '14	Maintaining EVIDENT database, further development if needed	EUnetHTA partners	LP
M13 Oct '13	M17 Feb '14	Development of the first draft of guidelines/position paper for AEG (ctd from year 1)	EUnetHTA partners, SAG	LP /volunteering WP members
M13 Oct '13	M14 Nov '13	Topic selection for the common core protocol	WP and SAG members	WP and SAG members
M18 Mar '14	M20 May '14	Review of the first draft of guidelines/position paper for AEG	EUnetHTA partners, SAG	WP and SAG members
M19 Apr '14	M22 July '14	Development of the first draft of the common core protocol	EUnetHTA partners	Volunteering WP members
M21 June '14	M24 Sep '14	Development of the second draft of guidelines/position paper for AEG	EUnetHTA partners, SAG	LP/volunteering WP members
M24 Sep '14	M24 Sep '14	Second interim report	EUnetHTA	LP, Co-LP

Strand of activities SG3: "General methodology guidelines"				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M13 Oct´13	M20 May´14	(continued) 1st guideline production wave following the chosen model of elaboration	EUnetHTA partners, EMA, industry	WP7 partners,
M16 Jan´14	M16 Jan´14	Guidelines review before public consultation - SAG	SAG	WP7 partners, WP5 and WP4 partners when adequate
M16 Jan´14	M18 Mar´14	Public Consultation on guideline drafts (new guidelines)	Stakeholders	Stakeholders
M13 Oct´13	M24 Sep´14	Updating / supplementing existing EUnetHTA methodolog. guidelines	EUnetHTA partners, EMA, industry	WP7 partners
M16 Jan ´14	M18 Mar´14	(evtl.) Public Consultation on updated / supplemented guideline drafts	Stakeholders	Stakeholders
M21 Jun´14	M22 Jul´14	Revision /Refinement of GL elaboration process	EUnetHTA partners	WP7 Co-LP
M23 Aug´14	M24 Sep´14	2nd guideline production wave following refined model of elaboration (new guidelines)	EUnetHTA partners, EMA, industry	WP7 partners
M24 Sep´14	M24 Sep´14	Preparing SG 3 special part for JA2-WP7 Interim Report	EU	WP7 LP, Co-LP

Strand of activities SG4: Templates for manufacturers files' submissions to support production of core HTA information and rapid assessments

Start	End	Activity steps	Target group	Parties involved
M13 Oct 13	M19 Apr 14	Piloting of 1st draft template	EUnetHTA partners	WP5
M20 May	M23 Aug 14	Using feedback from piloting to develop 2nd draft template	EUnetHTA partners	WP7 SG4

(see for overlap - year 3)

Year 3 (Oct 2014-Sep 2015)

Strand of activities: SG1 - Pilots and guidelines to improve quality and adequacy of initial evidence generation				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct '14	M27 Dec'14	2nd draft of disease specific guideline(s) (ctd from year 2)	WP7 partners, EMA, industry	Author and volunteering WP members (drafting group), WP7 partners
M26 Nov '14	M26 Nov '14	Presentation of 2nd draft of disease specific guideline(s) and results from public consultation on consolidated procedure for EDs at the FtF meetings,	WP7 partners, EMA, industry	LP, WP partners
M27 Dec'14	M27 Dec'14	Publication of the consolidated procedure for EDs	EUnetHTA, External parties	EUnetHTA, External parties
M28 Dec'14	M35 Aug '15	Final draft of disease specific guideline(s)	WP7 partners, EMA, industry	Author and volunteering WP members (drafting group), WP partners
M31 April'15	M33 June'15	Public consultation on the final draft of disease specific guideline(s)	External parties	External parties
M34 Jul'15	M 36 Sep'15	Final version of disease specific guideline(s)	EUnetHTA partners, EMA, industry	Author and volunteering WP members (drafting group)
M 36 Sep'15	M 36 Sep'15	Publication of the final version of disease specific guideline(s)	EUnetHTA, External parties	WP7 LP, EUnetHTA
M34 July '15	M 36 Sep'15	Final report	EUnetHTA	LP, Co-LP

Strand of activities: SG 2 - Guidelines and pilots to improve quality and adequacy of additional evidence generation

