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EUnetHTA

FINAL TECHNICAL REPORT

2010 - 2012



The EUnetHTA JA (2010-2012) received funding from the European Union, in the framework of the Health Programme

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT





eunethta
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA Joint Action

European network for Health Technology Assessment

FINAL TECHNICAL REPORT

delivered by the Coordinator

Danish Health and Medicines Authority (DHMA)

May 2013

List of contents

List of contents	iii
Abbreviations.....	viii
Technical Fact Sheet.....	xii
Deliverables.....	xiv
Additional output.....	xviii
Introduction.....	21
Overview of the EUnetHTA JA1 activities and results	2
Background	2
EUnetHTA aims and objectives	2
Objectives related to the general strategy and business model:	2
Objectives related to the development of tools and methods:	2
Objectives related to application and testing of the tools:.....	3
Structure and methods; partners and countries involved.....	1
Main activities.....	6
Building management structures and policies for sustainable collaboration	6
Policy for use of the HTA Core Model.....	8
Developing tools and guidelines to support collaboration.....	8
Testing the tools and guidelines in actual assessment projects	10
Communicating and training	12
External communication	13
Training in the tools.....	13
Stakeholder involvement	13
EUnetHTA Stakeholder Forum	13
EUnetHTA Stakeholder Advisory Groups (SAGs).....	14
Manufacturers	14
Collaboration with European Medicines Agency (EMA)	15
Public consultations.....	15
Stakeholder events organised by EUnetHTA partners.....	15
Adherence to the initial work plan	16
Project evaluation.....	16
Results of the project.....	16
Strategic relevance, contribution to the Health Programme, EU added value and level of innovation	16
Coordination with other projects or activities at European, national and international level	17
Specific outputs.....	17
Key findings of the evaluation.....	17
EUnetHTA consolidates its position.....	18
Discussion and recommendations	19
The benefits are obvious but efficiency and quality gains still need to materialise.....	19
Efficient communication is essential	20
Suggestions for management.....	20
The tools need to be further developed	21

The role of the methodological guidelines.....	21
Stakeholder involvement	22
The tools should be taken into routine use	22
Scoping is fundamental	22
Collaborative models need to be further developed	23
WP1 Objectives.....	25
WP1 Outputs	25
Deliverables	25
WP1 Activities	25
2010.....	25
2011.....	25
2012.....	26
WP1 Meetings 2010-2012	27
External meetings/presentations of EUnetHTA in 2010-2012	27
WP1 Stakeholder and external expert involvement.....	31
WP1 Cooperation with other WPs / LPs.....	31
WP1 Achievement of objectives	32
Results and recommendations	32
WP1 Manpower for the execution of activities.....	33
Partners and countries involved	33
Persons who participated in the WP	33
Appendices WP1	34
WP2 Objectives.....	37
WP2 Outputs	37
Deliverables	37
Other outputs	37
WP2 Activities	38
2010.....	38
2011.....	38
2012.....	38
WP2 Meetings 2010-2012	38
WP2 Stakeholder and external expert involvement.....	39
WP2 Cooperation with other WPs / LPs.....	39
WP2 Achievement of objectives	39
Results.....	39
Recommendations	39
WP2 Manpower for the execution of activities.....	39
Partners and countries involved	39
Persons who participated in the WP	40
Appendices WP2.....	41
WP 3 Objectives.....	43
WP 3 Outputs	43
Deliverables	43
Other outputs	43

WP 3 Activities	43
2010.....	43
2011.....	44
2012.....	44
WP 3 Meetings 2010-2012	44
WP 3 Stakeholder and external expert involvement.....	44
WP 3 Cooperation with other WPs / LPs.....	44
WP 3 Achievement of objectives	45
Results.....	45
Recommendations	45
WP 3 Manpower for the execution of activities.....	45
Partners and countries involved	45
Persons who participated in the WP	45
WP 4 Objectives.....	47
WP 4 Outputs	47
Deliverables	47
Other outputs	47
WP 4 Activities	48
2010.....	48
STRAND A.....	48
STRAND B.....	48
2011.....	48
STRAND A.....	48
STRAND B.....	48
2012.....	49
STRAND A.....	49
STRAND B.....	49
WP 4 Meetings 2010-2012	49
WP 4 Stakeholder and external expert involvement.....	50
STRAND A and B.....	50
WP 4 Cooperation with other WPs / LPs.....	51
WP 4 Achievement of objectives	51
Methods	51
Results.....	51
STRAND A.....	51
STRAND B.....	58
Recommendations	59
STRAND A.....	59
STRAND B.....	59
WP 4 Manpower for the execution of activities.....	59
Partners and countries involved	59
Persons who participated in the WP	61
Appendices WP4.....	69
WP5 Objectives.....	72

WP5 Outputs	72
Deliverables	72
Other outputs	73
WP5 Activities	75
2010	75
2011	75
2012	76
WP5 Meetings 2010-2012	77
WP5 Stakeholder and external expert involvement	80
WP5 Cooperation with other WPs / LPs	80
WP5 Achievement of objectives	80
Results	80
Conclusions and recommendations	81
WP5 Manpower for the execution of activities	82
Partners and countries involved	82
Persons who participated in the WP	83
WP6 Objectives	93
WP6 Outputs	93
Deliverables	93
Other outputs	93
WP6 Activities	93
2010	93
2011	94
2012	95
WP6 Meetings 2010-2012	95
WP6 Stakeholder and external expert involvement	96
WP6 Cooperation with other WPs / LPs	96
WP6 Achievement of objectives	97
Results	97
Recommendations	97
WP6 Manpower for the execution of activities	98
Partners and countries involved	98
Persons who participated in the WP	99
Appendices WP6	101
WP7 Objectives	103
WP7 Outputs	103
Deliverables	103
Other outputs	104
Work Package 7 Activities	105
2010	105
2011	106
2012	108
WP7 Meetings 2010-2012	110
WP7 Stakeholder and external expert involvement	112

WP7 Cooperation with other WPs / LPs.....	112
WP7 Achievement of objectives	113
Results.....	113
Recommendations	117
WP7 Manpower for the execution of activities.....	118
Partners and countries involved	118
Persons who participated in the WP	118
Appendices WP7	124
WP 8 Objectives	126
WP 8 Outputs	126
Deliverables	126
Other outputs	126
WP 8 Activities	126
2010.....	126
2011.....	127
2012.....	127
WP 8 Meetings 2010-2012	127
WP 8 Stakeholder involvement.....	129
WP 8 Cooperation with other WPs / LPs.....	129
WP 8 Achievement of objectives	129
Results and Recommendations.....	129
WP 8 Manpower for the execution of activities.....	130
Partners and countries involved	130
Persons who participated in the WP	131
Appendices WP8.....	133
List of Final Report Appendices	134
WP1	134
WP2.....	134
WP3.....	134
WP4.....	134
WP5.....	134
WP6.....	134
WP7	135
WP8.....	135

Abbreviations

AEG	“Access with Evidence Generation” mechanism
AETSA	Agencia de Evaluación de Tecnologías Sanitarias de Andalucía, Spain
AETS	Agencia de Evaluación de Tecnologías Sanitarias, Spain
AHRQ	Agency for Healthcare Research and Quality, USA
AHTAPol	Agency for HTA in Poland
AGENAS	Agenzia per i Servizi Sanitari Regionali, Italy
AIFA	Agenzia Italiano Del Farmaco, Italy
ARESS	Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency)
ASSR	Agenzia Sanitaria Regionale, Emilia Romagna, Italy
AP	Associated Partner (within the EUnetHTA Joint Action)
AVALIA-T	Galician Agency for Health Technology Assessment, Spain
CADTH	Canadian Agency for Drugs and Technologies in Health (former CCOHTA), Canada
CAHTA	Catalan Agency for Health Technology Assessment and Research, Spain
CAST	Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark, Denmark
CAVOD	Clinical Added Value of Orphan Drugs
CHMP	Committee for medicinal products for human use
CMTF	Center for Medical Technology Policy, USA
Co-LP	Co-Lead Partner (within the EUnetHTA Joint Action)
CP	Collaborating Partner (within the EUnetHTA Joint Action)
CRD	Centre for Reviews and Dissemination
CVZ	College voor zorgverzekeringen, The Netherlands
DC	Dublin Core (A reference set of meta data)
DES	Drug eluting stents
DG	Directorate General (of the European Commission)
DG SANCO	Directorate General for Health and Consumers
DIA	Drug Information Association
DIMDI	German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information, Germany
DHMA	Danish Health and Medicines Authority
DSI	Danish Institute for Health Services Research, Denmark
EAHC	Executive Agency for Health and
EFPIA	European Federation of Pharmaceutical Industries and Associations
EHFG	European Health Forum Gastein
EPPOSI	European Platform for Patients' Organisations, Science and Industry
EMA	European Medicines Agency

EUnetHTA JA1

EMKI	Institute for Healthcare Quality Improvement and Hospital Engineering, Hungary
EPAR	European Public assessment Report
ESKI	National Institute for Strategic Health Research, Hungary
EUCOMED	European medical technology industry association
EUnetHTA	European network for Health Technology Assessment
EUnetHTA JA1	EUnetHTA Joint Action (2010-2012)
EUPHA	European Public Health Association
EuropaBio	The European Association for bio-industries
EuroScan	The European Information Network on New and Changing Health Technologies
EVIDENT (former EIFFEL)	Database on additional evidence generation (EUnetHTA Tool)
EVAR	Endovascular aneurysm repair (or endovascular aortic repair)
FinOHTA	Finnish Office for Health Technology Assessment, Finland
f-t-f	Face-to-face (meeting)
GÖG/BIQG	Gesundheit Österreich GMBH, Austria
GSK	Glaxo-Smith-Kleine
GYEMSZY	National Institute for Quality and Organisational Development Health, Hungary
HAS	Haute Autorité de Santé, France
HIQA	Health Information and Quality Authority, Ireland
HRQoL	Health related quality of life
HTA	Health Technology Assessment
HTAi	Health Technology Assessment international
HVB	Hauptverband der Österreichischen Sozialversicherungsträger, Austria
ICT	Information and Communication Technologies
IJTAHC	International Journal on Technology Assessment in Health Care (Cambridge University Press)
INAHTA	International Network of Agencies for Health Technology Assessment
IQWIG	Institute for Quality and Efficiency in Health Care, Germany
IMS	Information Management System
INFARMED	Instituto Nacional Da Farmacia e Do Medicamento, Portugal
IPHRS	Institute Of Public Health of Republic of Slovenia
ISC III	Instituto de Salud Carlos III, Spain
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
IUMPS	Institut Universitaire de médecine sociale et préventive Lausanne, Switzerland
JA	Joint Action
KCE	Belgian Health Care Knowledge Centre, Belgium
KDTD	Turkish Evidence-Based Medicine Association
LBI-HTA	Ludwig Boltzmann Gesellschaft GmbH, Austria
LDAP	Lightweight Directory Access Protocol

EUnetHTA JA1

LP	Lead Partner (within the EUnetHTA Joint Action, organisation responsible for leading and managing work in a Work Package)
MAH	Marketing Authorisation Holder
MEDEV	Medical Evaluation Committee
MeSH	Medical Subject headings
MHEC	Ministry of Health, the elderly and Community Care, Malta
MO site	Members Only site
MoH	Ministry of Health
M1-36	Month 1-36 (in the Joint Action)
MS	Member State (of the European Union)
MSAC	Medical Services Advisory Committee, Australia
NBoH	National Board of Health
NCPHP	National Centre of Public Health Protection, Bulgaria
NETSCC	University of Southampton, United Kingdom
NHS	National Health Service
NICE	National Institute for Clinical Excellence, United Kingdom
NIHR	National Institute for Health Research, UK
NIPH	Institute of Public Health of the Republic of Slovenia
NOKC	Norwegian Knowledge Centre for the Health Services, Norway
NSPH	National School of Public Health, Greece
OAI-PMH	Open Archives Initiative Protocol for Metadata Harvesting
OECD	Organisation for Economic Co-operation and Development
OSTEBA	Basque Office for Health Technology Assessment, Spain
PA	EUnetHTA Plenary Assembly
POP db	Planned and Ongoing HTA Projects Database (EUnetHTA Tool)
REA	Relative Effectiveness Assessment
RSS	Really Simple Syndication
SAG	Stakeholder Advisory Group (within the EUnetHTA Joint Action)
SF	Stakeholder Forum (within the EUnetHTA Joint Action)
SG	Sub-group
SBU	Swedish Council on Technology Assessment in Health Care, Sweden
SDU	University of Southern Denmark, Denmark
SLOVAHTA	Slovak Agency for HTA
SNHTA	Swiss Network for Health Technology Assessment, Switzerland
SSD/MSOC	Ministry for social Policy/ Strategy and Sustainability Division, Malta
THL	National Institute for Health and Welfare, Finland
TOPRA	the organisation for professionals in regulatory affairs
TU Berlin	Technische Universität Berlin, Germany
UETS	Unidad de Evaluación de Tecnologías Sanitarias, Spain

EUnetHTA JA1

UCSC	Università Cattolica del Sacro Cuore, Policlinico universitario “A. Gemelli”, Italy
UTA	University of tartu, Estonia
VASPV	State Health Care Accreditation Agency under Ministry of Health, Lithuania
VEC	The Centre of Health Economics, Latvia
WP (1-8)	Work Package (within the EUnetHTA project)

Technical Fact Sheet

Joint Action	European network for Health Technology Assessment (EUnetHTA) Joint Action – EUnetHTA JA
Grant Agreement No.	2009 23 02 EUnetHTA Joint Action
Programme	Public Health Programme 2009-2013
Start Date of Project	January 1, 2010
Duration	37months
Joint Action General Objective	The overarching objective of the Joint Action (JA) on Health Technology Assessment (HTA) including work on relative effectiveness of pharmaceuticals is <i>to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.</i>
Tasks/Work packages	WP1 Coordination WP2 Dissemination WP3 Evaluation WP4 Core HTA WP5 Relative Effectiveness Assessment (REA) of Pharmaceuticals WP6 Information Management System (IMS) WP7 New technologies WP8 Strategy and Business Model development
EAHC Contacts	Mr. Guy Dargeant, Mr. Dimitri Agneskis
JA Coordinator	Danish Health and Medicines Authority (DHMA); JA Project Leader – Prof. Finn Børlum Kristensen
Co-Beneficiaries (Associated Partners) and their WP Affiliation	<ol style="list-style-type: none"> 1. Ludwig Boltzman Institute of Health Technology Assessment, LBI-HTA, Austria - 1, 4,6,7,8 2. Hauptverband der Österreichischen Sozialversicherungsträger, HVB, Austria – 2,4,5,6 3. Gesundheit Österreich GMBH, GÖG/BIQG, Austria – 4,5,6,8 4. Belgian Health Care Knowledge Centre, KCE, Belgium – 1,4,5,6,8 5. National Centre of Public Health Protection, NCPHP, Bulgaria - 2 6. University of Southern Denmark, SDU, Denmark – 4,5,7,8 7. University of Tartu, UTA, Estonia – 4,8 8. National Institute for Health and Welfare, THL, Finland – 1,4,5,6,7 9. Haute Autorité de Santé / French National Authority for Health, HAS, France – 1,5,6,7,8 10. Stiftung für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWiG, Germany – 4,5 11. German Institute for Medical Documentation and Information, DIMDI, Germany – 1,4,6,8

	<ol style="list-style-type: none"> 12. National School of Public Health, NSPH, Greece – 2,8 13. National Institute for Quality and Organisational Development Health, GYEMSZI, Hungary (<i>took over the rights and obligations of the predecessors ESKI and EMKI in 2011</i>) – 5,6,7 14. HIQA - Health Information and Quality Authority, Ireland – 4,5,7 15. Agenzia Nazionale per i Servizi Sanitari Regionali, AGENAs, Italy – 1,4,7 16. Agenzia Italiana del Farmaco, AIFA, Italy – 5,7,8 17. Regione del Veneto, Italy – 4,7,8 18. National Health Service, NHS, Latvia - 5 19. State Health Care Accreditation Agency under Ministry of Health, VASPVT, Lithuania – 7,8 20. Ministry of Health, the Elderly and Community Care, MHEC (<i>former SSD/MSOC</i>), Malta – 4,5,7,8 21. College voor zorgverzekeringen, CVZ, The Netherlands – 1,4,5,6,7,8 22. Norwegian Knowledge Centre for the Health Services, NOKC, Norway – 4,5,7,8 23. Agency for HTA in Poland, AHTAPol, Poland – 1, 4,5,7,8 24. Instituto Nacional da farmacia e do Medicamento, INFARMED, Portugal – 4,5,7 25. Institute of Public Health of the Republic of Slovenia, NIPH (<i>former IPH-RS</i>), Slovenia – 1,2,4,5,6,8 26. Ministry of Health and Social Policy, Spain – 2,5,8 27. Instituto de Salud Carlos III, Spain – 1,4,6,7,8 28. Swedish Council on Technology Assessment in Health Care, SBU, Sweden – 1,2,4,5,6,7,8 29. University of Southampton, NETSCC, UK – 1,3,6,7,8 30. National Institute for Health and Clinical Excellence, NICE, UK – 4,5,7 32. SLOVAHTA, Slovakian Agency for HTA , Slovakia (Ministry of health officially nominated to participate in the EUnetHTA JA in 2010; no participation in the budget) - 5 33. Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment* , Croatia (Ministry of health officially nominated to participate in the EUnetHTA JA in 200; no participation in the budget)- 4,8
Collaborating Partners	<ol style="list-style-type: none"> 1. University for Health Sciences, Medical Informatics and Technology, Austria – 4,8 2. RIZIV, National Institute for Health and Disability Insurance NIHDI, Belgium - 5 3. IRF, Institute for Rational Pharmacotherapy, Denmark - 5 4. Dept of Health Services Research and HTA, Centre for Public Health, Central Denmark Region, Denmark - 4 5. DSI, Danish Institute for Health Services Research, Denmark – 4,5 6. FIMEA Finnish Medicines Agency Finland (<i>joined 2011</i>) - 5 7. IPP Institute for Public Health and Nursing Research Bremen Germany - 4

	<ol style="list-style-type: none"> 8. National Centre for Pharmacoeconomics, St James's Hospital, Ireland - 7 9. ARESS, Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency), Italy – 4,6 10. ASSR, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna, Italy - 11. Laziosanità – Agenzia di Sanità Pubblica, Regione Lazio, Italy – 4,8 12. REGLOM-DGSAN - Regione Lombardia, Direzione Generale Sanità, Italy – 4,5 13. University Hospital “A.Gemelli”, Italy – 4,5,8 14. CEM Cellule d'Expertise Médicale Luxembourg (<i>joined 2011</i>) 15. SNSPMS National School of Public Health, Management and Professional Development, Romania (<i>joined 2011</i>) – 4,8 16. RCCEE&PH Research Center for Clinical and Economic Expertise and Pharmacoeconomics of the Russian National Research Medical University named after N.I.Pirogov Russia (<i>joined 2012</i>) – 5,8 17. Quality unit, Ministry of Health of Serbia - 8 18. Agency for Medicinal Products and Medical Devices, Slovenia – 5,7 19. IER Agency for Medicinal Products and Medical Devices The institute for Economic Research (IER), Ministry of Health, Slovenia - 4 20. AETSA, Andalusian HTA Agency, Spain – 4,5,7 21. CAHTAR, Catalan Agency for HTA and Research, Spain – 5,8 22. UETS, HTA Unit, Agencia, Laín Entralgo, Spain – 5,8 23. AVALIA-t, Galician Agency for HTA, Spain – 2,4,7 24. OSTEBA, Basque Agency for HTA, Spain – 2,4,6,7 25. Dental and Pharmaceutical Benefits Agency (TLV), Sweden - 5 26. SNHTA, Swiss Network for HTA, Switzerland – 1,2,4,5,6,7,8
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Deliverables

All deliverables were submitted to the Commission within the timeframe of the project.

Deliverable (number, title)	Nature	Access	Confidentiality level
D1 a) An online tool and service for producing, publishing, storing and retrieving HTA information.	Web tool and database Screening application available also as	<ul style="list-style-type: none"> • Both available through www.corehta.info 	Public

b) The screening application of the HTA Core Model.	Report		
D2 A set of 2 Core HTAs.	Report	<ul style="list-style-type: none"> Available via On-line Tools & Service website (www.corehta.info) 	Public
<p>D3-1A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals:</p> <p>Background review</p>	Report and publication	<ul style="list-style-type: none"> Available via EUnetHTA website: http://www.eunethta.eu/outputs/final-version-background-review-relative-effectiveness-assessment Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable document WP5_1a & Deliverable document WP5_1b; Publication: Kleijnen S, George E, Goulden S, d'Andon A, Vitre P et al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value Health. 2012 Sep;15(6). Deliverable document WP5_2; 	Public
<p>D3-2 A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals:</p> <p>Guidelines on methodology to be incorporated in model for rapid REA of pharmaceuticals</p>	Report and planned publication in IJTAHC	<ul style="list-style-type: none"> Final versions is available via EUnetHTA website: http://www.eunethta.eu Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable document WP5_3a & Deliverable document WP5_3b; Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public
<p>D3-3 A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals:</p> <p>Model for Rapid REA of pharmaceuticals</p>	Report/online tool and planned publication in IJTAHC	<ul style="list-style-type: none"> Final version is available via EUnetHTA website: http://www.eunethta.eu Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable document WP5_5a & Deliverable document WP5_5b; Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public
D3-4 A methodological guidance that will be appropriate for the assessment	Event	<ul style="list-style-type: none"> Instead of European Symposium, it was decided to organise a WP5 	Restricted

EUnetHTA JA1

of relative effectiveness of pharmaceuticals: European Symposium on the Methodology of REA		meeting with all WP5 members due to several discussion items needing 'internal debate' to improve final documents. In addition, an EUnetHTA – EFPIA and stakeholders workshop was organised (February 12, 2013) to discuss the methodology of four EUnetHTA guidelines on "endpoints".	
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D4 Operational web-based toolkit including database containing information on evidence generation on new technologies	Database (EVIDENT Database)	<ul style="list-style-type: none"> Available via the following link: https://evident.has-sante.fr/has/login.x.html <p>or from the Members' Only area of EUnetHTA's website (www.eunetha.eu), under the heading EUnetHTA tools.</p> <ul style="list-style-type: none"> Descriptive document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM) 	Restricted to EUnetHTA partners
D5 Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies	Protocol / POP Database	Document available (PDF enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)	Scientific community only/Restricted to EUnetHTA partners
D6 Information Management System (IMS) and the related documentation, processes and policies	Infrastructure, electronic tools, documents	See appendices and http://www.eunetha.be	Public/Access rights to certain areas

D7 Communication and Dissemination Plan (M18 – June 2011)	Communication and Dissemination Plan	<ul style="list-style-type: none"> Available via EUnetHTA website (Intranet section): www.eunetha.eu – document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM) 	Restricted/Confidential
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		<ul style="list-style-type: none"> Available via EUnetHTA website: 	
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EUnetHTA JA1

D8 Stakeholder Policy	Policy and SOP manual	www.eunethta.eu <ul style="list-style-type: none"> document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); 	Public
D9 Business model for sustainability	Written document, part of the EUnetHTA Strategy	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); 	Public
D10-I A relative effectiveness assessment of a pharmaceutical: Pilot report	Report and planned publication in IJTAHC	<ul style="list-style-type: none"> Available via EUnetHTA website: http://www.eunethta.eu/outputs/wp5-ja1-pilot-pazopanib-reportappendix Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable document WP5_4a & Deliverable document WP5_4b; Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public
D10-2 A relative effectiveness assessment of a pharmaceutical: Final report including plan for stimulation of usage of the Rapid and Full model (where appropriate) in European countries	Report	<ul style="list-style-type: none"> The plan for stimulation has been realised through the organisation of WP5 Joint Action 2 Final version of WP5 technical report is available as part of the Joint Action Technical Report 	Public
D 11 Interim and Final Technical and Financial Reports from the Joint Action (including evaluation results)	Report	<ul style="list-style-type: none"> Final Technical and Financial Report documents available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); Interim Technical Reports of 2010 and 2011 are enclosed on a CD ROM Both Final and Interim Technical Reports available¹ via EUnetHTA website: www.eunethta.eu 	Public

¹ Subject to approval of the final Technical report by the EAHC

Additional output

WP1			
Title/Short description	Nature	Access	
Two scientific articles scheduled for 2013	Journal articles	Planned for publication in the International Journal of Technology Assessment in Health Care	
WP2			
Title/Short description	Nature	Access	
Promotional leaflet	Printed promotional material	Distributed at conferences, meetings, via partners, etc.	
Inputs in Wikipedia	Web-based article	http://en.wikipedia.org/wiki/EUnetHTA	
HTA in Europe LinkedIn professional networking group	Web based professional networking tool	LinkedIn http://www.linkedin.com/groups?gid=3136408&trk=hb_side_g	
Informational video on HTA	Electronic format; part of the communication plan	<i>Publically</i> available via EUnetHTA website of JA1 and on http://www.youtube.com/watch?v=4FITjhTyJDc	
WP4			
Title/Short description	Nature	Access	
Policy for HTA Core Model and core HTA information	Report	www.corehta.info	
Two scientific articles scheduled for 2013	Journal articles	Planned for publication in the International Journal of Technology Assessment in Health Care	
WP5			
Title/Short description	Nature	Access	Notes
Collaboration with EMA	<ul style="list-style-type: none">Bi-annual meetings Permanent items on the agenda of the bi-annual meetings:	The minutes are available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Appendix WP1_4-8	
	1. EPAR improvement project	<ul style="list-style-type: none">Restricted: MEDEV's Comments on the Usefulness of EPAR's (Published Scientific Dhhiscussion) and	<ul style="list-style-type: none">Comments provided by MEDEV on EPARs, have been the basis for discussion

		<p>SmPC's (Summary of Product Characteristics) (Appendix 6a)</p> <ul style="list-style-type: none"> ○ Restricted: EPAR improvement plan drafted by the EMA (Appendix 6b1-6b3) ○ Restricted: Response EUnetHTA WP5 on draft guidance for improved EPARS (Appendix 6c) ○ Restricted: Presentation of results of EUnetHTA/EMA input on 10 analysed EPARS (Appendix 6d1&6d2) ○ Public: Planned publication in international scientific journal) 	<p>between EUnetHTA and EMA on possible improvements of the EPAR.</p> <ul style="list-style-type: none"> ○ EMA drafted an EPAR improvement plan. ○ EUnetHTA WP5 responded on the EPAR improvement plan. ○ The EUnetHTA recommendations were included in the EPAR template revision round leading to an improved template for EPARS. The improved EPAR template is an internal EMA document. <p>Subsequently WP5 co-analysed the 10 first EPARS that were produced according to the revised template together with EMA (see Appendix WP5_6b for decision).</p>
	1. Collaboration on methodology guidelines	Public	EMA has provided input on the WP5 methodological guidelines as part of the public consultation. The comments as well as the responses of how they were handled are included as deliverable "Guidelines on methodology to be incorporated in model for rapid REA of pharmaceuticals". See deliverable D3-2 WP5_3b.
	2. Early dialogue/scientific advice for drugs	<p>Public: Draft procedure for early dialogue pilots.</p> <p>(printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-</p>	

		ROM).	
Draft report about implementation barriers and success factors for European collaboration in relative effectiveness assessment	Report is under production	Restricted: Report is planned to be available in April 2013	
Comparison of national REA reports on pazopanib	Report is under production and planned publication	Restricted: Report is planned to be available in April 2013. Public: Planned publication in international scientific journal)	
WP6			
Title/Short description	Nature	Access	
Collaboration with HTAi Information resources group regarding the HTAi vortal	Electronic tool	http://vortal.htai.org	
Collaboration with HTAi-INAHTA HTA glossary	Electronic tool	http://htaglossary.net/	
WP7			
Title/Short description	Nature	Access	
Strand A			
<u>Title:</u> Minimum dataset to inform a prefunding registry for clinical studies designed to support clinical decision makers Short description: to enable funders to identify studies being planned or considered elsewhere, to facilitate the possibility of collaboration, either through joint funding or standardisation of outcome measures	Database items	<ul style="list-style-type: none">Integrated into EVIDENT database (https://evident.has-sante.fr/has/login.xhtml)Descriptive document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)See deliverable D.4. (restricted to EUnetHTA partners).	
<u>Title:</u> Criteria to select new technologies for additional evidence generation <u>Short description:</u> Selection/prioritization criteria are intended to help HTA doers, study funders and other stakeholders select, among new technologies, the ones for which complementary studies are really worth performing.	Policy document	<ul style="list-style-type: none">document available on EUnetHTA website:http://www.eunetha.eu/outputs/criteria-select-and-prioritise-health-technologies-additional-evidence-generation(printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)	

Strand B		
<p><u>Title:</u> Electronic, web-based database on ongoing/planned reports</p> <p><u>Short description:</u> stores basic information on planned/ongoing projects of EUnetHTA partners to facilitate collaboration</p>	Database, electronic tool	<ul style="list-style-type: none"> Available via the following link: http://eunetha.dimdi.de/PopDB/ or from the Members' Only area of EUnetHTA's website (www.eunetha.eu), under the heading EUnetHTA tools. <p>Descriptive document available (screenshots as PDF file enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)</p>
<p><u>Title:</u> Checklist for collaborations</p> <p><u>Short description:</u> includes possibilities for information exchange among EUnetHTA partners to facilitate ways of collaboration</p>	Policy document/Guideline	<ul style="list-style-type: none"> Document available (PDF enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); Distributed via e-mail to the partners (M3) Published in the WP7 workroom (M3)
<p><u>Title:</u> Joint assessments/collaborations</p> <p><u>Short description:</u> 12 joint assessments in 2,5 years coordinated and initiated by LBI-HTA</p>	Report	<ul style="list-style-type: none"> Reports are available on LBI-HTA website: http://eprints.hta.lbg.ac.at/ (list of reports with respective weblinks to be found in the WP7 Appendix)
WP8		
Title/Short description	Nature	Access
EUnetHTA Strategy	Written document	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunetha.eu
HTA training and capacity building	Report	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunetha.eu
Facilitation of national strategies for continuous development and sustainability of HTA	Report	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunetha.eu

Introduction

This report is the final Technical Report on Implementation of the European network for Health Technology Assessment Joint Action (2010-2012) – EUnetHTA JA1, delivered by the Co-ordinator – Danish Health and Medicines Authority (DHMA) to the Executive Agency for health and Consumers (EAHC).

The final Technical Report of EUnetHTA JA1 covers the period from January 1, 2010 to March 31, 2013 (the first 3 months of 2013 cover the activities associated with the reporting of the joint action results) and includes the overview of the overall joint action's objectives, methods, results and recommendations, Work Package 1 -8 individual reports - which provide the details on all activities performed, achievement of objectives, manpower, partners and countries involved within each Work Package - and administrative information as stipulated in the Reporting Requirements (Annex III of the Grant Agreement 2009 23 02).

The first Interim Technical Report was submitted to the EAHC on March 21, 2011 (it covered the period from January 1, 2010 till December 31, 2010); the second Interim Technical Report was submitted to EAHC on April 30, 2012 (it covered the period from January 1, 2011 till December 31, 2011). Both reports are enclosed as electronic documents on the CD-ROM.

All deliverables have been produced and submitted to the EAHC within the timeframe of the project.

The final Technical Report on Implementation of the EUnetHTA JA1 was prepared by the Coordinator in collaboration with the Lead and *Co-Lead* Partners of the Work Packages (WPs):

- WP2 (NIPH, *Slovenia*; SBU, *Sweden*),
- WP3 (NETSCC, *UK*),
- WP4 (THL, *Finland*, AGENAS, *Italy*),
- WP5 (CVZ, *Netherlands*; HAS, *France*),
- WP6 (KCE, *Belgium*; DIMDI, *Germany*)
- WP7 (HAS, *France*; LBI, *Austria*),

According to Article II.3.2 of the Grant Agreement, the beneficiaries grant the EAHC the right to make free use of the results of the action as it deems fit, provided it does not thereby breach its confidentiality obligations or existing industrial and intellectual property rights. The deliverables/output indicated as having a restricted confidentiality level should not be made public as per the Grant Agreement.

Additionally, the Co-ordinator has submitted a consolidated financial statement for the full joint action period including the first 3 months of 2013 for reporting of the results.

Overview of the EUnetHTA JA1 activities and results

Background

The EUnetHTA Joint Action 2010-2012 (EUnetHTA JA1) was a response to the request by the EU Commission and EU Member States, in the Work Plan 2009 of the Health Programme, to continue fostering the development of HTA in Europe. It builds on the methods and tools developed by the earlier EUnetHTA project (2006-2008) and EUnetHTA Collaboration 2009. Additionally, the results and recommendations of the Working group on Relative Effectiveness of the High Level Pharmaceutical Forum from 2008 were taken forward in EUnetHTA JA1.

EUnetHTA JA1 inherited a number of tools from the precedent EUnetHTA Project 2006-08 for use and further development. The HTA Core Model, a framework for producing and sharing structured HTA information, was already in existence and tested in two projects. An Adaptation Toolkit had been developed together with an Adaptation Glossary. The first version of the database for new technologies requiring additional evidence generation, called EIFFEL, was in place. There were websites, both public site and intranet, the latter providing Work Rooms for document sharing and access to the e-meeting facility. In addition to the tools, there were substantial developments made in the area of coordination and management, such as Standard Operating Procedures and Organisational Structure and Governance Guiding Principles, to mention some of them. Both areas of development, the tools and the management and governance structures, had the objective of supporting the building of a sustainable system for collaboration in HTA. An overview of the EUnetHTA Project Results 2006-2008 is found in <http://www.eunethta.eu/outputs/overview-eunethta-project-results-2006-2008>.

The broad intent of EUnetHTA JA1 was to take forward the prior developments of the EUnetHTA Project and bring them to a level that enables a genuine collaboration that is implemented in practice. Barriers to collaboration should be examined and overcome, and the importance of communicating with stakeholders acknowledged by developing a practice of stakeholder involvement. In order to reduce duplicate efforts in the production of HTAs, the EUnetHTA tools should be improved through further testing and user feed-back, and their actual implementation in the everyday practice of European HTA organisations should be promoted. The collaboration management structures should be further developed and the added value of participation shown by the participating organisations.

EUnetHTA aims and objectives

The overarching objective of the EUnetHTA JA1, including work on relative effectiveness of pharmaceuticals, was to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level. The following three specific objectives were defined in the Technical Annex of the Grant Agreement of EUnetHTA JA:

1. Development of a general strategy and a business model for sustainable European collaboration on HTA
2. Development of HTA tools and methods
3. Application and field testing of developed tools and methods

These three were further specified in the objectives of the EUnetHTA JA1 3-Year Work Plan in the beginning of the JA1.

Objectives related to the general strategy and business model:

- To update the Strategy and Standard Operating Procedures
- To develop the Stakeholder Involvement Policy
- To develop a business model for sustainable collaboration
- To develop an Information Management System
- To develop a Communication and Implementation Plan
- To prepare policies to steer the access to and use of the EUnetHTA tools and information

Objectives related to the development of tools and methods:

- To develop a tool and process to enable identifying planned or on-going HTAs in Europe, and to facilitate collaborative assessment projects on identical topics
- To further develop the HTA Core Model and the online tool for producing and storing of HTA information

- To develop a Core Model for the assessment of screening technologies
- To develop a Core Model and common methodology for the relative effectiveness assessment (REA) of pharmaceuticals
- To further develop the database of new technologies requiring additional evidence generation and turning it into an online tool (EVIDENT).

Objectives related to application and testing of the tools:

- To test the new online tool of the HTA Core Model in two full assessments (Core HTAs) on topics that are pertinent to several HTA agencies
- To test the new HTA Core Model and methodology for REA in one assessment of a pharmaceutical

Work Packages were aligned with specific objectives and each was expected to produce deliverables, as shown in Table 1. In addition, milestones were set over the three-year project period for each Work Package, taking account of interdependencies across Work Packages.

Table 1: Objectives and planned deliverables for each Work Package

Objectives	Key Deliverables ²	Work Package
Development of a general strategy and a business model for sustainable European collaboration on HTA	<ul style="list-style-type: none"> • Stakeholder Involvement Policy and SOP • Collaboratively developed business model for sustainability • Communication and dissemination Plan • Interim and Final Technical and Financial reports 	1 Coordination 2 Dissemination 3 Evaluation 8 Strategy and Business Model Development
Development of HTA tools and methods	<ul style="list-style-type: none"> • An online Tool and Service for producing, publishing, storing and retrieving HTA information • The screening application of the HTA Core Model • A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals 	4 Core HTA 5 REA of Pharmaceuticals 7 New Technologies
Application and field testing of developed tools and methods	<ul style="list-style-type: none"> • A set of 2 Core HTAs • Operational web-based toolkit including database containing information on evidence generation on new technologies • Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies • Information Management System (IMS) and the related documentation, processes, and policies • A relative effectiveness assessment of a (group of) pharmaceutical(s) 	4 Core HTA 5 REA of Pharmaceuticals 6 Information Management System 7 New Technologies

² Please see page viii for the list of final deliverables and outputs

Structure and methods; partners and countries involved

The EUnetHTA JA1 included eight Work Packages (WPs) - three horizontal WPs (1,2,3) and five core WPs (4,5,6,7 and 8), see Table 2. There were a total of 33 government appointed organisations from 26 EU Member States, Norway and Croatia involved in the work of the WPs, and a large number of regional agencies and non-for-profit organisations that produce or contribute to HTA.

The EUnetHTA JA1 was a complex undertaking involving the multi-disciplinary staff of 59 organisations in 33 countries across the world (the individual Work Package reports include the lists of the individuals that were involved in the WP work from each of the participating organisations. The EUnetHTA JA1 Financial Report provides details on the time and cost of each Associated Partner individual involved in the EUnetHTA JA1 work).

Meeting the JA1 objectives required a high level of commitment from the Lead, Co-Lead and Associated Partners and effective coordination within and between the EUnetHTA JA1 WPs.

Each Work Package had a Lead Partner who was responsible for coordination of activities in that Work Package and timely production of all deliverables according to the Grant Agreement and 3-year Work Plan. Five Work Packages (WP2,4,5,6,7) had a Co-Lead Partner that supported the Lead Partner in implementation of the WP 3-year work plan and management of the Work Package activities. In addition, Co-Lead Partners in WP4 and 7 were responsible for a specific Strand of activities inside the respective Work Package. WP8 had two specific lines of activities each of which had a dedicated organisation leading and coordinating the work of the organisations involved in the specific activity line.

