Annex I

Description of the action [Technical Annex]

Joint Action on HTA
Technical Annex

Proposal Title:	European network for HTA Joint Action
Acronym:	EUnetHTA JA
Duration:	36 months
Priority Area:	Generate and disseminate health information and knowledge
Action:	Exchange knowledge and best practice
Sub-action:	Building on the expertise already developed in the field of health technology assessment, ensure the continuation and development of Health Technology Assessment (HTA) in the EU, including work on relative effectiveness (RE) of drugs.

1. Executive Summary

The overarching objective of the Joint Action (JA) on Health Technology Assessment (HTA) 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. The JA will bring together 33 HTA agencies and institutional producers of HTA and assessments of pharmaceuticals in 23 EU and 1 EEA/EFTA country. The JA facilitates solutions to overcome barriers to collaboration and facilitates national solutions to deliver context specific reporting of HTA results.

HTA is a tool to improve quality and efficiency of public health and healthcare interventions and policies. Developing and increasing the efficiency of HTA across Europe addresses issues of strategic importance identified in the 2nd Health Programme. The need for closer collaboration in HTA has been identified by European HTA doers themselves and by the EU, whose member states (MS) have recognized that a sustainable Network for HTA is an urgent need.

This JA is a response to the request by EU Commission and MS in the work plan 2009 of the Health Programme to continue fostering the development of HTA in Europe. The JA brings into life the commitments made by governments by appointing national HTA bodies to participate.

The JA builds upon the methods and tools developed by the EUnetHTA Project. The JA's strategy to evolve cooperation according to current needs consists of three interrelated streams of activities.1. Construction of a detailed business model for collaboration addressing the sustainability of the HTA collaboration in Europe 2. Methodological developments to heighten the efficiency and transparency of HTA processes in Europe. 3. Applying those tools in European trans-national collaboration and at the national, regional and/or local levels. Through the constant interaction between the three streams the JA is able to be responsive to the evolving needs of HTA doers and users in health systems across Europe.

In stream 1 a separate work package will develop a detailed business model for sustainable collaboration. The deepening European collaboration in HTA will influence recommendations for facilitating country specific strategic plans on the establishment and continuous improvement of HTA.

In stream 2 the EUnetHTA Core Model will be expanded to cover screening technologies. An online tool will be developed to facilitate the use of the model, as well as policies and processes for producing, publishing and utilizing of information produced with the Model. In addition, methodological guidance on relative effectiveness assessment (REA) of pharmaceuticals will be produced and incorporated into the Core Model. The JA will develop a European HTA information management system (IMS) allowing single point of access to compatible EUnetHTA tools and allowing storage and exchange of information on planned and ongoing HTAs on new technologies, on additional evidence generation processes and on concluded assessments and their related policy decisions.

In stream 3 the Core Model will be applied to produce at least two collaborative HTAs and the methodological guidance on REA will be tested on a set of pharmaceuticals. The IMS will be used to coordinate at least three collaborative HTAs of new/emerging technologies identified as relevant at the European level.

The JA acknowledges the importance of communicating with stakeholders and of exchange of information with EMEA and the DG Enterprise Working Group on Clinical Investigation and Evaluation.

By the end of the JA, it is possible to ascertain in which areas and to which extent EU wide collaboration works best and consolidate permanent collaboration in these areas. Ad hoc groups of agencies – including newly created ones – produce Core HTAs and coordinate evidence generation while reducing duplication of work and increasing HTA responsiveness to decision-makers' needs.

2. Technical aspects of the project

2.1. Problem analysis including evidence base (Problem statement, analysis of the causes and evidence base of the proposed measure(s)

Health Technology Assessment (HTA) (for definition see http://www.eunethta.net/HTA/) aims at responding to decision-makers' information needs. Health care is a national issue, but need for decisions on the introduction, coverage, use or disinvestment of specific health technologies may be raised simultaneously in all EU Member States (MS). The globalised development of health technologies, and e.g. the mechanisms for marketing authorisations and funding or coverage decisions of drugs or devices frequently demand from competent decision-makers to simultaneously deal with the same technologies. As a consequence similar information needs are raised in parallel in MS – e.g. on relative effectiveness (RE) of drugs. In a situation of simultaneous information needs and a multiplicity of HTA agencies, duplication of efforts is frequent, even though the assessment of central aspects of a technology – e.g. safety, efficacy / effectiveness – will draw on the same evidence. While sharing a common aim and a set of principles (multidisciplinary, transparency, systematic, scientific and unbiased approach), the institutionalisation of HTA varies considerably across MS and does not currently take full advantage of the added value of closer collaboration.