Start	End	Activity steps	Target group	Parties involved
M25 Oct ‘14	M 36 Sep ‘15	Maintaining EVIDENT database, further development if needed	EUnetHTA partners	LP
M25 Oct ‘14	M26 Nov ‘14	Public consultation on the second draft of guidelines/position paper for AEG	EUnetHTA partners, SAG	External parties
M26 Nov ‘14	M27 Dec ‘14	Review of the first draft of the common core protocol (if not confidential)	EUnetHTA partners, SAG	SAG members
M26 Nov ‘14	M26 Nov ‘14	Presentation of the preliminary results of the public consultation on guidelines/position paper at the FtF meeting, discussion on the final version	WP members	LP, WP members
M27 Dec ‘14	M28 Jan ‘15	Development of the final version of the guidelines/position paper	EUnetHTA partners, SAG	LP/volunteering WP members
M28 Jan ‘15	M29 Feb ‘15	Development of the second draft of the common core protocol	EUnetHTA partners	Volunteering WP members
M29 Feb ‘15	M30 Mar ‘15	Validation of guidelines/position paper and publication of the final version	EUnetHTA, external parties	WP members
M30 Mar ‘15	M31 Apr ‘15	Public consultation on the second draft of the common core protocol (if not confidential)	EUnetHTA, external parties	External parties
M32 May‘15	M33 Jun ‘15	Development of the final version of the common core protocol	EUnetHTA, partners	Volunteering WP members
M34 July ‘15	M34 July ‘15	Publication of the common core protocol (if not confidential)	EUnetHTA, external parties	LP, Volunteering WP members
M34 July ‘15	M 36 Sep ‘15	Final report	EUnetHTA	LP, Co-LP

Strand of activities SG3: “General methodology guidelines”				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M25 Oct´14	M36 Sep´15	(continued) 2nd guideline production wave following refined model of elaboration (new guidelines)	EUnetHTA partners, EMA, industry	WP7 partners
M32 May´15	M32 May´15	SAG Review before public consultation	SAG	WP7 partners, WP5 and WP4 partners when adequate
M32 May´15	M34 Jul ´15	Public Consultation on guideline drafts (new guidelines)	Stakeholders	Stakeholders
M25 Oct´14	M36 Sep´15	Updating / supplementing the existing EUnetHTA methodolog. guidelines	EUnetHTA partners, EMA, industry	WP7 partners
M32 May´15	M34 Jul ´15	Public Consultation on updated / supplemented guideline drafts	Stakeholders	Stakeholders

M31 Apr´15	M36 Sep´15	Drafting of a final concept version for methodological guideline production at the end of project based on practical experience, finally approved by EUnetHTA	EUnetHTA	WP7 Co-LP
M36 Sep´15	M36 Sep´15	Preparing SG 3 special part for JA2-WP7 final Report	EUnetHTA	WP7 LP and Co-LP

Strand of activities SG4: Templates for manufacturers files' submissions to support production of core HTA information and rapid assessments				
Start	**End**	**Activity steps**	**Target group**	**Parties involved**
M24 Sept 14	M26 Nov 14	Targeted consultation on draft submission template with agencies receiving submissions and Industry	EUnetHTA partners, stakeholders	WP7 SG4 stakeholders EUnetHTA
M24 Nov 14	M32 May 15	Piloting of 2nd draft template	EUnetHTA partners	WP5
M33 Jun 15	M34 July 15	Targeted consultation on draft submission template with WP5 and Industry	EUnetHTA partners, stakeholders	WP5, stakeholders
M35 Aug 15	M37 Oct 15	Analyse consultation and 2nd piloting comments Develop final template and report	EUnetHTA partners, stakeholders	WP7 SG4

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery** (i.e. online or e-mail)	**Coordination with other WPs** (Yes/No – if yes which WP)
M8 May ’13 (end of the month) – M10 July ‘13	First survey on the possibilities and conditions for performing harmonised ADC (SG2)	WP7 members	e-mailed questionnaire	No
M13 Oct´13	Survey to participating HTA bodies, EMA, manufacturers and other stakeholders on ED process (drug and non drug) (SG1)	HTA participating organisations in pilots, company, EMA	e-mailed questionnaire	No
M13 Oct ’13 – M14 Nov ‘13	Topic selection for the common core protocol (SG2)	WP and SAG members	e-mailed forms	No

4.4.1 Stakeholder involvement

Stakeholders will be involved in WP7 in two different ways:
- Stakeholder advisory groups (SAG)
- Public consultation.

In addition, specific webinars or e-meetings might be organised to discuss topics foreseen in the work plan.

Stakeholder involvement per subgroup:

- **SG1** Stakeholders are expected to participate in the planned SAG and public consultation processes of non-confidential deliverables:
    - Input to be requested from SAG on choice of condition for disease specific guideline(s) (M7)
    - Review of the concept paper(s) for disease specific guideline(s) (M10)
    - An expert meeting or e-meeting with interested parties will be organised on the process of pilots of early dialogue (M16)
    - Review of draft consolidated procedure for ED for drugs and non drugs (M19-M21)
    - Review of the draft of disease specific guideline(s) (M20-M21)
    - Public consultation of consolidated procedure for ED for drugs and non drugs (M22-M24)
    - Public consultation on the final draft of disease specific guideline(s) (M31-M33)

  Further to SAG consultations, webinars might be organized if some points need further clarification.