Table 2: Work Package (WP) description

WP no	Lead and Co-Lead Partner(s)	Associated and Collaborating Partners	WPs with close collaboration
WP1	DHMA, Denmark	<ol style="list-style-type: none"> 1. AGENAS, Italy 2. AHTAPol, Poland 3. CVZ, Netherlands 4. DIMDI, Germany 5. HAS, France 6. ISCIII, Spain 7. KCE, Belgium 8. LBI, Austria 9. NETSCC, UK 10. NIPH-RS, Slovenia 11. SBU, Sweden 12. THL, Finland 	
WP2	NIPH-RS, Slovenia SBU, Sweden	<ol style="list-style-type: none"> 1. DHMA, Denmark 2. Hauptverband der Österreichischen Sozialversicherungsträger (HVB), Austria 3. National School of Public Health, Greece 4. National Center of Public Health Protection, Bulgaria 5. MoH, Spain 6. SLOVAHTA, Slovak Republic 7. SNHTA, Switzerland 8. OSTEBA, Spain 	<p>WP1: communication plan and materials</p> <p>WP6: the social networks, and EUnetHTA intranet</p>

WP3	NETSCC, UK	-		WP1 and WP8: strategy and business model. WP6 regarding survey design
WP4	THL, Finland (Strand A) and overall WP coordination AGENAS, Italy (Strand B)	<ol style="list-style-type: none"> 1. AGENAS, Italy (A/B) 2. AHTAPol, Poland (A/B) 3. CVZ, Netherlands (A) 4. DIMDI, Germany (A/B) 5. GÖG, Austria (B) 6. HIQA, Ireland (A/B) 7. HVB, Austria (A/B) 8. INFARMED, Portugal (A/B) 9. IPH-RS, Slovenia (A/B) 10. IQWIG, Germany (A/B) 11. ISCIII, Spain (A/B) 12. KCE, Belgium (A/B) 13. LBI-HTA, Austria (B) 14. NBoH, Denmark (A) 15. NICE, UK (A/B) 16. NOKC, Norway (A/B) 17. Regione Veneto, Italy (A/B) 18. SBU, Sweden (A) 19. SDU, Denmark (B) 20. SSD/MSOC, Malta (B) left in 2011 21. THL, Finland (A/B) 22. UTA, Estonia (A/B) • 	<ol style="list-style-type: none"> 1. AETSA, Spain (A/B) 2. ARESS, Italy (A) 3. ASSR Emilia Romagna, Italy (A/B) 4. Avalia-t, Spain (A/B) 5. Department of Health Services Research, Denmark (A/B) 6. DSI, Denmark (A/B) 7. KDTD, Turkey (A/B) 8. Lazio Sanità, Italy (A/B) 9. OSTEBA, Spain (A) 10. Quality unit, Ministry of Health of Serbia, Serbia (A/B) 11. Regione Lombardia, Italy (A/B) 12. SNHTA, Switzerland (A/B) 13. University of Health Sciences, Austria (B) 14. University Hospital "A.Gemelli", Italy (A/B) 15. Agency for Quality and Accreditation in Health, Croatia (B) 16. University of Bremen, Germany (joined in 2011, A) 17. Institute for Economic Research, Slovenia (joined in 2011, B) 	WP5: the REA model WP6: the interoperability of the tools

WP5	CVZ, The Netherlands HAS, France	<ol style="list-style-type: none"> 1. AHTAPol (Poland) 2. AIFA (Italy) 3. GYEMSZI (Hungary) 4. GOEG (Austria) 5. HIQA (Ireland) 6. HVB (Austria) 7. INFARMED (Portugal) 8. IPH-RS (Slovenia) 9. IQWIG (Germany) 10. KCE (Belgium) 11. NHS of Latvia (Latvia) 12. MoH (Czech Republic) 13. MoH (Spain) 14. NICE (UK) 15. NOKC (Norway) 16. SDU (Denmark) 17. SSD/MSOC (Malta) 18. THL (Finland) 	<ol style="list-style-type: none"> 1. AETSA (Spain) 2. A Gemelli (Italy) 3. AMPM (Slovenia) 4. CAHTAR (Spain) 5. DSI (Denmark) 6. IRF (Denmark) 7. KDTD (Turkey) 8. REGLOM-DSAN (Italy) 9. RIZIV (Belgium) 10. SNHTA (Switzerland) 11. SLOVATHA (Slovakia) 12. TLV (Sweden) 13. UETS (Spain) 14. NCHTA (Russia) • 	WP4 regarding the HTA Core Model and Online Tool
WP6	KCE, Belgium DIMDI, Germany	<ol style="list-style-type: none"> 1. CVZ (Netherlands) 2. GÖG (Austria) 3. GYEMSZI (Hungary, formerly EMKI and ESKI) 4. HAS (France) 5. HVB (Austria) 6. ISCIII (Spain) <p>LBI-HTA (Austria)</p> <ol style="list-style-type: none"> 7. NETSCC (United-Kingdom) 8. NIPH (Slovenia) 9. SBU (Sweden) 10. THL (Finland) 	<ol style="list-style-type: none"> 1. ARESS (Italy) 2. KDTD (Turkey) 3. OSTEBA (Spain) 4. SNHTA (Switzerland) 	<ul style="list-style-type: none"> • WP1: EUnetHTA public web site, EUnetHTA ID, information dissemination policy, and a stakeholder web site with restricted access • WP2: social networks and EUnetHTA Conference communication • WP3: internal surveys and the online tool for Adaptation Glossary; • WP4: Core Model • WP5: online survey; • WP7: POP

				database and online survey <ul style="list-style-type: none"> WP8: business model
WP7	HAS, France (Strand A) and overall WP coordination LBI-HTA, Austria (Strand B)	<ol style="list-style-type: none"> SDU, Denmark THL, Finland GYEMSZI, Hungary HIQA, Ireland AGE.NA.S, Italy AIFA, Italy Regione Veneto, Italy VASPV, Lithuania SSD/MSOC, Malta CVZ, Netherlands NOKC, Norway AHTAPol, Poland INFARMED, Portugal SLOVAHTA, Slovakia ISCIII, Spain SBU, Sweden NETSCC, UK NICE, UK 	<ol style="list-style-type: none"> National Centre for Pharmacoeconomics, Ireland ASSR, Italy Agency for Medical Products and Medical Devices, Slovenia AETSA, Spain AVALIA-t, Spain OSTEBA, Spain SNHTA, Switzerland KDTD, Turkey CMTP, USA 	WP6: POP database and the interoperability of EVIDENT and POP databases
WP8	DHMA, Denmark AETS-ISCIII, Spain (responsible for a specific line of activities on training in EUnetHTA tools) AHTAPol, Poland (responsible for a specific line of activities on facilitating national HTA strategies)	<ol style="list-style-type: none"> DHMA (former NBoH), Denmark AGENAS, Italy AHTAPol, Poland CVZ, Netherlands DIMDI, Germany HAS, France IPH-RS, Slovenia ISCIII, Spain KCE, Belgium LBI, Austria NETSCC, UK SBU, Sweden THL, Finland <p>Partners listed under a-l are only involved in the line of WP8 activities associated with the development of the</p>	<ol style="list-style-type: none"> ASSR, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna, Italy Laziosanità (Agenzia di Sanità Pubblica, Regione Lazio, Italy) University Hospital "A. Gemelli", Italy Quality unit, Ministry of Health of Serbia CAHTAR, Spain UETS, Spain SNHTA, Switzerland KDTD Turkish Evidence-Based Medicine Association, Turkey <ul style="list-style-type: none"> 	WP1: stakeholder involvement and business model development

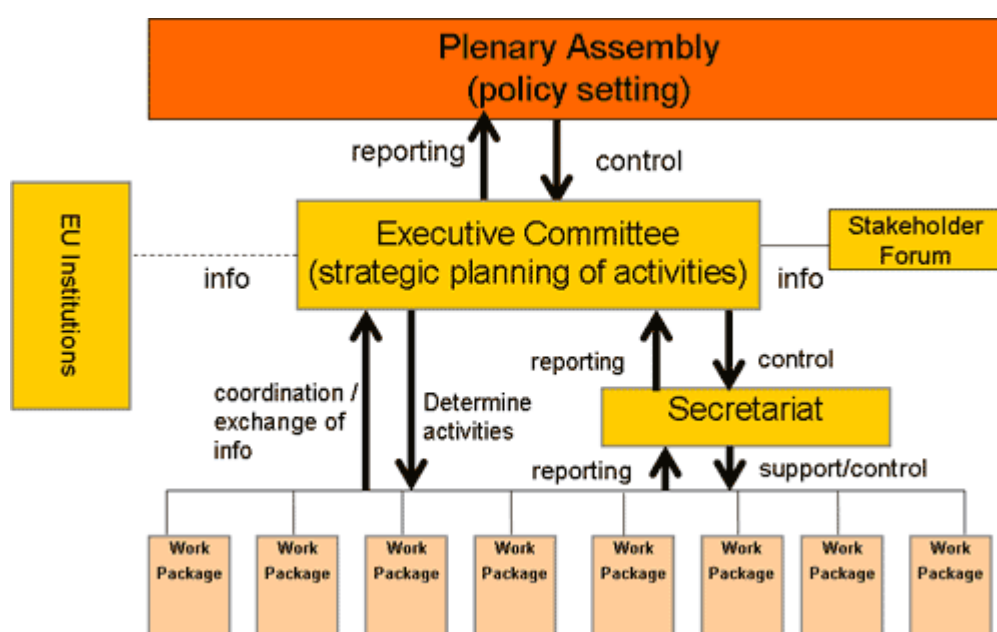
		<p>following business model component “facilitation of national strategies for continuous development and sustainability of HTA and HTA training and capacity building”</p> <ul style="list-style-type: none"> a. Agency for Quality and Accreditation in Health Care, Croatia b. AIFA, Italy c. GÖG, Austria d. MoH, Czech Republic e. MoH, Spain f. NOKC, Norway g. NSPH, Greece h. Regione del Veneto, Italy i. SDU, Denmark j. SSD/MSOC, Malta k. UTA, Estonia l. VASPVT, Lithuania • 		
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A variety of scientific approaches were used in the Work Packages including literature searches, survey questionnaires, Delphi surveys, pilot and applicability testing of tools, structured reviews of drafts, and many meetings and other forms of collaboration to build consensus. The methods used are described in detail in each Work Package report.

To ensure the achievement of objectives and consistency and high quality of work, clear delegation of management and coordination responsibilities was needed to ensure the adequate involvement and performance of each contributing organisation. Figure 1 shows the organisational structure of the EUnetHTA Joint Action. The Standard Operating Procedures (SOP) was developed and endorsed by the Plenary Assembly in the first half year of the Joint Action.

To ensure the responsiveness of the EUnetHTA Joint Action to the needs of the Member States and the EU, regular updates on the progress of the Project were given to DG SANCO and the EAHC. Additionally, the Secretariat regularly monitored and informed the Executive Committee and all EUnetHTA Partners about healthcare policy developments at the EU level. Partners were also encouraged by the Executive Committee to make contact with their Ministry of Health to discuss the work of the EUnetHTA Joint Action and gain support for ongoing work nationally. (See WP1 technical report for the details on the JA1 external meetings).

Figure 1. EUnetHTA Joint Action Organisational Structure



Main activities

Building management structures and policies for sustainable collaboration

Governance and organisational structure

The organisational structure of the EUnetHTA Project (2006-2008) was taken as the starting point for the governance and organisational structure of EUnetHTA JA1. The Governance Guiding Principles document was a part of the Grant Agreement with the EAHC.

The Executive Committee was composed of the Lead and Co-Lead Partners of the eight WPs (Co-LPs having conditional voting rights if delegated such right by the respective WP LP), the Chair of the Plenary Assembly (non-voting member) and three elected members (from the EUnetHTA JA1 member agencies). This Committee was the main executive body involved in strategic leadership of the Joint Action. Bi-annual face-to-face meetings were held and e-meetings were held every one-two months.

The Plenary Assembly was the main governance and policy-setting body of the EUnetHTA JA1. It was composed of the Head of each Partner organisation and some EUnetHTA Collaboration Founding Partner organisations (or their representative). The Chair was elected by Plenary Assembly members and ensured liaison between the Executive Committee and the Plenary Assembly. The annual meeting was of crucial importance because it represented the only meeting of all project organisations and its function was to agree policy and discuss vital strategic issues.

In formation of the EUnetHTA Joint Action the European Commission emphasised the importance of giving a greater focus to Stakeholders than had been given during the EUnetHTA 2006-2008 project. The Stakeholder Forum was established in 2010 to facilitate information exchange with the Stakeholders and was part of the governance structure for the JA. Stakeholder Forum members representing each of the four stakeholder groups in the Forum could participate in the Plenary Assembly meetings.

General strategy

The “EUnetHTA Strategy 2012 and Beyond” addresses the strategic positioning of EUnetHTA in the current and near future activities (5-7 years) in relation to HTA at the national, European and global level. It lays out EUnetHTA’s vision, mission, values, objectives supported by corresponding strategies. The strategy was developed by the Executive Committee with the involvement of EUnetHTA partners in general, the Stakeholder Forum, public consultation – and a final endorsement by the Plenary Assembly.

As part of the general strategy development an analysis of national strategies for sustainability of HTA was performed by means of semi-structured questionnaire and panel discussions among EUnetHTA partner organisations (WP8). This activity resulted in a set of consensus recommendations on a general strategy for continuous development as well as development of appropriate support systems for HTA capacity building, overcoming common problems, improving structures and processes. Another strategy relevant survey was performed to collect partners’ knowledge of the EUnetHTA tools and needs for training (WP8).

Information Management System

The intranet website of the EUnetHTA project 2006-08 (for members only) was taken as basis and improved in a stepwise approach (WP6). Workrooms were established and maintained for all Work Packages. News (RSS feeds) from partner organisations’ webpages were automated. A toolbar for web browser was developed to provide shortcuts to the EUnetHTA working areas, tools, and news. A common vocabulary (Medical Subject Headings - MeSH) and metadata were selected for use in all EUnetHTA tools. The contact database was turned into a new central authentication directory, which allowed individuals in partner organisations to access all the EUnetHTA tools with a single log-in and password. A procedure was developed for annual access renewal and a policy for information dissemination (WP1 and 6). Development of a new website for JA2 was started in the end of JA1.

Stakeholder policy

A policy and standard operating procedures were created for stakeholder involvement in actions performed for EUnetHTA JA1. Four stakeholder categories were identified as particularly important to interact with: Patient and healthcare consumer organisations; Healthcare providers (professionals and hospitals); Payers; and Industry. The policy differentiates between the involvement of stakeholder representatives and involvement of experts. Stakeholder involvement takes the form of participation in the EUnetHTA JA1 Stakeholder Forum, participation in the WP Stakeholder Advisory Groups (SAGs), and in public consultation on deliverables. Experts can be invited into the work of WPs based on their individual merits and relevance for the work, under the condition, that they disclose any potential conflict of interest, they do not represent a stakeholder organisation’s view, and that they do not constitute the majority in the work group. EU institutions are not defined as stakeholders.

Business model

A potential future business model for EUnetHTA was developed together with the general strategy (WP8). The business model follows the vision and mission of EUnetHTA and the overarching values of European Union for health systems. The EUnetHTA business model was developed on the basis of many years of empirical European cross-border collaboration on HTA and piloting of the work processes for HTA information production and sharing. It is therefore a key source of specific solutions and approaches for implementation of a permanent European network for HTA as a part of the Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare (CBHC Directive).

A visual overview, a Business Model Map, presents parties involved in EUnetHTA as blocks and arrows indicate transactions between them. Proposed value transfers are presented with specific symbols: these include content production, transparency of methods and data, quality assurance and training. The possibility of introducing fees for gaining access to certain value-bearing activities is introduced in the Business Model. A credit system is proposed in the model to reward the parties who create value to the system and allow them to extract corresponding amount of value from the network. This credit system raised mixed thoughts because it introduced value propositions and tokens that could be exchanged. However, these concepts are indeed integral parts of a business model. The work on the business model proved to be also a learning exercise for many of the individuals and partners involved in JA1. Considering the level of commitment and decision power within the collaboration, over time the model tentatively positions EUnetHTA closer to being a strategic alliance than a project collaboration, which indicates more commitment and formal agreeing and shared decision power. The organisational structure is envisioned to be designed with a central coordinating facility and a number of “Activity Centres” amongst partner organisations. Financing was considered a key issue to clarify during EUnetHTA JA2.

Policy for use of the HTA Core Model

A policy to steer the use and utilisation of the HTA Core Model and information produced by using the Model was prepared (WP4A). An extensive survey of possible options for more than thirty policy items was conducted between summer and autumn of 2011. Twenty-four agencies responded and expressed their preferences on various items. The draft was discussed within the Executive Committee in June 2012 and a final version was approved by the WP4 partner organisations. The Executive Committee approved the policy in its e-meeting in December 2012. The new policy necessitates several changes to the original Terms of Use of the HTA Core Model that derives from 2008. These will be implemented within the first months of 2013 and a license enabling also commercial use of the HTA Core Model will be developed by mid-2013.

Developing tools and guidelines to support collaboration

Planned and On-going Projects (POP) database

Development of the POP database (WP7B) was started in 2010 with a simple Excel worksheet. A dedicated work room was set up for it, and the partners were encouraged to provide information about their planned and on-going HTA projects. Similar topics were identified by hand searching and emails sent to alert partners for identification of possible duplicate work and potential collaboration. The manual sheet was turned into an online tool in 2011, with electronic search functions and automated identification of similar topics, based on MeSH terms (Medical Subject Headings) recorded with the individual project. Contact details of responsible persons for the projects are provided to facilitate contact. Quarterly reminders are sent to partners to update their project details and to check for possible collaboration. During the development phase of the POP database INAHTA released a similar database which led to a memorandum of understanding and terms of reference (WP6) with INAHTA to avoid overlapping and to enhance the usefulness of the POP Database in relation to the HTA Database hosted by Centre for Review and Dissemination (CRD) at the University of York, UK.

Online Tool for the HTA Core Model

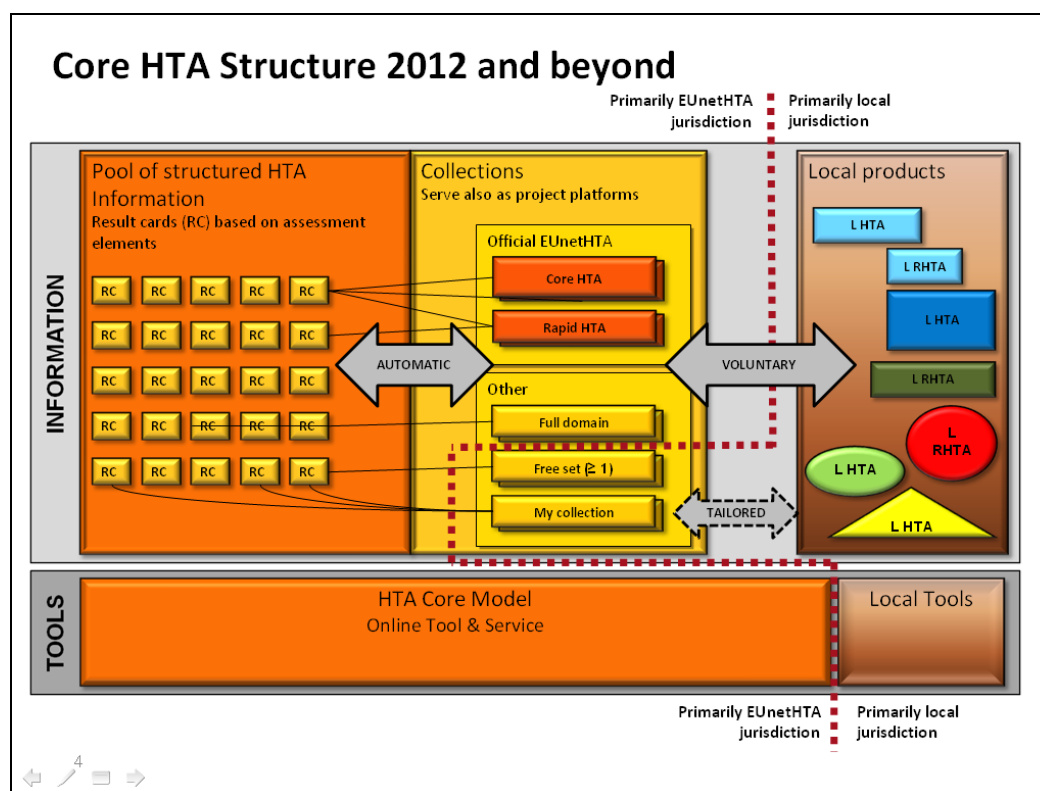
Basic concepts of the HTA Core Model were kept mostly as they were developed within EUnetHTA Project 2006-2008 and the EUnetHTA Collaboration 2009. The Model continues to be a methodological framework for production and sharing of HTA information. The concept of a pool of Structured HTA Information was launched during JA1. It describes the result of using the HTA Core Model as pieces of core (relevant and sharable) information that can be used for preparing local HTAs. The HTA Core Model, and the resulting structured HTA information and local HTAs were collectively labelled as the Core HTA Structure (Figure 2).

During JA1 the emphasis was put on making an earlier paper-based HTA Core Model usable in an online environment (WP4A). Work was divided into two phases, first focusing on the basic functionalities needed to support core HTA production, and second considering advanced functionalities, such as publishing, information search and retrieval and adaptation of information. Development was supported by continuous collection of user feedback. Two Core HTA assessment projects of EUnetHTA JA1 piloted the new online tool of the Core Model.

Plans were made for incorporating the Adaptation Toolkit which was developed during EUnetHTA Project 2006-2008 into the HTA Core Model online (WP4A and 3). Within JA2 features will be implemented in a 'reader' interface of the Core Model (currently the Core Model Online has interface for HTA doers only). The 'Speedy sifting' feature of the Adaptation Toolkit will be added to assist the reader of a particular Core HTA to quickly determine the relevance of the information for own use. The guidance provided in the main part of the Adaptation Toolkit will be placed in the relevant places within the Domains.

The correspondence of the HTA Core Model and a national HTA report regarding the content and order of the HTA information was examined through comparing a Dutch assessment report on endovascular repair of aneurysms (EVAR) with the HTA Core Model (WP4A and 5). The sentences and paragraphs of the EVAR report were tagged with the assessment element IDs of the Core Model. The authors of the EVAR report were asked to point out if there were relevant issues missing in their report after they had read the list of research questions suggested by the Core Model. The order and clustering of the pieces of core HTA information in the EVAR report were noted and the differences from Core Model structure analysed. Finally, some content elements were noted in the EVAR report which were missing in the Core Model. The results will be submitted for publication in the International Journal of Technology Assessment in Health Care (IJTAHC) in 2013.

Figure 2. The Core HTA Structure in 2012



New Core Model applications

During EUnetHTA JA1 two new applications were developed: One for screening technologies (Screening Model) and the other for rapid assessment of relative effectiveness of pharmaceuticals (REA Model). Two applications of the HTA Core Model had been developed during the EUnetHTA 2006-2008: One for medical and surgical interventions and the other for diagnostic technologies.

The screening model development (WP4A) involved 23 agencies from 16 countries. Sixty-eight individuals were divided in teams each working with one of the nine domains of the HTA Core Model: *Health problem and current use, description and technical characteristics, safety, clinical effectiveness, costs, ethical, organisational, social and legal aspects*. The teams modified the assessment elements of the earlier Core Model applications to meet the specific needs in the assessment of screening programs. Additionally, the authors updated the methodological guidance in their respective domain, and amended the text if there were specific methodological issues for assessing screening technologies. Drafts were sent for comments to the partners of WP4A, the SAG of WP4 and the final draft was submitted to public consultation.

REA model development (WP5) was preceded by a review of national practices in the assessment of the relative effectiveness of pharmaceuticals (REA). This was performed through a literature search and a survey to participating and other relevant organisations in 2010 and finalised as a report and a published article in 2011. Information was retrieved from 31 countries and was used to highlight the possible differing needs of Member States regarding REA that should be taken into account in Model development.

There were 19 agencies from 11 countries involved in the actual REA model development. Tens of individuals were divided in eight domain teams in June 2010. Significant changes were made in the original HTA Core Model structure. The costs and economic evaluation domain was removed from the REA model, and the assessment elements in the remaining eight domains were critically scrutinised for inclusion. All WP5 partner organisations were consulted in January 2011 for the first draft of the model and the Model was made available for piloting in March 2011.

After a pilot assessment project testing the first draft of the REA Model, further changes were made to the model to increase its usefulness in rapid assessment. The last four domains (ethical, organisational, social and legal) were removed and replaced with a checklist to make the assessment of the relevance of these aspects more efficient. The assessment elements in the remaining four domains were modified to better fit the conditions of the limited timeframe between market access and reimbursement decision, where the REA Model will most likely be used. This resulted in a simpler Model with only 39 questions in 4 domains; instead of the 150 questions in the 9 domains of the full HTA Core Model. Guidance on how to balance benefits and harms, and nine new draft methodological guidelines produced by WP5 during JA1 were added to the second version of the REA model. It was circulated internally in June 2012 and the comments were taken into the 3rd version of the REA Model, which was then submitted to public consultation in October 2012. The feedback from public consultation was taken into the final 4th version of the Model which was published in February 2013.

Methodological guidelines

Creating common understanding and preferred set of methods to be used in HTAs is essential for collaborative HTAs and probably also for raising the overall level of HTA in Europe. Since the EUnetHTA Project 2006-2008, assessment methods have been included in the HTA Core Model for each domain separately. These guidelines are brief and generic, presenting and providing links to established methods without taking strong stance on one method over the other.

During EUnetHTA JA1 a further step was taken in methodological guidance (WP5). The need for more instructive and focused method guidance for assessing the relative effectiveness of pharmaceuticals was the driving force for these new guidelines. The work started in 2010 by reviewing the methodological literature and identifying the most critical methodological topics requiring a guideline. The following guideline topics were taken forward: clinical endpoints, composite endpoints, surrogate endpoints, health related quality of life, internal validity, applicability, choice of comparator, direct and indirect comparisons, and safety. The guideline of patient relevant outcomes was merged into the guideline on clinical endpoints during the process, and the guideline on grading experience in experts and experience itself was discontinued. Instead of merely describing the methods available, the aim was to reach a consensus on a restricted set of preferred methods, and report them in a way that is directly helpful for an HTA doer.

First drafts of the new methodological guidelines were ready for internal consultation in the first months of 2011 and the modified second drafts were made available by June 2011 for the WP5 pilot HTA, testing the feasibility of the REA model and the guidelines (see later, the Pazopanib pilot). Based on the feedback received from the pilot and further group work, third drafts were made available for internal comments in June 2012. Five out of nine guidelines required further adjustments which were also discussed in a workshop with stakeholders in February 2013. The final versions of the Guidelines were finalised in March 2013.

Improving the usefulness of EPARS for REA

An activity related to the European Public Assessment Reports (EPAR) of European Medicines Agency (EMA) was taken up by EMA and EUnetHTA JA1 as a follow-up to the Pharmaceutical Forum. A joint effort was made to improve the quality and usefulness of EPARs (WP5). EPARs present in table format the essential evidence for market access decisions of a pharmaceutical. The aim was to improve the template of EPAR and consider the usefulness of similar reporting structure for the REA reports by EUnetHTA. First, a checklist was developed to evaluate EPARS. Subsequently 10 EPARS were evaluated by the WP5 partners in October 2011 using the draft template and the test feedback resulted in changes in EPARS.

EVIDENT Database

Development of the database for new technologies and evidence generation had resulted in a prototype, named EIFFEL, in 2009. During JA1 the development continued by surveying and analysing the needs of partners regarding the database with a new name, EVIDENT. A policy relevant minimum dataset, which should be recorded for each technology included in EVIDENT, was developed using Delphi technique among EUnetHTA partners. The criteria to select the technologies which particularly require additional evidence generation were developed through review of published literature, survey among WP7 partners and public consultation.

The new web-based EVIDENT database was launched in 2012. The agencies that are able to request or fund additional data generation may add the new technologies in the database. All other EUnetHTA partners are requested to add information about the assessment and reimbursements status of the technologies entered in EVIDENT. It was expected that every WP7 partner contributes with at least one entry to the system, and reminders will be sent on regular basis. The database stored 14 projects from 5 EUnetHTA partners by end of JA1.

Adaptation Glossary

The Adaptation Glossary developed during the EUnetHTA project 2006-2008, was updated into an online tool during EUnetHTA JA1 (WP3 and 6).

Testing the tools and guidelines in actual assessment projects

Topic selection

Topic selection and priority setting processes were analysed by WP4B in 2010 through a survey. Based on the results a procedure for topic selection and priority setting was developed for WP4 and tested when selecting the two Core HTA assessment topics. Another model for topic selection was elaborated for the WP5 pilot (rapid assessment of pharmaceutical). It started with mapping partners' preferences for assessment topic in 2011, followed by consultations of SAG and EMA, and identifying market authorisation holders who would volunteer to provide the pilot with the document they had prepared for their product's submission. The topic selection process was discussed and further elaborated in late 2012.

Collaborative models

The Core HTA pilot projects performed during EUnetHTA project 2006-08 had employed a collaborative model where single investigators from across the partner organisations could sign up in teams assessing one domain of HTA; e.g. safety or ethical aspects. Thus, a domain team consisted of typically 3 to 6 individuals from different agencies and countries.

During EUnetHTA JA1 new collaborative models were examined and tested (WP4B and WP5). An agency based model sought for agencies willing to assess all the questions belonging to one domain - e.g. an assessment where one agency analyses the cost effectiveness and another the legal issues of the technology. The agency based model was assumed to be more efficient while all the researchers in the team were based in the same agency, allowing more frequent and informal discussions.

The two collaborative models involve tens of individuals from, typically more than ten agencies and countries. Based on experiences in a pilot rapid assessment of a pharmaceutical a simplified collaborative model was developed (WP5). This model suggests involving two responsible agencies for authoring all the domains of the HTA, and involving up-to six other agencies as dedicated reviewers. This new collaborative model will be tested during JA2. Experiences gathered during the WP5 pilot about the barriers and success factors of European collaboration, and interviews carried out in January 2013, were compiled in a report which will be published in 2013.

Still another way to promote collaboration was tested during EUnetHTA JA1(WP7B). Using the POP database as starting point, identical assessment plans were identified among the partner organisations, and active brokering used to couple the agencies with similar interests and facilitate collaborative assessment. Two or three HTA agencies did the HTA together in a traditional manner: The HTA Core Model was not used in the preparation of these HTAs. The Austrian agency LBI-HTA acted as the coordinator and as one of the author partners in all the projects.

Assessments

There were altogether three pilot assessments performed using the HTA Core Model during EUnetHTA JA1 (Table 3).

Table 3. HTA projects using the Core Model in EUnetHTA JA1

Topic	The Core Model application	Number of participating organisations and countries	Duration of assessment	Collaborative model	WP and Lead partner
Screening for abdominal aortic aneurysm	Screening Model	9 HTA agencies from 6 countries	13 months	One agency authored one of the 9 domains	WP4B, Agenas
Prognostic tests for breast cancer recurrence	Diagnostic Model	12 HTA agencies from 10 countries	13 months	Individuals assigned to 9 domain teams, based on their expertise	WP4B, Agenas
Pazopanib for advanced renal cell carcinoma	REA Model (1 st version) and the draft methodological Guidelines of WP5	21 HTA agencies from 14 countries	3.5 months	Individuals assigned to 8 domain teams, based on their expertise	WP5, CVZ

There was a coordinator and an editorial team in all the assessments using the Core Model. Their task was to ensure the coherence and to communicate possible overlaps. Systematic literature searches were performed in all three projects. The Pazopanib pilot by WP5 put a special emphasis on the manufacturer's submission file and EPAR, which typically form the evidence base in rapid pre-reimbursement assessment of pharmaceuticals. An additional team of 6 individuals was established for the Pazopanib pilot project to make a balanced synthesis of benefits and harms. Draft reports were circulated among WP partner organisations and WP SAGs. Manufacturers were involved in two of the pilots: Technical information on prognostic breast cancer gene tests were requested from the test manufacturers during the assessment, and the draft Pazopanib pilot report was communicated face-to-face with manufacturer before sharing it outside the WP. The final versions were submitted to public consultation. An additional evaluation of the comprehensiveness and quality of the Pazopanib pilot report was performed through collecting all published national HTAs on Pazopanib in renal cell cancer, and comparing them to the pilot report.

Twelve rapid collaborative HTAs were performed based on the alerts from the POP database; they were performed using the traditional rapid assessment report structure including mainly the aspects of safety and effectiveness. Ten of the assessments were on oncological drugs, and two on new and expensive hospital treatments; list of topics is presented in the Specific outputs section, later in this document.

Communicating and training

Internal communication

The Workrooms dedicated to WPs on the EUnetHTA intranet (for members only), were actively used for document sharing. A series of self-learning materials, such as leaflets and Webcasts, were developed for the new features in the intranet (WP6), and they were used by the partners actively. There was a specific News section on the intranet maintained by the EUnetHTA Secretariat (WP1), and a regular newsletter delivered to partners (Members Update). News from partner organisations were made available through RSS feeds. A downloadable toolbar to be installed in the user's web-browser was provided. This allowed quick access to e.g. the workrooms, news sections and all EUnetHTA tools.

Access to an e-meeting facility (Saba Centra) was provided to all partners, which allowed sharing of voice and documents and provided the opportunity to vote. It was actively used for Executive Committee meetings but also for Work Package meetings. The lead partners of WPs were trained to set and host their own WP meetings using the e-meeting facility. The system proved to be practical and easy to use, particularly after a period of learning.

Active participation of all partners was sought by frequent surveys or consultations through email or web surveys. Table 4. lists the most extensive internal consultations.

Table 4 Internal surveys or consultations

WP	Topic	Time
WP4A	Screening model, 1 st version	January 2011
WP4A	HTA Core Model Online	September 2010 March 2011 September 2012
WP4B	Topic selection practices of partners	2010
WP4B	The two Core HTAs	September 2012
WP4A	Policies for HTA Core Model	July 2011 and July 2012
WP5	national REA practices	May 2010
WP5	REA model, 1 st version	January 2011
WP5	REA Model, 2 nd version	June 2012
WP5	Guidelines, 1 st drafts	Jan-March 2011
WP5	Guidelines, 3 rd drafts	March-May 2012
WP5	WP5 pilot assessment (Pazopanib pilot)	November 2011
WP7A	EVIDENT: needs and criteria	2010
WP7A	EVIDENT: draft criteria for entries	2011
WP8	Knowledge of tools and training needs	May 2010

Scheduled face-to-face meetings were held regularly for coordination purposes and additional internal meetings for specific content issues (Table 5).

Table 5. Internal face to-face meetings and workshops

Organizing WP	Number of meetings: scheduled + additional	Topics of additional meetings
WP1	5 (and 17 e-meetings)	
WP2	2+0	
WP3	0+0	
WP4	6+0	
WP5	5+4	Guideline methodologies
WP6	5+2	Interoperability of tools
WP7	4+6	minimal dataset for EVIDENT entries (2), POP

		database (4)
WP8	7 (and 9 e-meetings)	

External communication

A new structure for the EUnetHTA public website was developed with new functionalities: RSS feed, interactive timeline, print optimised page, and share on Facebook and Twitter (WP6). Electronic newsletter, EUnetHTA News, was distributed (WP1). A JA1 promotional leaflet was prepared and Power Point templates developed and distributed to partners to be used for their presentations (WP2). A limited number of press releases were issued. An article on HTA was authored for Wikipedia (WP2) and a network, called HTA in Europe Group, established and maintained on LinkedIn (WP1). After some piloting a Facebook Group was discontinued, and the LinkedIn group came into focus. It has gradually gained popularity with more than 1000 followers by end of 2012.

A EUnetHTA Conference with high level participants was organised in Gdansk in 2011 during the Polish EU Presidency in order to gain visibility, acceptance and support at a Member State and European policy level. It provided ample opportunity for a debate on the current and future role of the European HTA collaboration in policy-making on national and cross-border healthcare. There were representatives from EUnetHTA organisations, national Ministries of Health and industry, patients and health insurance stakeholder organisations. Extensive promotional materials were prepared (WP2 and 6) including a EUnetHTA video, which was premiered at the Gdansk Conference.

There will be EUnetHTA theme section in an issue of the International Journal of Technology Assessment in Health Care (IJTAHC) in 2014, where the main results of EUnetHTA JA1 will be presented in a series of articles subject to independent peer review lead by the editor in chief. Additionally, some of the partners have submitted and plan to submit manuscripts to scientific journals.

EunetHTA JA1 has been actively presented in several scientific congresses, events organised by other initiatives, organisations or companies, and meetings organised by HTA – please see technical report of WP1 for details on external presentations of EUnetHTA.

Training in the tools

Electronic training material, leaflets and web casts on how to use the Workrooms, E-meeting facility, Contact database, POP database and the Toolbar were provided (WP6). Support was provided and special training sessions organised for Workroom administrators and for WP1 as the content editor of EUnetHTA intranet. An internal workshop was organised on survey designs (WP6 and WP3). A 2-days face- to- face training session was organized (WP8) in October 2011 for EUnetHTA partners to introduce the new tools and allow people to try them hands-on. Another public half day training session on EUnetHTA tools was organised as a preconference workshop at the HTAi meeting in Bilbao in June 2012. A report on HTA training and capacity building was prepared (WP8). Based on the results of the report emphasis was put on organising face-to face-training sessions and create self-training materials for the methodological tools, HTA Core Model, POP and EVIDENT databases.

Stakeholder involvement

EUnetHTA Stakeholder Forum

European umbrella organisations with four types of interests were invited to apply to participate in the Stakeholder Forum; industry, patients/consumers, providers and payers. The Stakeholder Forum was established in 2010. It had four seats for each of the four stakeholder categories. There were more applicants than seats for the industry and patients/consumer groups and this meant that some applicants were excluded from having a seat in face-to-face and e-meetings.

- Industry
- The European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry (COCIR)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- The European Generic Medicines Association (EGA)
- EUCOMED
- Patients/Consumers
- The European Consumers' Organisation (BEUC)
- The European Cancer Patient Coalition (ECPC)
- The European Patients Forum (EPF)
- The European Rare Diseases Organisation (EURORDIS)

- Providers
- The Standing Committee of European Doctors (CPME)
- European Hospital and Healthcare Federation (HOPE)
- Payers
- Association Internationale de la Mutualité (AIM)
- European Social Insurance Platform (ESIP)
- Four organisation eligible for participation were not selected to the final list of the EUnetHTA Joint Action Stakeholder Forum members due to limitation of the number of seats. These organisations received all the information that was circulated to members of the Stakeholder Forum and were able to provide written comments on them.
- Association of the European Self-Medication Industry (AESGP)
- European Diagnostic Manufacturers Association (EDMA)
- EuropaBio
- The European Association of Pharmaceutical Full-line Wholesalers (GIRP)
- Regular stakeholder meetings were held (both electronically and face-to-face). Please see technical report of WP8 for details on activities.
- Members of the EUnetHTA Stakeholder Forum, as well as a representative of DG Sanco, were interviewed for the promotional video (WP2)

EUnetHTA Stakeholder Advisory Groups (SAGs)

- Stakeholder advisory groups (SAG) were nominated for three WPs: 4,5, and 7. Their formation and management followed the rules and procedures described in the Stakeholder Involvement Policy SOP.

SAGs reviewed the drafts of several deliverables and other outputs (Table 13).

- Table 6. Stakeholder Advisory Group consultations

SAG assigned to a WP	Topic	Time
SAG of WP4	Screening model	Jan 2011
	Online Tool	March/April 2011 and Sep 2012
	The two Core HTAs	July 2011 and Sep 2012
	Policies for use of the Core Model	Planned for 2013
SAG of WP5	Background review, draft	Jan/Feb 2011
	WP5 pilot, 2 nd draft	March/April 2012
	Guidelines, 3 rd drafts	April/May 2012
	REA Model 2 nd version	June/July 2012
SAG of WP7	EVIDENT database, pilot version	2011
	Minimum dataset for EVIDENT entries	2011
	Criteria to select EVIDENT entries	2011

Manufacturers

Manufacturers of the specific technologies in question were directly consulted in two pilot assessments: the Prognostic Tests for Breast Cancer (WP4B) and Pazopanib for renal cancer (WP5). In the breast cancer test HTA manufacturers were contacted for information related particularly to the technical details of the tests and the process in analysing them which was not found in published research or other documents. In the WP5 pilot on Pazopanib, where the manufacturer's willingness to provide essential documentation was a pre-requisite for topic selection, the draft report was discussed in a face-to-face meeting to identify possible errors, misunderstandings, and deficiencies.

Collaboration with European Medicines Agency (EMA)

Altogether five face-face meetings were held between EUnetHTA and EMA during 2010-2012, to discuss the EPAR improvement project, topic selection and regulatory-HTA interactions, collaboration on methodology guidelines, and early dialogue and early scientific advice for drugs. The meetings were held at EMA and at Lead Partner organisation premises (Amsterdam, Paris, Copenhagen). The EPAR improvement project included commenting on the EPAR template and testing the revised template with 10 topics (WP5). Comments of the usefulness of the EPARs were also provided by MEDEV, and responses were coordinated. A manuscript has been drafted to describe this collaborative activity. EMA has also provided input on the WP5 methodological guidelines as part of the public consultation.

Public consultations

- Public consultation was sought to the final drafts of several deliverables and other outputs (Table 7).
- Table 7 Public consultations of EUnetHTA JA1

WP	Topic	Time
WP4	Screening model, 1 st public version	Oct/Nov 2011
	Online Tool	Sep 2012
	The two Core HTAs	Sep/Oct 2012
WP5	Background review	April/May 2011
	REA Model, 3 rd version	Oct-Nov 2012
	Guidelines, 4 th versions	June-Oct 2012
	WP5 pilot (pazopanib)	June/July 2012
WP7	EVIDENT: content of the database	2011
	EVIDENT: selection criteria for entries	2012

Stakeholder events organised by EUnetHTA partners

The partners of EUnetHTA JA1 organised meetings and conferences targeted particularly to the stakeholders of EUnetHTA (Table 8)

Table 8. Stakeholder events organised by EUnetHTA partners.

Organising partner	time, place	Topic	Participants, topics
LBI	Sep 2010, Vienna	Meeting on collaboration in assessing oncological drugs	European HTA agencies
KCE	Oct 2010, Brussels	Workshop: Collaboration between HTA agencies in practice: learning from actual experiences	European HTA agencies, national health policy makers
CVZ, AhtaPOL, NBoH	Dec 2011, Gdansk	EUnetHTA Conference	National health policy makers, EU Commission/DG Sanco, EUnetHTA partners
CVZ	March 2012, Diemen, Netherlands	Meeting with GSK about the Pazopanib pilot report	EUnetHTA WP5 and GSK
HAS, CVZ	Feb 2013, Brussels	Meeting on WP5 Guidelines	EUnetHTA, EFPIA and other stakeholders

Adherence to the initial work plan

Some deliverables or objectives were changed for argued reasons. These are:

- POP database 2nd release was cancelled due to the upcoming changes in the EUnetHTA intranet site (WP7B) which need to be done first.
- The original objective of WP5 was to produce both a full and rapid Core Model for REA of pharmaceuticals. However, it was decided that WP5 should concentrate on the rapid Model only during JA1, in order to be able to thoroughly prepare and pilot the rapid model for REA and implement the changes received from consultation and the pilot.
- A training session of the EIFFEL toolkit (predecessor of EVIDENT) was cancelled and the number of internal surveys reduced from two to one. Instead a survey was performed to identify the required changes which were then implemented in EVIDENT (WP7A).
- Public consultation on the EVIDENT dataset was cancelled, while the information received from the Delphi rounds among partners were considered sufficient (WP7A)
- Instead of a planned European Symposium in relation to WP5, a meeting for WP members and stakeholders was organised. This was considered necessary as there were several discussion items requiring proper debate to improve the final documents of WP5.
- The methodological guidelines work by WP5 reported some deviations from the plan: The guideline on patient relevant outcomes was merged into the guideline on clinical endpoints. A guideline on grading experience in experts and experience was cancelled as it was not found feasible to produce a methodological guideline on a European level on this subject.
- The plan for stimulating the use of the model for rapid and full assessment in European countries was replaced by a report about implementation barriers and success factors for European collaboration in relative effectiveness assessment.

Project evaluation

Internal evaluations were made (WP3) to see to which extent the EUnetHTA JA and its individual WPs managed to produce the deliverables, meet the objectives stated in the Technical Annex of the Grant Agreement, and generate 'added value'. The project's effectiveness was evaluated by analysing how its processes had been performed; communication, administration, workings of individual WPs and involvement of external stakeholders.

Surveys were sent to members of EUnetHTA Plenary Assembly, and to all EUnetHTA Participants, each consecutive year of 2010-12. Stakeholder Forum members and the Stakeholder Forum applicants who were unsuccessful in becoming a member of the Forum were surveyed in 2010. In 2011 the evaluation survey was sent only to Stakeholder Forum members, and in 2012 to all EUnetHTA JA1 stakeholders. The participation was active in the surveys: mean response rates were 76% in Plenary Assembly surveys, 87% for all participant surveys, and 72% for stakeholder surveys.

Results of the project

Strategic relevance, contribution to the Health Programme, EU added value and level of innovation

The second Health Programme 2008-13 requires "pooling of resources and know-how between EU countries to address common problems, while enabling national governments to retain control over their own health care systems". This is largely identical to the objectives of EUnetHTA. Early dialogue on pharmaceuticals and devices which is requested in Health Programme is one of the lines of activities of EUnetHTA (WP7A of JA1 and WP7 of JA2)

Further, the Health programme states that "Sustainability of health care services and innovation is of strategic relevance, as well as cross boarder issues such as cross boarder threats (e.g. flu epidemics) but also patients moving across boarder to seek care. Due to demographic changes related to ageing populations the Health programme wishes to support the uptake of innovations to improve health care provision.

The policy objective for the third Health Programme, Health for Wealth (2014-20) include contributing to innovative, efficient and sustainable health systems in a situation where aging populations change the demographics in Europe. EUnetHTA has strategic relevance for the new programme because the programme seeks to fund "programs that aim pooling of resources and know-how between EU countries to address common problems, while enabling national governments to retain control over their own health care systems".