The EU funded EUnetHTA Project (involving the majority of the European HTA community, and extending results of previous EU funded projects and international collaborations in HTA) demonstrated that collaboration and information sharing is facilitated when having a shared organisational structure and HTA production tools that add value to existing international collaborations. An exhaustive synthesis of achievements including an analysis of what is done at the global level was reported in scientific articles and technical reporting to the EU (see Kristensen FB, Mäkelä M, Allgurin Neikter S, et al. European Network for Health Technology Assessment, EUnetHTA: Planning, development, and implementation of a sustainable European Network for Health Technology Assessment and Kristensen FB, Lampe K, Chase D, et al. Practical tools and methods for health technology assessment in Europe: The common planning, development, and piloting of structures, methodologies, and tools by the European Network for Health Technology Assessment, EUnetHTA. *Int J Technol Assess Health Care*. 2009;25(Suppl 2) and http://www.eunethta.net/Public/EUnetHTA_Deliverables_project_2006-2008/). Such experience encouraged a group of 25 European HTA agencies to establish a permanent collaborative network and fund basic functioning in 2009. including the development of the JA.

2.2. General objective of the joint action

The overarching objective of the Joint Action (JA) on Health Technology Assessment (HTA) 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.

2.3. Specific Objectives of the joint action

Number	Title	Description
1 **(WP8)** **Connected to deliverables 8 and 9)**	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.
2 **(WP4, 5, 7)** **Deliverables 1, 3**	Development of HTA tools and methods	Develop principles, methodological guidance as well as functional online tools and policies for – producing, publishing, storing and retrieving structured HTA information and Core HTAs (including a new application of the Core HTA Model structure in screening) – improved Relative Effectiveness Assessment (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 – structured exchange and storage of information on evidence generation on new technologies (data requirements following HTA, planned, ongoing, or completed data collection, e.g. registries and clinical trials).
3 **(WP 4, 5, 6, 7)** **Deliverables** **2, 4, 5, 6, 10**	Application and field testing of developed tools and methods	Test and implement – a web-based toolkit for structured exchange and storage of information on evidence generation on new technologies – application of the Core HTA model in common production of at least 2 Core HTAs – a REA of (a group) of pharmaceuticals in line with the core HTA development – real life support of information flow on new technologies prompting those where parallel assessments of same technologies are detected and alerting on opportunities for information sharing and closer collaboration (3 specific collaborations on new technologies coordinated). – 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.

Indicators:

Specific objective 1: Development of a general strategy and a business model for sustainable European collaboration on HTA		
Process indicators	**Output indicators**	**Outcome indicators**
Active participation of the partners in the strategy development and in producing deliverables Target: On-time submission of reports to the Commission and meeting deliverables deadlines.		Developed business model Target: At least 70% of partnership expressed official support of the proposed model

Specific objective 2: Development of HTA tools and methods		
Process indicators	**Output indicators**	**Outcome indicators**
		1. Recommendations on the Assessment of Relative Effectiveness identified and published Target: Publication of the recommendations in an international journal (submitted). 2. Core HTA Model on screening produced in online format Target: Online format of the model available for immediate practical application. 3. Database on evidence generation on new technologies established and process to use it available on line Target: Every WP7 partner has contributed with at least one entry to the system.

Specific objective 3: Application and field testing of developed tools and methods

Process indicators	Output indicators	Outcome indicators
		1. 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. 2. Database on evidence generation on new technologies operational and functioning with data entered (list of technologies and related information) Target: Every WP7 partner has contributed with at least one entry to the system. 3. Alerting system on parallel activities works (Outcome) Target: Opportunities for collaboration prompted including analysis of possibilities and hindrances resulting in at least 3 collaborations on new technologies coordinated. 4. Information management system developed and fully functioning (Process) Target: At least 90% of partners has contributed with at least one entry to the information system.

2.4. Target groups

The primary target groups of the EUnetHTA JA are the producers of HTA and bodies assessing RE in Europe. The JA will support their production processes and help increase their efficiency.

The secondary, more indirect – however central in terms of impact of HTA - target group comprises those who fund, commission or in other ways are users of HTA reports – the policy-makers and decision-makers of governments and payers who use the HTA information in their formulation of policies and decisions. All activities of the JA arise from the premise that its outputs will be used to inform but not mandate the content of national / regional / institutional HTA and appraisal reports. With increasing application of the EUnetHTA tools and services the indirect target groups, the key "consumers" of HTA, will be more exposed to EUnetHTA results, such as Core HTA information which can be used for HTA reporting that informs local policy making.