- **SG2:** : Stakeholders are expected to participate in the planned SAG and public consultation processes of non-confidential deliverables:
    - Review of the first draft of guidelines/position paper for AEG – SAG consultation (M18-M20)
    - Public consultation on the second draft of guidelines/position paper for AEG (M25-M26)
    - Review of the first draft of the common core protocol (if not confidential) (M26-M27)
    - Public consultation on the second draft of the common core protocol (if not confidential) (M30-M31)

  They are also expected to contribute to the choice of a common technology of interest (for the pilot core protocol) (planned for M13-M14).

  Further to SAG consultations, webinars might be organized if some points need further clarification.

- **SG3:** Stakeholders are expected to participate in the planned SAG and public consultation phases of the two cycles of methodological guideline development, to make proposals for guideline topic selection (permanent open process) and to contribute to the description of the GL elaboration process. In addition patient organisations or other interested parties (such as learned societies) may be consulted if adequate during the draft process of a guideline. This will be planned by the first author and the draft group during the concept phase of the guideline elaboration to inform the involved stakeholder groups or experts as early as possible.
- **SG4:** Industry stakeholders are expected to participate in the consultation on the draft template via expert meetings and targeted consultations;

SAG involvement			
Timing	**Purpose**	**Type of input from SAG**	**Info from SAG to be used for…**
M7 April 13	SG1 Choice of condition(s) for disease specific guideline(s)	Suggestions for conditions	Selection of condition
Spring 2013	SG4 Input into the development of the 1st draft submission template	Identification of differences between evidence requirements across Europe, suggestions how to overcome these differences, suggestions for the content of a submission template	development of 1st draft submission template to be used in piloting in WP5
M10 July 13	SG1 Review of the concept paper(s) for disease specific guideline(s)	Comments	Improvement of document
Summer 2013	SG4 Expert meeting	Discussion of issues mentioned above	development of 1st draft submission template to be used in piloting in WP5

M13 Oct '13 – M14 Nov '13	SG2 Choice of a common technology of interest (for the pilot core protocol)	Suggestions of technologies	Topic selection for the pilot core protocol
M16 Jan ´14	SG 3 Review of the guideline drafts before public consultation	Comments	Improvement of document
M16 Jan 14	SG1 Early dialogue process: results of survey to be presented, procedure	Expert meeting or e-meeting	Improvement of document
M19 March14 -M21 Jun14	SG1 Review of draft consolidated procedure for ED for drugs and non drugs	Comments	Improvement of procedure
M18 Mar '14 -M20 May '14	SG2 Review of the first draft of guidelines/position paper for AEG	Written comments + Webinar if needed to clarify received comments	Improvement of the document
Evtl. M 21 June ´14	SG3 Input for the revision of the first JA2 guideline elaboration phase, evtl. Workshop on methodological Guidelines (depending on the results of the planned public consultation)	E-meeting or f-t-f-Meeting Participation	Refinement of the EUnetHTA process of elaborating methodological guidelines
M20 May 14-M21 Jun 14	SG1 Review of the draft of disease specific guideline(s)	Comments	Improvement of document
M24 Sep' 14-M26 Nov'14	SG4 Consultation on 2nd draft submission template	Comments required on the completeness and workability of the suggested submission template	finalisation of the submission template
M26 Nov '14-M27 Dec '14	SG2 Review of the first draft of the common core protocol (if not confidential)	Written comments + Webinar if needed to clarify received comments	Improvement of the document
M 32 May ´15	SG 3 Review of the guideline drafts before public consultation	Comments	Improvement of document
Summer 2015	option of a SG4 expert meeting	discussion of final template following pilting and consulation	finalization of the submission template
M 36 Sept. 2015	SG3 Input for the final description of the EUnetHTA GL elaboration process, evtl. Workshop on methodological Guidelines (depending on the results of the planned public consultation)	E-meeting or f-t-f-Meeting Participation	Final draft of a EUnetHTA process of elaborating methodological guidelines

4.4.2 Public Consultation

- **SG1:** public consultation of the consolidated procedure for the early dialogues for drugs and non drugs (M22-M24) and of the disease specific guideline(s) (M31-M33)
- **SG2:** on the final versions of the deliverables:
    - Public consultation on the second draft of guidelines/position paper for AEG (M25-M26)
    - Public consultation on the second draft of the common core protocol (if not confidential) (M30-M31)

- **SG3:** Depending on the concrete new model of guideline elaboration at least one phase of public consultation is planned per guideline production wave.
- **SG4:** public consultation is not considered necessary

Public Consultations			
Timing	**Purpose**	**Target group** (EUnetHTA Web/other)	**Info used for**
M16-M18 Jan. - April 2014	Review of the methodol. Guideline drafts (SG3)	EUnetHTA Web, EMA	Quality assurance
M22 Jul 14 - M24 Sept 14	Consolidated procedure for the early dialogues for drugs and non drugs (SG1)		Improvement of procedure
M25 Oct '14 - M26 Nov '14	Public consultation on the second draft of guidelines/position paper for AEG (SG2)	EUnetHTA Web/other	Improvement of the document
M30 March '15 - M31 April '15	Public consultation on the second draft of the common core protocol (if not confidential) (SG2)	EUnetHTA Web/other	Improvement of the document
M31 April 15 - M33 Jun 15	Disease specific guideline(s) (SG1)		Improvement of document
M32-M34 May – July 2015	Review of the methodol. Guideline drafts (SG3)	EUnetHTA Web, EMA	Quality assurance

4.4.3 Conflict of interests

Conflict of interest will be managed accordingly with the general indications from EUnetHTA JA2 Conflict of Interest Policy.