Coordination with other projects or activities at European, national and international level

One of the tasks of the EUnetHTA Executive Committee (via activities of WP1 and 8) has been to facilitate collaboration with external parties and establishing contacts and working relationships with European institutions.

HTAi

WP6 participated to the editorial team of HTAi vortal and had contacts with HTAi Information resources group regarding the HTAi Vortal (<http://vortal.htai.org>) in order to avoid duplication of work (WP6).

INAHTA

There were contacts with HTAi Information resources group INAHTA HTA Glossary (<http://htaglossary.net/>) (WP6) which lead into developing a Memorandum of Understanding between INAHTA and EUnetHTA.

CRD

Contact has been developed with CRD database (WP6).

EMA

There has been regular bi-annual meetings between EUnetHTA and EMA during EUnetHTA JA where several issue of joint interest have been dealt with (WP5 and 7). Concrete actions have been undertaken in the area of EPAR development where EUnetHTA participated in the design and testing the updated draft EPAR template and suggested changes which were implemented. Further issues, such as collaborating with EVIDENT database regarding additional evidence generation of new technologies have been discussed in the meetings.

Defining the interfaces between the roles of EUnetHTA and EMA in the pre-reimbursement assessment of pharmaceuticals is an issue that would benefit from further clarification in the coming years. Collaboration with shared understanding of timing and responsibilities and probably also with same working methods and templates would reduce overlapping efforts and accelerate the assessment process within the tight timeline required by the Transparency directive.

ENCePP

WP7 had in 2011 a Meeting and exchanges with ENCePP about the possibility of EVIDENT/ENCePP collaboration.

EUREGIO II

There were discussion and information exchange between EUnetHTA WP4A and EUREGIO II project about the assessment elements in the legal domain of the HTA Core Model. EUREGIO had utilized the HTA Core structure, and particularly the legal domain issues, when developing their guideline for hospital based HTA in cross boarder regions.

Tapestry Networks

EUnetHTA participated as an observer in Tapestry Networks' European Innovation Healthcare Leadership Network

Specific outputs

Please see "Deliverables and additional outputs" section at the beginning of this report.

Key findings of the evaluation

This section draws on the independent internal evaluation report findings. This report was produced by NETSCC in WP3. The report has not undergone review by any of the EUnetHTA governing bodies or EUnetHTA partners.

Collaboration is needed

Overlapping and double work performed in HTA agencies in Europe has been one of the main drivers of developing the collaboration. Overlapping of assessment has been obvious but it was explicitly quantified during JA1 when building the POP-database. In 2010 the interest of EUnetHTA partners for assessing oncological drugs was screened. There were several oncological drugs for which 3 to 5 partners indicated immediate need for assessment. Later on, In November 2012 there were 1267 projects entered in the POP-database and 140 of them were identical with at least one other partner project, indicating that at least 140 HTA projects would very likely benefit from collaboration.

Collaboration is possible

Collaboration with HTA agencies from different countries and cultures is not necessarily straightforward due to variation in assessment practices, preferred report structure, use of research methods and language. Collaborative assessments had been tried already in the EUnetHTA Project 2006-2008 and the objective of JA1 was to advance the collaboration to next level by gradually growing common understanding.

To overcome the problem of varied content and reporting in the national HTA reports, EUnetHTA uses the HTA Core Model. The Model provides a template for joint English language assessment. It enables division of work by structuring

the content into a set questions and answers (assessment elements). The structure of the Model allows selecting only important and shareable assessment elements, and leaving the country specific or controversial issues out of the joint assessment. The question-answer pairs produced using the HTA Core Model can be used (as such or modified) for all national reports; they do not replace the need for national reports.

To overcome the problem of differing methods, the HTA Core Model provides methodological guidance for the users of the Model. During JA1 additional nine methodological guidelines were produced to increase common perceptions of preferred methods in HTA of pharmaceuticals. The methods used for assessing relative effectiveness of pharmaceuticals were surveyed and the survey revealed that, although differences, also substantial similarities exist across the countries on the choice of the comparator, preferred endpoints and the attitude towards indirect comparisons. Only few partners had experience with requiring or implementing additional evidence generation. The three pilot assessments using the HTA Core Model exposed different perceptions and practices in the use of methods, but there was a willingness to listen and adopt the ideas of others, reflecting an overall confidence that was increasing towards the end of most activities.

It was clearly seen in the pilot assessments that the HTA Core Model alone does not guarantee a successful project. Careful coordination and editorial input is needed to reach good quality Core HTA within a reasonable timeframe. Particularly when the assessment task is distributed across several agencies, a lead partner organisation's role is essential throughout from scoping, literature search, internal and external communication, project management, identifying overlaps and deviations, and intervening them, to stakeholder consultations, quality and coherence assurance, and editing. It was clearly seen that all these tasks need to be well resourced in a collaborative assessment involving several countries. Internal communication through e-meetings was considered easy by 63% of the evaluation survey participants in 2012 which indicates that more efforts are needed to facilitate an effective use of the e-meeting tool. This calls for local IT support to enable an institution's researchers to get into the e-meeting tool, and introduction and training provided to researchers and to conveners and chairs of e-meetings.

Collaborative assessments can also be done without the HTA Core Model. There were 12 shared traditional rapid HTA projects performed as part of JA1 assessing the effectiveness and safety of new and expensive hospital technologies. The topics with common interest of several partners were identified through the POP-database and with the facilitation and coordination support of one agency two or three agencies managed to produce a joint report in an acceptable timeframe. Here too, a lead organisation's active management was essential for the success.

A survey was conducted by Centre for Applied Health Services Research and Technology Assessment at University of Southern Denmark (CAST, Denmark) to identify the number of collaborative projects outside JA1, triggered by the POP database. The survey revealed 11 collaborations. This indicates that overlapping efforts within HTA production have already been reduced during JA1.

There is willingness to collaborate in the field of HTA in Europe. In the project evaluation survey in 2012 80% of the respondents found that collaboration is very useful. This has been shown also in the work of several Work Packages in EUnetHTA JA where significant commitment was shown and a tremendous amount of work done by partners. Particularly WP5 concluded that there is obvious willingness to collaborate in the area of relative effectiveness assessment of pharmaceuticals. A sign of willingness is the active input into the EUnetHTA web site and tools. Ninety-one per cent of the project evaluation survey respondents in 2012 had logged on to the project web site, and 31% had joined the LinkedIn HTA in Europe Group established and managed by EUnetHTA. Seventy-seven per cent of the associated partners of EUnetHTA provided at least one news in the web site. Approximately 20% of the evaluation survey respondents anticipated their willingness to use the tools through smartphone and tablet in the future. The proportion of partners who regularly updated their planned and on-going projects to the POP database rose from 0 to almost 80 % during the JA1 and the number of project entries in POP was 1267 by the end of year 2012. Sixty percent of the respondents of the evaluation survey in 2012 had used the HTA Core Model and additional 28% considered using it in the future. The corresponding usage figures for EVIDENT were 17% and 48%. English language was considered as no problem by 72% of the respondents.

EUnetHTA consolidates its position

In order to achieve a sustainable network an organisation needs to be accepted by its peers. Clear objectives and interfaces to other actors in the area are essential. There were several contacts and actual collaborative projects during EUnetHTA JA1 that showed that the functions and objectives of EUnetHTA are recognised and valued by others, and that there is interest to seek collaboration with EUnetHTA. Examples of organisations or networks with which there were collaborative interactions were EMA, EUCERD JA, PARENT JA, EUPATI, Cochrane Collaboration, INAHTA, HTAi, ISPOR, ENCePP and MEDEV.

The sustainability of EUnetHTA requires proper stakeholder involvement. EUnetHTA JA1 continued to host a Stakeholder Forum building on the experience from the Stakeholder Forum of the previous EUnetHTA Project. During JA1 the SAGs were launched to reduce the threshold for consultations on specific content issues of three of the WPs: 4, 5 and 7. All the SAGs were requested to provide feedback on draft documents and tools. The participation from the stakeholders' side was active and the feedback received was, in most cases, very useful. How stakeholder Forum and SAG involvement should be done was not strictly described by the Stakeholder Involvement Policy; it was left to the WP leads to decide to what extent and in which occasion the consultations should be done. The differences observed in the involvement may reflect differences in the tasks of the WPs and perhaps the different traditions of stakeholder involvement in the national HTA agencies participating.

The objectives of EUnetHTA JA1 were mostly achieved

The overarching objective of EUnetHTA JA1 which was “to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level” appears to have been met. EUnetHTA did put into practice an effective collaboration that is sustainable. This is reflected by the fact that a follow-up EUnetHTA JA2 project was considered needed and appropriate to sustain collaboration before the establishment of any permanent network. Most of the high-level objectives of the WPs were achieved: the deliverables were mostly produced in accordance with the Grant Agreement between the JA project and the EU Commission. The quality of the deliverables was not assessed, however.

The pilot projects testing the tools did not reflect the everyday practices of the partner organisations. Therefore, it is still too early to assess the benefit of the tools in practice, although prediction of use is encouraging. This suggests that the EUnetHTA JA's third objective of application and field testing of tools' has been partially met. Results at this stage are positive and suggest that they will be of future benefit.

Approximately half of the respondents of the internal evaluation survey in 2012 perceived the tools very useful. Networking emerged as one of the main benefits of the action and this 'added value' seemed to be of greater benefit than the tools developed. However, this conclusion requires careful consideration of the innovative nature of the developed tools coupled with a necessity to continue providing adequate training and support in their application. The tools and processes developed in EUnetHTA aim at improving efficiency and transparency of the HTA production process – however, quite a few HTA agencies are still to realise that greater scrutiny of their working processes to ensure resource efficiency and methodology transparency is inevitable: The ever growing access to information by patients, payers, and other stakeholder groups and the continuing depressed economic climate are strong forces behind the need to change. Adjustment of the HTA agencies' working processes to achieve greater transparency and better efficiency in using resources available for HTA nationally, regionally and at the European level is happening several places already.

Discussion and recommendations

The benefits are obvious but efficiency and quality gains still need to materialise

Collaboration for the common good is substantial, but sustainable collaboration requires that added value is received by the participating organisation. JA1 tested existing and new tools and new ways to collaborate, and surveyed peoples' knowledge of the tools and perceptions of the feasibility of the collaboration. The overall impression is positive: Institutions and researchers are willing to continue collaborative efforts and improve the tools. There is anecdotal evidence of success, but also long lists of requested improvements, both of the tools and the management of the collaborative projects. The quality and relevance of the HTA information produced was one of the major issues brought up.

Although participation in various JA1 activities was perceived beneficial by most, JA1 was not able to clearly establish the added value of participation for the agencies themselves. It remains for the JA2 to more systematically show that providing input for a common effort (e.g. providing entries in POP database and EVIDENT or participating in a joint Core HTA project) in the end reduces the overall expenses and resources required at the partner level - because of the access of HTA information provided by others in other topics.

JA1 collected information on incentives and barriers of collaboration and the use of tools. This information needs to be analysed carefully and any proposed changes should be implemented and further tested during JA2. Collaboration between multiple organisations with different levels of capacity and different cultures, and implementation of new tools is not likely to occur overnight. It most probably requires several rounds of testing and improvements, both for tools and the collaborative models in order to gain understanding and acceptance at the institutional and individual level.

The use of the tools and the Core HTA information in the national reports need to be monitored and the tools will be continually improved in the coming years of EUnetHTA. It is essential to know what the agencies actually do use in practice. If certain information in a Core HTA is constantly omitted by the partners it is likely not worth producing it anymore. But before doing that, well-managed promotion of tools and information should be done across Europe allowing informed decisions. Feedback of missing information or missing features of the tools should be obtained online. The number of surveys may be reduced by observing practice or on-line feedback – or by increased “bundling” of surveys.

The main success criteria of a project are meeting its objectives and delivering its deliverables according to plan. However, 'added-value' gains, such as networking and information exchange, are also important. Such 'tangible' benefits should be measured by the evaluation of the EUnetHTA JA2. Networking was an added benefit of the project process of the EUnetHTA JA1 and it will be important to further evaluate it in the EUnetHTA JA2. The benefit of collaboration must also be shown to the public. More communication and specific articles are needed that describe experiences with the use of tools and with participation in the collaborative projects in EUnetHTA. Success stories are needed to encourage people to try and go further, as well as more critical stories to show that EUnetHTA tools are not static but subject to constant improvements.

Efficient communication is essential

Internal communication systems within the EUnetHTA JA were considered as adequate or good by most of the respondent in the evaluation survey in 2012. Participants considered that communication could be improved in the JA2 by having a formal communications plan, devoting more resources to communication, improving the current systems (e-meetings, Secretariat, website), using social networks, online tools, project management techniques, and improving communication with stakeholders. There is a need to centrally maintain complete and up-to-date lists of contact details of participants in various tasks. As the turnover of participants was high in EUnetHTA JA1 a suggestion was made to produce a concise induction material about the project. More meetings were requested as was promotion of e-meetings over face-to-face meetings. The internal website needs still to be improved to support the collaboration and the use of social networks developed.

Approximately three-quarters of the evaluation survey respondents had not experienced any significant problems when communicating in English during the project.

However, the communication in the large scale subprojects within EUnetHTA JA was more of a challenge. This could be helped by greater use of project planning in the future. Attention must be given to the difficulty of communicating in English. For example, Scandinavians and North Europeans tend to use a 'low-context style', where communication is explicit and comprehensively unambiguous. This is in contrast with 'high-context styles', typical of Southern Europeans, where meanings of words can be hidden. Strategies to overcome language based problems could include factoring in more time for dialogue and getting the documents checked by native English speakers.

A preference for face-to-face meetings goes hand-in-hand with the importance of networking and reinforces the importance of participants meeting in person as opposed to work solely in virtual teams. However, the benefits of this communication method need to be balanced with the inherent implications in terms of financial and logistical costs. Therefore, it is important that face-to-face meetings are conducted in an optimal manner.

New kinds of communication channels have been suggested that could help to disseminate knowledge of the tools and show their benefit to in the daily work should be considered, e.g. user stories in the form of video interviews or story telling. This is required for gaining credibility and acceptance for EUnetHTA, and to spread knowledge and acceptance, and thus use, of EUnetHTA tools. The established collaborative activities with e.g. EMA and INAHTA should be continued and new considered.

Surveys are excellent tools to gather feedback but other ways should be considered too. Online feedback systems and systematic gathering of feedback along assessment or other projects could replace some of the surveys. A survey coupled with quantitative feedback report is easier to do than gathering actual feedback which requires responding and modification in the survey object, but a careful consideration is needed to not burden the partners with too many surveys. The design of the surveys is also a matter to be developed and the piloted before implementing. One message could be: "Do not send another survey if nothing was made with the former one's results".

Suggestions for management

The nature of the network itself (ie, interconnected group of independent organisations) will influence the search for and/or development of novel solutions to support sustainable cooperation on HTA across borders in Europe.

The General Strategy and Business Model should be further developed during EUnetHTA JA2 to further develop a sustainable European HTA Collaboration. This is pertinent in the light of the establishment of the permanent voluntary HTA Network as an implementation of the Directive 2011/24 EU on the application of patients' rights in cross-border healthcare. Consideration could be given to establish a support group for operational and project management of cross-border collaboration activities. This could meet virtually to strengthen links between the subprojects. The greater use of project management and budgeting techniques could be used in the EUnetHTA JA2 to ensure sufficient resources are allocated to organisations and specific tasks.

With a focus shifting more towards "production" of HTA information as the prioritised area of activities in the European network for HTA it will be necessary to dedicate more time, attention and appropriate resources to ensure effective and professional production process support. Interaction with the technology sponsors throughout the process requires adequate availability of staff resources at the HTA organisations involved in the production of the core HTA information. Interaction and alignment with the regulatory processes around health technologies require time and resources as well. The process of identification of the HTA organisations participating in the core HTA production process and allotting of adequate and appropriate budgets to them needs to be tailored to the realities of such production while simultaneously allow for predictability of the number of such "common actions". Planning of the number of the "common actions" and requirement to express commitment to participate in them are possible on a yearly basis while budget allocation to each participating institution should be done at the time when the subject matter for the common action becomes known. Availability of competence/expertise to join the "common actions" should then be assessed at each organisation that will join such common action.

More time should be factored in for the design stage for complex projects. It is important that individual participants feel included in this formative stage and communication is clear at the outset. Due to the specific nature of the EUnetHTA JA, it is important that the leaders have a strong steer for a project within EUnetHTA. It has been recommended that there would be two project leaders for the multi-national projects.

It is recommended that evaluation of the EUnetHTA JA2 includes consideration about the tangible benefits of networking and information exchange. This could include a case-study approach to demonstrate the practical benefits of networking – e.g. collaborations initiated, topics identified etc. Any benefits should be compared to the costs that face-to-face meetings entail.

Overall, participants of EUnetHTA JA1 were positive about the assistance offered by the Secretariat. Various additional activities were suggested for JA2, such as providing support with project budgeting and project management. The EUnetHTA SOP should be adjusted further to meet the needs of the newcomers to the EUnetHTA collaboration. This is particularly important as there are new organisations joining in constantly.

With the development of the complexity in cross-border HTA production (especially with the more involved and nuanced engagement with the stakeholders – industry in particular) it has become more and more apparent that the coordinating facility needs to have access to legal advice and staff resources dedicated solely to research and support in issues of health policy (especially at the European level), stakeholder involvement, and training. Sustainability, quality and professionalism of the activities of the European network for HTA will depend on this. Legal issues associated with an appropriate handling of personal information, intellectual property rights, receiving financing from various sources to ensure a stable, varied stream of financial support for sustainable operations need to be addressed and appropriate solutions found. A well-functioning Executive Committee whose members have first-hand insight in the management of the coordinated processes for HTA information production across borders coupled with a high-level commitment to the notion and implementation of the European HTA cooperation proved to be indispensable in ensuring that both operational and strategic initiatives are taken forward in an effective manner. In order to ensure effectiveness of the Executive Committee, it is necessary that organisation representatives in the Executive Committee allocate time for regular participation in the Executive Committee's activities (a dedicated staff member needs to be available for active, regular provision of input to the activities).

The composition of the Executive Committee that included non-executive partners of the partnership (ie, those organisations that do not have a Lead/Co-Lead Partner responsibility) and the Chair of the Plenary Assembly proved very valuable – it safeguarded against “managerial tunnel vision” and allowed to bring insights of the Plenary Assembly members into a regular work and considerations of the Executive Committee.

The tools need to be further developed

There is a need to investigate the quality and usability of the HTA methodology tools in ‘real world HTA practice’ and there should be an assessment of the quality, usability and cost-effectiveness of the HTA Core Model compared to other methods of HTA report production within the European Union. Similarly, the effectiveness and cost-effectiveness of the POP database should be assessed. -With regard to the POP database it is recommended to assess how many collaborations have been undertaken due to its use.

The following is a list of the most prominent requests for improving the content or functionality of the tools coming out of the internal evaluation:

- Better access for tools. An agency login, instead of individual user name and password, would enhance distribution of the tools in an organisation. The inclusiveness of access rights may be reconsidered.
- Improved user friendliness. Flexibility should be increased in the Core Model to support various types of HTAs. Greater simplicity required, including terminology: the development groups should include tool users to ensure this. Single point of access for all the tools. Tools could suggest workflow for tool users and provide opportunity to mark the roles of responsible persons in the agency. Automated alerts should be used whenever useful
- Tool development should be sustainable and maintenance costs reasonable. Using open source technologies for software development could be the preferred method.
- All tools should be able to provide analytics about their use in order to gain real life experience and feedback for updating the tool and training plans.
- Training materials should be included in the tools. Training sessions should be organised regularly.

The role of the methodological guidelines

Currently the guidance on assessment methods is provided in two levels in EUnetHTA. First, the HTA Core Model contains the methodology sections within each domain, which describe the basic methodological criteria for retrieving, appraising, synthesizing and reporting information from their area. Second, the WP5 of JA developed nine separate guidelines focused particularly to the assessment of relative effectiveness of pharmaceuticals. There are several similarities between the WP5 guidelines and the methods sections in the Core Model, but also clear dissimilarities. Parallel production of these two types of methodological help needs to be brought together in the future. The good elements from both document types should be examined and utilized, and the position of the guidelines identified in the

chain of EUnetHTA tools, in order to maximize their utilisation. It has been suggested also, that stakeholders should be included earlier and more intensively in the preparation of methodological guidance.

Stakeholder involvement

Stakeholder Forum meetings were appreciated and should continue in the EUnetHTA JA2. Improvements could be made e.g. by having a more participatory nature, greater dialogue about setting the agenda and considering having a Stakeholder Co-chair. In 2011 all members of the EUnetHTA JA1 Stakeholder Forum agreed that the Forum was fulfilling its purpose, which was cited as being a Special Advisory Group to the Executive Committee, commenting on the work of WPs, overseeing SAGs, and gaining consensus for decisions. The Forum was seen as being inclusive, evolving and that there was increasing trust. However, in 2012 about one-third of the members thought it was not fulfilling its purpose and about one-third did not know if it was or not. Of the third who thought it was not fulfilling its purpose, half were patient organisations and half were industry. It could be worth probing stakeholders in greater depth to analyse why the functioning of the Forum appeared to depreciate between 2011 and 2012. Thus, there is a need to review the documents and processes for Stakeholder involvement in EUnetHTA JA2.

Stakeholder Advisory Groups appeared to function well. Concerns, such as short timelines for responding to consultation and the difficulties of obtaining a balance view should be addressed in EUnetHTA JA2.

There were apparent differences in the use of the views of stakeholders in tool development and assessments. POP developers did not consult stakeholders whereas EVIDENT and Core Model developers did. The mode of stakeholder involvement was different in the assessment project too: the 12 rapid traditional (non-Core Model using) did not report any stakeholder contacts, the two full Core HTAs on screening and gene testing submitted the protocols and almost final versions to SAG and the latter also to public. The topic for rapid assessment of REA of pazopanib in renal cell cancer was already based on manufacturer's agreement to collaborate by providing data (submission file) for the project. The draft report was submitted to manufacturer and discussed face-to-face prior to sending the document to SAG or public.

In the project evaluation survey about one-third of stakeholders thought stakeholders' views were not adequately considered. Suggestions for improvement included involving stakeholders at an earlier stage in iterative planning, sharing the timelines of consultations earlier, producing summaries of contributions and making the Stakeholder Forum more participatory in nature. There was a sense that stakeholders thought they had much to offer the work of the EUnetHTA JA project but they could have been involved to a greater degree. One notion was the need for more balanced representation of stakeholders to avoid bias towards one stakeholder group.

Remarkable is that the manufacturers of pharmaceuticals have expressed their interest to examine the HTA Core Model for their submission file structure. More efficient sharing of information, e.g. by using the same template for all country submissions could increase common understanding of evidence requirements and reduce duplication of efforts.

The tools should be taken into routine use

The EUnetHTA tools should be gradually incorporated into the normal everyday routines of the national HTA agencies. POP database is already a valuable tool for identifying an assessment topic suitable for collaboration. This has required the engagement of the EUnetHTA partners to regularly submit information on their agencies' planned ongoing assessment projects. The same holds for the HTA Core Model and EVIDENT. More and regular input is needed from partner organisations to amend and test the new tools aimed at fostering collaboration.

The following concrete actions are recommended to foster the anchoring of the EUnetHTA tools in the organisations

Local IT managers should receive information of the technical requirements of EUnetHTA tools

- A brief presentation of the use of EUnetHTA tools should be provided for all national agencies
- It should be made explicit in every HTA agency that the EUnetHTA ID (= access to tools) is for every employee of an HTA agency, not only the contact persons
- The local user management process should be made very simple and central support provided
- Each agency should ideally have dedicated staff to ensure regular input and use of the tools
- All participant organisations should be responsible for outlining who will be locally responsible for an organisation's commitment to the multi-national project if key staff become unavailable
- Informing about and training in use of the EUnetHTA tools should be regular in national agencies and newcomers should be early involved

Scoping is fundamental

When several individuals from several countries aim at selecting and doing a joint assessment the task needs to be particularly well defined. Careful scoping is needed in order to be able to clearly determine the selected comparators and outcome measures for a collaborative assessment. Identifying comparators and endpoints which are relevant and acceptable for all seemed to be a challenge for some assessment projects of JA1. Using the PICO (Patients, Intervention, Control, Outcome) framework is well known and much used for scoping. The HTA Core Model proposes a more detailed

scoping framework (Technology, Intended use, Comparator, Outcome) which puts more emphasis on the intended use of the technology (including patient, disease, and purpose of use) than the traditional PICO framework. This adjustment was made because of the problems encountered when using PICO in the scoping of the earlier Core HTA assessments during EUnetHTA Project. Selecting appropriate controls may require a survey of the management practices in individual countries before starting the assessment. The new methodological guidelines by WP5 helps the proper selection of controls. There are differing views of proper and acceptable endpoints for the assessment: this was the case at least in the Pazopanib pilot of EUnetHTA JA1. Careful consultation of partners and stakeholders is probably necessary when selecting endpoint which are acceptable to everyone.

Collaborative models need to be further developed

JA1 tested two versions of the original collaborative model where tens of individuals are divided into the nine domain teams to produce one assessment. The other version allow people to join the domain they had most interest and the other model involved one agency responsible for one domain. The collaborative model where one agency authors one domain gained more support and satisfaction. This probably reflects the importance of face-to-face interactions and informal office contacts in the assessment work.

The WP5 pilot on Pazopanib tested the traditional collaborative model described above and concluded that it is not suitable for rapid assessment. The Pazopanib pilot teams managed to produce a voluminous report in a short time period, but it required a huge input from authors and coordinators. Although the substantial coordinating overlapping and inconsistencies were not completely controlled across the eight domain teams.

JA1 demonstrated clearly the importance of good coordination and project management in collaborative projects. Project delays resulted into increasing amount of problems while people from other organisations who had been assigned for certain period could not continue in the extended project timeline.



Work Package 1 – Coordination
FINAL Technical Report
Joint Action on HTA 2010-2012



WP1 Objectives

The WP1 objective of an effective coordination and management of the EUnetHTA JA facilitates the achievement of the EUnetHTA JA general objective to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.

No Specific Objective as per the Grant Agreement is connected to this WP.

WP1 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
D 11 Interim and Final Technical and Financial Reports from the Joint Action (including evaluation results)	Report	<ul style="list-style-type: none"> Final Technical and Financial Report documents available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); Interim Technical Reports of 2010 and 2011 are enclosed on a CD ROM Both Final and Interim Technical Reports available³ via EUnetHTA website: www.eunethta.eu 	Public

WP1 Activities

2010

- Development of 3-year work plan
- Preparation of a consortium agreement
- Preparation of the technical and financial reports
- Plenary Assembly meeting and EUnetHTA elections
- Communication
 - Cooperation with WP6 on development of the information management system
 - Cooperation with WP2 on public website development and promotion material/activities
 - Cooperation with EAHC and DG SANCO
- Additional activities:
- Cooperation with EMA
- Contribution to the development of a complimentary joint action on HTA (Joint Action 2 (JA2))
- Assistance in starting preparations for the EUnetHTA Conference to be held in December 2011 in Gdansk, Poland (CVZ and AHTAPol are main organisers)
- Details for each of the activities indicated above can be found in the EUnetHTA JA Interim Technical Report 2010.

2011

- Finalisation and delivery of the 1st Interim technical and financial reports, preparation of the 2nd Interim technical and financial reports; daily coordination of inter-WP activities and partners participation in the JA

³ Subject to approval of the final Technical report by the EAHC

- Plenary Assembly and WP1 Executive Committee meetings
- Facilitation of public consultations on WP deliverables
- Communication
 - Cooperation with WP6 on development of the information management system
 - Cooperation with WP2 on public website development and promotion material/activities
 - Cooperation with EAHC and DG SANCO
-
- Additional activities:
- Cooperation with EMA
- Establishing a Memorandum of Understanding and Terms of Reference with INAHTA
- Development and submission of the EUnetHTA JA2 application and preparation of the grant agreement for JA2
- EU Directive 2011/24 Article 15 implementation – coordination of the EUnetHTA partners involvement and cooperation with the EC
- EUnetHTA Conference, December 2011, Gdansk, Poland (CVZ and AHTAPol are main organisers), preparation, promotion, programme development and speakers management, etc
-
- Details for each of the activity indicated above can be found in the EUnetHTA JA Interim Technical Report 2011.

2012

- Finalisation and delivery of the 2nd Interim technical and financial reports, preparation of the Final technical and financial reports; daily coordination of inter-WP activities and partners' participation in the JA
- JA total budget adjustment and amendment of the Grant Agreement
- Organisation of the Plenary Assembly and WP1 Executive Committee meetings
- Facilitation of public consultations on WP deliverables
- Preparation for JA2 – specifically for the JA1/JA2 overlap period of October –December 2012
- Coordination of EUnetHTA External collaborations (INAHTA, EUCERD and PARENT Joint Actions, FP7 projects on HTA)
 - Development of the EUnetHTA policy for engagement in external collaborations
- Streamlining and clarifying procedures for new partners and associates joining EUnetHTA
- Communication
 - New public website/intranet structure and content development (cooperation with WP6 and WP2)
 - Provision of input to a EAHC Brochure on Joint Actions
 - Presentation at external (to the EUnetHTA JA) meetings and conferences
- Cooperation with EMA
- EU Directive 2011/24 Article 15 implementation
 - Interview by ECORYS
 - Consideration of the membership, organisation and financing of the permanent network structure (via Executive Committee mechanism with involvement of the DG SANCO representatives)
 - Informing EUnetHTA partners on the development stages and coordinating EUnetHTA partners active input into the process

WP1 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

Date	Place	Audience	Content of the presentation	Presenting Institution
01/2010	Zagreb, Croatia	National audience from ministry, public health, healthcare, and academia	European HTA collaboration, EUnetHTA JA	Secretariat
01/2010	London, UK	Tapestry Network meeting	EUnetHTA JA	Secretariat
01/2010	Brussels, Belgium	European Cervical Cancer Association, European Parliament workshop	Value of HTA, EUnetHTA JA	KCE
02/2010	Milan, Italy	HTA workshop, Direzione Generale Sanita' Regione Lombardia	HTA concept. EUnetHTA JA	Secretariat
03/2010	Washington, USA	CMR International Institute for Regulatory Science Workshop on Review and Reimbursement	EUnetHTA JA; HTA in Europe; HTA and regulation	Secretariat
05/2010	Brussels, Belgium	European Patients Forum, HTA Seminar	EUnetHTA JA; patients involvement in HTA	THL
05/2010	Atlanta, USA	ISPOR 15 th Annual International meeting	EUnetHTA Joint Action; HTA	Secretariat
05/2010	Krakow, Poland	5th European Conference on Rare Diseases	EUnetHTA working group on Monitoring emerging/new technology development and prioritisation of HTA	LBI
06/2010	Dublin, Ireland	HTAi Annual Conference	HTA and benchmarking, EUnetHTA JA; REA of Pharmaceuticals, etc (several posters and oral presentations)	KCE, Secretariat, CVZ, HAS
09/2010	Barcelona, Spain	EURORDIS Summer School in Regulatory Affairs and Health Technology Assessment for Advanced Patient Advocates	EUnetHTA JA	HAS
09/2010	Brussels, Belgium	Innovation and solidarity on Pharmaceuticals Ministerial Conference, EU Belgian Presidency	EUnetHTA JA	Secretariat
09/2010	London, United Kingdom	London School of Economics Patient Academy – HTA course	EUnetHTA JA; HTA concept	Secretariat
10/2010	Zagreb, Croatia	2 nd Croatian Congress on preventive medicine and health promotion with international participation, in	EUnetHTA JA	Croatian Agency for Quality and Accreditation in Health
10/2010	Washington, USA	Pharmaceutical Market Access World Conference	HTA panel discussion; European collaboration on HTA / EUnetHTA JA; early advice	Secretariat
11/2010	Prague, Czech Republic	ISPOR 13 th Annual European Congress	EUnetHTA JA update (incl. WP4,5 and 7 details)	Secretariat THL CVZ HAS

11/2010	Brussels, Belgium	EDMA workshop Reimbursement of Innovative Technologies	EUnetHTA JA; HTA concept	KCE
12/2010	London, United Kingdom	Health Technology Assessment World Europe Congress	European HTA collaboration; REA of Pharmaceuticals	Secretariat, CVZ
12/2010	Zagreb, Croatia	DG Enlargement - Workshop on Health Technology Assessment	EUnetHTA JA	Secretariat
03/2011	Cologne, Germany	Deutsche Gesellschaft für Medizinische Informatik, Biometrie and Epidemiologie	Core HTA Model, WP4 work	THL, University for Health Sciences, Medical Informatics and Technology (Austria)
03/2011	Berlin, Germany	International Healthcare Payers and HTA summit	EUnetHTA JA; HTA in Europe;	Secretariat
03/2011	Brussels, Belgium	Health European Voice Special Report	EUnetHTA JA	Secretariat
04/2011	Berlin, Germany	Tapestry meeting	EUnetHTA Joint Action; HTA	Secretariat
06/2011	Rio de Janeiro, Brazil	HTAi Annual Conference	National strategies for continuous development and sustainability of HTA in Europe, EUnetHTA JA (several posters and oral presentations)	AHTAPol, Secretariat, CVZ, KCE
09/2011	Brussels, Belgium	Health Technology Assessment Workshop (DG Research)	EUnetHTA JA	Secretariat
09/2011	Ohrid, Macedonia	5 th Congress of Pharmacy of Macedonia	EUnetHTA JA	Secretariat
09/2011	London, United Kingdom	CIRS HTA workshop	EUnetHTA JA; HTA concept	Secretariat
10/2011	Montreaux, Switzerland	Evolution Summit	EUnetHTA JA	Secretariat
10/2011	Florence, Italy	XXXII SIFO Congress	EUnetHTA JA, HTA Core Model	Secretariat
10/2011	Washington, USA	Market Access USA	EUnetHTA JA	Secretariat
11/2011	Brussels, Belgium	European Voice meeting	EUnetHTA JA; HTA concept	Secretariat
11/2011	London, United Kingdom	Health Technology Assessment World Europe Congress	European HTA collaboration; REA of Pharmaceuticals	Secretariat, CVZ
12/2011	Gdansk, Poland	EUnetHTA Conference	Work in progress in EUnetHTA JA; strategy; future of HTA in Europe	WP LPs and Co-LPs; APs
01/2012	Luxembourg	EUCERD Plenary Assembly	EUnetHTA activities	Secretariat
02/2012	Brussels, Belgium	AESGP Economic Affairs/ PR Committee meeting	EUnetHTA activities	Secretariat
02/2012	Washington DC, USA	Meeting with AHRQ (EC delegation)	EUnetHTA activities	Secretariat
03/2012	Seoul, South Korea	NECA Symposium	EUnetHTA activities	Secretariat
03/2012	Brussels, Belgium	EFPIA members (EFPIA Committees)	EUnetHTA information session for EFPIA	Secretariat, THL, HAS, CVZ
06/2012	Bilbao, Spain	HTAi Annual Conference	EUnetHTA JA (several	LBI, Secretariat,

			posters and oral presentations)	KCE, CVZ
06/2012	Luxembourg	Health Economics and Personalized Medicine Symposium	European Decision-Making Context for Personalized Medicine in Oncology	Secretariat
06/2012	Riga, Latvia	HTA Forum, Russian Academy of Medical Science	EUnetHTA activities	Secretariat
06/2012	Washington DC, USA	ISPOR 17 th International Annual Meeting	EUnetHTA activities	Secretariat
09/2012	Brussels, Belgium	EUPATI meeting	EUnetHTA activities	Secretariat
10/2012	Auckland, New Zealand	Cochrane Colloquium	EUnetHTA activities	Secretariat
10/2012	Brussels, Belgium	European Parliament, session on driving change for better management of MSDs as part of the EU Chronic Diseases Reflection Process	EUnetHTA perspectives and HTA approaches	Secretariat
10/2012	Bratislava, Slovakia	Optimalisation of Methods of Pharmacoeconomics and Health Technology Assessment: Importance for National Health Policy and Cross-Border Cooperation - Conference	EUnetHTA perspectives	AAZ (Croatia), HVB (Austria)
11/2012	Berlin, Germany	ISPOR European Annual Meeting	Panel Session on HTA developments in Europe (ISPOR-EUnetHTA joint initiative)	Secretariat, DG SANCO
11/2012	Sarajevo, Bosnia and Herzegovina	European Developments in HTA conference	EUnetHTA activities	Secretariat

EUnetHTA WP face-to-face meetings 2010-2012

Time	Location	Participants	Purpose
M2 2010-02-25/26	Copenhagen (DK)	WP1 partners and Executive Committee members; DG SANCO	Coordination of details in the EUnetHTA JA 3-year Work Plan, SOP manual, Stakeholder involvement Policy.
M4 2010-04-07	e-meeting	WP1 partners and Executive Committee members; DG SANCO	Regular coordination issues (preparation of the EUnetHTA presence at HTAi in Dublin)
M5 2010-05-05	e-meeting	WP1 partners and Executive Committee members; DG SANCO	Preparation for the Plenary Assembly meeting Regular coordination issues
M5 2010-05-20/21	Ljubljana, Slovenia	EUnetHTA Partners, DG SANCO, EAHC	Plenary Assembly meeting
M6 2010-06-30	e-meeting	WP1 partners and Executive Committee members; DG SANCO	Half-year activities review Regular coordination issues
M9 2010-09-08	e-meeting	WP1 partners and Executive Committee members, DG SANCO	Preparation for the EUnetHTA educational symposium at ISPOR (Nov 7) in Prague; agenda of the Brussels WP1 meeting Regular coordination issues (preparation for the 1 st Interim report)

M10 2010-10-14/15	Brussels (BE)	WP1 partners and Executive Committee members, DG SANCO	Regular coordination issues; Educational Symposium in Prague; discussion of the 1 st draft of the business model – agreement on fundamental components
M12 2010-12-09	e-meeting	WP1 partners and Executive Committee members, DG SANCO	1 st Interim report to EAHC Regular coordination issues
M13 2011-01-26	e-meeting	WP1 partners and Executive Committee members; DG SANCO	Regular coordination meeting (reporting for 2010)
M15 2011-03-21/22	Paris, France	WP1 partners and Executive Committee members; DG SANCO	Regular coordination issues; business model discussions
M17 2011-05-25/26	London, UK	EUnetHTA Partners, DG SANCO, EAHC, Stakeholder Forum representatives	Plenary Assembly meeting
M18 2011-06-15	e-meeting	WP1 partners and Executive Committee members; DG SANCO	Half-year activities review Regular coordination issues
M21 2011-09-07	e-meeting	WP1 partners and Executive Committee members, DG SANCO	Regular coordination issues (preparation for the 2 nd Interim report); discussion of the strategy document
M22 2011-10-5	Warsaw, Poland	WP1 partners and Executive Committee members, DG SANCO	Regular coordination issues; EUnetHTA Conference in Gdansk
M23 2011-11-16	e-meeting	WP1 partners and Executive Committee members, DG SANCO	2 nd Interim report to EAHC, EUnetHTA Conference in Gdansk Regular coordination issues
M25 2012-01-25	e-meeting	WP1 partners and Executive Committee members, DG SANCO	Overview of the accomplishments in Year 2 of the project, 2 nd interim report preparation, regular coordination issues. Finalisation of the JA2 application
M27 2012-03-28	e-meeting	WP1 partners and Executive Committee members, DG SANCO	PA preparation, budget adjustments, JA2 preparation, regular coordination issues, SF ftf meeting in Venice, EUnetHTA at the HTAi conference
M28 2012-04-18/19	Rome, Italy	WP1 partners and Executive Committee members, DG SANCO	WP progress updates, PA preparation, permanent HTA network structure and functions, JA1 budget reallocation update
M29 2012-05-24/25	Lisbon, Portugal	EUnetHTA Partners, DG SANCO, EAHC, Stakeholder Forum representatives	Plenary Assembly meeting
M30 2012-06-13	e-meeting	WP1 partners and Executive Committee members, DG SANCO	WP progress updates, PA follow-up, stakeholder involvement issues, JA2 preparation, public consultations, budget adjustment update, ToR with INAHTA, EUnetHTA external initiatives
M30 2012-06-20	e-meeting	WP1 partners and Executive Committee	Project management issues and logistics – JA2
M33 2012-09-12	e-meeting	WP1 partners and Executive Committee members, DG SANCO	WP progress updates, SF ftf meeting outcomes, EMA-EUnetHTA meeting, upcoming ftf WP1 meeting in Diemen (agenda, etc), HTA Core Model policy; final reporting to EAHC

M24 2012-10-3/4	Diemen, Netherlands	WP1 partners and Executive Committee members, DG SANCO	JA1 progress report and finalisation steps; EUnetHTA external initiatives and policy; results of the final surveys of the SF and EUnetHTA participants; EUnetHTA JA2 starting up
M35 2012-11-28	e-meeting	WP1 partners and Executive Committee members, DG SANCO	WP progress update and finalisation of deliverables; HTA Core Model policy approval; cooperation with EMA; EUnetHTA external initiatives
M36 2012-12-12	e-meeting	WP1 partners and Executive Committee members, DG SANCO	Finalising JA2: deliverables, tech/financial reporting; meeting with EFPIA on methodological issues, final approval of the HTA Core Model Policy

- Other EUnetHTA face-to-face meetings

Dates	Location	Meeting objective
February 11, 2010	London, UK	EUnetHTA-EMA meeting: EPAR improvement
June 3, 2010	London, UK	EUnetHTA-EMA meeting; EPAR improvement
March 7, 2011	Diemen, The Netherlands	EUnetHTA-EMA meeting; interaction on topics that involve regulatory and HTA institutions
December 8-9, 2011	Gdansk, Poland	EUnetHTA Conference
Feb 22, 2012	Paris, France	EUnetHTA-EMA meeting; interaction on topics that involve regulatory and HTA institutions
Nov 20, 2012	Copenhagen, Denmark	EUnetHTA-EMA meeting; discussion of next steps in developing cooperation.

WP1 Stakeholder and external expert involvement

No stakeholder involvement was foreseen in the activities of WP1 (due to the peculiarities of the EAHC structural requirements of the “horizontal” and “core” Work Packages”, ie, WP1 Coordination was supposed to perform strictly project coordination functions). The stakeholder involvement (including policy, SOP and strategy development with regards to stakeholders as well as coordination of stakeholder involvement in JA) was transferred to a separate work package – WP8.