The tertiary, indirect target group, are the stakeholders (and the general public). Since HTA reporting should be transparent and the reports made public, and especially because EUnetHTA results will be made available to the public the target groups de facto include all stakeholders including patients and citizens in general. They will be exposed to transparent, reliable information. Stakeholder umbrella organisations (i.e. policymakers, patient / consumer organisations, health care professionals, industry, and health related media) will be invited into a forum. Registered stakeholders will be given the opportunity to express their views on any JA products. Where relevant, public consultation will also be employed.

2.5. Methods and means

The JA builds upon the methods and tools developed by the EUnetHTA 2006-08 Project, relevant international collaborations, and previous EU supported HTA projects.

It consists of three interrelated streams of activities. The first is focused on the construction of a detailed business model for collaboration addressing the sustainability of the HTA collaboration in Europe with the best structure chosen among possible structures. A separate work package will be devoted to this stream which will have a special line of activities targeting training in EUnetHTA tools and facilitation of the national HTA strategies development. The second focuses on continuous methodological development of HTA, to enhance its efficiency and transparency in Europe. The third stream pilots the application of the tools in the practice of European cross-national HTA collaboration and at the national, regional and/or local levels. Through the constant interaction between these streams the JA is able to be responsive to the evolving needs of HTA doers and users. The approach allows identifying which areas and to what extent EU wide collaboration works best and how it can be sustained.

In the methodological stream, an online tool will be finalised to facilitate the production and retrieval of shareable HTA information. The Core Model will be expanded to cover screening technologies and to include relative effectiveness of drugs issues. The latter will be identified reviewing the state of the art on REA and taking into account the work by the WG on RE of the Pharmaceutical Forum and the methodological experience of HTA agencies.

The JA implements an European HTA information system which allows a single point of access to and compatibility of EUnetHTA tools. The system also allows the exchange and storage of information on planned and ongoing assessments and data collection on additional evidence generation processes and on concluded reports and their related policy decisions.
In the practical application stream, at least two Core HTAs will be produced jointly by a group of HTA Agencies to test and adjust the Core Model. The generated RE methodological guidance will

be piloted on a set of pharmaceuticals. The database and alert facilities of the information system will used to coordinate at least three collaborative assessments of new technologies. Independence from stakeholders is a paramount principle of HTA and the JA. At the same time, the JA seeks stakeholder views which have an informative, not binding character for the JA. Stakeholders registered in a "Forum" will be asked to provide written opinions on specific JA products. These will be acknowledged and reviewed for implementation The Forum meets periodically according to an agenda agreed with JA, including any issues for which the JA wishes to know the opinion of stakeholders and considering issues raised in written statements.

2.6. Expected outcomes

Based on a collaborative business model for organisational, functional and financial sustainability - that can be implemented as extension of the JA - EUnetHTA will support effective HTA collaboration in Europe that brings added value at the European, national and regional level. It will facilitate the generation of HTAs to inform policy and health care decision making in European countries.

The main outcome of the JA will be the consolidation of the permanent network for HTA in Europe (EUnetHTA) resulting from recognition of its added value. The commitment expressed by the Ministers of Health of 25 European countries (including both MS and States of the EEA / EFTA) to build a permanent collaborative network of HTA agencies will be renewed and reinforced by assuring long-term MS engagement in the EUnetHTA Collaboration together with the Commission. Additionally, countries not yet involved in the network, recognise its advantages and join the Collaboration while expressing their long-term commitment. At the end of the JA, sustainability of the Network is thus achieved provided that a collaborative business model and financial sustainability is implemented.

Exchange of information among agencies is increased and duplication of work in the field of HTA in Europe is reduced. An increasing number of national, regional and local HTA organisations across Europe include the utilisation of the Core Model in their work procedures – i.e. refer to it in their general guidelines or account for it in their specific project plans – and produce HTA information according to the HTA Core Model. HTA information produced by single agencies according to the Core Model is fed into a searchable database and is made available and retrievable for other agencies. Information on new and emerging technologies, on "additional evidence generation" projects as well as on the outcomes – i.e. coverage decisions – of HTAs, including REAs of drugs are made available in a similar way.