Each Work Package members, as EUnetHTA partner (AP or CP) have the responsibility of declaring any possible conflict of interest in relation to the topic at stake. Each partner should use common standards for the conflict of interest declaration.

In case of use of external contributors, conflicts of interests will be recorded for each contributor (Manufacturer, external experts, patients, etc).

4.4.4 Handling of confidentiality

It is assumed that confidentiality agreements are standard practice for the WP7 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP7 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP7.

4.4.5 Quality assurance procedures

Following activities will be applied in order to assure the quality of the produced documents:

- Authorship by at least two partners (one author and one co-author)
- Review by active WP7 partners (dedicated reviewers)
- Consultations with Market Authorisation Holders (MAHs);
- Consultations with other partners of WP7;

4.4.6 National HTA Report Production

Not applicable

4.4.7 Cooperation with other WPs / LPs

LP is member of the WP1 (Coordination and sustainable network implementation) and will contribute to the work as per the WP1 work plan and decisions made during the WP1 course of action.

Feedback on the use of EVIDENT database and the development of the Early dialogue procedure will be provided to WP2 in order to define needs for training. WP2 will be informed on the needs related to other WP7 deliverables (guidelines) as and when produced.

Cooperation per SG:

SG1 ED pilots will be linked to SG1 disease specific guideline(s) and to SG3 general methodology guidelines. If applicable, SG1 ED pilots will be linked to WP5 pilot production at the stage of the scoping phase.

SG2 will collaborate with WP6 for IT tools (especially EVIDENT database)..

SG3: WP5, WP4

SG4: WP5/ WP4: Close collaboration with WP5 and also, so some degree, with WP4 is required for the successful delivery of a manufacturer's submission template. The draft template, being for rapid assessments, will be piloted in WP5 and refined based on the feedback from the WP5 piloting. The resulting next version of the template will then undergo a consultation which will involve also WP4.

5. Dissemination plan

Output	Format	Time
Experiences from JA2 (per SG)	presentation (EUnetHTA Conference)	2014
SG1: Consolidated procedure for early dialogue pilots	Document published on EUnetHTA website	M27 Dec'14
SG1: concept paper for disease specific guideline(s)	Document published on EUnetHTA website	*M12* Sep'13
SG1: disease specific guideline(s)	Document published on EUnetHTA website	M 36 Sep '15
SG2: Guidelines/position paper on additional evidence generation	Document published on EUnetHTA website	M29 Feb '15
SG2: Common core protocol for additional data collection	Document published on EUnetHTA website (dissemination to external parties only if not confidential, otherwise results shared only with EUnetHTA members)	M34 July '15
SG3: Methodological guidelines developed or updated during the first production wave	Document published on EUnetHTA website	M22 Jul´14
SG3: Methodological guidelines developed or updated during the second production wave	Document published on EUnetHTA website	M36 Sep ´15
SG3: Final draft of a process description for the topic selection, elaboration and maintenance of EUnetHTA methodological guidelines	Document published on EUnetHTA website	M36 Sep ´15
SG4: Final template(s) for evidence requirements for manufacturers submissions for rapid assessments based on 1st 4 CORE HTA model domains	Template(s) published on EUnetHTA website	M36 Sep ´15

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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Joint Action 2 on HTA 2012-2015

Work Package 8
Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information

3-year Work Plan

NATIONAL INSTITUTE FOR HEALTH AND WELFARE

FINLAND

Finohta

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1. WP Title

WP8 - Maintenance of HTA Core Model infrastructure to support shared production and sharing of HTA information