In reality, coordination of the involvement of stakeholders was performed through the mechanism of the EUnetHTA Executive Committee (which consisted of the WP1 member organisations plus 3 elected members and Chair of the Plenary Assembly). It has proven to be more efficient if the coordination of the stakeholder involvement including policy, strategy and operations management is included as part of the WP1 Coordination in the context of the European network for HTA activities performed in the framework of the joint actions (Description of tasks and functions of **JA2** WP1 includes coordination and management of all aspects of the stakeholder involvement).

WP1 Cooperation with other WPs / LPs

In addition to the regular coordination tasks of the WP1 coordination, special close attention and consequent activities were performed with regards to WP2, WP3 and WP6:

WP2 LP and Co-LP

Close cooperation on development of the content of the dissemination/communication material and establishing contacts with external parties.

WP3

Close cooperation with WP3 to be ensured for the best use of the evaluation process and results. Coordination with the Secretariat in preparation of the Plenary Assembly meetings to facilitate completion of the WP3 surveys.

WP6

EUnetHTA Members Only site support (information to partners) and support in developing the information management and service platform further (participation in the Task Force on developing structure and requirements for the new CMS for the public website and intranet solution).

WP1 Achievement of objectives

Results and recommendations

Timeliness and completeness in the submission of the JA deliverables (including the technical and financial reports) as well as continuation of the EUnetHTA activities and their financing (with an increased supporting budget) via the EUnetHTA JA2 (2012-2015) can be taken as an indication of achieving an objective of WP1 in providing effective coordination and management of the EUnetHTA JA that facilitated the achievement of the EUnetHTA JA general objective to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level. Details on the timeliness and content of the EUnetHTA JA deliverables are available in the final technical reports of the specific Work Packages.

Only one Associated Partner went passive during the JA (Czech Republic) while 2 new organisations were nominated by their respective MoHs to join the JA (Slovakia, Croatia) and both participated actively and at their own expense. Organisations from Finland, Luxembourg, Romania, Russia, USA joined an original list of the Collaborating Partners and actively provided scientific input to the activities of EUnetHTA JA. Furthermore, Ministries of Health of Cyprus, Luxembourg, Romania officially nominated organisations to participate in EUnetHTA JA2 during a preparation of a proposal for EUnetHTA JA2 effectively bringing the coverage of EU MS to 100% in being represented as APs in the final few months of the EUnetHTA JA and in the ensuing EUnetHTA JA2 activities.

An effective coordination and timely information sharing and encouragement combined with focused, specific input/instructions from the EUnetHTA Coordinator and the Executive Committee allowed for a well-coordinated and managed response and input (both scientific and administrative) from 39 Associated Partners from all 27 Member States, Croatia and Norway to a detailed proposal for EUnetHTA Joint Action 2 which was prepared over a short time span (spring 2011). The proposal received high evaluation marks (78 out of 100) and needed minor further adjustments during the negotiation phase (a contract with the EAHC was signed in early 2012). Experience of putting together a major project proposal of such proportions (ie, number of countries and organisations involved) during an on-going major joint action put a lot of strain in terms of budget and staff availability on the participating organisations. In future planning, such unaccounted for overlap should be avoided.

Activities of the EUnetHTA joint action went beyond developing tools and processes facilitating information sharing across borders – they included “putting into practice” processes for common/coordinated processes for production of HTA information by the European HTA organisations. Experiences from these activities highlighted the need for a sharper focus on more professional project management both at the level of each individual participating organisation and especially at the level of the coordinating focus points, ie, Lead and Co-Lead Partners and the Coordinator. Professional project and operations management, public management and administration, financing and accounting competence coupled with competence in communications and public relations are minimum requirements for the organisations that intend to perform coordinating functions in the activities of major initiatives such as the European network for HTA. Competence and expertise in the matters of HTA is a prerequisite as well. English language proficiency (knowledge of other European language is definitely a plus) and cultural sensitivity to differences in perception and working styles of professionals from so many cultural and professional backgrounds may also be pointed out among main factors contributing to the success of the coordination activities in cross-border initiatives such as EUnetHTA JA.

With a focus shifting more towards “production” of HTA information as the prioritised area of activities in the European network for HTA it will be necessary to dedicate more time, attention and appropriate resources to ensure effective and professional production process support. Interaction with the technology sponsors throughout the process requires adequate availability of staff resources at the HTA organisations involved in the production of the core HTA information. Interaction and alignment with the regulatory processes around health technologies require time and resources as well. The process of identification of the HTA organisations participating in the core HTA production process and allotting of adequate and appropriate budgets to them needs to be tailored to the realities of such production while simultaneously allow for predictability of the number of such “common actions”: Planning of the number of the “common actions” and requirement to express commitment to participate in them are possible on a yearly basis while budget allocation to each participating institution should be done at the time when the subject matter for the common action becomes known and availability of competence/expertise are then assessed at each organisation that will join such common action.

With the development of the complexity in cross-border HTA production (especially with the more involved and nuanced engagement with the stakeholders – industry in particular) it has become more and more apparent that the coordinating facility needs to have access to legal advice and staff resources dedicated solely to the research and support in issues of health policy (especially at the European level), stakeholder involvement, training in order to ensure sustainability, quality and professionalism of the activities of the European network for HTA. Legal issues associated with an appropriate handling of personal information, intellectual property rights, receiving financing from various sources to ensure a stable, varied streams of financial support for sustainable operations need to be addressed and appropriate solutions found. The nature of the network itself (ie, interconnected group of independent organisations) will influence the search for and/or development of novel solutions to support sustainable cooperation on HTA across borders in Europe.

A well-functioning Executive Committee whose members have first-hand insight in the management of the coordinated processes for HTA information production across borders coupled with a high-level commitment to the notion and implementation of the European HTA cooperation proved to be indispensable in ensuring that both operational and strategic initiatives are taken forward in an effective manner. In order to ensure effectiveness of the Executive Committee,

it is necessary that organisation representatives of the Executive Committee allocate time for regular participation in the Executive Committee's activities (a dedicated staff member needs to be available for active, regular provision of input to the activities).

The composition of the Executive Committee that included non-executive partners of the partnership (ie, those organisations that do not have a Lead/Co-Lead Partner responsibility) and the Chair of the Plenary Assembly proved very valuable – it safeguarded against “managerial tunnel vision” focusing on the needs of the LPs and Co-LPs only and allowed to bring insights of the Plenary Assembly members into a regular work and considerations of the Executive Committee.

Coordination across borders requires regular contact between the participating parties – both inside the EUnetHTA network but also with the participating parties that are external to the immediate EUnetHTA partnership. Face-to-face meetings will continue to be an important tool in supporting working contact inside and outside EUnetHTA. However, the electronic means to support communication – and project management – will grow in importance not least due to the financial pressures and lack of time for travel in participating organisations. Online meeting facilities (e-meetings), collaboration tools offered via intranets (for internal collaboration and collaboration with external parties) will grow in importance and frequency of application. EUnetHTA has been using online meeting facilities since 2006 – and continued to do so more frequently during the joint action. A new intranet platform was developed at the end of the joint action that provides tools and functions supporting actual HTA collaboration/production activities across borders.

The awareness and understanding of the importance, implications and benefits of the European cooperation on HTA was built not only via an active involvement of the relevant and interested parties in the work of EUnetHTA, but also through a continuous regular promotion and educational efforts by the EUnetHTA partners. Over the span of 3 years of the joint action EUnetHTA, its activities, work-in-progress, results were presented on more than 100 occasions to various target audiences around the globe, primarily geographical Europe. The number of active requests to EUnetHTA to present and inform on its activities, results, etc have increased dramatically over the past 2 years of the joint action. This increase indicates a growing interest in the EUnetHTA developments and presents a valuable opportunity to promote in Europe as well globally European initiatives in the area of the cross-border cooperation on HTA. It will be necessary to allocate appropriate resources to support responding to such requests.

WP1 Manpower for the execution of activities

Partners and countries involved

13. DHMA (former NBoH), Denmark
14. AGENAS, Italy
15. AHTAPol, Poland
16. CVZ, Netherlands
17. DIMDI, Germany
18. HAS, France
19. ISCIII, Spain
20. KCE, Belgium
21. LBI, Austria
22. NETSCC, UK
23. NIPH-RS, Slovenia
24. SBU, Sweden
25. THL, Finland

Persons who participated in the WP

Persons participated in WP1

M = meeting participation

TR = technical/financial report production

TF/RI – task force and regular input to the Exec Comm activities between the meetings

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	M	TR	TF/RI
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Marina Cerbo	AGENAS	Italy	X	X	x
Nicola Vicari	AGENAS	Italy	X	X	x
Alexandra LoScalzo	AGENAS	Italy	X	X	x
Iga Lipska	AHTAPol	Poland	X	X	X
Anna Zawada	AHTAPol	Poland	X	X	X
Adriana Zawiślak	AHTAPol	Poland		X	
Genowefa-Ewa Szatkowska	AHTAPol	Poland		X	
Ewa Kiersztyn	AHTAPol	Poland	X	X	X
Tomasz Garbaty	AHTAPol	Poland		X	
Wim Goettsch	CVZ	Netherlands	X	X	X
Sarah Kleijnen	CVZ	Netherlands	X	X	X
Albert Boer	CVZ	Netherlands	X		
Dietrich Kaiser	DIMDI	Germany	X	X	X
Francois Meyer	HAS	France	X	X	X
Mira Pavlovic	HAS	France	X	X	X
Sun-Hae Lee Robin	HAS	France	X	X	X
Irena Guzina	HAS	France	X	X	X
Stéphanie Bankoussou	HAS	France		X	
Christine Mayol	HAS	France		X	
Setefilla Luengo	ISCIII	Spain	X	X	X
Raf Mertens	KCE	Belgium	X	X	X
Patrice Chalon	KCE	Belgium	X	X	X
Claudia Wild	LBI-HTA	Austria	X	X	X
Gerda Hinterreiter	LBI-HTA	Austria	X	X	X
Judit Erdös	LBI-HTA	Austria	X	X	X
Marisa Warmuth	LBI-HTA	Austria	X	X	X
Eleanor Guegan	NETSCC	UK	X	X	X
Andrew Cook	NETSCC	UK	X	X	X
Eva Turk	MIPH-RS	Slovenia	X	X	X
Susanna Allgurin	SBU	Sweden	X	X	X
Måns Rosen	SBU	Sweden	X	X	X
Sigurd Vitols	SBU	Sweden	X	X	X
Sophie Werkö	SBU	Sweden	X	X	X
Kristian Lampe	THL	Finland	X	X	X
Marjukka Mäkelä	THL	Finland	X	X	X
Iris Pasternack	THL	Finland	X	X	X

Appendices WP1

1. WP1/Exec Comm f-t-f meeting summary, April 18-19, 2012, Rome, Italy
2. EUnetHTA Plenary Assembly meeting summary, May 24-25, 2012, Lisbon, Portugal

3. WP1/Exec Comm f-t-f meeting summary, October 3-4, 2012, Diemen, Netherlands
4. EUnetHTA-EMA f-t-f meeting summary, February 11, 2010, London, UK
5. EUnetHTA-EMA f-t-f meeting summary, June 3, 2010, London, UK
6. EUnetHTA-EMA f-t-f meeting summary, March 7, 2011, Diemen, Netherlands
7. EUnetHTA-EMA f-t-f meeting summary, February 22, 2012, Paris, France
8. EUnetHTA-EMA f-t-f meeting summary, November 20, 2012, Copenhagen, Denmark



Work Package 2
FINAL Technical Report
Joint Action on HTA 2010-2012



WP2 Objectives

No Specific Objective as per the Grant Agreement is connected to this WP.

The main objective of WP2 was to facilitate coherent, effective and sustainable external communication of the EUnetHTA JA, where its aims, objectives, work in progress, results and final products are known to all partners, identified stakeholders and target groups on the EU and national/regional levels:

- Responsible for developing, creating, maintaining and producing the promotional material (leaflet, templates for power point presentations and e-newsletter)
- Support the Secretariat in producing press releases
- Pilot developing the general input about EUnetHTA on Wikipedia, and translation into Work Package 2 languages
- Develop and organise the communication and dissemination plan for the JA
- Giving advice on potential dissemination activities to WP leaders
- Serve the Secretariat with ideas and solutions on different communication needs, as well as in ensuring on time deliverables for which Work Package 2 is directly responsible for.

WP2 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
D7, Communication and Dissemination Plan (M18 – June 2011)	Communication and Dissemination Plan	<ul style="list-style-type: none"> • Available via EUnetHTA website (Intranet section): www.eunethta.eu – • document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM) 	Restricted/Confidential

Other outputs

Title/Short description	Nature	Access
3-year work plan for WP2 Dissemination	Internal project management document	Part of the 1 st interim Technical report
Promotional leaflet	Printed promotional material	Distributed at conferences, meetings, via partners, etc.
Inputs in Wikipedia	Web-based article	http://en.wikipedia.org/wiki/EUnetHTA
HTA in Europe LinkedIn professional networking group	Web based professional networking tool	LinkedIn http://www.linkedin.com/groups?gid=3136408&trk=hb_side_g
Informational video on HTA	Electronic format; part of the communication plan	Publicly available via EUnetHTA website of JA1 and on http://www.youtube.com/watch?v=4FITjhTyJdc

WP2 Activities

2010

EUnetHTA newsletters and PowerPoint slides: a new design and production of templates for the public e-newsletter (EUnetHTA News) and the members' e-newsletter (Members Update); new PowerPoint templates with logos of EUnetHTA and the EU.

EUnetHTA public website: new structure and design with new functionalities: RSS feed, interactive timeline, print optimized page, share on Facebook and Twitter, etc.

Work Package 2 meetings: WP 2 held the first face-to-face meeting March 11–12th in Vienna, and an e-meeting on November 29th.

EUnetHTA leaflet: a promotional leaflet was created and presented at the Plenary Assembly meeting, May 20–21 in Ljubljana. The leaflet was used for promotional activities at the 2010 HTAi, EHFG and ISPOR meetings, and printed copies were made available to EUnetHTA members for distribution at their own organisations.

Pilot creation of Groups for Social Networks (LinkedIn and Facebook) and Wikipedia text as marketing tools, with prior agreement with the Executive Committee, Secretariat and WP6 LP on the issues of security, maintenance, moderation and content of such pages, and creation of the community. The initial experience with both groups indicated that further focus of efforts regarding social networks would put on LinkedIn, while Facebook presence would be discontinued.

2011

Informational video: In order to foster the usage of EUnetHTA JA results and inform the wider public of the project itself, WP2 produced an informational video for distribution through the EUnetHTA website and YouTube. The video explains the aims and objectives of EUnetHTA JA and includes Questions and Answers in a dialogue between main stakeholders, including patients, HTA institutions and policy makers from EU MS etc., and the EUnetHTA JA Partners regarding eg, the purpose of EUnetHTA and what can be achieved through the network. In March 2011, the last version of the scenario was approved by the WP2 members at the face-to-face meeting in Madrid, March 28-29, 2011. At the Plenary assembly in London, May 2011, EUnetHTA members, representatives of DG Sanco and Stakeholder Forum members were interviewed for the purpose of the video. In collaboration with an external communication agency, the informational video was prepared by December 2011 and launched online at the EUnetHTA conference in Gdansk.

Upgrading of the LinkedIn Group HTA in Europe: after the first half of the pilot period for EUnetHTA on Social Networks, Facebook group was discontinued. Only LinkedIn group "HTA in Europe" remains as a tool for informing the wider public on EUnetHTA activities and as a discussion board for HTA activities in Europe. Current total number of members in the group – 1000 persons.

For the purpose of the EUnetHTA 2011 conference in Gdansk, the posters for each Work Package were designed and exhibited at the conference.

Main deliverable of WP2 was the Dissemination and Communication Plan in M18.

Assistance at Workshops at ISPOR and panel discussion at EHFG Conference in Europe

- <http://www.ispor.org/congresses/Prague1110/EduSymposiums110710.asp>
- **EHFG 2010 Panel discussion HTA session** (FB Kristensen, Coordinating Secretariat and Chairman, EUnetHTA Executive Committee, National Board of Health, Denmark, Copenhagen
E Turk, Young Gasteiner, Senior Researcher, Institute of Health, Republic of Slovenia
J Boehm, Policy Officer, DG SANCO, European Commission)
- EUnetHTA Conference in Gdansk, 8-9. December 2011 in support of the launch of the business model for a sustainable collaboration (preparation in cooperation with Secretariat, AHTAPol and CVZ). Program at the website: <http://www.eunetha2011.pl/>

2012

E-meeting June 2012 to wrap up and finalize work of WP2.

WP2 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

Date	Place	Audience	Content of the presentation	Presenting Institution
6-9.10.2010	Bad	Health policy makers	European collaboration	NBoH, DK

	Hofgastein			NIPH, SI
6-9.11.2010	Prague	Pharmaco-economic, health outcomes society	Tools and methods for cross-border collaboration in HTA	NBoH, THL, HAS, CVZ

EUnetHTA WP face-to-face meetings 2010-2012

WP	Location	Number of meetings	Schedule
WP2	Vienna, Austria	1	2010-03-11/12
	Madrid, Spain	1	2011-03-28/29

WP2 Stakeholder and external expert involvement

- WP2 closely cooperated with the stakeholders in the preparation of the informational video on EUnetHTA that is now freely and publically available on youtube.com. For the interview the following representatives were involved: For the interview: representatives from the Stakeholder Forum present at the Plenary Assembly (Providers, Industry, Payers); patients representatives; representative of DG Sanco; chair of Plenary Assembly and Chair of Executive Committee; New MS - without institutionalized HTA; institutionalized HTA and not institutionalized.

WP2 Cooperation with other WPs / LPs

The work of WP2 depended on the information provided and the needs expressed by other WPs and LPs and the concrete products delivered by the WPs. WP2 did its best in identifying the interest and different needs of the other WPs. Close collaboration with WP6 with regards to the EUnetHTA Members Only structure development was ensured throughout the period of JA EUnetHTA.

WP2 Achievement of objectives

Results

WP2 facilitated to a degree possible visibility and active dissemination of the activities and achievements in the period of the EUnetHTA JA1 in accordance to the objectives of the Grant Agreement 2009 23 02. All deliverables were produced on time.

Recommendations

WP2 of JA1 would recommend keeping up with the maintenance and development of LinkedIn HTA group and dissemination of the work of EUnetHTA in general. Also, it would recommend JA2 to ensure the translation of the definition and understanding of HTA in as many European languages as possible on Wikipedia and newly established portals of the kind.

WP2 Manpower for the execution of activities

Partners and countries involved

- NBoH, Denmark
- Hauptverband der Österreichischen Sozialversicherungsträger (HVB), Austria
- National School of Public Health, Greece
- National Center of Public Health Protection, Bulgaria
- MoH, Spain
- SLOVAHTA, Slovak Republic
- SNHTA, Switzerland
- OSTEBA, Spain

Persons who participated in the WP

Persons participated in WP2						
V = Participated in the development of video						
C = Participated in the conference preparations						
WS = Participated in WP2 meetings or workshops						
SM = Participated in social media discussion groups						
* Employees of the WP LP that contributed also as members of WP coordinating team.						
Name	Agency	Country	V	C	WS	SM
LP: Eva Turk (2010 – 2011)	National Institute of Public Health (NIPH)	Slovenia	X	x	x	x
Anne-Marie Yazbeck (from March 2012)	National Institute of Public Health (NIPH)	Slovenia			x	
Co-LP: Susanna Allgurin-Neikter (2010)	SBU - The Swedish Council for Technology Assessment in Health Care	Sweden			x	
Susanne Eksell and Sophie Werko (2011-2012)	SBU - The Swedish Council for Technology Assessment in Health Care	Sweden			x	
P: Finn B. Kristensen	National Board of Health (NoBH)	Denmark	X	X	x	
P: Julia Chamova	National Board of Health (NoBH)	Denmark		X	x	
P: Naomi Dayan	National Board of Health (NoBH)	Denmark	X	X		
P: Gottfried Endel	Hauptverband der Österreichischen Sozialversicherungsträger (HVB)	Austria			x	
P: Elpida Pavi	National School of Public Health	Greece			x	
P: Vasiliki Tsiantou	National School of Public Health	Greece			x	
P: Eleftheria Karampli	National School of Public Health	Greece			x	
P: John Kyriopoulos	National School of Public Health	Greece			x	
P: Plamen Dimitrov	National Center of Public Health Protection	Bulgaria			x	
P: Isabel Saiz	Ministry of Health	Spain			x	
P: Isabel Peña-Rey	Ministry of Health	Spain			x	
P: Adriana Liptokova	Slovenska agentura pre HTA (SLOVAHTA)	Slovak Republic			x	
CP: Christoph Künzli	Swiss Network for Health Technology Assessment (SNHTA)	Switzerland			x	
CP: Rosa Rico	OSTEBA	Spain			x	
CP: Marta Lopez de Argumedo	OSTEBA	Spain			x	

LP: Lead partner

Co-LP: co-lead partner

P: partner CP: collaborating partner

Appendices WP2

1. WP2 e-meeting summary, June 11, 2012.
2. EUnetHTA Conference Banner -300x600
3. LinkedIn-proposal__20110810



Work Package 3 - EVALUATION
FINAL Technical Report
Joint Action on HTA 2010-2012



WP 3 Objectives

Title
WP3 will provide an evaluation, the main purpose of which is to identify to what extent the individual Work Packages enable the JA to meet its objectives. No Specific Objective as per the Grant Agreement is connected to this WP.
Description
<p>Specifically the evaluation will address;</p> <ul style="list-style-type: none"> Will the JA will achieve its overarching objective, and ultimately did it? <p>The definition of the EUnetHTA JA objective has been taken from the Joint Action on HTA Technical Annex¹ as, “The overarching objective of the JA, including work on relative effectiveness of pharmaceuticals, is to put into practice an effective and sustainable HTA collaboration in Europe that brings added value at the European, national and regional level.”</p> <ul style="list-style-type: none"> Will the JA achieve its specific objectives, and ultimately did it? <p>3 specific EUnetHTA JA objectives have been defined¹;</p> <ol style="list-style-type: none"> Development of a general strategy and a business model for sustainable European collaboration on HTA Development of HTA tools and methods Application and field testing of developed tools and methods
Indicators
<p>Analysis of results from evaluation activities. This will primarily be done by questionnaire surveys, although interviews might be conducted if judged to be necessary by the evaluation team.</p> <p>A report of evaluation results will feed into the Final Report from the Joint Action in M36.</p>

WP 3 Outputs

Deliverables

- WP3 contributed to the Interim and Final Technical and Financial Reports from the EUnetHTA JA Report (Deliverable 11) by preparing a report of the evaluation results; M12, M24, M36. An Evaluation Report has been submitted as the Deliverable from WP3. None of the 4 ‘internal deliverables’ for WP3 were put forward for the “specific” deliverables of the JA.

Other outputs

- No other outputs are listed from WP3.

WP 3 Activities

2010

Four surveys were performed and the reports included as Appendices to the Interim Technical Report 2010;

- Plenary Assembly Evaluation Survey** The survey was completed by 74% - 29 out of 39 who were eligible to complete an evaluation form did so.
- EUnetHTA JA Participants’ 2010 Baseline Survey** This baseline survey was sent to all registered individual participants of the EUnetHTA JA from EUnetHTA member organisations in the Summer of 2010. The survey was completed by 88% - 154 of the 175 recipients surveyed

- **EUnetHTA JA Stakeholder Forum 2010 Baseline Survey** This baseline survey was sent to all registered participants of the EUnetHTA JA Stakeholder Forum in the Summer of 2010. The overall response rate was 83% - 10 of the 12 recipients surveyed.
- **EUnetHTA JA Baseline Survey 2010 for those that applied to join the Stakeholder Forum but were not successful** This baseline survey was sent to the 5 stakeholder umbrella organisations who had applied to join the Stakeholder Forum but had been unsuccessful in becoming a member of the Forum.

2011

Three surveys were performed and the reports included as Appendices to the Interim Technical Report 2011;

- **Plenary Assembly 2011 Evaluation Survey** The survey was completed by 36 of the 47 meeting participants, giving a response rate of 77%.
- **EUnetHTA JA Participants' 2011 Interim Survey** The survey was completed by 172 respondents – 86% of the 201 recipients surveyed.
- **EUnetHTA JA Stakeholder Forum 2011 Interim Survey** The overall response rate was 67% - 8 of the 12 recipients surveyed responded.

2012

Three surveys were performed and the reports included as Appendices to this Interim Technical Report 2012;

- **Plenary Assembly 2012 Evaluation Survey** The survey was completed by 39 of the 50 meeting participants, giving a response rate of 78%.
- **EUnetHTA JA Participants' 2012 Final Survey** The survey was completed by 179 respondents – 88% of the 204 recipients surveyed.
- **EUnetHTA JA Stakeholders' 2012 Final Survey** The overall response rate was 65% - 11 of the 17 recipients surveyed responded.

WP 3 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

- No external meetings or presentations involved WP3.

EUnetHTA WP face-to-face meetings 2010-2012

- NETSCC was the only partner in WP3 and therefore no WP3 face-to-face meetings were held.

Other EUnetHTA face-to-face meetings

- No other EUnetHTA face-to-face meetings were held involving WP3.

WP 3 Stakeholder and external expert involvement

- Members of the Stakeholder Forum were asked to respond to annual questionnaire surveys. Stakeholders who applied to join the Stakeholder Forum but whose application was unsuccessful were surveyed at baseline (2010) and near the end of the JA (2012).

WP 3 Cooperation with other WPs / LPs

- The Lead Partner of WP3 (NETSCC) was a member of WP1; Co-ordination and WP8; Strategy and Business Model Development and contributed to the work as per the WP1/WP8 work plan and decisions made during the WP1/WP8 course of action.
- The Lead Partner was also an Associate Partner of WP6 and specifically included questions from WP6 (Information Management) in the Project Participant surveys; baseline (2010) and near end (2012). This involved holding survey design workshops at WP6 face-to-face meetings and reporting about survey results.
- The Lead Partner cooperated with the lead for the training strand in WP8 (ISC-III) to incorporate their questions about the EUnetHTA JA tools in the annual Project Participant surveys; baseline (2010), interim (2011) and near end (2012).

WP 3 Achievement of objectives

Results

- WP3 contributed to the Interim and Final Technical and Financial Reports from the EUnetHTA JA Report (Deliverable 11) by preparing a report of the evaluation results; M12, M24, M36. An Evaluation Report has been submitted as the Deliverable from WP3. None of the 4 'internal deliverables' for WP3 were put forward for the "specific" deliverables of the JA.

Recommendations

- These have been included as part of the Evaluation Report.

WP 3 Manpower for the execution of activities

Partners and countries involved

- NETSCC was both the Lead partner and the only partner in WP3.

Persons who participated in the WP

- Eleanor Guegan and Andrew Cook, NETSCC
- Ruairidh Milne, NETSCC participated as a reviewer for activities in 2010 and 2011.

Persons participated in WP3 P = involved in planning of WP3 E = involved in evaluation activities R = involved in reporting activities					
Name	Agency	Country	P	E	R
Eleanor Guegan	NIHR Evaluation Trials and Studies Coordinating Centre	UK	x	x	x
Andrew Cook	NIHR Evaluation Trials and Studies Coordinating Centre	UK	x	x	x



Work Package 4 – CORE HTA
FINAL Technical Report
Joint Action on HTA 2010-2012



WP 4 Objectives

Develop a functional online Tool & service with defined policies for structured HTA information and Core HTAs, including testing with at least two topics.

Title	Description	Indicators
Development of HTA tools and methods	Develop principles, methodological guidance as well as functional tools and policies for producing, publishing, storing and retrieving structured HTA information and Core HTAs (including a new application of the HTA Core Model on screening)	HTA Core Model available in online format for immediate practical application, including the new application on screening.
Application and field testing of developed tools and methods	Develop two joint Core HTAs and methods for the production of Core HTAs on common topics, including experimenting different methods of collaboration among agencies and agreeing upon methods to select topics and to involve stakeholders in the assessment process.	Production of Core HTAs using the software tool and general use of the Core Model Target: At least two (2) Core HTAs have been produced and 90% of WP4 partners have contributed information for at least one report following the Model to the database of HTA information pieces.

WP 4 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
D4-1: An online tool and service for producing, publishing, storing and retrieving HTA information. The screening application of the HTA Core Model.	Web tool and database Screening application available also as Report	<ul style="list-style-type: none"> Both available through www.corehta.info 	Public
D4-2: A set of 2 Core HTAs.	Report	<ul style="list-style-type: none"> Available freely via On-line Tools & Service website (www.corehta.info) Off-line versions available for limited distribution 	Public

Other outputs

Title/Short description	Nature	Access
Policy for HTA Core Model and core HTA information	Report	www.corehta.info
Two scientific articles scheduled for 2013	Journal articles	Planned for publication in the International Journal of Technology Assessment in Health Care

WP 4 Activities

The work within WP4 was divided into two strands, Strand A developing the Online Tool and Service and the screening Model, and Strand B piloting Strand A products through producing two core HTAs.

2010

STRAND A

- Development of Online Tool and Service, basic functionalities (1st pilot ready)
- First pilot testing of Online Tool & Service (focus on Core HTA protocol design)
- Development of the HTA Core Model and its Application for Screening Technologies (1st draft ready for review by January 2011)
- Agreement on methods for developing a policy for Online Tool and Service
- WP4 Workshop 1, Helsinki, 18 March 2010 (Strand A and B)
- WP4 Workshop 2, Rome, 25 November 2010 (Strand A and B)
- Online Tool & Service Workshop 1, Helsinki, 19 March 2010
- Screening Application Workshop 1, Helsinki, 19 March 2010
- Online Tool & Service Workshop 2, Rome, 26 November 2010
- Screening Application Workshop 1, Rome, 26 November 2010

STRAND B

- Analysis of WP4 participants' topic selection and priority setting processes
- Analysis of WP4 participants' stakeholder involvement practices
- Surveys on topic selection/priority setting and stakeholder policies. Surveys were crafted after a literature search (with ad hoc search strategies) and analysis of the common practices of topic selection and prioritisation procedures and stakeholder involvement with the aim of improving the knowledge on these topics and facilitating the creation of ad hoc questionnaire. Data from surveys were used to find a shared procedure for topic selection and prioritisation and for stakeholder involvement (see next point).
- Agreed upon procedures for topic selection and priority setting and for stakeholder involvement in WP4/B. A procedure for topic selection and priority setting was agreed on and used for the identification of the technologies for the 2 Core HTAs; this process included a first proposal for the use of POP database (not useful at that time for the broad definition of planned projects) and a second proposal with the creation of an ad hoc identification form and criteria rank.
At the same time, a Stakeholder Involvement Procedure was developed; it foresaw the possibility for selected Stakeholder Forum members (forming a Stakeholder Advisory Group) to review and comment earlier drafts of the Core HTAs
- Consideration of collaborative models for producing Core HTAs
- WP4 Workshop 1, Helsinki, 18 March 2010 (Strand A and B)
- WP4 Workshop 2, Rome, 25 November 2010 (Strand A and B)

2011

STRAND A

- Survey to identify EUnetHTA members' preferences regarding various policies for HTA Core Model
- Pilot testing of HTA Core Model Online
- Public consultation of HTA Core Model on screening

STRAND B

- Survey to identify the topics for the production of the two Core HTAs was developed within WP4; its development started in 2010 and the final round of the survey was carried out in 2011 with a final response rate of 62%. For

one of the topic selected, a third round was requested in order to choose a specific genetic test; each partner ranked 3 types of genetic tests and results were then discussed in an e-meeting with Primary Investigators.

- Survey for Technology, Collaborative Model and Technology vs. Collaborative Model preference. Two different collaborative models were developed, with the aim of test which one would be the most appropriate for a collaborative production of core HTA information. In Collaborative Model 1 each of the 9 domains is managed by researchers from different agencies participating in WP4/B while in Collaborative Model 2 each of the 9 domains is managed by one agency participating in WP4/B. Agencies involved in WP4 Strand B were asked to choose the preferred Collaborative Model in relation to the 2 topics selected for assessment.
- Formations of Domain Teams (i.e. expert groups working on a specific domain of HTA, e.g. effectiveness, ethical analysis or organisational aspects)
- Face to face Core HTA Workshop 1 (Rome, 6th/7th April, 2011)
- Face to face Core HTA Workshop 2 (Wien, 15th/16th September, 2011)

2012

STRAND A

- Further development of HTA Core Model Online
- Policy for HTA Core Model Online and core HTA information
- Second public draft of HTA Core Model for screening technologies
- Validation of HTA Core Model Online and the application for screening technologies (Strand A and Strand B)
- Incorporating basic features of the Adaptation Toolkit (of WP5 of EUnetHTA Project) into the HTA Core Model Online
- Testing adaptability of the structured information of HTA Core Model in a national HTA report (Case EVAR)
- WP4 Workshop 3, Helsinki, June 4-5 (Strand A and B)

STRAND B

- Core HTAs production (finalisation of reports and final version ready for Public consultation)
- Survey for retrieving information on the use of technology in European countries. Due to the lack of information on the use of the technologies under assessment, it was decided to carry out surveys for retrieving information from European Countries. One survey was for clinicians and one for lead administrators. Both surveys consisted of mainly multiple choice questions with the option of selecting more than one answer per question. Results were then shared with the Domain Teams (teams of researchers working on one of the nine domain of the Core Model) and used in the Core HTA information production.
- Validation of the 2 core HTAs (Strand A and Strand B)
- Core HTA workshop, Vienna, March 29-30
- WP4 Workshop 3, Helsinki, June 4-5 (Strand A and B)

WP 4 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

Date	Place	Audience	Content of the presentation	Presenting Institution
2011-10-17/18	Madrid	WP8: Strategy and Business Model Development Line of activity: HTA Training and Capacity Building Pilot Course on EUnetHTA Tools (focused on the HTA core model) Organised by ISCIII Audience: EUnetHTA	HTA Core Model, online tool, working on core HTA	THL and AGENAS

		member agencies		
2012-06-24	Bilbao	HTAi Annual Meeting 2012	EUnetHTA tools for collaborative HTA production	THL and AGENAS
2012-06-24	Bilbao	HTAi Annual Meeting 2012	International collaboration on HTA: lessons learned from the EUnetHTA collaboration and other European initiatives of HTA production	THL, AGENAS, CVZ, NOKC, LBI-HTA
2012-06-24	Bilbao	HTAi Annual Meeting 2012	A new generic approach for scoping HTA: a new feature in HTA Core Model	THL

EUnetHTA WP face-to-face meetings 2010-2012

WP	Location	Number of meetings	Schedule
WP4	Helsinki, Finland	3	2010-03-18/19
	Rome, Italy	3	2010-11-25/26
	Rome, Italy	1	2011-04-6/7
	Wien, Austria	1	2011-09-15/16
	Wien, Austria	1	2012-03-29/30
	Helsinki, Finland	1	2012-06-4/5

- Other EUnetHTA face-to-face meetings

Dates	Location	Meeting objective
2011-12-8/9	Gdansk	Current achievements of the EUnetHTA Joint Action (2010-2012) – EUnetHTA Conference

WP 4 Stakeholder and external expert involvement

STRAND A and B

A Stakeholder Advisory Group (SAG) was set up for WP4. SAGs of EUnetHTA are expert panels into which members of the EUnetHTA Stakeholder Forum can nominate representatives to support the work of EUnetHTA work packages by providing relevant stakeholder views.

The WP4 SAG was consulted during various development processes during the period 2010-2012, i.e. when producing the HTA Core Model online, the screening model, the two core HTAs, and the policies and adaptation processes. Feedback was typically sought for first drafts before wider distribution. Feedback from Stakeholder Advisory Group was shared with different expert groups working on the deliverables and whenever feasible, they were taken into account in the final version.

Key deliverables of WP4 were also subject to public consultation and validation by HTA agencies during 2012. Different surveys were prepared and submitted to EUnetHTA partners, Stakeholders and Public bodies for retrieving feedback on the main deliverables and processes of WP4.

For Core HTA 1 on Prognostic Tests for Breast Cancer Recurrence, manufacturers were contacted in order to retrieve information on the technology; this information was used by some domain teams (i.e. TEC and ORG domain team).

The following table summarises the key consultations of the SAG. Further smaller tasks and discussions may have taken place in addition to these.

What	When	Type of involvement	Purpose
Stakeholder Forum	2010	Identification of a WP4 Stakeholder Advisory Group	Identify representatives for review and comment
Pilot testing of Online Tool and Service	Mar-Apr 2011	Testing of the tool	Test and provide feedback to the current implementation
Core HTAs 1 st draft protocol	Jul 2011	E-mail survey with feedback form	Review and comment the 1 st draft protocol of each Core HTA.
Screening model	Jan 2012	Email survey with feedback form	Review and comment 1 st draft.
Core HTAs validation	Sep 2012	On-line survey	Validate WP4 deliverables as stated in the Grant Agreement
Online Tool and Service validation	Sep 2012	On-line survey	Validate WP4 deliverables as stated in the Grant Agreement

WP 4 Cooperation with other WPs / LPs

Representatives from both WP4 LP and CoLP participated as members of WP1, in particular the EUnetHTA Executive Committee.

Active contact was kept with WP5 to find out about the needs and developments of relative effectiveness assessment of pharmaceuticals.

LP was also AP of WP6 to ensure close contact with interoperability plans and requirements.

During the last months of 2012 LP collaborated with WP7 CoLP (LBI-HTA) to consider the inclusion of rapid assessments as part of the HTA Core Model Online.

WP 4 Achievement of objectives

Methods

The various tasks of WP4 were carried out by several working groups formed by representatives of WP member agencies. These groups are described in more detail in Appendix 10. Members of Strand A were requested in the beginning of the project to indicate whether they wanted to focus on the development of the Online Tool and Service or the screening model. Approximately half of agencies participated in each. Most member agencies were members of both strands and hence the work of both strands was well integrated.

Practical work was led by internal teams of THL and AGENAS, each for the strand they were leading. Several workshops provided opportunities to plan and discuss basic solutions, timelines and challenges encountered.

Deliverables were subjected to review by member agencies and in most cases by the SAG and also the general public. Feedback was collected through online surveys and improvements were made to the products whenever feasible.

Results

STRAND A

An Online Tool and Service for the HTA Core Model

Building on earlier work within EUnetHTA project 2006-2008 and EUnetHTA Collaboration 2009, WP4 developed a new online tool and service to support producing, sharing and utilising structured HTA information using the HTA Core Model.

Basic concepts of the HTA Core Model were kept mostly unchanged as they were developed earlier within EUnetHTA 2006-2008. The Model continues to be a methodological framework for production and sharing of HTA information. The

Model consists of three components: 1) an ontology containing a set of generic questions that define the contents of an HTA, 2) methodological guidance that assists in answering the questions and 3) a common reporting structure that enables standardised reporting of HTAs. Information is created and presented as assessment elements. Some elements are prioritised over others to support European collaboration through defining them as "core elements". More detailed description has been given earlier elsewhere^{4,5}.

The new tool and service, designated as HTA Core Model Online is available at www.corehta.info. A description of its basic features is available as Appendix 7.

The overall process of producing information with the resulting tool is divided into five phases:

- 1) Project definition (setting up the project, as well as its scope and participants)
- 2) Protocol design (selecting relevant questions and formulating the to match the scope)
- 3) Research (finding answers to the questions)
- 4) Entering results into a collection of core HTA information (consists of results cards and general texts for the whole collection)
- 5) Viewing and submitting results (emphasis on viewing at this point)

In this Joint Action, the emphasis of the development work was in making the earlier paper-based HTA Core Model usable in the online environment. Work was divided into two phases, first focusing on the basic functionalities needed to support core HTA production within Strand B and then considering advanced functionalities, such as publishing, information search and retrieval and adaptation of information. Development was supported by collecting continuously user feedback. Two specific pilot testing phases were carried out.

The first pilot took place in Sep-Nov 2011. The focus was on designing a protocol for a core HTA. The task was to create at least one core HTA protocol and to provide feedback on the Tool and the Handbook using an online questionnaire. A core HTA protocol defines the contents of the core HTA through identifying relevant issues that are translated into practical research questions. It serves as basis for a more detailed research protocol in which much more detail (typically e.g. on the background and methodology) is included.

A total of 22 responses were acquired from 21 agencies. A clear majority, 85 % of respondents were either clearly or mostly satisfied with the current implementation of the protocol design process. According to 67 % of the respondents both the content and format of the resulting protocol would be useful in steering the design of a more detailed research protocol. Almost all respondents were very satisfied or mostly satisfied with the technical functionality of the system and the Handbook (90 % and 95 % respectively).

The second pilot was carried out in March - April 2011 and was similar in principle to the first pilot. Two different online questionnaires were provided for feedback: a shorter questionnaire for those who already had participated in the first pilot and a copy of the longer questionnaire of the first pilot for those who had not.

A total of 14 responses were acquired from 12 agencies for the shorter questionnaire and 6 responses from 6 agencies for the longer. The focus of the shorter questionnaire was on the improvements made on the tool following the first pilot. All respondents but one felt that improvements had been made in different areas of the tool since the first pilot. However, about a third of the respondents felt that there was still room for more improvements.

The six first-time pilot participants of the longer questionnaire were mostly or very satisfied with the tool and handbook. All but one found the tool helpful for defining the contents of their HTA at least to some extent.

Within both pilots also detailed free text comments were gathered and considered.

The primary use of the HTA Core Model was defined in the earlier project as production of Core HTAs, i.e. comprehensive and multidisciplinary assessments that have been conducted using the HTA Core Model and considering all core elements. Core HTAs also contain a summary of findings in each domain, but refrain from giving recommendations on using the technology. Through the wide scope, focus on core elements and the summary chapter, a Core HTA gives an overview of a technology that is likely to be useful in the European context. A Core HTA can be used as a basis for producing local HTA reports that take into account local circumstances, e.g. epidemiology, organisation, resources and values.

An alternative, secondary use through a free selection of assessment elements, perhaps from only one or few of the domains was also earlier identified in order to better cater for specific situations.

⁴ Lampe K, Mäkelä M, Garrido MV, et al. The HTA core model: a novel method for producing and reporting health technology assessments. *Int J Technol Assess Health Care*. 2009 Dec;25 Suppl 2:9-20.

⁵ Pasternack I, Anttila H, Mäkelä M, et al. Testing the HTA core model: experiences from two pilot projects. *Int J Technol Assess Health Care*. 2009 Dec;25 Suppl 2:21-7.

Both the Core HTAs and any use of the HTA Core Model was seen to result in a pool of *Structured HTA Information* that also can be used for local HTAs. The HTA Core Model and the resulting Core HTAs and local HTAs were collectively designated as the *Core HTA Structure* (Figure 1).