2. Partners

Lead and Co-Lead Partners - LP and Co-LP	Description of responsibilities and input
Lead Partner: THL (National Institute for Health and Welfare, Finland)	Overall coordination of WP, technical infrastructure for the HTA Core Model Online, provision of training on HTA Core Model Online in training meetings organized by WP8 and WP2. Member of EUnetHTA Executive Committee. LP will follow the AP's responsibility as described in the EUnetHTA JA2 Standard Operating Procedures Manual (EUnetHTA JA2 SOP), EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
Co-Lead Partner	N/A
Associated partners – (AP 9 partners)	
1. THL, Finland 2. KCE, Belgium 3. Central Denmark Region, Denmark 4. UTA, Estonia 5. HAS, France 6. CVZ, the Netherlands 7. NSPHMPD, Romania 8. SBU, Sweden 9. FIMEA, Finland	Participation in all key tasks, i.e. development of the HTA Core Model Online (including tools for information production and the core HTA information database), updating of the existing HTA Core Model contents, developing the full pharmaceutical application, support for training and implementation. Aps will follow the AP's responsibility as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
Collaborating partners – CP (2 partners)	
1. UMIT, Austria 2. NCHTA, Russia	Participation in all key tasks, i.e. development of the HTA Core Model Online (including tools for information production and the core HTA information database), updating of the existing HTA Core Model contents, developing the full pharmaceutical application, support for training and implementation. CP will be asked to follow the CP's responsibilities as described in the EUnetHTA JA2 S SOP and 2011 23 01 EUnetHTA JA2 Grant Agreement
Other Parties	
All EUnetHTA partners	Testing and validating the new version of HTA Core Model Online, particularly within projects of WP4 and WP5, as well as through adapting core HTA information into local HTA products. Feedback to WP8. EUnetHTA JA2 Partners will follow the responsibilities in submitting information for the preparation of the interim and final technical and financial reports as described in the EUnetHTA JA2 SOP, EUnetHTA JA2 Consortium agreement and 2011 23 01 EUnetHTA JA2 Grant Agreement
EUnetHTA Stakeholders	Support for all key tasks from the viewpoint of

	stakeholders. This includes reviewing and commenting on a) the updated HTA Core Model applications, b) the policy for HTA Core Model and core HTA information, as well as c) the suggested use of core HTA information for local HTA products.

PLEASE NOTE: Participants are subject to change – for current participants in the Work Package check: ***www.eunethta.eu***

3. Objectives

Title	Description	Indicators
Provide a conceptual and information management infrastructure and related services to support the piloting of collaborative production of HTAs by partner agencies, and facilitate the tasks and team working of the other WPs	Development and maintenance of conceptual and technological infrastructure enabling effective use of the HTA Core Model for producing, storing, publishing, sharing and utilizing core HTA information.	Core HTA Models and online tool updated; Core HTA Database has information on at least 17 commonly produced Core HTAs (including rapid HTAs). Further specification regarding the Model and online tool: Renewed HTA Core Model Online (intermediate pilot versions and final version) Updated applications of HTA Core Model online to enable assessment of medical and surgical interventions, diagnostics, screening and pharmaceuticals Updated instructions for using the HTA Core Model Online

4. Organisation of the Work

4.1 Milestones and Deliverables

Milestones	Deadline
Updated versions of already existing HTA Core Model applications ready	M12 (Sep 2013)*
First version of the upgraded pharmaceutical application ready	M12 (Sep 2013)
First renewed version of the online service and database ready	M14 (Nov 2013)
Final version of the online service and database ready	M36 (Sep 2015)

*The original deadline for this milestone was M9 in the Grant Agreement. Since the original project plan was put together, it has become clear that the updating process of the existing applications should be done simultaneously with developing the full pharmaceutical model. Consequently the deadline for these should be the same. This has been agreed on with WP4, for whom the change of deadline does not cause problems, and with the Secretariat.

Deliverables	Deadline
Upgraded and updated application package of the HTA Core Model	M36 (Sep 2015)

4.2 Methods

The HTA Core Model Online will be further developed within THL servers by in-house development team, in collaboration with WP8 participants and guided by needs of WP4 and WP5. Active continuous input to this work is expected from all WP8 members in the form of providing ideas, commenting plans and piloting new features. Certain key features may also be piloted through inviting WP4 and WP5 members to participate. User experience from WP4 and WP5 will be sought to identify successful features and further development needs.

The HTA Core Model currently contains the following four applications developed within earlier EUnetHTA work: 1) model for medical and surgical interventions, 2) model for diagnostic technologies, 3) model for screening technologies and 4) model for rapid relative effectiveness assessment of pharmaceuticals.

These four applications will be further developed through a process in which the various domain contents are updated, complemented and - to the extent possible - harmonized, so that all relevant content is visible to users in all settings in its most up-to-date version. Instead of updating each application separately, the update working groups will be set up for domains. Hence e.g. contents of the safety domain will be updated for all four HTA Core Model applications simultaneously by the same persons.

Experience gained during JA2 in WPs 4 and 5 will be used for further refining the model applications before the end of JA2. Approval of rapid REA model application will be sought together with WP5.

The domains are organized in groups of three domains, "domain clusters", each updated by an international working group. Each active Associated Partner leads the work within at least one domain by providing a primary investigator for the domain. Leading the work of a domain may also be shared with other APs. In order to ensure cross-border applicability of the new deliverables, each WP8 member agency should be involved in all three domain clusters by providing either the primary investigators, investigators or internal reviewers. Division of work will be done based on the expertise available in each WP8 member agency and time allocated to WP8.

Basic features of the Adaptation Toolkit developed by WP5 of the original EUnetHTA project 2006-2008 were implemented in the HTA Core Model Online within Joint Action 2. Further utilization and connection to possible online version of the Toolkit produced elsewhere will be explored and - if possible - implemented during JA2.

The new policy for the HTA Core Model and core HTA information developed within JA1 allows commercial use of the HTA Core Model, once a commercial license has been crafted by May 2013. Two companies - Roche and Medtronic - have expressed their interest in piloting the use of the HTA Core Model in their internal processes. This piloting will be discussed and initiated during the first months of 2013. Feedback from the pilot will be used for further development of the HTA Core Model so that it can better capture the information needs that are relevant from the viewpoint of assessing health technologies.

The Policy for the HTA Core Model and core HTA information will be reviewed during Spring 2013 and Spring 2015 to ensure its applicability in various settings and compatibility with EUnetHTA's business model and other aspects.

WP7 produces guidelines for different aspects of HTA. These guidelines contain detailed methodological advice for various research settings. Most methodological guidance within the HTA Core Model does not go into such detail, but instead provides and overview of relevant methodologies and links to available detailed advice. The guidelines of WP7 provide also the HTA Core Model with an important methodological resource. Different guidelines will be connected to relevant parts of the more general guidance within the HTA Core Model with links.

A Coordinating Working Group (CWG) will be set up together with Work Packages 4 and 5 to steer the overall development of the HTA Core Model and production and publication of core HTA information. The CWG acts as a stand-in for the Editorial Board mentioned in the EUnetHTA Policy for HTA Core Model and core HTA information.

4.3 Meetings

Date	Location	Duration (nights)	Participants	Purpose
Jan 16-17, 2013	Helsinki	1	All APs and CPs of WP8	General WP meeting
Apr 17-18, 2013	Helsinki	1	All APs and CPs of WP8	Online Tool and Service development
Apr 18-19, 2013	Helsinki	2	All APs and CPs of WP8	HTA Core Model update (applications)
June 5-6, 2013	Helsinki	2	All APs and CPs of WP8	HTA Core Model update (applications)
Oct 17-18, 2013	Helsinki	1	25-35 persons from EUnetHTA partners and associates	HTA Core Model training
Feb 2014	Stockholm or Tartu (to be confirmed)	1	All APs and CPs of WP8	General WP meeting
June 2014	Helsinki	1	All APs and CPs of WP8	Online Tool and Service development
June 2014	Helsinki	1	25-35 persons from EUnetHTA partners and associates	HTA Core Model training
Feb 2015	Tartu or Stockholm (to be confirmed)	1	All APs and CPs of WP8	General WP meeting
June 2015	Helsinki (right before or after the meeting below)	1	All APs and CPs of WP8	Online Tool and Service development
June 2015	Helsinki	1	25-35 persons from EUnetHTA partners and associates	HTA Core Model training

4.4 Specific activities per year

Year 1 (Oct 2012-Sep 2013)

Start	End	Activity steps	Target group	Parties involved
M1 Oct '12	M4 Jan '13	3-year work plan	WP members	WP8 APs and CPs
M4 Jan '13		1st WP8 face-to-face meeting	WP members	WP8 APs and CPs
M4 Jan '13	M12 Sep '13	Update of existing HTA Core Model applications	All users of HTA Core Model	WP8 APs and CPs, SAG
M4 Jan '13	M12 Sep '13	Modification and expansion of rapid REA model into a core HTA model, including all nine domains by way of checklists where appropriate	All users of HTA Core Model	WP8 APs and CPs, SAG
M4 Jan '13	Cont…	Upgrade HTA Core Model Online to support production of rapid HTAs and local reports (first pilot version)	All users of HTA Core Model Online	WP8 APs and CPs, SAG

M5 Feb '13	M8 May '13	Licence development for commercial use of HTA Core Model	All users of HTA Core Model	WP8 APs and CPs, SAG
M6 Mar '13	M8 May '13	Review of the Policy for HTA Core Model and core HTA information by EUnetHTA member agencies, stakeholders and the public. Review of existing policy by member agencies, SAG and the public takes place in April/May. Possible changes are discussed, implemented and approved within May.	All users of HTA Core Model	WP8 APs and CPs, SAG, SF, General public
M6 Mar '13	Cont…	Piloting of HTA Core Model for internal process of technology manufacturers (with Roche and Medtronic)	Technology manufacturers as potential users of the HTA Core Model	WP8 APs and CPs, Roche, Medtronic
M7 Apr '13		1st Online Tool and Service meeting	WP members	WP8 APs and CPs (OTS experts)
M7 Apr '13		1st HTA Core Model application update meeting	WP members	WP8 APs and CPs (Model experts)
M9 Jun '13		2nd HTA Core Model application update meeting	WP members	WP8 APs and CPs (Model experts)
M12 Sep '13	Cont…	Interim (technical and financial) reports	EU DG Sanco	WP8 APs and CPs