Within the Joint Action this structure was further discussed. The various compilations of structured HTA information were defined as core HTA information *collections*. Core HTA was designated as one collection type and a new core HTA structure was defined to better take into account different collection types. (Figure 2).

Figure 1. The Core HTA Structure in 2008

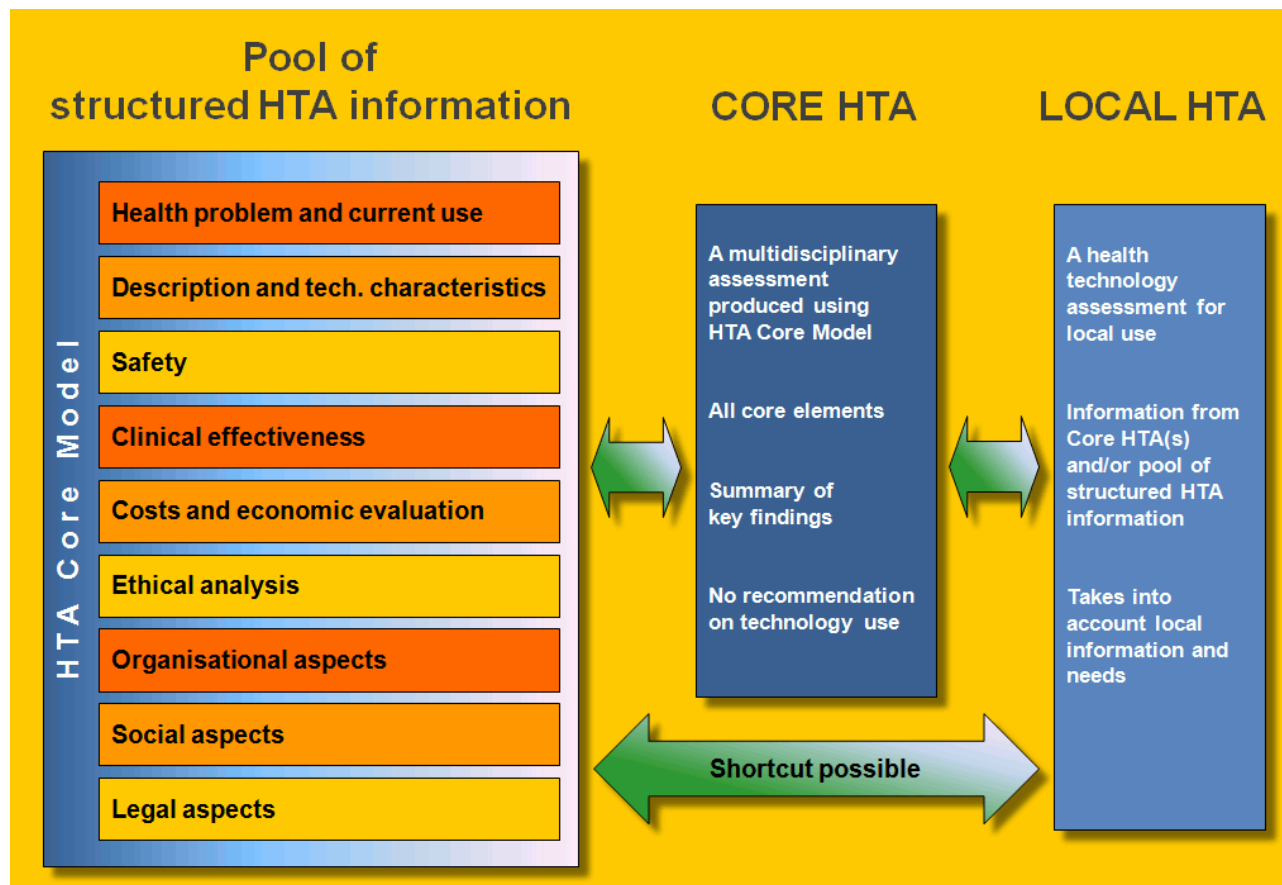
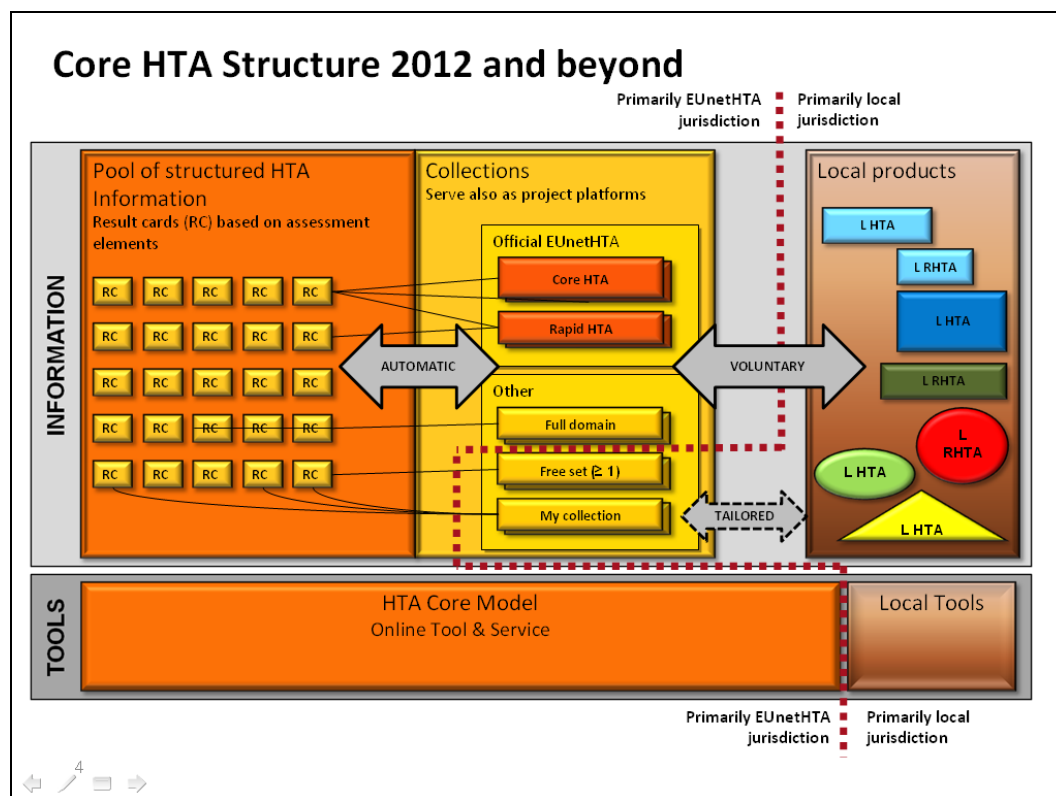


Figure 2. The Core HTA Structure in 2012



In the new version technical tools - primarily the HTA Core Model Online - and actual information produced through the tools are separated. Assessment elements have been replaced by result cards that contain the answer to the question defined by the assessment elements. Cards are organised into collections that fall into two major categories, "official" standard types defined by EUnetHTA and other types defined by users. The "full domain" type, i.e. a collection that would focus on a single domain, will be considered in the future as a possible additional EUnetHTA collection type.

The new version also outlines the primary jurisdictions of the EUnetHTA Network and local HTA agencies.

Handbook

The Handbook for HTA Core Model was updated to reflect the changes made within 2010-2012. It is available both in online format and as a PDF document. The earlier three sections dealing with introduction, core HTA information production and methodological guidance were updated and supplemented by a fourth chapter on searching and viewing information.

The relatively brief Handbook connects with more extensive materials that are part of the HTA Core Model. The Handbook e.g. gives an overview of domain descriptions, but users can easily access the more extensive domain descriptions in the Model. This solution was developed after an extensive discussion in the Tartu workshop within the earlier project and it will be reconsidered in the next Joint Action taking into account e.g. the work on guidelines by WP5 and the growing experience with using the HTA core Model by other WPs and in HTA research "outside" EUnetHTA JA. The Handbook is available at <http://www.corehta.info/ViewHandbook.aspx>.

Screening Model

Resulting from the EUnetHTA project 2006-2008, the main contents of the HTA Core Model is organised as "applications". Two applications, one on medical and surgical interventions and the other on diagnostic technologies existed when commencing work within Joint Action. A new application to enable assessment of screening technologies was developed as collaborative cross-border work of working groups, each focusing on one domain of the HTA Core Model.

The first draft was submitted for public consultation in Oct-Nov 2011. Eight individuals from seven organisations responded (3 HTA agencies and 4 from industry). Altogether 96 comments were processed individually and feedback given to those respondents who had provided their contact details. A second draft was published in March 2012 and this version was used for validation during the fall.

The model is available through the HTA Core Model Online at www.corehta.info. A PDF copy was also produced, available as Appendix 9.

Adaptation Toolkit

Key contents of the Adaptation Toolkit developed within WP5 of the EUnetHTA project 2006-2008 were included in the HTA Core Model Online to support adaptation of core HTA information into local settings. See Appendix 7, pages 50-52. Another exercise related to the adaptability of information from core HTA information to national reports and vice versa was performed by comparing the assessment elements in the current HTA Core Model with the order and content of a regular national report. A Dutch assessment report on endovascular repair of aneurysms (EVAR) was chosen as an example. The similarities and missing issues were noted and reported in a manuscript which will be published in the EUnetHTA theme issue of IJTAHC 2013. The work was done as a joint effort of WP4 Strand A and WP5.

Policies

Several policies are needed to steer the use and utilisation of the HTA Core Model and information produced by using the Model. Crafting a general policy document to include these was part of WP4's tasks. A policy crafting process was designed and agreed on during the first two WP4 meetings in 2010. An extensive survey of possible options for more than thirty policy items was conducted between summer and fall 2011. Twenty-four agencies responded and expressed their preferences on various items. Then a proposal was drafted by WP4 LP, consulting WP4 agencies. The draft was discussed within the Executive Committee first time in June 2012 and after that the WP4 LP produced a final version, which was sent for WP4 agencies' approval, including 21 Associated Partners⁶ and 17 Collaborating Partners. Altogether 18 WP4 agencies responded, including 15 of the 21 Associated Partners. All but one agency said that they would approve the proposed policy. One agency hesitated a bit regarding the inclusion of non-EUnetHTA collections (see above) in the same database as EUnetHTA collections. Likewise 17 agencies indicated that the proposed policy fits their agencies' principles, practices and expectations very well (3) or mostly well (14). One agency did not provide an answer to this

⁶ excluding Malta, which dropped out of WP4 before this phase.

question. The approval request indicated that non-responding would be interpreted as an approval, so it is likely that the agreement rate was good also within the non-respondents.

The Executive Committee approved the policy in its e-meeting on the 12th of December 2012. Although originally planned, the WP4 SAG was not consulted on the policy prior to its approval. This was decided during the busy last period of the JA with the extensive validation exercise and planning for JA2. It was agreed in the Executive Committee that the policy would be subjected to SAG review by WP8 of JA2 early in 2013 and reconsidered during the spring of 2013.

The new policy necessitates several changes to the original Terms of Use of the HTA Core Model that derives from 2008. These will be implemented within the first months of 2013 and a license enabling also commercial use of the HTA Core Model will be developed by May 2013.

Validation

Online surveys were used to gather validation data on the HTA Core Model Online and the screening model. The validation took place in September and October 2012 and separate questionnaires were used for HTA agencies, SAG members and the general public. Also members of the International Network of Agencies for Health Technology Assessment (INAHTA) were invited to participate.

Since THL and AGENAS were conducting the validation, they did not respond to the surveys. Consequently there were altogether 16 agencies for which one of the two validation surveys was obligatory (Associated Partners of Strand A, excluding THL and AGENAS). Member agencies of Strand A were focusing their efforts within in most cases either on the Online Tool and Service (i.e. HTA Core Model Online), or on the screening model. Agencies were requested to validate the deliverables they had not participated in developing themselves, i.e. to choose either of the two (OTS or screening model, 8 agencies in both groups). For all others (Strand B members and Collaborative Partners), responding was voluntary.

Some key results are presented in this technical report. A more detailed, for the time being confidential, document is prepared to support work within the JA2 and to be published as a scientific article.

Validation of the HTA Core Model Online

Fifteen responses were received, representing 14 agencies from 11 countries, including eight Strand A Associated Partners. The respondents were able to test the system either by an actual or simulated future project, or to use an already existing project. Most (73 %) tested the system to see if the protocol of an already existing or finished project could be designed.

Overall, the responses were supportive of the current implementation of the online tool and service. In particular the phases where the project and its protocol are defined, received high ratings for ease of use and user satisfaction (approximately three out of four respondents or more). The research phase and entering results received lowest scores. Only approximately half of the respondents perceived these easy and were satisfied with them. The phase used for viewing results got intermediate results regarding ease of use and user satisfaction, with approximately 2 out of 3 finding it easy and being satisfied with it.

The table below indicates some more detailed results regarding perceived ease of use and user satisfaction. Whereas phase 1,2 and 5 received positive feedback, the research and entering results phases were not equally successful. In this context one should notice, however, that these questions had typically more respondents who answered “cannot say” than most of the other questions. This results most likely from the fact that most respondents were testing the system with an already existing project and focused on phases 1 and 2. Hence the results excluding “cannot say” answers are also presented below. Those results are far more favourable for the tool.

Overall easiness of five phases (asked as statements) n=15	Agreed or strongly agreed
	Share of all who responded to question
1. Project definition phase	13 (87 %)
2. Protocol design phase	11 (73 %)
3. Research phase	7 (47 %) (64 % for those who did not answer “cannot say”)
4. Entering results phase	7 (47 %) (58 % for those who did not answer “cannot say”)
5. View results phase	10 (67 %)

User satisfaction (asked as level of satisfaction) n=15 unless otherwise specified	Very satisfied or mostly satisfied
1. Project definition phase	14 (93 %)
2. Protocol design phase (n=14)	12 (86 %)
3. Research phase (n=9)	5 (55 %) (83 % for those who did not answer “cannot say”)
4. Entering results phase	8 (53 %) (80 % for those who did not answer “cannot say”)
5. View results phase	11 (73 %)

All but one respondent (93 %) were very satisfied or mostly satisfied with the technical functioning of the HTA Core Model Online and 67 % were very satisfied or mostly satisfied with the Handbook (and 27 % could not say). Three members of the WP4 Stakeholder Advisory Group also tested the HTA Core Model Online primary through reviewing its Handbook. All were either very satisfied or mostly satisfied with the Handbook.

The number of respondents was not very high, but one should keep in mind that the aim of this validation was not to attract tens or hundreds of respondents. Instead the aim was to acquire feedback from the primary target group of the Online Tool and Service, i.e. from national or regional agencies. It was explicitly emphasised that the response should reflect the opinion of the respondent's organisation, and not that of an individual expert.

Validation of the screening model

Nine responses were received to the validation survey on the HTA Core Model for Screening Technologies, representing eight countries and nine HTA agencies, all but one members of EUnetHTA and one from Canada. Included were six Strand A member agencies.

Within the last five years five agencies had produced at least one full HTA report on screening technologies. Of the four remaining agencies two had produced at least one rapid HTA or mini-HTA on similar topics. Two agencies did not have experience on screening technologies within the last five years.

A clear majority (7 respondents) agreed on the feasibility of the general concept and structure of the model. All respondents agreed or strongly agreed that the nine domains represent well the main aspects of HTA and that the available topics and issues cover the domains adequately. A clear majority also agreed that the inclusion of assessment elements into the “core” should be based on their importance and transferability and that the model does not contain major conceptual conflicts or inconsistencies. Respondents were somewhat more critical about the definition of terms used in the model, with two disagreeing that the terms would be adequately defined. Respondents used a PDF version of the model, but the validation results speak for the need of both a PDF and an online version, which was preferred by six respondents.

If the responding agency would start a project on screening within the next 12 months, four would aim at producing a HTA that is mostly compatible with the model and three would use parts of the model. If the project should start after Joint Action 2, four would again aim at a HTA mostly compatible with this model and two would use parts of the model. Not assessing screening technologies or agency's own screening model were reported as reasons for not using the model. Respondents provided more detailed feedback on the various domains. This information will be included in the detailed validation report.

Like with the OTS survey, the aim was to gather agencies' response. Despite the relatively low absolute number of respondents, there is a wide variety of health care settings included in the responses.

Adherence to the Work Plan

Some key tasks of Strand A required adjustment of timelines in order to ensure adequate quality of deliverables. Despite some delays, the overall final timeline of deliverables was not changed.

The second piloting of the HTA Core Model Online was postponed from 2010 to 2011 to allow development needs identified within the first piloting to be implemented in the system.

The public consultation timeline of the screening model was postponed from 2010 to 2011 partly because there were some delays in the extensive content production, but mostly because the developers wanted to allow experience from Strand B pilot core HTA to be gathered and implemented before more public release.

The original plan regarding the policy for the Online Tool and Service contained two review rounds during 2011 and 2012. Since the task was more complex than originally anticipated, the time allocated for finding out agencies' opinions on different policy options was increased and there was only one review of the final policy set. The end result, however, was approved by member agencies and there were no clear objections. In contrast to the original plans, the SAG was not consulted regarding the final policy, but it will be done within JA2 by WP8 in 2013.

STRAND B

Application and field testing of developed tools and methods

Production of 2 different Core HTAs was achieved during the period 2010-2012 as indicated in the 3-year workplan. More than 100 researchers were involved in different production phases of the 2 Core HTAs, as Primary Investigators, Investigators and Reviewers; of 22 EUnetHTA Associate Partners (APs) involved in WorkPackage 4/B, a total of 18 partners were actively involved in the production process (in one or more role); a total of 9 Collaborating Partners (CPs) of 13 involved in WP4 strand B collaborated in the Core HTA production phase.

The two core HTAs are available through the HTA Core Model Online at www.corehta.info.

Two collaborative models (Colmod 1 and Colmod 2) were put in place, both based on domain teams (9 for each core HTA). The domain teams of Colmod1 were set up with researchers from different organisations taking the role respectively of primary investigators (PI), investigators (I) and reviewers. In the Colmod2 each domain team was set up by one organisation. The two different groups of researchers (one for each Core HTA) were coordinated by an Editorial Team formed by the nine Primary Investigators (one for each domain of the Core HTA) plus a Chair and a Vice-Chair.

Core HTA production

Core HTA production started in May 2011, with a delay of 2 months compared with what indicated in the 3-year work plan (March 2011); this was due to some difficulties in defining the technologies to be assessed. The process of topic selection and the linkage to the specific collaborative model was a multistep process with 3 different surveys among participants and it took more time than scheduled. Moreover, changes in researchers from different agencies involved in EUnetHTA resulted in a slower work (i.e.: if the Primary Investigator of a Domain changes his/her job, it can cause delays in the domain work).

First drafts of both Core HTAs were finalised at the end of June 2012. Final versions of both Core HTAs were finalised in December 2012, after the validation process and proof-reading of the documents.

Validation of core HTAs

The validation process consisted of the three following surveys: Screening Core Model, Core HTA Production and Core HTA Content and Format. A simplified version of the survey, without the Screening Model application questions (as feedback from SAG on this was got earlier in 2012), where also sent for Stakeholder Advisory Group and Public consultation. Key findings were that the general concept and structure of the Core HTA were found to be feasible, moreover the core HTA concept was recognised to have an excellent potential in supporting local HTA. There was overall a high user satisfaction although there were some problems relating to model applications (overlaps, lacking methodological guidance, diagnostic model not suitable for one of the core HTA dealing with a prognostic test and other minor issues). Also respondents found that the protocol could support research planning better. A PDF version was felt to be needed (currently not available). Respondents thought the core HTAs would be useful if they were to inform policy on these topics and that they would use the information if they were to start a project on similar topics within 12 months or after JA1 Furthermore roles and work load specifications (relative to Reviewers, Primary Investigators, Investigators, Editorial team, Project Leader, Coordinator, etc.) should be better specified and planned if possible. A better clarification of the major steps of Topic selection and Prioritisation process and of Stakeholder involvement should be sought in the next Joint Action The Collaborative model 2 (one agency one domain) collected more satisfaction than model 1 (different agencies work on one domain). At last the conflict of interest was brought up as an issue to be dealt with.

Adherence to the Work Plan

In 20120 all the activities were performed according to the work plan. The results of identification of topics for two core HTAs, (M9) have been presented to the partners during the workshop in Rome (M11). The discussion showed the need to narrow down the scope of the identified topics through a second survey which was submitted to the partners that had made a proposal during the first survey (M12). A new survey was carried out in order to collect the preferences of all WP4 partners on topics identified (through the 1st and 2nd survey, December 2010) for the prioritisation through a third survey that was completed in January 2011.

In 2011, according to the 3-year work plan, start of the Core HTA production was scheduled in M15 (March 2011); the production of both Core HTAs started in May 2011 due to some difficulties in defining the technologies to be assessed. The process of topic selection and link to a collaborative model was a multistep process with a 3 different surveys among participants and it took more time than scheduled. Moreover, changes in researchers from different agencies involved in

EUnetHTA resulted in a slower work (i.e.: if the Primary Investigator of a Domain changes his/her job, it can cause delays in the domain work).

In 2012, the Validation of the 2 Core HTAs was scheduled in M30 (June); preparatory works started in June but the validation process effectively was sent out in September; this timing was mainly due to better refinement of the surveys crafted for the validation process but it did not affected its regular working out.

Recommendations

STRAND A

The technical report of EUnetHTA Project 2006-2008 WP4 recommended that "For full use, an online version of the Model needs to be implemented." The online version has now been set up and is fully functional.

HTA organisations are continuously encouraged to test and apply the HTA Core Model Online in their work and to provide feedback on their experiences.

Feedback from users, as well as experience and suggestions gathered during this Joint Action regarding further development needs and opportunities will be considered and feasible ones will be implemented if prioritised within the limitations of the budget during JA2.

In addition to information production and sharing, the Model can also be used in education and training.

The HTA Core Model currently enables assessment of interventions, diagnostics and screening. Future work within JA2 Joint Action 2 will update the contents of the Model and in that context the updating and expansion processes should be considered based experience and needs of its users.

The HTA Core Model has moved from initial piloting phase to early adoption phase. Hence training should be provided to potential users in the near future. JA2 has plans for this both within WP2 and WP8.

STRAND B

Topic selection process: The first experience of topic selection was time consuming , requiring three surveys to identify topics and set up researchers groups. This was due to the initial generic definition of technologies of interest and to different interest of researchers into different technologies. The recommendation is that participant organisations should propose the technologies to be jointly assessed using a more detailed definition and taking into account also their own research interests. This information should be collected at the start of any new project.

Collaborative models: The two collaborative models have shown different pros and contras. The Colmod 1, in which a Domain of assessment was carried out by researchers from different Agencies/Countries led by a Primary Investigator, allowed more positive interactions between organisations and researchers, facilitating a wider approach to the Core HTA information production with different points of view. On the other hand, ColMod 1 required a stronger coordination and management work especially when there was changes of manpower by one of the participant organisations; it also required more attention to ensure coherence of the work, as Core HTA information production involved researchers from different countries with different background and way of working.

The Colmod 2, in which a single domain was carried out by a single agency, worked easily, smoothing over allowing to go over manpower turnover failing, but required more interactions between domains' teams to ensure coherence of the work. This ColMod needs also a strong communication and coordination approach.

There is no a clear advantage in choosing a priori one model rather than another, the recommendation is that different models should be adopted at the same time according to the availability and interests of partners organisations.

One important aspect that need a particular attention is the domain sequencing; as a core HTA is a collection of structured HTA information conventionally organised in 9 domains (TEC, CUR, EFF, SAF, ECO, LEG, SOC, ORG, ETH), in order to avoid duplication of work and overlapping questions within domains the approach to the whole assessment should be facilitated defining the sequence of the domains to be included. It is reasonable to begin producing information in three domains (CUR, TEC and EFF) in the first phase; information from these domains will be useful for the assessment of the remaining domain.

To speed the assessment the development of the other domains will take place depending on the results of the collections of AEs in the three domains and be influenced by them.

WP 4 Manpower for the execution of activities

Partners and countries involved

Associated Partners (APs, participation in strands in brackets):

1. AGENAS, Italy (A/B)

2. AHTAPol, Poland (A/B)
3. CVZ, Netherlands (A)
4. DIMDI, Germany (A/B)
5. GÖG, Austria (B)
6. HIQA, Ireland (A/B)
7. HVB, Austria (A/B)
8. INFARMED, Portugal (A/B)
9. IPH-RS, Slovenia (A/B)
10. IQWIG, Germany (A/B)
11. ISCIII, Spain (A/B)
12. KCE, Belgium (A/B)
13. LBI-HTA, Austria (B)
14. NBoH, Denmark (A)
15. NICE, UK (A/B)
16. NOKC, Norway (A/B)
17. Regione Veneto, Italy (A/B)
18. SBU, Sweden (A)
19. SDU, Denmark (B)
20. SSD/MSOC, Malta (B) left in 2011
21. THL, Finland (A/B)
22. UTA, Estonia (A/B)

Collaborating Partners (CPs, participation in strands in brackets):

1. AETSA, Spain (A/B)
2. ARESS, Italy (A)
3. ASSR Emilia Romagna, Italy (A/B)
4. Avalia-t, Spain (A/B)
5. Department of Health Services Research, Denmark (A/B)
6. DSI, Denmark (A/B)
7. KDTD, Turkey (A/B)
8. Lazio Sanità, Italy (A/B)
9. OSTEBA, Spain (A)
10. Quality unit, Ministry of Health of Serbia, Serbia (A/B)
11. Regione Lombardia, Italy (A/B)
12. SNHTA, Switzerland (A/B)
13. University of Health Sciences, Austria (B)
14. University Hospital "A.Gemelli", Italy (A/B)
15. Agency for Quality and Accreditation in Health, Croatia (B)
16. University of Bremen, Germany (joined in 2011, A)
17. Institute for Economic Research, Slovenia (joined in 2011, B)

Persons who participated in the WP

STRAND A

Persons participated in WP4 Online Tool and Service development				
* Employees of the WP LP that contributed also as members of WP coordinating team.				
Name	Agency	Country	Member of development working group	Responded to validation questionnaire
Kristian Lampe*	THL	Finland	X	
Iris Pasternack*	THL	Finland	X	
Oskari Saarekas*	THL	Finland	X	
Leena Raustia-Tarvainen*	THL	Finland	X	
Linda Akiola*	THL	Finland	X	
Daniela Pertl	GÖG	Austria		X
Gottfried Endel	HVB	Austria	X	
Chris de Laet	KCE	Belgium	X	
Irina Cleemput	KCE	Belgium	X	X
Mattias Neyt	KCE	Belgium		X
Anonymous	CAST	Denmark		X
Finn Børlum Kristensen	NBoH	Denmark	X	X
Kristi Liiv	UTA	Estonia		X
Christiane Barbara Pierl	DIMDI	Germany		X
Alric Rüther	IQWIG	Germany	X	
Julia Kreis	IQWIG	Germany	X	
Michelle O'Neill	HIQA	Ireland		X
Alessandra Lo Scalzo	AGENAS	Italy	X	
Maria Rosaria Perrini	AGENAS	Italy	X	
Marina Cerbo	AGENAS	Italy	X	
Mirella Corio	AGENAS	Italy	X	
Tom Jefferson	AGENAS	Italy	X	
Valeria Romano	ARESS-PIEMONTE	Italy		X
Roberto Grilli	EMILIO-ROMAGNA	Italy	X	
Angelica Carletto	A. GEMELLI	Italy		X
Chiara Filippi	VENETO	Italy	X	
Teresa Gasparetto	VENETO	Italy	X	
Ronald Kooistra	CVZ	Netherlands	X	
Sarah Kleijnen	CVZ	Netherlands	X	X
Wim Goettsch	CVZ	Netherlands	X	
Gro Jamtvedt	NOKC	Norway	X	
Ingvil Sæterdal	NOKC	Norway	X	

Persons participated in WP4 Online Tool and Service development

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	Member of development working group	Responded to validation questionnaire
Katrine Frønsdal	NOKC	Norway	X	
Katarzyna Sejbuk	AHTAPol	Poland		X
Aurora Llanos - Mendez	AETSA	Spain		X
Nora Ibargoyen Roteta	OSTEBA	Spain		X
Iñaki Imaz	ISCIII	Spain	X	
Måns Rosén	SBU	Sweden	X	
Sophie Werkö	SBU	Sweden	X	
Gurleen Jhuti	NICE	UK		X

Persons participated in WP4 Screening Model development and WP4 workshops

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops (Strand A or Joint A/B meetings)

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Daniela Pertl	GÖG	Austria			X	
Sophie Brunner	GÖG	Austria			X	
Gottfried Endel	HVB	Austria			X	
Ingrid Wilbacher	HVB	Austria	X		X	
Stefan Mathis-Endenhofer	LBI-HTA	Austria			X	
Petra Schnell-Inderst	UMIT	Austria	X	X	X	
Uwe Siebert	UMIT	Austria	X	X		
Chris de Laet	KCE	Belgium		X	X	X
Irina Cleemput	KCE	Belgium	X		X	
Anonymous	IHE	Canada				X
Mirjana Huic	AAZ	Croatia			X	
Lotte Groth Jensen	Central Denmark	Denmark	X		X	
Claus Loevschall	Central Denmark	Denmark	X			
Camilla Palmhøj Nielsen	NBOH	Denmark	X	X	X	
Finn Børlum Kristensen	NBOH	Denmark			X	
Lisa von Huth Smith	NBoH	Denmark		X		
Anne Lee	SDU/CAST	Denmark			X	
Janek Saluse	UTA	EE	X		X	

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* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Kristi Liiv	UTA	Estonia			X	
Raul-Allan Kiivet	UTA	Estonia		X		
Heidi Anttila	THL	Finland		X		
Ilona Autti-Rämö	THL	Finland	X	X	X	
Iris Pasternack*	THL	Finland	X		X	
Jaana Leipälä	THL	Finland	X		X	
Juha Koivisto	THL	Finland		X		
Kristian Lampe*	THL	Finland			X	
Leena Raustia*	THL	Finland			X	
Linda Akiola*	THL	Finland			X	
Oskari Saarekas*	THL	Finland			X	
Pirjo Räsänen	THL	Finland		X		
Samuli Saarni	THL	Finland	X			
Sinikka Sihvo	THL	Finland	X	X	X	
Sirpa Soini	THL	Finland	X			
Sirpa-Liisa Hovi	THL	Finland			X	
Suvi Mäklin	THL	Finland	X		X	
Taru Haula	THL	Finland			X	
Ulla Saalasti-Koskinen	THL	Finland	X	X	X	
Nea Malila	Through THL	Finland		X		
Sunya-Lee Antoine	DIMDI	Germany	X	X	X	
Alric Rüther	IQWiG	Germany			X	
Andreas Gerber	IQWiG	Germany		X		
Joerg Lauterberg	IQWiG	Germany				X
Sigrid Droste	IQWiG	Germany		X		
Stefan Sauerland	IQWiG	Germany		X	X	
Anne Stich	IQWiG	Germany		X	X	
Caroline Waldron	HIQA	Ireland			X	
Patricia Harrington	HIQA	Ireland	X	X	X	
Americo Cicchetti	A. Gemelli	Italy		X		
Angelica Carletto	A. Gemelli	Italy		X	X	
Dario Sacchini	A. Gemelli	Italy		X		
Marco Marchetti	A. Gemelli	Italy		X		
Marco Oradei	A. Gemelli	Italy		X		

Persons participated in WP4 Screening Model development and WP4 workshops

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops (Strand A or Joint A/B meetings)

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
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Pietro Refolo	A. Gemelli	Italy		X		
Alessandra Lo Scalzo	Agenas	Italy	X		X	
Antonio Migliore	Agenas	Italy	X		X	
Eliana Ferroni	Agenas	Italy			X	
Francesca Gillespie	AGENAS	Italy			X	
Maria Rosaria Perrini	Agenas	Italy	X		X	
Marina Cerbo	Agenas	Italy		X	X	
Mirella Corio	Agenas	Italy	X		X	
Nicola Vicari	Agenas	Italy			X	
Tom Jefferson	Agenas	Italy	X	X	X	
Alessandro Beux	ARESS	Italy		X		
Carlo Senore	ARESS	Italy		X		
Chiara Rivoiro	ARESS	Italy		X		
Elisa Giani	ARESS	Italy		X		
Fabio Trimaglio	ARESS	Italy		X		
Valeria Romano	ARESS	Italy		X		
Nereo Segnan	ARESS-Piemonte	Italy		X	X	
Paolo Giorgi Rossi	AUSL RE	Italy	X	X	X	
Michele Tringali	Reg. Lombardia	Italy			X	
Chiara Filippi	Reg. Veneto	Italy			X	
Luca Vignatelli	Regione Emilia-Romagna	Italy			X	
Luciana Ballini	Regione Emilia-Romagna	Italy			X	
Teresa Gasparetto	Regione Veneto	Italy			X	X
Renzo Pace Asciak	SSD/MSOC	Malta			X	
Joke Derksen	CVZ	Netherlands		X	X	
Juanita Heymans	CVZ	Netherlands		X		
Payam Abrishami Shirazi	CVZ	Netherlands		X		
Sarah Kleijnen	CVZ	Netherlands			X	
Björn Hofmann	NOKC	Norway	X			
Ingvil Sæterdal	NOKC	Norway			X	X
Katrine Frønsdal	NOKC	Norway	X	X	X	
Aleksandra Zagórska	AHTAPol	Poland	X		X	
Lidia Becla	AHTAPol	Poland	X		X	

Persons participated in WP4 Screening Model development and WP4 workshops

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops (Strand A or Joint A/B meetings)

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Isaura Vieira	INFARMED	Portugal	X	X	X	
Valentina Prevolnik Rupel	IER	Slovenia			X	X
Eva Turk	IPH-RS	Slovenia	X	X	X	
Marjetka Jelenc	IPH-RS	Slovenia	X		X	
Belen Corbacho	AETSA	Spain	X	X	X	
Aurora Llanos-Méndez	AETSA	Spain	X			
Gerardo Atienza	AVALIA-T	Spain				X
Leonor Varela Lema	AVALIA-t	Spain	X			
Teresa Quiero Verdes	AVALIA-t	Spain		X		
Iñaki Imaz	ISCIII	Spain			X	X
Helena Dahlgren	SBU	Sweden			X	
Måns Rosén	SBU	Sweden			X	
Marianne Heibert Arnlind	SBU	Sweden				X
Sophie Werkö	SBU	Sweden			X	
Bernard Burnand	SNHTA	Switzerland			X	
Heike Raatz	SNHTA	Switzerland	X		X	
Chris Lawinski	NICE	UK	X			
Mirella Marlow	NICE	United Kingdom	X		X	
Nick Crabb	NICE	United Kingdom			X	

STRAND B

Persons participated in WP4

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Daniela Pertl	GÖG	Austria	X		X	X
Alexandra Ramssl-Sauer	GÖG	Austria		X		
Eva-Maria Kernstock	GÖG	Austria		X		
Sophie Brunner	GÖG	Austria	X		X	
Gottfried Endel	HVB	Austria	X	X	X	
Ingrid Wilbacher	HVB	Austria	X		X	X
Wilhelm Donner	HVB	Austria		X		
Claudia Wild	LBI-HTA	Austria	X	X	X	X
Judit Erdos	LBI-HTA	Austria			X	
Stefan Mathis-Endenhofer	LBI-HTA	Austria	X		X	
Narine Sahakyan	UMIT	Austria	X	X		
Petra Schnell-Inderst	UMIT	Austria	X	X	X	
Chris de Laet	KCE	Belgium			X	
Irina Cleemput	KCE	Belgium			X	
Frank Hulstaert	KCE	Belgium				X
Mirjana Huic	AAZ	Croatia	X	X	X	X
Lotte Groth Jensen	Central Denmark	Denmark	X	X	X	
Claus Loevschall	Central Denmark	Denmark	X			
Camilla Palmhøj Nielsen	NBOH	Denmark			X	
Finn Børlum Kristensen	NBOH	Denmark			X	
Anonymous	SDU/CAST	Denmark				X
Anne Lee	SDU/CAST	Denmark	X	X	X	X
Janek Saluse	UTA	EE	X		X	
Kristi Liiv	UTA	Estonia	X	X		X
Raul-Allan Kiivet	UTA	Estonia	X	X		
Oskari Saarekas	THL	Finland			X	
Sinikka Sihvo	THL	Finland			X	
Iris Pasternack	THL	Finland	X		X	
Jaana Leipälä	THL	Finland	X			
Kristian Lampe	THL	Finland			X	
Linda Akiola	THL	Finland			X	
Suvi Mäklin	THL	Finland	X		X	
Taru Haula	THL	Finland	X			X

Persons participated in WP4

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

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Christiane Barbara Pierl	DIMDI	Germany				X
Sunya-Lee Antoine	DIMDI	Germany			X	
Siw Waffenschmidt	IQWIG	Germany		X		
Stefan Lange	IQWIG	Germany		X		
Stefan Sauerland	IQWIG	Germany		X		X
Alric Rüther	IQWiQ	Germany			X	
Anne Stich	IQWiQ	Germany			X	
Julia Kreis	IQWiQ	Germany		X	X	
Caroline Waldron	HIQA	Ireland			X	
Michelle O'Neill	HIQA	Ireland		X		X
Patricia Harrington	HIQA	Ireland		X	X	X
Americo Cicchetti	A. Gemelli	Italy	X			X
Angelica Carletto	A. Gemelli	Italy	X		X	X
Dario Sacchini	A. Gemelli	Italy	X			X
Emanuela Midolo	A. Gemelli	Italy	X			X
Marco Marchetti	A. Gemelli	Italy	X		X	X
Marco Oradei	A. Gemelli	Italy		X		
Marina Casini	A. Gemelli	Italy	X			X
Pietro Refolo	A. Gemelli	Italy	X			X
Roberta Minacori	A. Gemelli	Italy	X			X
Alessandra Lo Scalzo	Agenas	Italy		X	X	
Antonio Migliore	Agenas	Italy	X	X		X
Eliana Ferroni	Agenas	Italy			X	
Emilio Chiarolla	Agenas	Italy	X		X	
Maria Rosaria Perrini	Agenas	Italy	X		X	X
Marina Cerbo	Agenas	Italy		X	X	X
Mirella Corio	Agenas	Italy	X		X	X
Nicola Vicari	Agenas	Italy			X	
Tom Jefferson	Agenas	Italy	X		X	
Nereo Segnan	ARESS-Piemonte	Italy			X	
Paolo Giorgi Rossi	AUSL RE	Italy		X	X	
Matteo Ruggeri	Marco Oradei	Italy	X		X	
Michele Tringali	Reg. Lombardia	Italy			X	

Persons participated in WP4

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Chiara Filippi	Reg. Veneto	Italy	X			
Luca Vignatelli	Regione Emilia-Romagna	Italy		X		
Luciana Ballini	Regione Emilia-Romagna	Italy		X	X	
Susanna Maltoni	Regione Emilia-Romagna	Italy			X	
Laura Cacciani	Reg. Lazio	Italy				X
Massimo Gion	Regione Veneto	Italy	X			X
Teresa Gasparetto	Regione Veneto	Italy	X	X	X	X
Renzo Pace Asciak	SSD/MSOC	Malta			X	
Joke Derksen	CVZ	Netherlands			X	
Sarah Kleijnen	CVZ	Netherlands			X	X
Ingvil Sæterdal	NOKC	Norway	X	X	X	X
Katrine Frønsdal	NOKC	Norway	X	X	X	X
Anna Zawada	AHTAPol	Poland				X
Aleksandra Zagórska	AHTAPol	Poland			X	
Anna Panasiuk	AHTAPol	Poland	X			
K. Sejbuk	AHTAPol	Poland	X			
Lidia Becla	AHTAPol	Poland	X	X	X	X
Monika Orzel	AHTAPol	Poland	X			
Ana Bação	INFARMED	Portugal		X		
Isaura Vieira	INFARMED	Portugal	X		X	
Judite Neves	Infarmed	Portugal		X		
Vesna Kovač	IER	Slovenia		X		
Eva Turk	IPH-RS	Slovenia			X	
Marjetka Jelenc	IPH-RS	Slovenia	X	X	X	
Aurora Llanos - Mendez	AETSA	Spain		X	X	X
Belen Corbacho	AETSA	Spain			X	
Sergio Marquez	AETSA	Spain		X		
Leonor Varela Lema	AVALIA-t	Spain	X	X		X
Cari Almazan	CAHIAQ	Spain		X		
Iñaki Imaz	ISCIII	Spain	X	X	X	X
Sonia García-Pérez	ISCIII	Spain	X	X		
Andrés Fernández-Ramos	ISCIII	Spain	X			
Antonio Sarria-Santamera	ISCIII	Spain	X			
Carmen Bouza	ISCIII	Spain	X			

Persons participated in WP4

I = Investigator in one or more domain teams

R = Reviewer in one or more domain teams

WS = Participated in WP4 meetings or workshops

V = Responded to validation questionnaire(s)

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	I	R	WS	V
Javiera Valdés	ISCIII	Spain	X			
Jesús González-Enríquez	ISCIII	Spain	X			X
Marta Lopez-Argumedo	OSTEBA	Spain				X
Helena Dahlgren	SBU	Sweden			X	
Thomas Davidson	SBU	Sweden				X
Måns Rosén	SBU	Sweden			X	
Sophie Werkö	SBU	Sweden			X	
Burnand Bernard	SNHTA	Switzerland			X	
Heike Raatz	SNHTA	Switzerland	X	X	X	
Mark Pletscher	SNHTA	Switzerland		X		
Urs Brügger	SNHTA	Switzerland		X		
Jennifer Butt	NICE	United Kingdom	X		X	X
Grace Jennings	NICE	United Kingdom		X		
Gurleen Jhuti	NICE	United Kingdom	X			X
Hanan Bell	NICE	United Kingdom		X		
Mirella Marlow	NICE	United Kingdom		X		
Fay McCracken	NICE	United Kingdom				X
Nick Crabb	NICE	United Kingdom			X	X
Sarah Baggaley	NICE	United Kingdom	X			X
Scott Goulden	NICE	United Kingdom		X		

Appendices WP4

1. Minutes of WP4 meeting in March 2010
2. Minutes of WP4 meeting in November 2010
3. Minutes of WP4 meeting In April 2011
4. Minutes of WP4 meeting in September 2011
5. Minutes of WP4 meeting in March 2012
6. Minutes of WP4 meeting in June 2012
7. HTA Core Model Online Tool and Service basic features
8. Policy for HTA Core Model and core HTA information
9. HTA Core Model for Screening Technologies
10. WP4 working groups
11. Core HTA on AAA freely available at www.corehta.info (select browse - collections). Off-line version available for limited distribution (electronic copy).

12. Core HTA on PTBCR freely available at **www.corehta.info** (select browse - collections). Off-line version available for limited distribution (electronic copy).



**Work Package 5 - Relative Effectiveness Assessment (REA) of
Pharmaceuticals**

**FINAL Technical Report
Joint Action on HTA 2010-2012**



WP5 Objectives

The objectives of WP5 (as defined in the EUnetHTA Grant Agreement 2010-2012) were:

- Development of HTA tools and methods: improved relative effectiveness assessments (REA) by identifying areas where methodological guidance is needed and by providing it, suggesting ways to integrate REA of pharmaceuticals as a special version of the HTA Core Model;
- Application and field testing of developed tools and methods: a REA of (a group) of pharmaceuticals in line with the core HTA development.

The outcome indicator (as defined in the EUnetHTA Grant Agreement 2010-2012):

- Recommendations on the assessment of relative effectiveness (RE) identified and published. Target: publication of the recommendations in an international journal (submitted).

WP5 Outputs

Deliverables

Deliverable	Nature	Access	Confidentiality level
Background review	Report and publication	<ul style="list-style-type: none"> • Available via EUnetHTA website: http://www.eunethta.eu/outputs/final-version-background-review-relative-effectiveness-assessment • Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable WP5_1a & Deliverable WP5_1b; • Publication: Kleijnen S, George E, Goulden S, d'Andon A, Vitre P et al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value Health. 2012 Sep;15(6). Deliverable WP5_2; 	Public
Guidelines on methodology to be incorporated in model for rapid REA of pharmaceuticals	Report and planned publication in IJTAHC	<ul style="list-style-type: none"> • Final versions is available via EUnetHTA website: http://www.eunethta.eu • Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable WP5_3a & Deliverable WP5_3b; • Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public
Pilot report	Report and planned publication in IJTAHC	<ul style="list-style-type: none"> • Available via EUnetHTA website: http://www.eunethta.eu/outputs/wp5-ja1-pilot-pazopanib-reportappendix • Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable WP5_4a & Deliverable WP5_4b; • Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public

Deliverable	Nature	Access	Confidentiality level
Model for Rapid REA of pharmaceuticals	Report/online tool and planned publication in IJTAHC	<ul style="list-style-type: none"> Final version is available via EUnetHTA website: http://www.eunethta.eu Document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Deliverable WP5_5a & Deliverable WP5_5b; Publication will be submitted to the International Journal of Technology Assessment in Health Care 	Public
Final report including plan for stimulation of usage of the Rapid and Full model (where appropriate) in European countries	Report	<ul style="list-style-type: none"> The plan for stimulation has been realised through the organisation of WP5 Joint Action 2 Final version of WP5 technical report is available as part of the Joint Action Technical Report 	Public Public
European Symposium on the Methodology of REA	Event	<ul style="list-style-type: none"> Instead of European Symposium, It was decided to organise a WP5 meeting with all WP5 members due to several discussion items needing 'internal debate' to improve final documents. In addition, an EUnetHTA – EFPIA and stakeholders workshop was organised (February 12, 2013) to discuss the methodology of four EUnetHTA guidelines on "endpoints". 	Restricted

Other outputs

Title/Short description	Nature	Access	Notes
Collaboration with EMA	<ul style="list-style-type: none"> Bi-annual meetings Permanent items on the agenda of the bi-annual meetings: 	The minutes are available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Appendix WP1_4-8	
	<ul style="list-style-type: none"> EPAR improvement project 	<ul style="list-style-type: none"> Restricted: MEDEV's Comments on the Usefulness of EPAR's (Published Scientific Discussion) and SmPC's (Summary of Product Characteristics) (Other outputs document 6a) Restricted: EPAR improvement plan drafted by the EMA (Other outputs document 6b1-6b3) Restricted: Response EUnetHTA WP5 on draft guidance for improved EPARS (Other outputs document 6c) Restricted: Presentation 	<ul style="list-style-type: none"> Comments provided by MEDEV on EPARs, have been the basis for discussion between EUnetHTA and EMA on possible improvements of the EPAR. EMA drafted an EPAR improvement plan. EUnetHTA WP5 responded on the EPAR improvement plan.

Title/Short description	Nature	Access	Notes
		<p>of results of EUnetHTA/EMA input on 10 analysed EPARs (Other outputs documents 6d1&6d2)</p> <ul style="list-style-type: none"> Public: Planned publication in international scientific journal) 	<ul style="list-style-type: none"> The EUnetHTA recommendations were included in the EPAR template revision round leading to an improved template for EPARs. The improved EPAR template is an internal EMA document. Subsequently WP5 co-analysed the 10 first EPARS that were produced according to the revised template together with EMA (see Appendix WP5_6b for decision).
	<ul style="list-style-type: none"> Collaboration on methodology guidelines 	Public	EMA has provided input on the WP5 methodological guidelines as part of the public consultation. The comments as well as the responses of how they were handled are included as deliverable "Guidelines on methodology to be incorporated in model for rapid REA of pharmaceuticals". See appendix WP5_3b.
	<ul style="list-style-type: none"> Early dialogue/scientific advice for drugs 	<p>Public: Draft procedure for early dialogue pilots.</p> <p>(printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM). Other outputs document WP5_7;</p>	
Draft report about implementation barriers and success factors for European collaboration in relative effectiveness assessment	Report is under production	Restricted: Report is planned to be available in April 2013	
Comparison of national REA reports on pazopanib	Report is under production and planned publication	<p>Restricted: Report is planned to be available in April 2013.</p> <p>Public: Planned publication in international scientific journal)</p>	

WP5 Activities

2010

Initiation of background review (Subgroup 1)

- Project manual was written and agreed upon
- Data abstraction form was completed
- Data abstraction for 26 out of 31 countries was completed
- Report writing initiated

Initiation of rapid model (rapid technology assessment of relative effectiveness of pharmaceuticals) (Subgroup 2/3)

- Domain teams were established
- Working manual was written and agreed upon
- Adaptation of HTA core model domains to REA of pharmaceuticals was initiated in June 2010

Initiation of full model (full technology assessment of relative effectiveness of pharmaceuticals) (Subgroup 2/3)

- Domain teams were established
- Working manual was written and agreed upon
- Adaptation of HTA core model domains to REA of pharmaceuticals was initiated in June 2010

Initiation of methodological guidelines (Subgroup 4)

- Project manual was written and agreed upon
- Literature searches and writing of guidelines were initiated in 2010

2011

Finalisation of background review (Subgroup 1)

- Data abstraction for 4 countries was completed in 2011 (the other 26 countries were completed in 2010).
- Data were processed and analysed.
- Report writing was finalized (including consultation of SAG and public consultation).
- Manuscript of results on major methodological aspects was submitted to a scientific journal

1st version of model for rapid assessment of relative effectiveness of pharmaceuticals (Subgroup 2/3)

- Consultation of WP5 members on the 1st draft of domain text of models was finished in January 2011.
- Adaptation of HTA core model domains to REA of pharmaceuticals was finalised in February 2011.
- 1st version of HTA core model adapted to the REA of pharmaceuticals was available per March 2011.

1st version of model for full relative effectiveness of pharmaceuticals (Subgroup 2/3)

- Adaptation of HTA core model domains to REA of pharmaceuticals was finalised in February 2011.
- 1st version of HTA core model adapted to REA of pharmaceuticals was available in March 2011.

Draft versions of methodological guidelines (Subgroup 4)

- Draft versions of guidelines were produced and subjected to WP5 consultation in 3 Batches (Jan – March 2011)
- Three (3) f-t-f meetings were organised to discuss relevant aspects of the guidelines
- The 2nd versions of guidelines were made available for the pilot assessment in February – June 2011: clinical endpoints, composite endpoints, surrogate endpoints, health related quality of life, internal validity, applicability, choice of comparator, direct and indirect comparisons, and safety.

One guideline - patient relevant outcomes - was merged into the guideline on clinical endpoints. A guideline on grading experience in experts and experience has been dropped as it was not found feasible to produce a methodological guideline on a European level on this subject.

Pilot of rapid assessment of a pharmaceutical (Subgroup 2/3)

- Topic selection process (including consultation of EMA/SAG) was finalised at the beginning of May 2011.
- Domain teams started operating in May 2011.

- Domain reports were finished in October 2011.
- Draft report was finished in November 2011.
- Questionnaires were prepared for the consultation of the WP5 members/Marketing authorization holder (MAH) and pilot participants.
- Consultation of the WP5 members/MAH and pilot participants occurred in November/December 2011.

EPAR review

- Checklist was developed for reviewing EPARS
- 10 EPARS were reviewed as of October 2011
- The results were compiled by the end of 2011.

2012

Publication of results of background review in scientific journal (Subgroup 1)

- A scientific article was published about the results of the background review in September 2013. Reference: Kleijnen S, George E, Goulden S, d'Andon A, Vitre P et al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value Health. 2012 Sep;15(6)

Final version of model for rapid assessment of relative effectiveness of pharmaceuticals (Subgroup 2/3)

- Based on the results of the pilot, the HTA core model adaptation to REA of pharmaceuticals was discussed at the Vienna meeting in February 2012.
- A 2nd version of the model was produced in June 2012 according to input from the pilot.
- WP5 and SAG consultation of the 2nd version of the model from 18 June to 31 July 2012
- A revised 2nd version of the model was produced based on input from WP5 and SAG consultation by the end of September 2012
- Public consultation of the revised 2nd version of the model from 1 October to 30 November 2012
- A 3rd and final version of the model was produced and published at the beginning of March 2013.

2nd version of model for full relative effectiveness of pharmaceuticals (Subgroup 2/3)

- It was decided at the WP5 face-to-face meeting in Vienna (February 2012) that based upon the higher workload in WP5 as originally anticipated, the WP5 will focus only on the further development of the model for rapid assessment (the original focus of WP5 is found in the JA Contract Technical Annex).

Final version of methodological guidelines (Subgroup 4)

- Two (2) f-t-f WP5 Meetings were organised to discuss relevant aspects of the guidelines
- A 3rd version of the guidelines was made available for internal consultation by EUnetHTA partners and stakeholder representatives from March to May 2012.
- A 4th version of the guidelines was made available for public consultation (including the EMA) from June to October 2012
- A workshop (organised by EFPIA), with the presence of representatives of member organisations in the EUnetHTA Stakeholder Forum, was held on 12 February 2013 to discuss common endpoints related issues of the 5th version of methodology guidelines on clinical endpoints, composite endpoints, surrogate endpoints and health related quality of life
- A 5th version of methodology guidelines on choice of comparator, direct and indirect comparison, internal validity, applicability and safety and the revised 5th version of endpoint related guidelines was produced at the end of January 2013
- A 6th and Final version of all the guidelines was produced at the end of February 2013

Pilot of rapid assessment of a pharmaceutical (Subgroup 2/3)

- A 2nd version of the report was produced in March 2012 based on input from WP5 and marketing authorisation holder consultation
- SAG consultation of 2nd version of report from 20 March to 27 April 2012
- A 3rd version of the report was produced based on input from SAG consultation in June 2012
- A public consultation of the 3rd version of the report was held from 6 June to 23 July 2012

- The 4th version of the report was produced based on input from the public consultation during December 2012
- The 4th and final version of the report was published on the EUnetHTA website in January 2013

EPAR review

- Two (2) f-t-f WP5 meetings and 2 EUnetHTA-EMA meetings were held, wherein the outcome of the review was presented and discussed

Country comparison of national REA reports on pazopanib

- Data were gathered from March to July 2012
- Report will be written in spring 2013

Report about implementation barriers and success factors for European collaboration in relative effectiveness assessment

- Interview guide was finalised by December 2012
- Interviews were conducted during December 2012/January 2013
- Report will be drafted in spring 2013.

WP5 Meetings 2010-2012**External meetings/presentations of EUnetHTA in 2010-2012**

Date	Place	Audience	Content of the presentation	Presenting Institution
2010				
08/06/2010	Dublin, Ireland	HTAi conference	Panel session: Comparative Effectiveness and/or Relative Effectiveness Assessments of Pharmaceuticals across the world.	CVZ
08/06/2010	Dublin, Ireland	HTAi conference	Activities in WP5 JA	CVZ
30/09/2010	Vienna, Austria	Workshop on onco drugs organised by LBI-HTA	Preliminary SG1 results	CVZ
12/10/2010	Brussels, Belgium	KCE workshop	International collaboration	CVZ
07/09/2010	Prague	ISPOR conference 2010	Update of WP5 activities during plenary session	CVZ
07/09/2010	Prague	ISPOR conference 2010	Update of WP5 activities during EUnetHTA session	HAS
08/09/2010	Prague	ISPOR conference 2010	Relative efficacy and relative effectiveness	CVZ
09/11/2010	Prague, Czech Republic	ISPOR conference 2010	Poster presentation of preliminary SG1 results	CVZ/NICE
15/11/2010	Brussels, Belgium	MEDEV meeting	Presentation of preliminary SG1 results	CVZ
22/11/2010	Krakow, Poland	Central and Eastern European Society of Technology Assessment in Health Care	Update of WP5 activities	CVZ
2011				
30/01/2011	London, UK	HTAi Policy Forum	Interaction between EMA and EUnetHTA	CVZ
02/02/2011	London, UK	Tapestry meeting	Update of WP5 activities	
22/02/2011	Ankara, Turkey	Turkish Ministry of Health	Update of WP5 activities	CVZ
01/03/2011	Brussels,	CAVOD meeting	Update of WP5 activities	CVZ

Date	Place	Audience	Content of the presentation	Presenting Institution
	Belgium			
16/03/2011	Cologne, Germany	IQWiG	Update of WP5 activities	CVZ
26/06/2011	Rio de Janeiro, Brasil	HTAi 2011	Interaction between EMA and EUnetHTA	CVZ
26/06/2011	Rio de Janeiro, Brasil	HTAi 2011	Collaboration in WP5	CVZ
07/10/2011	Bad Gastein, Austria	European Health Forum	Update of WP5 activities	CVZ
07/11/2011	Madrid, Spain	ISPOR	Relative effectiveness and observational data	CVZ
07/11/2011	Madrid, Spain	ISPOR	Stakeholder involvement in HTA national and international experiences	CVZ
07/11/2011	Madrid, Spain	ISPOR	Using real world data in CED	CVZ
18/11/2011	Udinese, Italy	Italian HTA conference	Interaction between EMA and EUnetHTA	CVZ
8/11/2011	Gdansk, Poland	EUnetHTA conference 2011	Update of WP5 activities	CVZ/HAS
2012				
06/02/2012	London, UK	La-Ser congress “Benefit-Risk in real life”	Interaction between regulators, industry and HTA.	CVZ
20/02/2012	Paris, FR	LEEM (industry)	EUnetHTA WP5 activities	HAS
27/03/2012	Copenhagen, Denmark	DIA Europe	Update on WP5 activities, interaction with regulators	CVZ
29/03/2012	Brussels, Belgium	EFPIA meeting	Update on WP5 activities	CVZ, HAS
17/04/2012	Brussels, Belgium	Conference PharmaBE	European collaboration on relative effectiveness assessment of pharmaceuticals	CVZ
02/05/2012	EMA, UK	EMA, industry	HRQoL and oncology	HAS, NICE, IQWiG
15-16/05/2012	NICE, UK	NICE annual conference	EUnetHTA guidelines	HAS
21/05/2012	Moscow, Russia	HTA in Russia	Update on WP5 activities	CVZ, HAS
19/06/2012	Amsterdam, Netherlands	Vancouver Group	Update on WP5 activities	CVZ/HAS
24/06/2012	Bilbao, Spain	HTAi conference	Industry involvement in EUnetHTA WP5 REA of pharmaceuticals,	CVZ,
25/06/2012	Bilbao, Spain	HTAi conference	Learning from the first WP5 pilot: Rapid assessment of pazopanib	CVZ
25/06/2012	Bilbao, Spain	HTAi conference	Methodology development and evidence generation	HAS
24/06/2012	Bilbao, Spain	HTAi conference	Workshop on EUnetHTA Tools: Model for Rapid Relative Effectiveness Assessment of	CVZ

Date	Place	Audience	Content of the presentation	Presenting Institution
			Pharmaceuticals	
25/06/2012	Bilbao, Spain	HTAi conference	Relative effectiveness assessment of pharmaceuticals in 29 jurisdiction	CVZ
26/06/2012	Bilbao, Spain	HTAi conference	International collaboration on HTA: Rapid assessment of pharmaceuticals	CVZ
13-14/09/2012	Amsterdam, NL	DIA	Early dialogues EUnetHTA	HAS
08/10/2012	Brussels, Belgium	EuropaBio conference	Update on WP5 activities, introduction of new activities in WP5 JA2	CVZ
15/10/2012	Munich, Germany	11th Annual Evolution Summit	Discussing role of REA in innovation of pharma	CVZ
05/11/2012	Berlin, Germany	ISPOR	Will the EUnetHTA model for Rapid Relative Effectiveness Assessment (REA) of pharmaceuticals work?	CVZ
05/11/2012	Berlin, Germany	ISPOR	Short update on WP5 JA1 and JA2	CVZ
05/11/2012	Berlin, Germany	ISPOR	How to assess co-dependent technologies	HAS
26/11/2012	Berlin, Germany	PharmaAccess forum	HTA in France and in Europe	HAS
30/11/2012	London, UK	TOPRA	Early dialogue EUnetHTA	HAS
05/12/2012	London, UK	Health Technology Assessment World Europe	Update of WP5 activities, introduction of new activities in WP5 JA2	CVZ

EUnetHTA WP face-to-face meetings 2010-2012

WP	Location	Number of meetings	Schedule
WP5	Diemen, Netherlands	1	2010-01-21/22: WP5 meeting
	Paris, France	1	2010-11-18/19: WP5 meeting
	Paris, France	1	2010-12-05/06: Meeting of lead/co-lead partner
	Brussels, Belgium	1	2011-05-03: Discussion on guidelines
	Paris, France	1	2011-05-05: Discussion on guidelines
	Oslo, Norway	1	2011-06-9/10: WP5 meeting
	Vienna, Austria	1	2012-02-9/10: WP5 meeting
	Diemen, Netherlands	1	2012-03-07: Meeting with GSK about pilot report
	Budapest, Hungary	1	2012-11-22/23: WP5 meeting
	Brussels, Belgium	1	2013-01-21: Meeting with stakeholders on endpoint related methodological guidelines

Other EUnetHTA face-to-face meetings

Dates	Location	Meeting objective
February 11, 2010	London, UK	EUnetHTA-EMA meeting: EPAR improvement
June 3, 2010	London, UK	EUnetHTA-EMA meeting; EPAR improvement
March 7, 2011	Diemen, The Netherlands	EUnetHTA-EMA meeting; interaction on topics that involve regulatory and HTA institutions
Feb 22, 2012	Paris, France	EUnetHTA-EMA meeting; interaction on topics that involve regulatory and HTA institutions
Nov 20, 2012	Copenhagen, Denmark	EUnetHTA-EMA meeting; discussion of next steps in developing cooperation.

WP5 Stakeholder and external expert involvement

Stakeholders have been involved in WP5 in three different ways:

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

1. The following products have been subject to public consultations:

- Draft background review (April/May 2011);
- Pilot report (June/July 2012);
- Guidelines on methodological issues for REA (Jun-Oct 2012, in 2 batches)
- Model for rapid REA of pharmaceuticals (Oct/Nov 2012)

2. The following products have been subject to SAG consultations:

- Draft background review (Jan/Feb 2011);
- Pilot report (March/April 2012);
- Guidelines on methodological issues for REA (April/May 2012, in 2 batches)
- Model for rapid REA of pharmaceuticals (Jun/Jul 2012)

Finally, a face-to-face meeting was planned with stakeholders to discuss the draft methodological guidelines on endpoints in February 2013.

3. Specific product assessments

External experts were involved in the production of the methodological guidelines. For the pilot assessment of the model, the Marketing Authorisation Holder (MAH) was involved in the consultation of the pilot report.

WP5 Cooperation with other WPs / LPs

There has been close collaboration with WP4 in order to avoid unnecessary variation between other core HTA models and the REA model of pharmaceuticals. In addition, there was close collaboration with WP4 in order to include the REA model of pharmaceuticals in the online tool.

WP5 Achievement of objectives

Results

Adherence to work plan:

The following adaptations of the initial WP5 work plan have occurred:

- The pilot was limited to a rapid assessment (not rapid and full assessment) (2011).
- One guideline - patient relevant outcomes - was merged into the guideline on clinical endpoints. A guideline on grading experience in experts and experience was dropped as it was not found feasible to produce a methodological guideline on a European level on this subject (2011).

- It was decided that based upon the higher workload in WP5 as originally anticipated, WP5 should focus only on further development of the model for rapid assessment (not rapid and full assessment) (2012).
- Originally, the final technical report should have contained a plan for stimulation of usage of the model for rapid and full assessment (where appropriate) in European countries. A plan for stimulation was however already realised through the planned follow-up activities in WP5 EUnetHTA JA2. Therefore the plan for stimulation was replaced by a draft report about implementation barriers and success factors for European collaboration in relative effectiveness assessment. The aim of the report is to identify implementation barriers and success factors that should be considered while drafting the procedure and methods for pilot rapid assessments in WP5 EUnetHTA JA2. Hereby, WP5 tries to maximise the uptake of the pilot rapid assessments that will be produced in WP5 EUnetHTA JA2.

No deviation from the initial work programme set out in annex I to the grant agreement occurred.

Published results:

Description of the indicator targets according to the Grant Agreement: Recommendations on the assessment of relative effectiveness (RE) identified and published. Target: publication of the recommendations in an international journal (submitted).

Indicator targets have been met by publication of the following specific products on the EUnetHTA website:

- Background Review on Relative Effectiveness Assessment of Pharmaceuticals
- Guidelines on 9 methodological issues for Relative Effectiveness Assessment of Pharmaceuticals
- Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals (published on EUnetHTA website end of February 2013)

Publications in international journals:

- Results of the background review have been published: Kleijnen S, George E, Goulden S, d'Andon A, Vitre P et al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value Health. 2012 Sep;15(6)
- One or more articles regarding the guidelines on methodological issues for Relative Effectiveness Assessment of Pharmaceuticals will be submitted in the special Joint Action section of the International Journal of Technology Assessment in Health Care in 2013
- An article regarding the Model for Rapid Relative Effectiveness Assessment of Pharmaceuticals will be submitted in the special Joint Action section of the International Journal of Technology Assessment in Health Care in 2013
- An article regarding the results of the pilot will be submitted in the special Joint Action section of the International Journal of Technology Assessment in Health Care in 2013

Conclusions and recommendations

Collaboration of HTA organisations in the field of relative effectiveness assessment

- WP5 members have demonstrated a high degree of willingness to collaborate in the field of relative effectiveness assessment of pharmaceuticals in Europe on various levels which is proven by the tremendous amount of work that has been completed during the past 3 years.
- The pilot assessment of pazopanib showed that the traditional mode of collaboration for the HTA Core Model in which multiple agencies are functioning as authors is not suitable for doing rapid assessments. It was considered time consuming due to the efforts needed by the coordinators to combine all results into one report and duplication of efforts as authors from a specific domain had to go through the evidence of the other domains in order to present solid conclusions. In addition it was considered that less authoring agencies and individuals can avoid overlapping, increase consistency and improve communication. For rapid assessments we propose a limited number of authoring agencies. For example one authoring agency and one co-authoring agency. The benefit of broad participation as well as quality assurance will be ensured by involving several agencies in an in-depth review. Production of pilot reports with a limited number of authoring agencies should be tested in WP5 JA2 Strand A.

Development of methods and tools for relative effectiveness assessment

- The traditional HTA Core Model has undergone significant adaptations in order to be suitable for rapid assessments on the relative effectiveness assessment of pharmaceuticals. A rapid assessment is an assessment of a specific technology within a limited timeframe in comparison with one or more relevant alternative interventions. It may assess a new pharmaceutical launched onto the market, or (re)assess a

pharmaceutical for a new indication or when new relevant data are available (Kleijnen et al. 2012). The following issues have been considered relevant and specific to the Model for Rapid REA of Pharmaceuticals:

- Following the European transparency directive (Transparency Directive 89/105/EEC), some countries are legally obliged to assess pharmaceuticals within a specified time period (90/180 days). The Model for Rapid REA of Pharmaceuticals has been developed with these strict timelines in mind.
- Instead of the nine domains included in the other applications of the Core Model, only the first four domains are included in the Model for Rapid REA of Pharmaceuticals. The 'Cost and Economic Considerations Domain' was explicitly excluded based on the recommendations of the High Level Pharmaceuticals Forum. In addition, the ethical, organisational, social and legal domains are replaced by a short checklist for quickly assessing the relevance of the ethical, organisational, social and legal issues for the project.
- There is more focus on the relative nature (in comparison to comparators) of the assessment.
- The methods, normally presented separately for each domain, are merged into one methods section in the Model for Rapid REA of Pharmaceuticals.
- The assessment elements in the four domains represent a subset of the elements in the HTA Core Model selected for their relevance and feasibility for inclusion in a rapid assessment.
- A submission file by the marketing authorisation holder and the European Public Assessment Report (EPAR) are the primary sources of information for the assessment. The submission file and the EPAR are checked for the completeness of the scientific literature listed; however, a full systematic literature search in reference databases is only performed if needed.
- Guidance is added on how to produce a summary of relative effectiveness of the pharmaceutical based on evidence from the four domains.
- This application of the HTA Core Model is developed with a different collaboration model in mind than the collaboration model that is generally used for other HTA Core Model applications. Instead of involving several agencies each working on specific domain(s), it is envisaged for rapid assessments that authoring of all four domains is limited to one or two organisations. To ensure broad participation several organisations are involved in in-depth review.
- Although this WP5 was mostly focused on the development of a rapid REA model for pharmaceuticals, many WP5 members also have indicated that a full pharmaceutical Core Model will be useful in the near future. The development of such a full model needs to be continued in WP8 in EUnetHTA JA2.
- Generating guidelines was extremely useful for all actors in REA process to establish the state of the art and general recommendations for the current thinking. However it was a very resource and time consuming process that requires more focused attention in EUnetHTA JA2 in order to optimise the process for generating guidelines for efficiency purposes.

Collaboration with stakeholders

- The pilot assessment of pazopanib indicated that collaboration with the MAH of the product is worthwhile. In the consultation phase of the draft pilot report the MAH indicated that also contact in the phase before the start of the assessment is very important. It is therefore suggested that in the next phase of EUnetHTA (JA2) in which 10 pilots on REA are performed the MAH is also consulted in the scoping phase. In addition, it is relevant to include them during the identification of topics for pilots as the pilot should be based on a REA submission file that should be provided by the MAH.
- Involvement of the expertise from stakeholders early in the process by the Stakeholder Advisory Group (SAG) has shown to have additional value. Therefore we suggest also to involve the SAG whenever possible in EUnetHTA JA2 also specifically in the further development of the REA model.
- For efficient generation of guidelines, earlier/more intensive involvement of stakeholders in the production process and discussions on outstanding issues in an earlier phase is recommended, instead of sending comments by e-mail in a later phase.

WP5 Manpower for the execution of activities

Partners and countries involved

Organisations Involved	Associated partners
	26. AHTAPoI (Poland) 27. AIFA (Italy) 28. GYEMSZI (Hungary)

	29. GOEG (Austria) 30. HIQA (Ireland) 31. HVB (Austria) 32. INFARMED (Portugal) 33. IPH-RS (Slovenia) 34. IQWIG (Germany) 35. KCE (Belgium) 36. NHS of Latvia (Latvia) 37. MoH (Czech Republic) 38. MoH (Spain) 39. NICE (UK) 40. NOKC (Norway) 41. SDU (Denmark) 42. SSD/MSOC (Malta) 43. THL (Finland) Collaborating partners 1. AETSA (Spain) 2. A Gemelli (Italy) 3. AMPM (Slovenia) 4. CAHTAR (Spain) 5. DSI (Denmark) 6. IRF (Denmark) 7. KDTD (Turkey) 8. REGLOM-DSAN (Italy) 9. RIZIV (Belgium) 10. SNHTA (Switzerland) 11. SLOVATHA (Slovakia) 12. TLV (Sweden) 13. UETS (Spain) 14. NCHTA (Russia)
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Persons who participated in the WP

Persons who participated in the production of the background review (subgroup 1)						
I = Investigator (gathering data)						
A = Author of report/publication						
C= Co-author of report/publication						
V= validation of results/responded to consultation						
* Employees of the WP LP that contributed also as members of WP coordinating team.						
Name	Agency	Country	I	A	C	V
B. Corbacho	AETSA	Spain	X		X	
B. Nagy	GYEMSZI	Hungary	X		X	
A. d'Andon	HAS	France	X		X	
P. Vitre	HAS	France	X		X	
E. George	NICE	UK	X		X	
S. Goulden	NICE	UK	X		X	
B. Osińska	AHTAPol	Poland	X		X	
R. Rdzany	AHTAPol	Poland	X		X	
A. Zawada	AHTAPol	Poland	X		X	

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I = Investigator (gathering data)						
A = Author of report/publication						
C= Co-author of report/publication						
V= validation of results/responded to consultation						
* Employees of the WP LP that contributed also as members of WP coordinating team.						
S. Thirstrup	IRF	Denmark	X		X	
W. Goettsch	CVZ*	Netherlands			X	
S. Kleijnen	CVZ*	Netherlands	X	X	X	
Isabelle Zahra Pulis/Bernardette Rossi	DPPM/MHEC	Malta				X
Anna Bucsics	HBV	Austria				X
HendrikVondeling	SDU	Denmark				X
NÚRIA PALADIO	CAHTAR	Spain				X
Gustaf Befrits	TLV	Sweden				X
Beate Wieseler	IQWIG	Germany				X
Patricia Harrington	HIQA	Ireland				X
Agnese Cangini	AIFA	Italy				X
Pertti Happonen	Fimea	Finland				X
Antra Fogale	NHS of Lavia	Latvia				X
Chris de Laet	KCE	Belgium				X
Mercedes Martínez Vallejo	Ministry of Health, Social Policy and Equality	Spain				X
Rosario Trindade	Infarmed	Portugal				X
Dominik Tomek	SLOVATHA	Slovakia				X

Persons who participated in the production of the HTA Core Model for rapid REA of pharmaceuticals and/or the pilot REA (subgroup 2/3)

DM= Domain lead model

AM = Author of model

RM = Reviewer of model

DP= Domain lead pilot report

AP= Author of pilot report

RP= reviewer of pilot report

V= responded to consultation

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	DM	AM	RM	DP	AP	RP	V
Ameli Kruselerf	FOPH							X	
Agnese Cangini	AIFA			X	X		X		X
Alexander Eisenmann	GÖG/BIQG				X		X		X
André De Swaef	RIZIV							X	
Anna Bucsecs,	HBV			X	X		X		X
Antra Fogle	NHS of Latvia			X	X				X
Áron Vincziczki	GYEMSZI							X	
Beate Wiesler	IQWIG			X	X				X
Belén Corbacho	AETSA			X	X			X	
Bence Nagy	GYEMSZI							X	X
Bernardette Rossi	DPPM		X	X	X	X	X		X
Bogusława Osińska	AHTApol								X
Cari Almazan	CAHTAR			X	X				
Chris De Laet	KCE			X	X	X	X		X
Conor Teljeur	HIQA								X
Daiga Behmane	NHS of Latvia			X	X				
Dario Sacchini	A. Gemelli			X			X		
Dominik Tomek	SLOVATHA								X
Elisabeth George	NICE								X
Eva Zebedin	HBV						X		
Fredrika Rydén	TLV								X
Hans Seyfried	HBV			X	X			X	
Hindrik Vonderling	SDU							X	X
Ilona Autti-Ramo	FINOHTA/THL			X	X				
Ingrid Wilbacher	HBV			X	X				
Iris Pasternack,	FINOHTA/THL		X	X					
Isabelle Zahra Pulis,	MALTA				X	X	X		
Jean Christian Krayenbühl	SNHTA			X	X				
Juan-Antonio Blasco	UETS			X				X	

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* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	DM	AM	RM	DP	AP	RP	V
Laila Abdel-Kader Matin	AETSA			X	X				
Lisa Landersholm	TLV								X
Lone Bilde	DSI								X
Luisa Muscolo	AIFA				X		X		
Marc van de Castelee	RIZIV		X	X		X	X		
Marco Marchetti	A.Gemelli			X	X		X	X	
Marianne Klemp	NOKC							X	
Mariad Vega	AETSA								
Marjetka Jelenc	IVZ-RS			X	X		X		X
Matteo Ruggeri	A.Gemelli			X	X		X		
M Auxiliadora Castillo	AETSA						X		X
Mercedes Martínez Vallejo	Ministry of Health, Social Policy and Equality							X	X
Pauline Vitré	HAS						X		X
Mira Pavlovic, Julie Biga, Bachir Dahmani, Emmanuelle Cohn, Anne Solesse	HAS								X
Núria Paladio	CAHTAR			X	X			X	
Olga Rebrova	NCHTA								X
Payam Abrishami	CVZ		X	X		X	X		
Pertti Happonen, Piia Peura	Fimea			X	X	X	X		X
Pietro Folino Gallo	AIFA			X					
Pietro Refolo	A.Gemelli						X		
Roberta Minacori	A.Gemelli						X		
Rossella Di Bidino	A.Gemelli			X	X	X	X		X
Sarah Kleijnen	CVZ*			X	X				
Simona Montilla	AIFA			X	X		X		X
Sinikka Sihvo	FINOHT/ THL						X		
Sirpa Soini	THL					X			
Stephan Lange	IQWIG								X

Persons who participated in the production of the HTA Core Model for rapid REA of pharmaceuticals and/or the pilot REA (subgroup 2/3)

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RP= reviewer of pilot report

V= responded to consultation

* Employees of the WP LP that contributed also as members of WP coordinating team.

Name	Agency	Country	DM	AM	RM	DP	AP	RP	V
Tove Ringerike	NOKC							X	
Wim Goettsch	CVZ			X	X				
Zoltan Huszti	GYEMSZI	Hungary						X	X

Persons who participated in the production of methodological guidelines for REA of pharmaceuticals (subgroup 4) C = Coordinator A = Author R = Reviewer WS = Participated in WP5 meetings or workshops						
Name	Agency	Country	C	A	R	WS
Mira Pavlovic	HAS	FR	X	X	X	X
Anne Gourvil	HAS	FR	X		X	X
Pauline Vitré	HAS	FR	X			X
Valérie Izard, Nathalie Merle, Paul Merckx, Sophie Stamenkovic, Maryse Lapeyre-Mestre, Laura Zanetti, Leslie Pibouleau Catherine Rumeau-Pichon, Anne Solesse, Emmanuelle Cohn, Anne D'Andon, François Meyer External experts : M. Cucherat, O. Chassany, M. Lièvre, D. Costagliola, Jean-Pierre Boissel, Pascal Auquier	HAS	FR			X	
Wim Goettsch	CVZ	NL			X	X
Sarah Kleijnen	CVZ	NL		X	X	X
Johan van Luijn, M.W. Van der Linden, H. Schelleman & M. Danz, Sylvia Vijgen, Caroline van der Meijden, Krista Schutte, Pauline Pasman Caroline van der Meijden, Nynke Dragt, Carola Kaandorp	CVZ	NL			X	
Elisabeth George	NICE	UK		X	X	X
Tarang Sharma, Alfred Sackeyfio, Ellie Donegan, Jennifer Priaux and Elisabeth George, Fiona Rinaldi, patient involvement unit, Alfred Sackeyfio, Helen Starkie, Grace Jennings and Scott Goulden	NICE	UK			X	
Beate Wieseler	IQWiG	GE			X	X
Joerg Lauterberg	IQWiG	GE		X		X
Alric Ruether	IQWiG	GE				X
Stefan Lange	IQWiG	GE		X	X	X

Persons who participated in the production of methodological guidelines for REA of pharmaceuticals (subgroup 4) C = Coordinator A = Author R = Reviewer WS = Participated in WP5 meetings or workshops						
Name	Agency	Country	C	A	R	WS
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Agnese Cangini	AIFA	IT		X	X	X
Simona Montilla	AIFA	IT			X	X
Luisa Muscolo	AIFA	IT			X	
Sinikka Sihvo	FINOHTA/THL	FI		X	X	X
Pertti Happonen	Fimea	FI			X	
Vesa Kiviniemi, Esa Kokki, Tuomas Oravilahti, Enlund Hannes, Kiviniemi Vesa, Kokki Esa	Fimea	FI			X	
Iris Pasternack,	FINOHTA/CVZ	FI			X	X
Anna Bucsics	HVB	AU			X	X
Eva Žebedin	HVB	AU			X	X
Michael Karall, Silke Näglein, Robert Sauermann	HVB	AU			X	
Patricia Harrington	HIQA	IR		X		X
Conor Teljeur	HIQA	IR		X		X
Marianne Klemp	NOCK	NO		X	X	X
Ingvil Sæterdal, Inger Natvig Norderhaug, Gunhild Hagen	NOCK	NO			X	
Irina Cleemput	KCE	BE		X	X	
Mattias Neyt	KCE	BE		X		
Chris De Laet	KCE	BE			X	X
Frank Hulstaert, Raf Mertens, Dominique Roberfroid, Patrice Chalon	KCE	BE			X	

Persons who participated in the production of methodological guidelines for REA of pharmaceuticals (subgroup 4) C = Coordinator A = Author R = Reviewer WS = Participated in WP5 meetings or workshops						
Name	Agency	Country	C	A	R	WS
Marc Van de Casteele	RIZIV-INAMI	BE			X	
Hindrik Vondeling	SDU/CAST	DE		X	X	X
Lisa Landerholm, Jonas Lindblom, Karin Melén	TLV	SE			X	X
Magnus Köping-Höggård, Fredrik Nilsson, Stefan Odeberg, Karl Arnberg, Anja Wikström	TLV	SE			X	
Isabelle Zahra Pulis, Bernardette Rossi, Sylvana Magrin Sammut, Diane Spiteri	DPPM/MHEC	MA			X	X
Rossella Di Bidino	A.Gemelli Hospital	IT			X	X
Núria Paladio	CAIHAQ	ES			X	X
Mercedes Martínez Vallejo, Javier García del Pozo, Piedad Ferré	MoH	ES			X	X
Rosario Trindade, Sonia de Jesus Vestia Caldeira	Infarmed	PT			X	X
Juan Antonio Blasco	UETS	ES				X
María Auxiliadora Castillo Muñoz	AETSA	ES				X
Heiner C. Bucher	Swiss Network for HTA	CH				X
Alexander Eisenmann	GOEG	AU				X
Anna Nachtnebel, Katharina Hintringer	LBI-HTA	AU				X
Rafał Rdzany	AHTAPol	PO				X
Nagy Bence, Zoltan Huszti, Gabriella Jona	GYEMSZI	HU				X
Marjetka Jelenc	IPH-RS	Slovenia				X
Kristina Tomekova	SLOVAHTA	Slovakia				X
Antra Fogle	NHS of Latvia	LV				X
Anita Viksna	National Health Service	Latvia				X

Persons who participated in the production of methodological guidelines for REA of pharmaceuticals
(subgroup 4)

C = Coordinator

A = Author

R = Reviewer

WS = Participated in WP5 meetings or workshops

Name	Agency	Country	C	A	R	WS
Olga Rebrova	NCHTA	Russia				X



Work Package 6
FINAL Technical Report
Joint Action on HTA 2010-2012



WP6 Objectives

Provision of a contemporary information management system which ensures compatibility and interoperability across WPs' tools to support collaborative HTA work, and ensure rapid dissemination of HTA results within the JA.

WP6 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
6. Information Management System (IMS) and the related documentation, processes and policies	Infrastructure, electronic tools, documents	See appendices and http://www.eunethta.be	Public/Access rights to certain areas

Other outputs

Title/Short description	Nature	Access
Collaboration with HTAi Information resources group regarding the HTAi vortal	Electronic tool	http://vortal.htai.org
Collaboration with HTAi-INAHTA HTA glossary	Electronic tool	http://htaglossary.net/

WP6 Activities

2010

Surveys: The 1st survey has been designed with – and conducted by WP3. All EUnetHTA Partners and Associates were invited to participate in order to get information about information produced at local level that could be shared at EUnetHTA level, knowledge of ICT tools, and training preferences for the EUnetHTA tools. Survey results were presented during the face to face meeting M10; learning from this survey will be used to support the development of tools.

Communication: Communication within WP6 occurred through a specific mailing list; documents were shared through a dedicated workroom. Communication with WP6 work groups occurred through the e-meeting facility. Communication about the progress of WP6 to EUnetHTA partners occurred through the News section of the Members Only site, and through the Newsletter edited by Secretariat. LP participated to a WP7 face to face meeting to present the development planning of the POP database. Communication about WP6 to the scientific community happened by having LP participating to the EUnetHTA workshop at HTAi Conference, and provided one oral communication and one poster (see external meetings / presentation and appendices).

Members-only site: Structure of the Members-only site has been improved in a stepwise approach. Adaptation has been implemented to the Contact database to turn it into a source of data and credentials for the central authentication directory (EUnetHTA ID).

Interoperability and common standards: A standard (Lightweight Directory Access Protocol - LDAP) has been selected to allow the access of all EUnetHTA tools using the same login and password through a central authentication directory. A common vocabulary (Medical Subject headings – MeSH) has been selected to describe topics in all EUnetHTA tools requiring such a functionality. A common reference layout has been agreed for all EUnetHTA tools. A reference set of meta data (Dublin Core – DC) for use with EUnetHTA tools has been selected.

Planned and Ongoing Projects database: WP7b started to collect description of projects from Partners and Associates and compile it in a Microsoft Excel worksheet. LP and WP7b evaluated the options to disseminate the results of this activity. It was decided to continue the process while preparing the development of an online database to be developed by WP6 Co-LP. Until the database is delivered, a dedicated Work room has been set up to host worksheet. Support has been provided to WP7b for the current POP database. LP participated to the WP7 face to face meeting (M6, Dublin) to present the roadmap of the POP database development. An e-meeting has occurred in M9 to prepare the development of the next version of the POP (needs assessment).