Year 2 (Oct 2013-Sep 2014)

Start	End	Activity steps	Target group	Parties involved
Cont…	M14 Nov '13	Upgrade of HTA Core Model Online to support production of rapid HTAs and local reports (first pilot version)	All users of HTA Core Model Online	WP8 APs and CPs, SAG
Cont…	M13 Oct'13	Interim (technical and financial) reports	EU DG Sanco	WP8 APs and CPs
Cont…	M15 Dec '13	Piloting of HTA Core Model for internal process of technology manufacturers (with Roche and Medtronic)	Technology manufacturers as potential users of the HTA Core Model	WP8 APs and CPs, Roche, Medtronic
M13 Oct '13		1st HTA Core Model training meeting	All EUnetHTA Partners and Associates	LP and WP8 APs belonging to training task force
M15 Dec '13	M16 Jan '14	Public consultation on updated HTA Core Model applications	All users of HTA Core Model	WP8 APs and CPs
M15 Dec '13	Cont…	Further refinement of HTA Core Model Online based on experience from WP4 and WP5, and other users (final version)	All users of HTA Core Model Online	WP8 APs and CPs, WP4, WP5, SAG
M15 Dec '13	Cont…	Further refinement of HTA Core Model applications	All users of HTA	WP8 APs

		based on experience from WP4 and WP5, and other users (final version)	Core Model	and CPs, WP4, WP5, SAG
M17 Feb '14		2nd WP8 face-to-face meeting	WP members	WP8 APs and CPs
M21 Jun '14		2nd HTA Core Model training meeting	All EUnetHTA Partners and Associates	LP and WP8 APs belonging to training task force
M24 Sep '13	Cont…	Interim (technical and financial) reports	EU DG Sanco	WP8 APs and CPs

Year 3 (Oct 2014-Sep 2015)

Start	End	Activity steps	Target group	Parties involved
Cont…	M25 Oct'14	Interim (technical and financial) reports	EU DG Sanco	WP8 APs and CPs
Cont…	M36 Sep '15	Further refinement of HTA Core Model Online based on experience from WP4 and WP5, and other users (final version)	All users of HTA Core Model Online	WP8 APs and CPs, WP4, WP5, SAG
Cont…	M36 Sep '15	Further refinement of HTA Core Model applications based on experience from WP4 and WP5, and other users (final version)	All users of HTA Core Model Online	WP8 APs and CPs, WP4, WP5, SAG
M29 Feb '15		3rd WP8 face-to-face meeting	WP members	WP8 APs and CPs
M30 Mar '15	M32 May '15	Update of HTA Core Model policy	All users of HTA Core Model	All EUnetHTA Partners and Associates, SAG, SF, General public
M30 Mar '15	M36 Sep '15	Scientific article: Conceptual description of HTA Core Model new version	All users of HTA Core Model	WP8 APs and CPs
M33 Jun '15		3rd HTA Core Model training meeting	All EUnetHTA Partners and Associates	LP and WP8 APs belonging to training task force
M36 Sep '15	M37 Oct'15	Final (technical and financial) reports	EU DG Sanco	WP8 APs and CPs

Surveys				
Timing	**Type of survey/topic**	**Target group**	**Method of delivery** (i.e. online or e-mail)	**Coordination with other WPs** (Yes/No – if yes which WP)
M7-8 Apr-May '13	Policy for HTA Core Model and core HTA information	EUnetHTA member agencies, WP8 SAG, Stakeholder Forum, General public	Online	No
M8 May '13	Updated HTA Core Model applications (second draft)	WP4, 5, 7 and WP8 SAG	Online	No
M10-11 Jul-Aug '13	Updated HTA Core Model applications (third draft)	EUnetHTA member agencies, WP8 SAG	Online	No
M15-16 Dec '13 - Jan '14	Public consultation on updated HTA Core Model applications	General public	Online	No
2014 to be confirmed	Production processes and tools to support local reports based on core HTA information	EUnetHTA member agencies, WP8 SAG	Online	Possibly
M30-31 Mar-Apr '15	Policy for HTA Core Model and core HTA information	EUnetHTA member agencies, WP8 SAG, Stakeholder Forum, General public	Online	No

4.4.1 Stakeholder involvement

The EUnetHTA Stakeholder Forum is asked to nominate a Stakeholder Advisory Group (SAG) for WP8, similarly as was done within Joint Action 1. Advanced draft documents and other key material will be sent to the WP8 SAG for review usually prior to their publication. The SAG has a particularly important role in ensuring that stakeholder views are known when updating the contents of the HTA Core Model and the policies steering its use.