Tools supporting day to day collaboration: Workrooms have been activated for all Work packages. A news aggregator (RSS aggregator) demonstrator has been set up to collect Partners' websites News feeds. A toolbar for web browser has been developed to provide shortcuts to the EUnetHTA websites (public and Members Only), the EUnetHTA tools, the working areas and online resources related to HTA, News from the EUnetHTA website and the News aggregator and other HTA related organisations. An OAI-PMH aggregator demonstrator has been set up to automatically aggregate the description HTA reports stored in Institutional repositories (OAI-PMH compliant), creating a central point to search for HTA reports published by partners.

Training and support: Training sessions using the e-meeting facility has been provided to all administrators of Workrooms (at least one person per work package). Training material has been created regarding the Work rooms, the e-meeting facility, the contact database, the Members only site (for administrators), the Toolbar. Support has been provided to Work room administrators, technical bugs related to the Work rooms required external consultancy.

Interim technical Report and Financial Statement: Interim technical report and Financial Statement have been prepared (delivered M13).

Supplemental activities: Support was provided to WP1 regarding templates of documents, the management of the contact database, and the annual access renewal procedure. A policy describing the information dissemination has been created in collaboration with WP1 and tools developers. Support has been provided to WP2 regarding social networks (concepts + application to Twitter, LinkedIn, FaceBook). A sub site with limited access has been set up for the Stakeholder Forum to support WP1 (this was not activated due to the limited resources available to the EUnetHTA Secretariat to enter content and actively manage maintenance of an up-to-date Stakeholder Forum site). Support has been provided to WP1 regarding structure of the Public site and technical questions.

Stakeholder involvement: Stakeholder involvement was not initially foreseen due to the technical context of WP6, A question was received from stakeholder forum asking to clarify. The topic was discussed at WP6 second face to face meeting, all partners agreed on providing a description of WP6 activities to the Stakeholder Forum, and ask the forum to indicate in which activities they would like to be involved (see appendices, meeting minutes).

Collaborations: In order to avoid duplication of work and evaluate interoperability between tools developed by EUnetHTA, WP6 LP contacted the editorial team of HTAi vortal, the Steering Committee of the HTA

glossary, CRD (HTA database) and INAHTA (release in November 2010 of a tool that is similar to the EUnetHTA POP developed by WP7b and active since 2009).

2011

Communication: Communication within WP6 occurred through a specific mailing list; documents were shared through a dedicated workroom. Communication with WP6 work groups occurred through the e-meeting facility. Communication about the progress of WP6 to EUnetHTA partners occurred through the News section of the Members Only site, and through the Newsletter edited by Secretariat. LP participated to a WP7 face to face meeting to present the development planning of the POP database. Communication about WP6 to the a wider audience happened at the EUnetHTA conference (poster, see external meetings / presentation and appendices).

Interoperability and common standards: Single Sign on, Common vocabulary and Common Layout have been implemented in tools developed by WP6 and WP4. A reusable application framework has been derived from the development of POP database (considered to be used by WP7a).

Planned and Ongoing Projects database: Development of the POP database continued in collaboration with WP7b and was delivered in Sept. 2011

Information about policy decisions: Taking into account the results of the 1st survey (indicating that few information was already available to share, and, when existing, not written in English), and the need to re allocate resources in favor of the Planned and Ongoing Projects database, the development of this tool has been canceled.

Tools supporting day to day collaboration: An online infrastructure has been set up for NETSCC (former EUnetHTA Project WP5 LP) in order to publish the EUnetHTA adaptation glossary developed during the EUnetHTA project (2006-2008). EUnetHTA JA WP4 (THL) was informed on the development and demonstrated the solution provided to NETSCC.

Workrooms, Aggregators and toolbar are maintained.

Training and support: Training sessions using the e-meeting facility has been provided to administrators of Workrooms (update of previous series) and content editors of the MObite (WP1). Additional training material has been created regarding the Members Only site, Members Only library, Contact database. Support has been provided to Work room administrators, some problems required consultancy to fix technical bugs. Support has also been provided to Secretariat regarding technical questions. Support to WP2 has continued regarding social networks (LinkedIn, Twitter). LP participated to the face to face training session organized by WP8 in Madrid (Spain). IMS and WP6 tools (MO site, toolbar, news aggregator, OAI aggregator,...) were presented, as well as the POP database (in agreement with WP7b). LP provided support to WP7b regarding POPdb documentation (template, revision); and produced Webcasts about the POP db.

Interim technical Report and Financial Statement: Interim technical report and Financial Statement have been prepared (delivered M25).

Supplemental activities: WP6 LP provided support to WP2 regarding promotion material for the Gdansk Conference (support to the creation of the folder and banners for websites), folder describing the EUnetHTA tools (WP8 training session, Gdansk Conference), poster describing WP6 for the Gdansk Conference. LP provided two Webforms to support a survey of WP5, and one Webform to support a survey of WP7b. LP participated to a WP1/WP8 face to face meeting dedicated to the Business model (brainstorming, place of EUnetHTA tools and the IMS).

Collaborations: In order to avoid duplication of work and evaluate interoperability between tools developed by EUnetHTA, WP6 LP participated to the editorial team of HTAi vortal, represented EUnetHTA at the Steering Committee of the HTA glossary and participated to the task force INAHTA Memorandum of Understanding. Contact has been maintained and developed with CRD (HTA database).

2012

Surveys: The 2nd survey has been designed with – and conducted by WP3. All EUnetHTA Partners and Associates were invited to participate in order to get information about information produced at local level that could be shared at EUnetHTA level, knowledge of ICT tools, and training preferences for the EUnetHTA tools. Survey results were presented during the face to face meeting M32.

Communication: Communication within WP6 occurred through a specific mailing list; documents were shared through a dedicated workroom. Communication with WP6 work groups occurred through the e-meeting facility. Communication about the progress of WP6 to EUnetHTA partners occurred through the News section of the Members Only site, and through the Newsletter edited by Secretariat. LP participated to a WP7 face to face meeting to present the development planning of the POP database. Communication about WP6 to the scientific community happened by having LP presenting a poster describing the development process of the POP database at the 9th HTAi Conference, and presenting EUnetHTA tools at the EUnetHTA workshop, and opportunities of collaboration (in the context of the Memorandum of Understanding) at the INAHTA annual meeting (see external meetings / presentation and appendices).

Members-only site: Development of the MO site has been stopped due technical limitations that have been identified thanks to the surveys and could not be solved without expansive investments. In preparation of Joint Action 2, supplementary activity identified as “New websites” has been defined. With the help of a task force, WP6 LP designed and conducted surveys (LPs, partners and associates, but also members of the Stakeholder forum), defined the requirements for websites and identified providers to deliver new websites (Public site, Intranet).

Interoperability and common standards: Common standards about layout of the EUnetHTA tools has been updated. LDAP schema has been updated related to the supplementary activity “New websites”.

Planned and ongoing Project database: Functionalities for release 2 have been defined, implementation has been postponed to 2013 due to supplementary activity “New websites”.

HTA reports and supplemental material: A proof of concept has been set up. Evaluation will happen in 2013.

Tools supporting day to day collaboration: Work rooms, aggregator and toolbar are maintained. Due to new websites project, mailing list server has been canceled (functionality to be integrated in the new Intranet).

Training and support: Support regarding the Work rooms has been delivered to partners.

Evaluation and final report: Technical report and Financial Statement have been prepared (delivered M37).

Supplemental activities: Preparation of the New websites (public site, Intranet and Work rooms) has been conducted under JA1. Support has been provided to WP1/2 regarding the social networks.

Collaborations: In order to avoid duplication of work and evaluate interoperability between tools developed by EUnetHTA, WP6 LP participated to the editorial team of HTAi vortal, represented EUnetHTA at the Steering Committee of the HTA glossary and prepared the description of a first collaboration with INAHTA (POP database). Contact have continued with CRD regarding the HTA db.

WP6 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

Date	Place	Audience	Content of the presentation	Presenting Institution
2010-06-07	Dublin, Ireland	HTAi Annual Meeting	EUnetHTA Information Management System (presentation workshop)	KCE
2010-06-07	Dublin, Ireland	HTAi Annual Meeting	Standards to enhance interoperability of information systems and efficiency of information exchange (poster).	KCE
2010-06-07	Dublin, Ireland	HTAi Annual Meeting	A KM Framework to support a multinational network (presentation)	KCE

2011-12-08	Gdansk, Poland	EUnetHTA Conference	Information Management System (WP6) (poster)	KCE
2012-06-24	Bilbao, Spain	HTAi	EUnetHTA Information Management System (presentation workshop)	KCE
2012-06-23/27	Bilbao, Spain	HTAi	EUnetHTA POP db, the EUnetHTA Planned and Ongoing Projects database - development and functionalities (poster, nominated for best poster award)	KCE
2012-06-23/27	Portugalete, Spain	INAHTA	EUnetHTA and EUnetHTA Information management System: Interoperability, collaboration (presentation)	KCE

EUnetHTA WP face-to-face meetings 2010-2012

WP	Location	Number of meetings	Schedule
WP6	Köln, Germany	1	2010-02-08
	Paris, France	1	2010-04-15/16
	Brussels, Belgium	1	2010-10-12/13
	Paris, France	1	2011-09-06
	Vienna, Austria	1	2011-10-13/14
	Köln, Germany	1	2012-05-31
	Köln, Germany	1	2012-08-23/24
WP7	Dublin, Ireland	1	2010-06-10

Other EUnetHTA face-to-face meetings

Dates	Location	Meeting objective
2010-12-15>16	York, UK	Collaboration CRD HTA database
2011-01-20	Copenhagen, Denmark	Strategy / business model (WP1/8)
2011-10-27/28	Madrid, Spain	EUnetHTA Training Workshop (WP8)

WP6 Stakeholder and external expert involvement

Stakeholder involvement was not foreseen at the beginning of the JA due to the particular nature of WP6 (technical); this has been reconsidered in 2010, but no request has been received from SF since then.

WP6 Cooperation with other WPs / LPs

WP2, 3, 4, 5, 7: those WPs were AP in WP6 in order to ensure involvement in decisions, and regular communication.

WP1/8: LP and Co-LP are members of the WP1 Coordination and WP8 Strategy and Business Model Development. Support has been provided regarding the business model.

WP2: Support has been provided regarding the public site, the social networks strategy and implementation, the EUnetHTA Conference communication.

WP3: WP6 worked in close collaboration with WP3 regarding the users surveys.

WP5: WP6 provided support regarding online survey.

WP7: WP6 provided support regarding online survey.

WP6 Achievement of objectives

Results

This section should also include the reporting on achievement of targets for each indicator set for your WPs (please see p. 34-35 of the EUnetHTA JA Grant Agreement for the full list of indicators and targets).

The objective for WP6 was described as follow: “Information Management System developed and fully functional (Process). Target: At least 90% of partners contributed with at least one entry to the Information Management system”.

The Information Management System has been delivered and is “fully functional”. It encompasses:

- Tools: MO site, Work rooms, Centralized authentication server (EUnetHTA ID), Planned and Ongoing Projects database (developed in collaboration with WP7 Co-LP), HTA Core Model online (developed by WP4 LP), EVIDENT database (developed by WP7 LP), Aggregator.
- Standards: Vocabulary, meta data, web site layout, authentication (LDAP implementation)
- Policies: Information Dissemination policy
- Training material: user manuals, webcasts

A total of 96% of WP6 partners have provided at least one entry in the IMS (by entry, we take into account information = 82% – in other word news through the news aggregator or project description through the POP database; or knowledge = 82% – e.g. input for the development of common standards).

A total of 77% of JA active partners (LP, Co-LP, AP) and 64% of less active partners (CP) have provided at least one entry to the IMS. (by entry, we take into account information – in other words news through the aggregator or project description through the POP database).

Recommendations

Communication / training

- Taking into account the renewal of personal at the partners, it is important that communication about the tools happens regularly to remind the basics of the EUnetHTA tools: all employees may benefit from a EUnetHTA ID, show how the tools are placed in the HTA workflow, ... Collaboration with WP2 should be enhanced on this aspect.
- Tools developers should collaborate with JA2 WP2 to provide a structured offer of training material and sessions regarding the tools
- Communication about the tools should take care to avoid jargon
- New kind of communication channels that could help to disseminate information about the tools and show their benefit to potential users in their day to day work should be considered, e.g.: user stories in the form of video interviews or story telling
- A document should be produced for local IT managers regarding the requirements for SABA Centra e-meeting (network ports, Java runtime mandatory for local app, ...)

Development

- Guidelines for tools developers should be maintained and further develop for areas of standardisation that have not been identified yet.
- Workflow for information encoding should be considered to cover all possible scenarios at the agency level: sometimes, several people encode information into a tool, but one would validate it before publishing it.
- Training material should be accessible from the tools themselves.
- An adaptation of the authentication process should be considered in order to allow organisation access too tools where individual authentication not required: this would fasten the access to the shared information and could potentially raise its use.
- The possibility to provide a meta search engine (a search engine that searches across all the EUnetHTA tools) should be evaluated, as it could simplify the identification of shared information
- All tools should be able to provide analytics about their use in order to monitor their use and adapt the communication / training strategy for each of them
- Developing tools with open source technology should be a requirement since it helps to reduce maintenance costs (prepare end of EUnetHTA funding)

Collaboration / interoperability

- Continue to explore potential collaboration with external parties to avoid duplication of effort and support development of interoperability
- To avoid redundant encoding and enhance exchange and reuse of information, Partners should favor the implementation of interoperability standards at their own information systems. RSS should be

implemented on the website of the partners, separated feeds are suggested: HTA news, HTA publications, HTA projects (planned, ongoing), ... OAI-PMH should be implemented on the website / library catalogue / digital repository of the partners, where their HTA publications (reports, articles, ...) are described.

WP6 Manpower for the execution of activities

Partners and countries involved

LP - KCE (Belgium)

Co-LP - DIMDI (Germany)

AP - CVZ (Netherlands)

AP - GÖG (Austria)

AP - GYEMSZI (Hungary, formerly EMKI and ESKI)

AP - HAS (France)

AP - HVB (Austria)

AP - ISCIII (Spain)

AP - LBI-HTA (Austria)

AP - NETSCC (United-Kingdom)

AP - NIPH (Slovenia)

AP - SBU (Sweden)

AP - THL (Finland)

CP - ARESS (Italy)

CP - KDTD (Turkey)

CP - OSTEBA (Spain)

CP - SNHTA (Switzerland)

Persons who participated in the WP

Persons that participated in WP6

- D = Developer of one or more WP6 tool
- R = Reviewer of one or more WP6 tool
- WS = Participated in WP6 meetings or workshops
- V = not applicable to WP6
- * Employees of the WP LP that contributed also as members of WP coordinating team (administrative support, organisation of face to face meeting).

Name	Agency	Country	D	R	WS	V
Raf MERTENS	KCE	Belgium		x		
Gudrun BRIAT	KCE	Belgium		x		
Patrice CHALON	KCE	Belgium	x	x	x	
Carl DEVOS	KCE	Belgium		x		
Kirsten HOLDT HENNINGSEN	KCE	Belgium		x		
Nadia BONNOUH*	KCE	Belgium				
Dorothee BULTE*	KCE	Belgium				
Jean-Pierre CLOSON*	KCE	Belgium				
Geert DE MEULENAERE*	KCE	Belgium				
Luc HOURLAY*	KCE	Belgium				
Christian LEONARD*	KCE	Belgium				
Pascale MARTOU*	KCE	Belgium				
Elisabeth PETIT*	KCE	Belgium				
Karen VANDEVELDE*	KCE	Belgium				
Ine VERHULST*	KCE	Belgium				
Peter KRAEMER	DIMDI	Germany	x	x	x	
Aida JERTILA	DIMDI	Germany	x		x	
Peter SCHLÖMER	DIMDI	Germany	x			
Claudia WILD	LBI-HTA	Austria	x	x		
Gerda HINTERREITER	LBI-HTA	Austria	x	x	x	
Marisa WARMUTH	LBI-HTA	Austria	x	x	x	
Judit ERDOS	LBI-HTA	Austria	x	x	x	
Gottfried ENDEL	HVB	Austria		x	x	
Ingrid WILBACHER	HVB	Austria		x	x	
Johannes ZSIFKOVITS	GÖG	Austria		x	x	
Finn BORLUM KRISTENSEN	NboH	Denmark			x	
Julia CHAMOVA	NboH	Denmark			x	
Kristian LAMPE	THL	Finland	x	x	x	
Oskari SAAREKAS	THL	Finland	x	x	x	
Sun Hae LEE ROBIN	HAS	France	x	x	x	
Cédric CARBONNEIL	HAS	France	x	x	x	

Sorin STANEL	HAS	France	x	x	x	
François-Xavier RATNAM	HAS	France	x	x	x	
Céline CHAINTRON	HAS	France			x	
Karine ROZET	HAS	France			x	
Aron VINCSZICZKI	ESKI/GYEMSZI	Hungary		x	x	
Lajos KOVACS	EMKI	Hungary		x	x	
Zita DAROCZY	EMKI	Hungary		x	x	
Sarah KLEIJNEN	CVZ	The Netherlands		x	x	
Eva TURK	NIPH	Slovenia		x	x	
Urška KALOOPER	NIPH	Slovenia		x	x	
Andres FERNANDEZ RAMOS	ISC-III	Spain		x	x	
Susanne VILHELMSDOTTER ALLANDER	SBU	Sweden			x	
Eleanor GUEGAN	NetSCC	UK	x	x	x	
Christoph KÜNZLI	SNHTA	Switzerland		x	x	

Appendicies WP6

1. WP6_Communication_ 2010 HTAi Conference KM concept
2. WP6_Communication_ 2010 HTAi Conference Standards
3. WP6_Communication_ 2010 HTAi Conference workshop
4. WP6_Communication_ 2011 EUnetHTA Conference
5. WP6_Communication_ 2012 HTAi Conference POP database dev
6. WP6_Communication_ 2012 HTAi Conference workshop
7. WP6_Communication_ 2012 HTAi Conference_nominated
8. WP6_Communication_ 2012 INAHTA annual meeting
9. WP6 meeting 2010 Paris minutes
10. WP6 meeting Brussels 2010 – minutes
11. WP6 meeting Koeln minutes
12. WP6 meeting Vienna 2011 – minutes
13. EUnetHTA Workrooms_user manual
14. EUnetHTA_MOsite_admin manual
15. WP6_Webcast_ EUnetHTA Contact db edit profile (audio file; available electronically only)
16. WP6_Webcast_ EUnetHTA ID renewal (audio file; available electronically only)
17. WP6_Webcast_ EUnetHTA ID renewal_2011 (audio file; available electronically only)
18. WP6_Webcast_ EUnetHTA MOlibrary Updating document (audio file; available electronically only)
19. WP6_Webcast_ EUnetHTA work rooms_create news (audio file; available electronically only)
20. WP6_Webcast_ EUnetHTA_POP_db_browse (audio file; available electronically only)
21. WP6_Webcast_ EUnetHTA_POP_db_collab (audio file; available electronically only)
22. WP6_Webcast_ EUnetHTA_POP_db_public_pages (audio file; available electronically only)
23. WP6_Webcast_ EUnetHTA_POP_db_quicklinks (audio file; available electronically only)
24. WP6_Webcast_ EUnetHTA_POP_db_search (audio file; available electronically only)
25. WP6_Webcast_ EUnetHTA_POP_db_search_and_browse (audio file; available electronically only)
26. WP6_Webcast_ saba_centra_basic (audio file; available electronically only)
27. WP6_Webcast_ toolbar_201006 (audio file; available electronically only)



Work Package 7 – “New Technologies”
FINAL Technical Report
Joint Action on HTA 2010-2012

WP7 Objectives

The general objective of WP7 was to support collaboration on new technologies and to contribute to reducing duplication of work by:

- Exchanging information on and developing tools to facilitate evidence generation (Strand A).
- Exchanging information on current assessments of new health technologies (Strand B).

Strand A: Facilitating evidence generation on new health technologies

Development of HTA tools and methods and application and field testing of developed tools and methods:

- a database for structured exchange and storage of information on evidence generation on new technologies.
- an agreed dataset to facilitate exchange and sharing of information on planned prospective data collection including pragmatic trials
- criteria to select new technologies for which additional evidence generation is important.

Strand B: Pre-market/pre-reimbursement assessment of new non-pharmaceutical health technologies

- To support information flow on new medical interventions (between market approval and reimbursement decision).
- To reduce duplication on the assessment of new medical interventions by alerting on parallel activities (between market approval and reimbursement decision).
- To facilitate collaboration on new medical interventions (between market approval and reimbursement decision).

WP7 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
D4 Operational web-based toolkit including database containing information on evidence generation on new technologies	Database	<ul style="list-style-type: none"> • Available via the following link: https://evident.has-sante.fr/has/login.xhtml or from the Members' Only area of EUnetHTA's website (www.eunetha.eu), under the heading EUnetHTA tools. • Descriptive document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM) 	Restricted to EUnetHTA partners
D5 Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies	Protocol	Document available (PDF enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)	Scientific community only/Restricted to EUnetHTA partners

Other outputs

Strand A

Title/Short description	Nature	Access
<p><u>Title:</u> Minimum dataset to inform a prefunding registry for clinical studies designed to support clinical decision makers</p> <p><u>Short description:</u> to enable funders to identify studies being planned or considered elsewhere, to facilitate the possibility of collaboration, either through joint funding or standardisation of outcome measures</p>	Database items	<ul style="list-style-type: none"> Integrated into EVIDENT database (https://evident.has-sante.fr/has/login.xhtml) Descriptive document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)
<p><u>Title:</u> Criteria to select new technologies for additional evidence generation</p> <p><u>Short description:</u> Selection/prioritization criteria are intended to help HTA doers, study funders and other stakeholders select, among new technologies, the ones for which complementary studies are really worth performing.</p>	Policy document	<ul style="list-style-type: none"> document available on EUnetHTA website (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)

Strand B

Title/Short description	Nature	Access
<p><u>Title:</u> Electronic, web-based database on ongoing/planned reports</p> <p><u>Short description:</u> stores basic information on planned/ongoing projects of EUnetHTA partners to facilitate collaboration</p>	Database, electronic tool	<ul style="list-style-type: none"> Available via the following link: http://eunetha.dimdi.de/PopDB/ or from the Members' Only area of EUnetHTA's website (www.eunetha.eu), under the heading EUnetHTA tools. Descriptive document available (screenshots as PDF file enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM)
<p><u>Title:</u> Checklist for collaborations</p> <p><u>Short description:</u> includes possibilities for information exchange among EUnetHTA partners to facilitate ways of collaboration</p>	Policy document/ Guideline	<ul style="list-style-type: none"> Document available (PDF enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); Distributed via e-mail to the partners (M3) Published in the WP7 workroom (M3)
<p><u>Title:</u> Joint assessments/collaborations</p> <p><u>Short description:</u> 12 joint assessments in 2,5 years coordinated and initiated by LBI-HTA</p>	Report	<ul style="list-style-type: none"> Reports are available on LBI-HTA website: http://eprints.hta.lbg.ac.at/ (list of reports with respective weblinks to be found in the Appendix)

Work Package 7 Activities

2010

Strand A and B:

- WP 7 1st face-to-face meeting, June 10, 2010 in Dublin: Preparation and organisation in cooperation with HIQA as the local host.
- Definition of interoperability of EUnetHTA tools (with WP6)

Strand A:

Database on additional evidence generation

- Analysis of the use of the Eiffel web-based toolkit⁷ prototype during EUnetHTA Collaboration (2009)
- Definition of area of improvement of the web-based toolkit prototype (database)
- The analysis of the use of the Eiffel toolkit and areas of improvement with WP7 partners at face to face meeting in Dublin - Presentation and discussion
- Constructed, circulated and analysed Survey on needs, possibilities and implementation mechanisms for additional studies for new technologies among a subgroup of relevant WP7 partners (for further development of both database and selection criteria)

Development of a registry for policy relevant studies in development

- Developed project plan
- Planned out phases for developing first draft of dataset, identifying Delphi participants, invitation of participants, construction and execution of 2 (possibly 3) Delphi rounds to refine dataset, and efficacy testing of the resulting dataset
- Shared project plan with WP7 partners at face to face meeting in Dublin
- Used a snowballing process⁸ to identify Delphi participants
- Constructed, circulated and analysed first Delphi round, then refined dataset in light of information received
- Constructed and circulated second Delphi round, closing data for response was 20th December.

Criteria to select new technologies for Additional evidence generation (AEG)

- Review of published selection/prioritisation criteria for new technologies relevant for AEG
- Presentation and discussion of the review with WP7 partners at the face to face meeting in Dublin
- Survey on needs, possibilities and mechanisms of selection/prioritization among a subgroup of relevant WP7 partners (common survey for database and selection criteria)

Other tasks

- Organisation of WP6 face-to-face meeting in Paris (mostly in relation with WP7 activities)
- Participation in 6 ff meetings and 7 e-meetings (M1-12)
- Writing the interim technical and financial report 2010 (M12)
- Activities concerning SF/SAG:
 - Participation in SF meetings and e-meetings
 - Definition of the modalities of consultation of Stakeholder involvement, in coordination with WP4, WP5 and the Secretariat
 - Contribution to the development of Stakeholder policy

⁷ Eiffel toolkit has been developed during EUnetHTA project 2006-2008 aiming to facilitate European collaboration on new health technologies in need of additional evidence generation. This tool contained structured and standardized forms for requesting or posting information. The results of the analysis pointed out the need to focus on the database function rather than on the information exchange function (request/post).

⁸ After identifying the initial organisations (personal contacts, organisations identified through INAHTA, organisations identified through EUnetHTA), these organisations were asked to help identify other organisations with a similar trait. The process has been repeated until the obtaining of sufficient number of organisations.

- Contribution to the WP7 SAG
- Administration of WP7 workroom
- Update of WP7 workplan

Strand B:

- A **checklist for collaboration** was developed and distributed.
- **4 POP requests and reminders** (email requests for planned and ongoing projects) were carried out.
- **3 POP updates** (synthesis of information) including alert lists of redundancies and similar projects were published in the POP workroom.
- **3 POP communication protocols** were written (not public).
- **POP database development**, preparation activities already started in late 2010 (in cooperation with WP 6).
- A **common classification system** for indexing all planned and ongoing projects (first by using a self-made indexing system, afterwards by using MeSH terms) was piloted and introduced.
- Continuous **POP workroom administration, communication and information provision** (POP workroom, EUnetHTA members only news area, EUnetHTA members updates...).
- **Coordination of collaboration** on new health technologies:
 - **2-days workshop** on collaboration on oncological drugs in Vienna hosted by LBI-HTA in Sept/Oct 2010.
 - **Active brokering** of collaboration on two **oncological drugs** - call for joint assessments (M12).
 - **Preparation of the active brokering** of collaboration on **new high technology interventions in hospitals** (preparation in M12, first call for collaboration in M13).
- Participation in **9 ftf meetings and 9 e-meetings** (M1-12) (LBI participation)
- Writing the **interim technical and financial report** 2010 (M12)
- **Other tasks**
 - POP database development: Preparation activities and communication with WP 6 already started in the 2nd half of 2010.
 - Active brokering for collaboration:
 - Workshop on oncological drugs organised and hosted
 - Collaboration on the assessment of two oncological drugs initiated
 - Call for collaboration on two new high technology interventions in hospitals prepared in Dec 2010, first call in performed in Jan 2011
 - Administration of POP workroom
 - Administration of POP admin workroom

2011

Strand A and B:

- **WP7 2nd face-to-face meeting**, March 03-04, 2011 in Valetta/Malta: Preparation and organisation in cooperation with SSD/MHEC as the local host
- EVIDENT/POP interoperability meeting (with WP6 LP)
- **WP7 3rd face-to-face meeting**, September 29-30, 2011 in Rome/Italy: Preparation and organisation in cooperation with AIFA as the local host.

Strand A:

Database on additional evidence generation (EVIDENT):

- Upgrading of the database's items and functionalities

- Presentation of 1st survey results (performed at the end of 2010) and of the upgraded list of items (FTF meeting : Valetta)
- Survey on data processing and functionalities
- Database pilot test phase
- SAG consultation on the database proposal
- Presentation of the results of the survey on data processing and functionalities, pilot test phase and SAG consultation (FtF meeting: Rome)
- Survey on points needing further clarification regarding EVIDENT database
- Public consultation on the final version of database's proposal before IT upgrading

Development of a dataset for policy relevant clinical studies in development

- SAG consultation on the dataset
- Test and validation of dataset for 4 health technologies (Monoclonal antibodies for breast cancer, Endovascular valve replacement for aortic stenosis, Vetebroplasty for osteoporosis, Anti-VEGF agents for macular degeneration)
- Analysis of test and validation of dataset
- Relevant **dataset** for exchange of useful information on prospective data collection **finalized** with examples of health technologies for which information was exchanged using the defined dataset **(1st WP7A output)**

Criteria to select new technologies for Additional evidence generation (AEG)

- Internal definition of the first draft of selection criteria
- Presentation of the first draft of selection criteria (FtF meeting : Valetta)
- SAG and WP7 partners' consultation on the first draft of criteria
- Presentation of the results of the two consultations and of the upgraded version of selection criteria (FTF meeting: Rome)
- Choice of health technologies to be used as examples for the testing of selection criteria by WP7 partners

Other tasks

- Survey on the new name of the database on additional evidence generation (Eiffel became EVIDENT)
- Meeting and exchanges with ENCePP about the possibility of EVIDENT/ENCEPP collaboration
- Preparing a poster presentation "WP7A: EVIDENT database" for the EUnetHTA Conference on December 08-09, 2011 in Gdansk
- Organisation of WP1 face-to-face meeting in Paris
- Participation in 4 FtF meetings and 7 e-meetings (M13-24)
- Participation in the Plenary Assembly
- JA 2 proposal preparations and negotiations in close cooperation with the EUnetHTA Secretariat and IQWIG/GE (for WP7)
- Contribution to the definition of EUnetHTA strategy 2012 and to the elaboration of the document on the Strategy
- Writing the interim technical and financial report 2011 (M23, 24)
- Activities concerning SF/SAG:
 - Participation in 1 SF meetings and 4 e-meetings
 - Contribution to the WP7 SAG
- Administration of WP7 workroom

Strand B:

Planned and Ongoing Projects database (POP database)

- **3 POP requests and reminders** (email requests for planned and ongoing projects) were carried out (M14, M17, M23).
- **2 POP updates** (synthesis of information) including alert lists of redundancies and similar projects were published in the POP workroom (M15, M18).
- **3 POP communication protocols** were written (M14 for the 4th POP request, M16 for the 5th request, M18 for the 6th request, *communications protocols are not public*).

- **POP workroom administration** at the EUnetHTA Members Only area - Information Management System/IMS (until M20 when the online POP database was released)
- **Communication and information provision** (POP workroom, EUnetHTA members only news area, EUnetHTA members updates, Emails).
- **POP database development** in close cooperation with WP6 LP/ KCE and WP6 Co-LP/ DIMDI (since M10, ongoing);
 - 1st POP database launch** the end of August (M20):
 - General project management (software development by WP6 Co-LP)
 - Needs assessment (including experiences from WP7 Co-LP with the known POP process, results from the online survey among POP contact persons and additional ideas from WP6 LP and from the software developer at DIMDI WP6 Co-LP).
 - Procedure elaboration
 - Data preparation for 1st database import
 - MeSH terms assignment to all 1.200 projects listed in the POP database
 - Website texts and content provision
 - Several database testing rounds, commenting
 - Implementing, upgrades
 - Provision of training materials, the user manual, worksheets
 - POP db communication, presentation and demo (e-mails, WP7 ftf meeting, WP6 ftf meeting, ..)
 - POP database V1 evaluation, survey among POP db training participants (WP7 partners) and analysis
 - POP database user and access rights management (continuing)
 - POP database moderation and maintenance
- **Coordination of collaboration on new health technologies:**
 - Active brokering of collaboration on oncological drugs: managing and performing 3 joint assessments (M14, M16, M18).
 - Active brokering of collaboration on new high technology interventions in hospitals: managing and performing 2 joint assessments (preparation in M12, finished M16).
- **Other tasks**
 - Participation (LBI-HTA) in **13 face-to-face meetings, 9 POP database development e-meetings** and **7 WP1/ Executive Committee e-meetings** (M13-24).
 - Organisation and hosting of the **3rd WP6 face-to-face meeting** on October 13-14, 2011 in Vienna (M22)
 - **JA 2 proposal preparations** and negotiations in close cooperation with the EUnetHTA Secretariat and CVZ/NL „WP5 (CVZ/ LP and LBI-HTA/Co-LP): Testing partners' capacity to apply the HTA Core Model for Rapid Assessment in collaborative production of HTA information for national adaptation and reporting, Strand A: pharmaceuticals, Strand B: other health technologies
 - Writing the **interim technical and financial report 2011** (M23-M24)
 - Preparing a **poster presentation** “WP7B: POP database” for the EUnetHTA Conference on December 08-09, 2011 in Gdansk (M23)

2012

Strand A and B:

- **WP7 4th face-to-face meeting**, May 10-11, 2012 in Vienna/Austria: Preparation and organisation

Strand A:

Database on additional evidence generation (EVIDENT):

- Analysis of comments received during public consultation and elaboration of the document on the results of the public consultation
- Finalisation of database's proposal and validation at the 4th FtF meeting
- IT implementation: subcontracted operational database development (regular meetings with the subcontractor, follow-up of the implementation, help with the layout)
- Testing the preliminary version
- Preparation of database's prelaunch – elaboration of documents, contacts with specific partners, analysis of feedback and troubleshooting
- Elaboration of the final document on the database and the user's manual
- Operational database launch (**final WP7A deliverable**)

Criteria to select new technologies for Additional evidence generation (AEG)

- Testing of selection criteria by WP7 partners to select 3 new health technologies for which additional evidence generation is of importance (coordination, analysis of responses, elaboration of the document on the results)
- Subcontracted update of literature review on existing selection criteria (meetings with the subcontractor, follow-up of the project, review of the document)
- Public consultation on the selection criteria (coordination, analysis of responses, elaboration of the document on the results)
- Presentation and validation of the final version of selection criteria (4th FtF meeting, Vienna)
- Publication of the final version of selection criteria on EUnetHTA's website (**2nd WP7A output**)

Other tasks

- Writing the final technical and financial report
- Participation in 3 ftf meetings and 6 e-meetings
- Participation to WP4 CWG as observer
- Completion of POP database
- Producing Members' Update for WP7A
- Preparation of WP7 Overview report for the Plenary assembly
- Presenting EVIDENT database at the Workshop on EUnetHTA tools at the HTAi annual meeting in Bilbao
- Presenting a poster on selection criteria at the HTAi annual meeting in Bilbao
- Presenting EVIDENT database at the EUnetHTA-EMA meeting in Paris and in Copenhagen
- Activities concerning SF/SAG:
 - Participation in 1 SF meeting and 3 e-meetings
 - Participation to EUnetHTA Information session for EFPIA members
- Administration of WP7 workroom

Strand B:

Planned and Ongoing Projects database (POP database)

- **4 POP requests and reminders** (email requests for planned and ongoing projects) were carried out (M26, M29, M32, M35)
- **5 POP communication protocols** were written (M25, M27, M30, M33, M36, communication protocols are not public).
- **Communication and information provision** (EUnetHTA members updates, emails)

- **POP database development** in close cooperation with WP6 LP/ KCE and WP6 Co-LP/ DIMDI
 - Software development by WP6 Co-LP
 - General project management
 - Needs assessment (online survey in M26-27) for POP database v2
 - Elaboration of ideas
 - POP database v1 evaluation, survey among POP database information providers (“creators”) and analysis
- POP database **moderation and maintenance (MesH term verification, database monitoring)**
- POP database **user and access rights management**
- **Coordination of collaboration** on new high technologies:
 - Active brokering for collaboration on **oncological drugs**: managing and performing 6 joint assessments
- **Other tasks:**
 - Participation in **7 face-to-face meetings**, **4 POP database development e-meetings** and **6 WP1/ Executive Committee e-meetings** and **2 WP6 Task Force e-meetings** (M25-36)
 - Organization and hosting of the **4th WP7 face-to-face meeting** in May 10-11 in Vienna (M29)
 - **Data preparation and MeSH terms assignment** to NICE and NETSCC projects entered into the POP Database
 - Preparing a **presentation** for the **HTAi Conference in Bilbao**, June 24, 2012 (M30)
 - Writing the **final technical and financial report** 2010-2012 (M35-M36)
 - Cooperation with CAST-SDU on the **evaluation of the Quarterly Communication Protocols** (M35-36)

WP7 Meetings 2010-2012

External meetings/presentations of EUnetHTA in 2010-2012

Date	Place	Audience	Content of the presentation	Presenting Institution
June 24, 2012	Bilbao, Spain	HTAi	Workshop on EUnetHTA tools	HAS for EVIDENT database and selection criteria ; LBI-HTA for the POP database
June 25, 2012	Bilbao, Spain	HTAi	Poster presentation of selection criteria	HAS
June 25, 2012	Bilbao, Spain	HTAi	Panel “How to best use limited capacity for pragmatic evidence generation internationally”	HAS, NETSCC
June 26, 2012	Bilbao, Spain	HTAi	Poster presentation of collaboration on common segments of an HTA in France and Finland established thanks to the POP database	HAS
June 26, 2012	Bilbao, Spain	HTAi	Panel „EUnetHTA - collaborations on onco drugs”, lessons learnt from	LBI-HTA

			the EUnetHTA collaboration and other European initiatives of HTA production”,	
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EUnetHTA WP face-to-face meetings 2010-2012

WP	Location	Number of meetings	Schedule
WP7	Dublin, Ireland	1	2010-06-10
	Valletta, Malta	1	2011-03-3/4
	Rome, Italy	1	2011-09-29/30
	Vienna, Austria	1	2012-05-10/11

Other EUnetHTA face-to-face meetings**Strand A and Strand B**

Dates	Location	Meeting objective
Oct 12-13, 2010	Brussels, Belgium	Definition of interoperability of EUnetHTA tools (with WP6)
Sep 6, 2011	Paris, France	EVIDENT – POP interoperability meeting (with LP WP6)
Dec 8-9, 2011	Gdansk, Poland	EUnetHTA Conference (HAS: poster presentation “WP7A: EVIDENT database”, LBI-HTA: “WP7B: POP database”)

Strand A

Dates	Location	Meeting objective
April 15, 2010	Paris, France	HAS – NETSCC coordination meeting on the development of the minimal dataset
March 21, 2011	Paris, France	HAS – NETSCC coordination meeting on the development of the minimal dataset
June 17, 2011	Paris, France	ENCEEP – EVIDENT meeting, discussions of possibilities to develop cooperation
Feb 22, 2012	Paris, France	EUnetHTA-EMA meeting; presentation of EVIDENT database proposal, discussion of next steps in developing cooperation.
Nov 20, 2012	Copenhagen, Denmark	EUnetHTA-EMA meeting; presentation of operational EVIDENT database, discussion of next steps in developing cooperation.

Strand B

Dates	Location	Meeting objective
Apr 15-16, 2010	Paris, France	Meeting with WP6, POP database development
Oct 12-13, 2010	Brussels, Belgium	Meeting with WP6, POP database development

Oct 13-14, 2011	Vienna, Austria	Meeting with WP6, POP database development
Aug 23-24, 2012	Cologne, Germany	Meeting with WP6, POP database development

WP7 Stakeholder and external expert involvement

- The involvement of stakeholders in WP7 has been restricted to WP7A, as no rationale of stakeholders participation was identified for WP7B.

Stakeholders have been involved in WP7A in two different ways:

1. Stakeholder advisory groups (SAG) – reviews of the first drafts of WP7A deliverables and outputs
2. Public consultation – on final proposals of WP7A deliverables and outputs

➤ Activities performed:

1. Stakeholder advisory groups (SAG)

Three SAG consultations have been performed:

- Review of the first draft of criteria to select and prioritize new technologies for additional evidence generation before the testing of these criteria
- Review of the draft of the dataset, following completion of the Delphi activity, on prospective data collection in development
- Review of the first draft of relevant items to be included in the EVIDENT database.

2. Public consultation

Two public consultations have been performed:

- Comments on the final version of relevant items to be included in the database for additional evidence generation on new technologies before IT upgrading
- Comments on the final version of the criteria to select and prioritize new technologies

It has been initially considered to perform a public consultation on the dataset also. After completing the Delphi rounds and having received comments from the stakeholder advisory group NETSCC considered that input had reached saturation, and the next important stage was to have an active database. There may be a role for a wider consultation once there is an experience with a database in practice.

Overall, all tasks were performed according to the initial or amended Workplan and in respect of the Standard procedure of Stakeholder involvement.

Received feedback helped improve the deliverables. Great interest has been expressed for the deliverables, especially by industry representatives

WP7 Cooperation with other WPs / LPs

LP and Co-LP are members of the WP1 Coordination and WP8 Strategy and Business Model Development and have contributed to the work according to the WP1/WP8 work plan and decisions made during the WP1/WP8 course of action.

Strand A

Cooperation with Strand B and WP6 “Information Management System” on

- Definition of interoperability of EUnetHTA tools in 2010
- Identifying possibilities for EVIDENT/POP interoperability in 2011.

Strand B

- WP6: the web-based database was jointly developed with WP6, lead KCE and co-lead DIMDI. POP database version 2 development (elaboration, prioritization of needs and development of advanced functionalities/ project management)

- POP database maintenance version 1 (POP database rights management – also in close cooperation with EUnetHTA secretariat/ WP1; POP database moderation and verification of database entries according to MeSH terms assignment).

WP7 Achievement of objectives

Results

a) Strand A

The main objective of WP7A – to facilitate evidence generation on new health technologies - has been achieved through the development of the following “tools”:

1. **a database on additional evidence generation integrating the minimum dataset** that should enable:

- to identify studies being planned or considered elsewhere and that way help reducing the duplication of work
- to contact similar studies' funders either in order to implement a joint funding or in order to standardize the outcomes, contributing to the facilitation of collaboration.

The database is currently open only to EUnetHTA members. It could be of potential interest for study funders, public authorities and other stakeholders.

2. **selection-prioritization criteria** that should help HTA doers, study funders and other stakeholders select, among new technologies, the ones for which complementary studies are really worth performing, and that way enable the best use of limited resources and ensure the transparency of selection making.

The Database on evidence generation on new technologies – EVIDENT database (deliverable #4) has been established and process to use it is available on line, at <https://evident.has-sante.fr/has/login.xhtml>. The database contains information on additional studies requested by European HTA bodies, as well as information on assessment and reimbursement of new technologies.