Key tasks include:

SAG involvement			
Timing	**Purpose**	**Type of input from SAG**	**Info from SAG to be used for…**
April-May 2013	Review of policy for the HTA Core Model and core HTA information	Feedback on the various policy items and the whole set.	Ensuring that the policy adequately takes into account stakeholder views.
May 2013	Review of updated HTA Core Model applications (confidential draft)	Feedback on any aspects of the updated versions.	Improving the HTA Core Model contents.
July/August 2013	Review of updated HTA Core Model applications (public draft)	Feedback on any aspects of the updated versions.	Improving the HTA Core Model contents.
2014/2015 (Detailed timeline will be defined later)	Use of existing core HTA information for local HTA products	Feedback on the suggested process and features of utilization of core HTA information.	Ensuring that the suggested processes and tools take into account stakeholder views.
March - April 2015	Review of policy for the HTA Core Model and core HTA information	Feedback on the various policy items and the whole set.	Ensuring that the policy adequately takes into account stakeholder views.

Stakeholders should notice that during spring and summer 2013 the SAG consultation will have only 2-3 weeks' response time, since the updated HTA Core Model applications are needed for work within WP4 and WP5 by the end of the summer.

Stakeholders' views on the HTA Core Model will be also sought in the pilot regarding the feasibility of the HTA Core Model in technology manufacturers' internal processes, in collaboration with Roche and Medtronic.

4.4.2 Public Consultation

The existing policy for the HTA Core Model and core HTA information will be subject for public consultation in April-May 2013 and in 2015 during the second review.

The updated application package will be subject to public consultation after its completion in fall 2013. The results will be used together with the feedback from WP4 and WP5 for further revisions of the application package.

Public Consultations			
Timing	**Purpose**	**Target group** (EUnetHTA Web/other)	**Info used for**
M7-8 Apr-May '13	Policy for HTA Core Model and core HTA information	EUnetHTA Web	Improve the policy and ensure that various views are taken into account.
M15-16 Dec '13 - Jan '14	Public consultation on updated HTA Core Model applications	EUnetHTA Web, relevant scientific societies	Improve the HTA Core Model
M30-31 Mar-Apr '15	Policy for HTA Core Model and core HTA information	EUnetHTA Web	Improve the policy and ensure that various views are taken into account.

4.4.3 Conflict of interest

WP8 will ask those who update HTA Core Model contents to declare such conflict of interest that might affect their work. Lead Partner will decide on possible problems on a case-by-case basis. Additionally, WP8 refers to the EUnetHTA JA2 Conflict of Interest Policy at the network level.

4.4.4 Handling of confidential data

It is assumed that confidentiality agreements are standard practice for the WP8 organisations or institutions when hiring personnel. As a result, no separate confidentiality agreements will be drafted for participation in EUnetHTA activities. Individual WP8 partner organisations or institutions (neither coordinating agencies nor EUnetHTA secretariat) are responsible and accountable for the deliverance and maintenance of confidentiality agreements for participating in EUnetHTA activities of WP8.

4.4.5 Quality assurance procedures

All products of WP8 will be prepared by international expert groups and they will also be subject to external review by e.g. the SAG, public consultation and other EUnetHTA members (particularly those within WP4, WP5 and WP7).

4.4.6 National HTA Report Production

The HTA Core Model Online will be developed to support production of local HTA reports based on core HTA information. The use of that component of the tool is voluntary for agencies. The policy for core HTA information requires that users of core HTA information must include in the HTA Core Model Online a summary of the final conclusions of their local report in English language. This policy was added to assist further users of the same information, but at the same time it provides JA2 a method of following up how many local products have been made using the core HTA information (provided that the users follow the policy).

4.4.7 Cooperation with other WPs / LPs

A Coordination Working Group (CWG) will be set up together with WP4 and WP5 to coordinate the actions within JA2 and to serve as a stand-in Editorial Board for the HTA Core Model and the HTA information collections produced with it.

Feedback mechanisms will be planned jointly with WP4 and WP5 to capture practical experience in using the HTA Core Model Online within their information production projects.

Active contact will be kept with WP2 to coordinate and reinforce relevant information dissemination activities. This includes provision of learning materials and participation of WP8 LP and possibly other member agencies in teaching activities.

Active contact will be kept with WP7 to ensure that there are appropriate link with the HTA Core Model methodological guidance (WP8) and the guidelines developed within WP7.

5. Dissemination plan

Output	Format	Time
HTA Core Model Handbook	Online document	Exists already, continuous updating
Three HTA Core Model training meetings	Face-to-face meeting	October 2013 June 2014 June 2015
HTA Core Model Online Quick Reference Guide	Online document	May 2013
Conceptual description of HTA Core Model new version	Scientific article	2014/2015
Updated HTA Core Model applications	Online document	August/September 2013
Final version of HTA Core Model applications	Online document	September 2015
Presentations at international conferences, primarily HTAi, ISPOR	Presentation or poster	To be confirmed later