Only the HTA agencies that can recommend/request/fund additional data collection further to the identification of evidence gaps during HTA could enter information about their recommendations/requests in the database. The database currently stores 14 projects from 5 EUnetHTA partners.

On the other hand, all EUnetHTA partners could enter information on the assessment and reimbursement of technologies for which additional data collection has been requested/recommended. It is expected that every WP7 partner contributes with at least one entry to the system, and reminders are sent on regular basis.

Adherence to the Work Plan

The initial work plan has been adjusted during 2010 and at the beginning of 2011 regarding following points:

- it was decided not to perform a training session on the use of EIFFEL toolkit prototype initially planned for the first WP7 face to face meeting, as major improvements of EIFFEL were considered to be necessary. Instead of a training session, the analysis of the use of EIFFEL and areas of improvement were presented and discussed by WP7 partners.
- instead of two individual surveys, a single survey was performed, aiming to further develop both the database and the selection/prioritization criteria
- no public consultation has been performed for the dataset, as comments received during Delphi rounds and SAG consultation have been considered sufficient.

Overall, all tasks were performed according to the initial or amended Work Plan. Some delays occurred at the end of 2010 due to the departure of one project manager at LP and time needed for staff recruitment. The elaboration of the JA2 proposal in 2011 while performing JA1 activities slightly postponed some actions in the development of selection criteria (testing and public consultation).

It has been also noted that the fact that only few partners had experience on requiring or implementing additional evidence generation within WP7 resulted in:

- different capacity to contribute to the development of the EVIDENT database and later provide input
- more time needed to reach common understanding and agreement.

b) Strand B

By installing the POP Database all **3 objectives** were met:

- To **support information flow** on new medical interventions (between market approval and reimbursement decision).
- To **reduce duplication** on the assessment of new medical interventions **by alerting on parallel activities** (between market approval and reimbursement decision).
- To **facilitate collaboration** on new medical interventions (between market approval and reimbursement decision).

The focus of Strand B has been on new technologies, defined as “after market approval, but before general/broad reimbursement” and their assessment as decision support for reimbursement. Information on ongoing and planned projects/assessments of new pharmaceutical and non-pharmaceutical technologies have been collected, synthesized electronically (in close cooperation with WP6) first in an excel list, later in a web-based-database, called the POP (planned and ongoing projects) database.

The POP database is now routine: information flow on new medical interventions is supported.

Every WP7 partner has contributed with at least one entry to the system. EUnetHTA partners keep their database entries updated, but quarterly reminders are still sent to them.

An alerting system on parallel activities work in routine: collaboration on new medical interventions is facilitated by POP Database.

Partners working on identical or similar projects have been alerted. Coordination of collaboration between those with similar projects has been facilitated (with special focus on non-pharmaceutical technologies and oncological drugs).

Collaborations on new technologies happened: a reduction of duplication took place.

Opportunities for collaboration prompted including analysis of possibilities and hindrances resulting in at least 3 collaborations on new technologies were coordinated. Exchange of information among agencies is increased and duplication of work in the field of HTA in Europe is reduced. The survey about the role of the POP database on reducing the duplication of effort- conducted at the end of JA1 by CAST (Centre for Applied Health Services Research and Technology Assessment, Denmark) - revealed both straightforward reduction of duplication on report-level and partial collaboration with exchange of information. All in all, 23 collaborations were reported, of which 12 were self-initiated by LBA-HTA. A slight reduction of work can be documented.

Table: POP database statistics

	POP workroom using Excel sheets						no POP request performed	POP online database update done by agencies themselves with moderation by WP7 Co-LP				
POP request number	01-2010	02-2010	03-2010	04-2010	01-2011	02-2011	03-2011	04-2011	01-2012	02-2012	03-2012	04-2012
Response rate in %	64,8%	72,2%	75,9%	76,4%	71,4%	71,4%	-	76,8%	78,6%	77,4%	78,2%	70,2%
	(35 out of 54)	(39 out of 54)	(41 out of 54)	(42 out of 55)	(40 out of 56)	(40 out of 56)	-	(43 out of 56)	(44 out of 56)	(41 out of 53)	(43 out of 55)	(40 out of 57)
Total projects	1.022	896	1.070	1.099	1.045	1.154	-	968	1126	1266	1259	1267
Alert topics	28	95	101	129	117	148	-	83	120	150	143	140
Similar projects (within alert topics)	277	312	316	419	376	450	-	219	350	390	394	380
Date of request	Jan 11, 2010	April 29, 2010	Aug 20, 2010	Dec 3, 2010	Feb 10-11, 2011	May 12, 2011	-	Nov 8, 2011	Febr 20, 2012	May 23, 2012	Aug 28, 2012	Nov 26, 2012
Pop list published/results email sent	March, 11, 2010	June 18, 2010	Sept 22, 2010	Jan 17, 2010	March 31, 2010	June 20, 2011	POP db v1 released on Sept 1 2011	Jan 9, 2012	April 2, 2012	July 17, 2012	Oct 22, 2012	
Access to POP workroom/database (JA partners)	34	39	41	42	40	40	-	42	43	42	43	40
number of countries	19	21	22	23	24	24		24	24	24	24	22

Adherence to the Work Plan

Overall, the initial work plan was respected

- Quarterly POP request: 4 performed in M26/M29/M32/M35. Quarterly POP requests to be continued in 2013.
- Quarterly communication protocols: 3 finished in M27/M30/M33, 1 in progress.
- Alerts: quarterly updated POP excel list made available at the EUnetHTA Members Only website in a separate POP workroom. Access to the workroom was given only to those partners who provided information on their planned and ongoing projects. The Excel lists were published in the workroom until M20 (launch of the online database).
- POP maintenance, administration, POP workroom administration
- Coordination and collaboration on new health technologies (M12-M36)

except one (in cooperation with WP6):

- POP database version2 release: was planned for M30-36 (no fix date). Preparation activities and communication with WP6 already started in M26. The development came to a halt due to the change of the EUnetHTA intranet site, which has several immediate implications for the EUnetHTA identity repository (LDAP). The LDAP is also the source of authentication and management for the POP database. Limited human resources at the Co-Lead DIMDI was the other reason for the delay.

LBI-HTA participation in EUnetHTA meetings 2012

1. 7 Face-to-face meetings

- WP4 face-to-face meeting, Vienna/ Austria, March 29-30, 2012 (Stefan Mathis, Claudia Wild, Judit Erdös)
- WP1 face-to-face meeting, Rome/ Italy, April 18-19, 2012 (Marisa Warmuth, Judit Erdös)
- WP7 face-to-face meeting, Vienna/ Austria, May 10-11, 2012 (Marisa Warmuth, Claudia Wild, Judit Erdös)
- Plenary Assembly meeting, Lisbon/ Portugal, May 23-24, 2012 (Claudia Wild)
- WP6 face-to-face meeting, Cologne/ Germany, August 23-24, 2012 (Judit Erdös)
- WP1 face-to-face meeting, Diemen/ Netherlands, October 3-4, 2012 (Claudia Wild, Anna Nachtnebel)
- WP5 face-to-face meeting, Budapest/Hungary, November 22-23, 2012 (Anna Nachtnebel)

2. 12 E-meetings 2012

- WP1 Executive Committee e-meeting, January 25, 2012, 13.00-15.00 (Claudia Wild, Judit Erdös)
- WP1 Executive Committee e-meeting, March 28, 2012, 13.00-15.00 (Claudia Wild, Judit Erdös)
- WP1 Executive Committee e-meeting, June 13, 2012, 13.00-15.00 (Claudia Wild, Judit Erdös)
- WP1 Executive Committee e-meeting, September 12, 2012, 13.00-15.00 (Claudia Wild)
- WP1 Executive Committee e-meeting, November 28, 2012, 13.00-15.00 (Claudia Wild)
- WP1 Executive Committee e-meeting, December 12, 2012, 13.00-15.00 (Claudia Wild)
- WP7B & WP6 POP database development e-meeting, January 27, 2012 (Claudia Wild, Judit Erdös)
- WP7B & WP6 POP database development e-meeting, February 3, 2012 (Judit Erdös)
- WP7B & WP6 POP information providers` survey preparation e-meeting, February 8, 2012 (Judit Erdös)
- WP7B & WP6 POP information providers` survey evaluation e-meeting, March 2, 2012 (Judit Erdös)
- WP6 Task Force e-meeting, April 26, 2012 (Claudia Wild, Judit Erdös)
- WP6 Task Force e-meeting, May 22, 2012 (Judit Erdös)

Recommendations

Strand A

- Each agency should ideally have dedicated staff to ensure regular input in the database.
- Further promote the use of EVIDENT database and consider enlarging its scope and access rights.

Strand B

LBI-HTA has three recommendations:

1. It is recommended that EUnetHTA partners **enter** their new **projects in the database** when they are still **in a planning phase** and not to wait until the projects are ongoing. This would increase the potential for collaboration.
2. It is recommended that EUnetHTA partners **include the search in the POP database** as a –eventually the 1st – step before starting to work on a new project.
3. It is recommended that EUnetHTA partners **increase their willingness to collaborate and engage actively in “active brokering”** activities (call for collaboration) of their new projects.

WP7 Manpower for the execution of activities

Partners and countries involved

	Agency	Country	Role
1.	Haute Autorité de Santé (HAS)	France	Lead Partner
2.	Ludwig Boltzmann Institute for Health Technology Assessment (LBI-HTA)	Austria	Co-Lead Partner
3.	Ministry of Health	Czech Republic	Associated Partners (19)
4.	SDU	Denmark	
5.	THL	Finland	
6.	GYEMSZI	Hungary	
7.	HIQA	Ireland	
8.	AGE.NA.S	Italy	
9.	AIFA		
10.	Regione Veneto		
11.	VASPVT	Lithuania	
12.	SSD/MSOC	Malta	
13.	CVZ	Netherlands	
14.	NOKC	Norway	
15.	AHTAPol	Poland	
16.	INFARMED	Portugal	
17.	SLOVAHTA	Slovak Republic	
18.	ISCIII	Spain	
19.	SBU	Sweden	
20.	NETSCC	United Kingdom	
21.	NICE		
22.	National Centre for Pharmacoeconomics	Ireland	Collaborating Partners (9)
23.	ASSR	Italy	
24.	Agency for Medical Products and Medical Devices	Slovenia	
25.	AETSA	Spain	
26.	AVALIA-t		
27.	OSTEBA		
28.	SNHTA	Switzerland	
29.	KDTD	Turkey	
30.	CMTP	USA	

Persons who participated in the WP

Strand A

Persons participated in WP7 Strand A
S = Responded to survey(s)

R = Reviewer of the first draft(s), participated to testings							
WS = Participated in WP4 meetings or workshops							
PC = responded to public consultation(s) [not mandatory]							
* Employees of the WP LP that contributed also as members of WP coordinating team.							
Name	Agency	Country	S	R	WS	PC [not mandatory]	
Gerda Hinterreiter	LBI-HTA	Austria	2/2	3/3	3/4	-	
Claudia Wild					4/4	-	
Marisa Warmuth					4/4	-	
Erdos Judit			-	-	1/4	-	
Iris Pasternack	THL	Finland			1/4	1/2	
Sirpa Lisa-Hovi			2/2	3/3	3/4	-	
Lajos Kovacs	GYEMSZI	Hungary	-	-	1/4	-	
Zita Daroczy			2/2	2/3	3/4	-	
Martin Flattery	HIQA	Ireland	-	1/3	2/4	-	
Patrick Moran			2/2	2/3	3/4	-	
Marina Cerbo	AGENAS	Italy	1/3*	1/3	3/4	-	
Maria Rosaria Perrini			-	-	1/4	-	
Antonio Migliore			2/3*	2/3	2/4	1/2	
Luisa Muscolo	AIFA		-	-	2/4	-	
Pietro Folino Gallo			1/3*	-	2/4	-	
Paolo Daniele Siviero			-	-	-	1/2	
Alessandro Monaco			-	-	1/4	-	
Agnese Cagnini			2/3*	1/3	2/4	-	
Stefania Lopatriello	Regione Veneto		-	-	1/4	-	
Teresa Gasparetto			2/3*	3/3	3/4	-	
Gintare Pakolkaite	VASPVT	Lithuania	-	-	1/4	-	
Gintare Miksiene			2/2	3/3	2/4	-	

EUnetHTA JA1 – List of Appendices

Juozas Galdikas			-	-	1/4	-
Sylvana Magrin Sammut	Ministry of health	Malta	-	-	1/4	1/2
Renzo Pace Asciak			-	-	2/4	-
Isabelle Zahra Pulis, Bernardette Rossi			1/2	1/3	1/4	-
Alison Anastasi			1/2	1/3	2/4	-
Marka Kuijpers			CVZ	Netherlands	-	-
Sarah Kleijnen	3/3*	3/3			2/4	-
Inger Norderhaug	NOKC	Norway	1/2	2/3	2/4	-
Vigdis Lauvrak			1/2	3/3	3/4	-
Jadwiga Czczot	AHTAPol	Poland	2/2	3/3	2/4	-
Tomasz Garbaty			1/2	1/3	2/4	-
Isaura Vieira	Infarmed	Portugal	2/3*	1/3	4/4	-
Martin Visansky	SLOVAHTA	Slovakia	1/2	-	1/4	-
Andrés Fernandez Ramos	ISC III	Spain	-	1/3	1/4	-
Setefilla Luengo			3/3*	3/3	3/4	-
Susanne Allander	SBU	Sweden	1/3*	1/3	-	-
Sigurd Vitols			-	-	-	1/2
Monica Hultcrantz			-	-	1/4	-
Frida Mowafi			-	-	1/4	-
Måns Rosén			1/3*	-	-	-
Eleanor Guegan	NETSCC	UK	1/3*	1/3	2/4	-
Andrew Cook			2/3*	1/3	3/4	-
Hannah Patrick	NICE		1/3*	-	-	-
Moni Choudhury	-		1/3	1/4	-	
Bhash Naidoo			3/3*	2/3	1/4	-

EUnetHTA JA1 – List of Appendices

Roberta Bartoloni	ASSR	Italy	2/2	1/3	-	-
Ballini Luciana			-	-	-	1/2
Elena Banos Alvarez	AETSA	Spain	-	1/3	-	-
Aurora Llanos Méndez			-	1/3	1/4	1/2
Inaki Ibarluzea	Osteba		-	-	1/4	1/2
Rosa Rico Iturrioz			1/2	-	-	1/2
Leonor Varela Lema	Avalia-T		1/2	1/3	-	-
Beatriz Casal			1/2	-	-	-
Bailat Sylvie	SNHTA	Switzerland	2/3*	2/3	4/4	-
Sean Tunis, Kathleen Blake	CMTP	USA	-	-	-	1/2
Ingrid Rosian-Schikuta	GOEG	Austria				1/2
Johannes Zsifkovits					1/4	
Elisabeth Breyer					2/4	
Patrice Chalon	KCE	Belgium			1/4	
Mirjana Huic	AAZ	Croatia				1/2
Marco Marchetti	A. Gemelli	Italy	-	-	-	1/2
Silvia Gabriela Scintee	SNSPMS	Romania	-	1/3	-	1/2
Eva Turk	NIPH-RS	Slovenia	-	-	1/4	-
Núria Paladio	AIAQS	Spain	-	-	-	1/2

* the first survey concerned only a subgroup of 10 partners, these partners have been invited to complete 3 surveys during JA1, while others have been concerned by 2 surveys

Strand B

<u>Persons participated in WP7 Strand A</u> S = Responded to survey(s) R = Responded to POP requests/Updated the POP database WS = Participated in WP7 meetings or workshops PC = Technical support, database development * Employees of the WP LP that contributed also as members of WP coordinating team.							
Name	Agency	Country	S	R	WS	PC	
Gerda Hinterreiter	LBI-HTA	Austria	x	x	x	x	
Claudia Wild			x		x		
Marisa Warmuth			x	x	x	x	
Erdos Judit			x	x	x	x	
Johannes Zsifkovits			GÖG	x	x	x	
Ingrid Wilbacher			HVB		x		
Petra Schnell-Inderst			UMIT		x		
Patrice Chalon	KCE	Belgium	x	x	x	x	
Mirjana Huic	AAZ	Croatia	x	x			
Jana Zizalova	MoH CZ	Czech Republic		x			
Louise Thiesen	IRF	Denmark		x			
Lene Vistisen	DACEHTA			x			
Karla Douw	CAST-SDU			x			
Hindrik Vondeling				x			
Kristi Liiv	UTA	Estonia		x			
Iris Pasternack	THL	Finland	x	x	x		
Sirpa Lisa-Hovi				x	x		
Pertti Happonen	FIMEA			x			
Irena Guzina	HAS	France	x	x	x		
Sorin Stanel				x	x		
Peter Krämer	DIMDI	Germany	x		x	x	
Swetlana Frei			x	x			
Jürgen Klsostermann	IQWIG			x			
Anna Sypra			x	x			
Zita Daroczy	GYEMSZI	Hungary	x	x	x		
Patrick Moran	HIQA	Ireland	x	x	x		
Cara Usher	NCPE			x			
Antonio Migliore	AGENAS	Italy	x	x	x		
Marina Cerbo			x		x		
Valeria Romano	ARESS			x	x		
Luisa Muscolo	AIFA			x	x		
Agnese Cagnini				x	x		

EUnetHTA JA1 – List of Appendices

Luciana Ballini	ASSR		x	x		
Teresa Gasparetto	Regione Veneto		x	x		
Srefania Lopatriello				x	x	
Angelica Carletto	UH A.Gemelli		x	x		
Marco Marchetti				x		
Beatriz Casal	AVALIA			x		
Paolo Giorgi Rossi	ASP Lazio			x		
Viktorija Baire	VEC	Latvia		x		
Gintarė Mikšienė	VASPV	Lithuania		x	x	
Alison Anastasi	SSD/MSOC	Malta	x	x	x	
Isabelle Zahra Pulis				x	x	
Sarah Kleijnen	CVZ	Netherlands		x	x	
Ingrid Harboe	NOKC	Norway		x		
Vigdis Lauvrak			x	x	x	
Jadwiga Czczot	AHTAPol	Poland		x	x	
Tomasz Garbaty				x	x	
Isaura Vieira	INFARMED	Portugal		x	x	
Martin Visnansky	SLOVAHTA	Slovak Republic		x	x	
Eva Turk	NIPH-RS	Slovenia	x	x	x	
Anne-Marie Yazbeck				x		
Valentina Prelovnik Rupel	IER			x		
Andres Fernandez Ramos	ISCIII	Spain	x	x	x	
Setefilla Luengo				x	x	
Aurora Llanos Méndez	AETSA		x	x		
Leonor Varela Lema	AVALIA-t			x		
Rosa Rico	OSTEBA			x		
Sophie Werköe	SBU	Sweden		x		
Monica Hultcrantz				x	x	
Lisa Landerholm	TLV			x		
Sylvie Bailat	SNHTA	Switzerland		x	x	
Rabia Kahveci	KDTD	Turkey		x		
Eleanor Guegan	NETSCC	United Kingdom		x	x	
Cathryn Hall	NICE			x		
Jennifer Alty				x		

Appendices WP7

1. WP7 Strand A+B meeting minutes, Dublin, 2010
2. WP7 Dublin meeting presentation of Strand B
3. WP7 Strand A+B meeting minutes, Malta, 2011
4. WP7 Malta meeting presentation of Strand B
5. WP7 Strand A+B meeting minutes, Rome, 2011
6. WP7 Rome meeting presentation of Strand B
7. WP7 Strand A+B meeting minutes, Vienna, 2012
8. WP7 Vienna meeting presentation of Strand B
9. Poster on selection/ criteria presented at HTAi 2012 in Bilbao
10. Summary of NETSCC's contribution to EUnetHTA JA1 (2010-12) WP7
11. Poster presentation of EVIDENT for EUnetHTA Conference on December 08-09, 2011 in Gdansk/Poland
12. POP Presentation EUnetHTA HTAi 2012 Bilbao
13. POPdatabase_poster_HTAiconference_Bilbao
14. PopInfoProvider_surveyresults
15. PopInfoProvider_survey results_comparison
16. List of website links to individual joint reports on oncological drugs



Work Package 8 – Strategy and Business Model development
FINAL Technical Report
Joint Action on HTA 2010-2012



WP 8 Objectives

Development of a general strategy and a business model for sustainable European collaboration on HTA.

Construction of a detailed business model for collaboration addressing the sustainability of the HTA collaboration within EU.

WP 8 Outputs

Deliverables

Deliverable (number, title)	Nature	Access	Confidentiality level
D8 Stakeholder Policy	Policy and SOP manual	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); 	Public
D9 Business model for sustainability	Written document, part of the EUnetHTA Strategy	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu document available (printed copy enclosed with the Technical Report and on the EUnetHTA final Technical report CD-ROM); 	Public

Other outputs

Title/Short description	Nature	Access
EUnetHTA Strategy	Written document	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu
HTA training and capacity building	Report	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu
Facilitation of national strategies for continuous development and sustainability of HTA	Report	<ul style="list-style-type: none"> Available via EUnetHTA website: www.eunethta.eu

WP 8 Activities

2010

- Development of the stakeholder involvement policy and SOP
- Implementation of the stakeholder policy, establishment of the EUnetHTA Stakeholder Forum and facilitation of its activities
- Support in managing stakeholder advisory groups (SAGs) formed in WP4,5 and 7.
- International workshop/seminar under the Belgian EU presidency
- Business model development
- HTA training and capacity building line of activities: Survey on use, barriers and training needs of EUnetHTA tools
- Facilitation of the national HTA strategies line of activities: Preparation and execution of the survey on national HTA strategies

Additional activities:

- Preparatory work on organisation of the EUnetHTA Conference 2011 in Gdańsk, Poland, 8-9 December 2011

Details for each of the activity indicated above can be found in the EUnetHTA JA Interim Technical Report 2010.

2011

- Finalising Business model development
- Updating and further developing EUnetHTA Strategy
- Managing stakeholder involvement activities (Stakeholder Forum, SAGs, stakeholder input to the Plenary Assembly meetings)
- Facilitation of the national HTA strategies line of activities
 - M14 – workshop delivery
 - M13-M16 – working on the 1st draft of the ‘Facilitation of the national HTA strategies development document’
 - M14-M16 - regular e-meetings to finalize the document and to prepare Ljubljana meeting
 - M16 - 1st draft of the Facilitation of the national HTA strategies development document ready
 - M16-M18 – preparation of the meeting in Ljubljana (agenda, background materials)
 - M16-M23 – development of the Facilitation of the national HTA strategies development document final version (including process of public consultation of business model)
 - M18 – Ljubljana consensus meeting
 - M23 - final document ready
- Facilitation of the national HTA strategies line of activities
 - Finalisation and delivery of the report on training and capacity building on the EUnetHTA tools
 - Delivery of a training course on the EUnetHTA tools

Additional activities:

- Organisation of the EUnetHTA Conference 2011 in Gdańsk, Poland, 8-9 December 2011

Details for each of the activities indicated above can be found in the EUnetHTA JA Interim Technical Report 2011.

2012

- Finalising development of the EUnetHTA business model and strategy
- Managing stakeholder involvement activities (Stakeholder Forum, SAGs, stakeholder input to the Plenary Assembly meetings)

All deliverables and input that were expected from the HTA training and capacity building and national HTA strategies lines of activities were in place by the end of 2011. No further activities were performed during 2012 in these two activity lines.

WP 8 Meetings 2010-2012

EUnetHTA WP8 and Stakeholder Forum meetings 2010-2012

Time	Location	Participants	Purpose
M4 2010-05-11/12	Warsaw, Poland	WP8 partners	The objective of the meeting was to discuss and agree on proposed thematic areas and target groups and furthermore on specific questions for the planned survey. There were 22 participants from 10 countries.
2010-06-09	Dublin, Ireland	Stakeholder Forum members, Exec Comm and DG SANCO	Stakeholder Forum face-to-face meeting; info on the EUnetHTA JA organisation, structure, activities; Stakeholder Forum tasks; evaluation activities within EUnetHTA – input from stakeholders

EUnetHTA JA1 – List of Appendices

2010-09-22	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; review of and comments on the stakeholder involvement policy and SOP, clarification of the 3-year Work Plan
2010-11-24	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; practical implementation of the SAGs, discussion on the efficacy and effectiveness; draft plan of SF activities in 2011-2012
2011-02-2/4	Warsaw, Poland	WP8	Discussion of the detailed contents of the national HTA strategies report
2011-03-02	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; update on the SAG activities; JA2 update, EUnetHTA conference in Gdansk; Plenary assembly in London in May; EPF survey on stakeholder activities in HTA agencies
2011-05-03	Brussels, Belgium	Stakeholder Forum members, Exec Comm and DG SANCO	Annual Stakeholder Forum face-to-face meeting; EUnetHTA JA work-in-progress update; general discussion on the experience with the stakeholder involvement in JA1, stakeholder involvement in the context of the CBHC Directive Article 15; EUnetHTA business model discussion; JA2 and training for the stakeholders in JA2
2011-06-08	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; Plenary Assembly meeting update; update on pilots in JA1 WP4 and 5; stakeholder access to the JA1 deliverables; JA WP3 survey of the stakeholders
2011-06-16/17	Ljubljana, Slovenia	WP8	Finalising the HTA strategies report and training needs report
2011-09-20	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; update on Gdansk conference preparations; Business model discussion, JA2 update, status of implementation of Article 15 of the CBHC Directive; EUnetHTA on LinkedIn
2011-11-21	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; Strategy document discussion, final Gdansk conference preparations;
2011-10-27/28	Madrid, Spain	EUnetHTA members	Course on the EUnetHTA tools
2012-02-02	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; Gdansk conference follow-up, Plenary assembly in Lisbon in May, update on Article 15 implementation; pilots on early dialogue; EUnetHTA in the IMI projects, EUPATI project; Updates from the JA WPs; EUnetHTA at HTAi in Bilbao in June; information on the new website development
2012-05-03	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; updates on the WP and SAG activities; Article 15 implementation update, Plenary Assembly final preparation – input from and participation of the SF representatives, bilateral contacts with the individual SF members (EFPIA and EPF), stakeholder input to the EUnetHTA newsletter
2012-09-03	Venice, Italy	Stakeholder Forum members, Exec Comm and DG SANCO	Annual Stakeholder Forum face-to-face meeting; update on developments in the JA1; EUnetHTA JA2 update incl. stakeholder expectations, CBHC directive Article 15 implementation update
2012-11-12	e-meeting	Stakeholder Forum members, Exec Comm and DG SANCO	Regular Stakeholder Forum e-meeting; SF input to the upcoming Exec Comm meeting in Diemen in October 2012; JA2 Stakeholder Forum – open call for expression of interest; update on the developments in JA2; update on Article 15; new staff members in the EUnetHTA

			secretariat; update on the finalisation of JA1
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WP 8 Stakeholder involvement

The development and management of the stakeholder involvement activities including the development of the stakeholder involvement policy, SOP, management stakeholder involvement in the Stakeholder Forum and in specific activities of the WPs through Stakeholder Advisory Groups (SAGs) was assigned to WP8, with the Executive Committee and WP1 (coordination) effectively performing these tasks during the Joint Action (please see section “Stakeholder involvement” section of WP1 technical report for explanation on the division of work between WP1 and WP8). As a part of the stakeholder involvement activities, nine public consultations in total were performed during the joint action – draft documents developed by WP4, 5, 7 and 8 were subjects to public consultation (please see individual technical reports of the above-mentioned WPs; WP8 held a public consultation on the stakeholder involvement policy and SOP).

The finalisation of the policy as well as the SOP for the involvement of stakeholders, the establishment of the Stakeholder Forum and the specific SAGs took place in 2010 (see WP1 1st Interim Report on details of the process). In the organisational structure of EUnetHTA the Stakeholder Forum was working directly with the EUnetHTA Executive Committee providing input and advice on the overall activities in the EUnetHTA Joint Action (please see the Policy and SOP for the details on the procedures, tasks, etc) The members and participants of the Stakeholder Forum were yearly surveyed about their experience (please see WP3 Evaluation Report for details on the survey results).

The Executive Committee and the Stakeholder Forum met yearly face-to-face (3 meetings in total) and held 10 e-meetings (each 2 hour long) over 3 years of the Joint Action. Summaries of discussions from the meetings are publicly available at www.eunetha.eu

The three SAGs established to provide input to WP4, 5 and 7 were continuously working during 2011 and 2012 commented on draft documents prepared by the WPs (details on involvement are provided in the WP4,5 and 7 technical reports).

WP 8 Cooperation with other WPs / LPs

Close cooperation with WP1 and EUnetHTA Executive Committee on the strategy and business model development. Close cooperation with CVZ, Netherlands (WP5 Lead Partner) in preparation of the EUnetHTA Conference in Gdansk in December 2012.

WP 8 Achievement of objectives

Results and Recommendations

EUnetHTA strategy and business model

Common interests and policies in relation to HTA have been explored and developed at the strategic level in the European Union for more than ten years. EUnetHTA (European network for HTA) has been a major platform for supporting this process, since its inception in 2006. Operating currently through Joint Action 1 (2010-12) and entering Joint Action 2 (2012-15), EUnetHTA continues collaborative production of HTA information between partner organisations and developing tools for such. The “EUnetHTA Strategy 2012 and Beyond” looks at the strategic positioning of EUnetHTA in the current and near future activities (5-7 years) in relation to HTA at the national and European level. It lays out EUnetHTA’s vision, mission, values, objectives supported by corresponding strategies.

The EUnetHTA business model document, prepared by the EUnetHTA Secretariat and further developed within the EUnetHTA Executive Committee and approved by the EUnetHTA Plenary Assembly (as a part of the EUnetHTA Strategy), describes a potential business model for EUnetHTA after JA2 with a view of being updated and detailed further during the different phases of the EUnetHTA development (Joint Action 2 and post-Joint Action 2). Unanimous endorsement of the strategy at the Plenary Assembly meeting in Lisbon on May 2012 is a manifestation of an achievement of the WP8 objectives (indicator for success was set at 70% of the partners expressing support).

The EUnetHTA strategy and business model have been developed on the basis of many years of empirical European cross-border collaboration on HTA and piloting of the working processes for HTA information production and sharing. It is therefore a key source of specific solutions and approaches for implementation of the permanent European network for HTA as a part of the CBHC Directive (Article 15).

Stakeholder Involvement

The EUnetHTA Joint Action was the first in developing concrete approaches and practices of stakeholder involvement in a European initiative of such proportions and nature in the EU Health Programme (joint action between the European Commission and the Member States in putting into practice a sustainable HTA collaboration in Europe). The development process itself as well as the concrete involvement practices employed during the EUnetHTA joint action proved to be very valuable (as assessed both by the HTA organisations and the participating stakeholder organisations) although the development and implementation process was at times time/resource-consuming. It provided an opportunity to test in practice various approaches to stakeholder involvement – the lessons learned gave a chance to improve the practice

further, eg extended membership in the Stakeholder Forum, identification of new approaches to involve stakeholders in pilots (through expert workshops), building up trust and establishing working relationships bilaterally with various stakeholder group representative organisations (eg, EFPIA, EPF, etc). It also gave an insight into the resource needs to manage the process professionally and into the specific needs, limitations and competences available on the part of the stakeholders to effectively provide input to the HTA processes.

The stakeholder involvement practice being developed in the EUnetHTA Joint Action 2 look now into the practical approaches of further engagement with the stakeholders in specific pilots on producing core HTA information. That means being able to effectively engage with the technology sponsors. The trust and working relationships built through the functioning of the Stakeholder Forum might prove helpful in establishing contacts and appropriate working relationship with the technology sponsors.

EUnetHTA training in HTA and facilitation of the national HTA strategies

The proposed business model for sustainable cooperation on HTA in Europe is a network business model where key partners are MS-nominated HTA organisations. An essential part of building a sustainable business model and ensuring its viability is to recognize and understand the differences between partners in the network, and the impact of those differences on the partners' behaviour and expectations towards the network. Overall the network is a combination of rather similar and equal organisations, in terms of function and nomination. These parameters are considered to be differentiating:

- Focus on HTA only or HTA as a part of wider activities
- Very well established or newly established
- National – Regional
- Tax – Insurance based system
- Remit: evaluation of certain technologies only

The above parameters are important factors in searching for effective approaches to training and capacity building activities offered in EUnetHTA as well as in offering recommendations in overcoming barriers in performing HTA activities and/or establishing HTA activities in national/regional context.

Recommendations provided in the reports on the HTA training and capacity building and on facilitation of the national HTA strategies include approaches which implementation would allow effectively manage the differences between partners and benefit from them.

WP 8 Manpower for the execution of activities

Partners and countries involved

Associated Partners:

14. DHMA (former NBoH), Denmark
15. AGENAS, Italy
16. AHTAPol, Poland
17. CVZ, Netherlands
18. DIMDI, Germany
19. HAS, France
20. IPH-RS, Slovenia
21. ISCIII, Spain
22. KCE, Belgium
23. LBI, Austria
24. NETSCC, UK
25. SBU, Sweden
26. THL, Finland

WP8 Special lines of Activity

Partners listed under a-l are only involved in the line of WP8 activities associated with the development of the following business model component “facilitation of national strategies for continuous development and sustainability of HTA and HTA training and capacity building”

- m. Agency for Quality and Accreditation in Health Care, Croatia
- n. AIFA, Italy
- o. GÖG, Austria
- p. MoH, Czech Republic
- q. MoH, Spain
- r. NOKC, Norway
- s. NSPH, Greece

- t. *Regione del Veneto, Italy*
- u. *SDU, Denmark*
- v. *SSD/MSOC, Malta*
- w. *UTA, Estonia*
- x. *VASPV, Lithuania*

Collaborating Partners

- 9. ASSR, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna, Italy
- 10. Laziosanità (Agenzia di Sanità Pubblica, Regione Lazio, Italy)
- 11. University Hospital "A.Gemelli", Italy
- 12. Quality unit, Ministry of Health of Serbia
- 13. CAHTAR, Spain
- 14. UETS, Spain
- 15. SNHTA, Switzerland
- 16. KDTD Turkish Evidence-Based Medicine Association, Turkey

Persons who participated in the WP

The persons listed below are from the Associated Partner organisations only.

Persons participated in WP1 M = meeting participation TR = technical/financial report production TF/RI – task force and regular input to activities between the meetings * Employees of the WP LP that contributed also as members of WP coordinating team.					
Name	Agency	Country	M	TR	TF/RI
Marina Cerbo	AGENAS	Italy	X	X	x
Nicola Vicari	AGENAS	Italy	X	X	x
Mirella Corio	AGENAS	Italy	X	X	x
Alexandra LoScalzo	AGENAS	Italy	X	X	x
Iga Lipska	AHTAPol	Poland	X	X	X
Anna Zawada	AHTAPol	Poland	X	X	X
Ewa Kiersztyn	AHTAPol	Poland	X	X	X
Tomasz Garbaty	AHTAPol	Poland		X	
Aleksandra Pajor	AHTAPol	Poland	X	X	X
Marta Durczak	AHTAPol	Poland	X	X	X
Krzysztof Orłowski	AHTAPol	Poland	X	X	X
Marta Stasiak	AHTAPol	Poland	X	X	X
Karolina Szewczyk	AHTAPol	Poland	X	X	X
Anna Czerwieniec	AHTAPol	Poland	X	X	X
Adriana Zawiślak	AHTAPol	Poland	X	X	X
Iwona Myszk	AHTAPol	Poland	X	X	X
Genowefa Ewa Szatkowska	AHTAPol	Poland	X	X	X
Anna Panasiuk	AHTAPol	Poland	X	X	X
Wim Goettsch	CVZ	Netherlands	X	X	X
Sarah Kleijnen	CVZ	Netherlands	X	X	X
Albert Boer	CVZ	Netherlands	X		
Dietrich Kaiser	DIMDI	Germany	X	X	X
Francois Meyer	HAS	France	X	X	X

EUnetHTA JA1 – List of Appendices

Mira Pavlovic	HAS	France	X	X	X
Sun-Hae Lee Robin	HAS	France	X	X	X
Irena Guzina	HAS	France	X	X	X
Stéphanie Bankoussou	HAS	France		X	
Christine Mayol	HAS	France		X	
Setefilla Luengo	ISCI	Spain	X	X	X
Raf Mertens	KCE	Belgium	X	X	X
Patrice Chalon	KCE	Belgium	X	X	X
Claudia Wild	LBI-HTA	Austria	X	X	X
Gerda Hinterreiter	LBI-HTA	Austria	X	X	X
Judit Erdös	LBI-HTA	Austria	X	X	X
Marisa Warmuth	LBI-HTA	Austria	X	X	X
Eleanor Guegan	NETSCC	UK	X	X	X
Andrew Cook	NETSCC	UK	X	X	X
Eva Turk	MIPH-RS	Slovenia	X	X	X
Susanna Allgurin	SBU	Sweden	X	X	X
Måns Rosen	SBU	Sweden	X	X	X
Sigurd Vitols	SBU	Sweden	X	X	X
Sophie Werkö	SBU	Sweden	X	X	X
Kristian Lampe	THL	Finland	X	X	X
Marjukka Mäkelä	THL	Finland	X	X	X
Iris Pasternack	THL	Finland	X	X	X
Luisa Muscolo	AIFA	Italy	X	X	X
Pietro Folino Gallo	AIFA	Italy	X	X	X
Simona Montilla	AIFA	Italy	X	X	X
Agnese Cangini	AIFA	Italy	X	X	X
Ingrid Rosian-Schikuta	GÖG	Austria	X	X	X
Elisabeth Breyer	GÖG	Austria	X	X	X
Isabel Peña-Rey	MoH	Spain	X	X	X
Hege Kornør	NOKC	Norway	X	X	X
Eleftheria Karampli	NSPH	Greece	X	X	X
Elpis Pavi	NSPH	Greece	X	X	X
John Kyriopoulos	NSPH	Greece	X	X	X
Nikolaos Maniadakis	NSPH	Greece	X	X	X
Sabrina Medici	Regione Veneto	Italy	X	X	X
Teresa Gasparetto	Regione Veneto	Italy	X	X	X
Chiara Filippi	Regione Veneto	Italy	X	X	X
Hindrik Vondeling	SDU	Denmark	X	X	X
Renzo Pace Asciak	SSD/MSOC	Malta	X	X	X
Alison Anastasi	SSD/MSOC	Malta	X	X	X

Raul Kiivet	UTA Tartu	Estonia	X	X	X
Neringa Kuliesiute	VASPVT	Lithuania	X	X	X

Appendices WP8

1. SF-Executive Committee ftf meeting summary, June 2010, Dublin, Ireland
2. SF-Executive Committee ftf meeting summary, May 2011, Brussels, Belgium
3. SF-Executive Committee ftf meeting summary, September 2012, Venice, Italy

List of Final Report Appendices

WP1

1. WP1/Exec Comm f-t-f meeting summary, April 18-19, 2012, Rome, Italy
2. EUnetHTA Plenary Assembly meeting summary, May 24-25, 2012, Lisbon, Portugal
3. WP1/Exec Comm f-t-f meeting summary, October 3-4, 2012, Diemen, Netherlands
4. EUnetHTA-EMA f-t-f meeting summary, February 11, 2010, London, UK
5. EUnetHTA-EMA f-t-f meeting summary, June 3, 2010, London, UK
6. EUnetHTA-EMA f-t-f meeting summary, March 7, 2011, Diemen, Netherlands
7. EUnetHTA-EMA f-t-f meeting summary, February 22, 2012, Paris, France
8. EUnetHTA-EMA f-t-f meeting summary, November 20, 2012, Copenhagen, Denmark

WP2

1. WP2 e-meeting summary, June 11, 2012.
2. EUnetHTA Conference Banner -300x600
3. LinkedIn-proposal__20110810

WP3

No appendices

WP4

1. Minutes of WP4 meeting in March 2010
2. Minutes of WP4 meeting in November 2010
3. Minutes of WP4 meeting In April 2011
4. Minutes of WP4 meeting in September 2011
5. Minutes of WP4 meeting in March 2012
6. Minutes of WP4 meeting in June 2012
7. HTA Core Model Online Tool and Service basic features
8. Policy for HTA Core Model and core HTA information
9. HTA Core Model for Screening Technologies
10. WP4 working groups
11. Core HTA on AAA freely available at **www.corehta.info** (select browse - collections). Off-line version available for limited distribution (electronic copy).
12. Core HTA on PTBCR freely available at **www.corehta.info** (select browse - collections). Off-line version available for limited distribution (electronic copy).

WP5

No appendices

WP6

28. WP6_Communication_ 2010 HTAi Conference KM concept
29. WP6_Communication_ 2010 HTAi Conference Standards
30. WP6_Communication_ 2010 HTAi Conference workshop
31. WP6_Communication_ 2011 EUnetHTA Conference

32. WP6_Communication_ 2012 HTAi Conference POP database dev
33. WP6_Communication_ 2012 HTAi Conference workshop
34. WP6_Communication_ 2012 HTAi Conference_nominated
35. WP6_Communication_ 2012 INAHTA annual meeting
36. WP6 meeting 2010 Paris minutes
37. WP6 meeting Brussels 2010 – minutes
38. WP6 meeting Koeln minutes
39. WP6 meeting Vienna 2011 – minutes
40. EUnetHTA Workrooms_user manual
41. EUnetHTA_MOsite_admin manual
42. WP6_Webcast_ EUnetHTA Contact db edit profile (audio file; available electronically only)
43. WP6_Webcast_ EUnetHTA ID renewal (audio file; available electronically only)
44. WP6_Webcast_ EUnetHTA ID renewal_2011 (audio file; available electronically only)
45. WP6_Webcast_ EUnetHTA MOlibrary Updating document (audio file; available electronically only)
46. WP6_Webcast_ EUnetHTA work rooms_create news (audio file; available electronically only)
47. WP6_Webcast_ EUnetHTA_POP_db_browse (audio file; available electronically only)
48. WP6_Webcast_ EUnetHTA_POP_db_collab (audio file; available electronically only)
49. WP6_Webcast_ EUnetHTA_POP_db_public_pages (audio file; available electronically only)
50. WP6_Webcast_ EUnetHTA_POP_db_quicklinks (audio file; available electronically only)
51. WP6_Webcast_ EUnetHTA_POP_db_search (audio file; available electronically only)
52. WP6_Webcast_ EUnetHTA_POP_db_search_and_browse (audio file; available electronically only)
53. WP6_Webcast_ saba_centra_basic (audio file; available electronically only)
54. WP6_Webcast_ toolbar_201006 (audio file; available electronically only)

WP7

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