In addition, *ad hoc* groups of agencies produce Core HTAs (following the EUnetHTA Core Model and the methodological recommendations on REA of drugs) on technologies relevant for several countries simultaneously. Such Core HTAs summarize the global part of the evidence on central aspects of a technology, such as safety and RE – i.e. provide the systematic overview of context-independent evidence – which is shareable/ common to all assessments. Availability of Core HTAs allows agencies to focus/ redirect resources to the methodologically sound assessment of context-dependent aspects of the specific technology. Thus reduction of duplication of work for some aspects allows implementing the broadness of the HTA approach more frequently which increases the responsiveness of HTA to the needs of decision-makers (i.e. providing information on context-dependent aspects, providing HTA information timely). Parallel activities regarding new and emerging technologies are coordinated and, when feasible, assessments conducted in collaboration.

Finally, while taking advantage of European collaboration new HTA agencies or formalised HTA programmes are established in countries lacking such in 2009, which contributes to improve the quality of healthcare.

2.7. Deliverables

Deliverables identified in the following table shall be submitted within 1 month of the indicated delivery date unless otherwise indicated.

Number	Title	Description	Confidentiality level	Month of delivery
1 WP4	a) An online Tool & Service for producing, publishing, storing and retrieving HTA information. b) HTA Core Model on screening	a) It facilitates the use of the paper-based HTA Core Model developed previously, allowing to produce, publish, store and retrieve Core HTAs and other HTA information not included in Core HTAs. It supports production of local reports using Core HTAs. b) a new application of the HTA Core Model	a) Public for certain areas/EUnetHTA JA partners for all Public areas	a) M36 b) M15
2 WP4	A set of 2 Core HTAs.	Two completely new Core HTAs on topics that are pertinent to several HTA agencies and that can be utilized when producing local HTA reports on the same topics.	Public	M36
3 WP5	A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals.	A common methodology for the relative effectiveness assessment (REA) of pharmaceuticals consisting of a tutorial that describes the fundamental principles of REA and a toolbox that can be used in daily practice for REA in standardized fashion.	Public	M36

Number	Title	Description	Confidentiality level	Month of delivery
4 **WP7**	Operational web-based toolkit including database containing information on evidence generation on new technologies.	Database including information on - questions that deserve additional evidence generation (AEG), - technologies with (conditional approval) requirements for AEG, - planned, ongoing or completed collection of data, e.g. (pragmatic) clinical trials.	Public for certain areas/EUnetHTA JA partners for all Publicareas	M33
5 **WP 7**	Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies.	Protocols containing information on ongoing/planned national assessments of identical and therefore alerted topics, to facilitate the analysis of hindrances and chances of collaboration on specific topics.	scientific community only	M36
6 **WP6**	Information Management System (IMS) and the related documentation, processes and policies.	The IMS provides a single point of access - ensuring compatibility - to resources that help to conduct HTA, with emphasis on automation of the content update processes.	Public /Access rights to certain areas	M33
7 **WP 2**	Communication and Dissemination Plan.	Building on the communication strategy developed during EUnetHTA 2006-08 Project, an elaborated Communication and Dissemination Plan will be written and implemented as part of the JA.	Confidential	M18
8 **WP8**	Stakeholder Policy	Development of a stakeholder involvement policy for implementation through a Stakeholder Forum (i.e. European umbrella organisations of policymakers, patient organisations, health care professionals, industry, health related media)	Public	M10

Number	Title	Description	Confidentiality level	Month of delivery
9 **WP8**	Collaboratively developed business model for sustainability.	Development of a collaborative business model for sustainability	Public	M24
10 **WP5**	A relative effectiveness assessment of a (group of) pharmaceutical(s)	As a part of methodological guidance development and in line with the core-HTA development	Public	M27
11 **WP1, WP3**	Interim and Final Technical and Financial Reports from the Joint Action. WP1, WP3	Including evaluation results.	Public	M12+2 M24+2 M36+2

Overview table showing the distribution and target audience for all project deliverables:

Number	Title	Distribution channel	Target audience
1	An online Tool & Service for producing, publishing, storing and retrieving HTA information. New application of the HTA Core Model on Screening	Electronic media, presentation at conferences, publications in printed media (journals)	HTA producers and users, relevant HTA stakeholder groups
2	A set of 2 Core HTAs.	Electronic media, presentation in the conferences, reports	HTA producers and users (including policy makers)
3	A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals.	Electronic media, presentation at conferences, publications in printed media (journals), report	RE and HTA producers, relevant HTA stakeholder groups
4	Operational web-based toolkit including database containing information on evidence generation on new technologies.	Electronic media, presentation at conferences, publications in printed media (journals)	HTA producers and users
5	Quarterly communication protocol for information flow on ongoing/planned national assessments of same technologies.	Electronic media, reports	HTA producers and users
6	Information Management System (IMS) and the related documentation, processes and policies.	Electronic media, presentation at conferences	HTA producers and users
7	Communication and Dissemination Plan.	Electronic media	EUnetHTA JA partners
8	Stakeholder Policy.	Electronic media	HTA stakeholder groups, EUnetHTA Partners, HTA producers and users in general
9	Collaboratively developed business model for sustainability.	Electronic media, report	MS health policy makers, EUnetHTA Partners, relevant EU-institutions, stakeholder groups

Number	Title	Distribution channel	Target audience
10	A relative effectiveness assessment of a (group of) pharmaceutical(s)	Electronic media, presentation at conferences, publications in printed media (journals), report	RE and HTA producers, relevant HTA stakeholder groups, health policy makers??
11	Interim and Final Technical and Financial Reports from the Joint Action.	Electronic media, presentation at conferences, EU-commission report	MS health policy makers, relevant EU-institutions, HTA stakeholder groups, HTA producers and users in general

3. Policy and context relevance

3.1. Adequacy of the joint action with social, cultural and political context

By way of providing broad scoped scientific information to the public domain HTA contributes positively to peoples' right to be empowered in relation to their health and healthcare. The JA provides channels for stakeholder participation while warranting the independence of HTA. Work emerging from the JA aims to improve and assure quality through use of the best available evidence, common methodological and process standards and good review processes.

3.2. Contribution to the second Health Programme and annual work plan

While building on the expertise already developed in the field of HTA, the JA will ensure the continuation and development of HTA in Europe, including work on relative effectiveness of drugs. HTA contributes to improvements in health by supporting and facilitating quality and efficiency of public health and healthcare policies and interventions. The JA will proactively ensure synergy and avoidance of duplication with 7th Research Framework Programme.

3.3. Pertinence of geographical coverage (in relation to joint action scope)

A total of 33 organisations from 23 EU MS and Norway including HTA agencies, Medicines agencies, Health insurance Boards, Ministries of Health, public health and research institutions participate in the JA on HTA. Regional HTA institutions in countries with regionalised health care (e.g. Spain, Italy) will participate as collaborating partners. Due to global aspects of the scope of the JA the current developments in the area of Comparative Effectiveness in the United States will be monitored and opportunities for exchange of information will be explored.

3.4. Strategic relevance and EU added value and innovation

The JA is a response to an explicit request by EU and member states for a sustainable network for HTA.

The innovative nature of this JA is three-fold and manifest in comparison with previous projects (e.g. ECHTA/ECAHI and EUnetHTA 2006-8). First, creating an implementable collaborative business model for sustainability (including financial viability) of a European network for HTA beyond the current JA time period. Second, the committed participation by governments through appointed HTA bodies, which is a new mechanism. Third, the activities that will provide permanent channels for collaboration and innovative outputs. The JA will support effective collaboration that brings added value at the European, national and regional level and will exchange information and avoid duplication with EMEA in the area of pharmaceuticals and DG Enterprise Working Group on Clinical Investigation and Evaluation in the area of medical devices. Finally strategic relevance is enhanced by the involvement of research institutions and universities to provide scientific excellence and by developing links to important developments in other parts of the world.

4. Management of the project

4.1. Quality of the partnership

The partnership is the strongest possible – it includes all relevant national HTA institutions and bodies from participating EU and EEA/EFTA countries. The involvement as Collaborating Partners

(CP) of agencies from countries with regionalised healthcare systems ensures nearly universal inclusion of HTA institutions in Europe.

The network is capable of developing a collaborative business model for economic sustainability to support collaborative activities. The partnership consists of a combination of links from the previous EUnetHTA Project (2006-2008), the current EUnetHTA Collaboration 2009, and new partners, especially from the new member states and from the field of drug assessment. Where appropriate, universities and research institutions with outstanding experiences in methodological development of HTA and in the production of assessments will be involved in the work as CPs and/or subcontractors. A key mode of involving such institutions will be by way of involving experts from such institutions.

The fact that partners have been appointed by the competent MS Ministries provides a new quality in the sense that commitment to be involved is now on behalf of government.

The network will take advantage of the fact that Partners are appointed by national governments to improve the communication with Member State governments. To facilitate this the Coordinating Secretariat and the Executive Committee will work with a "rolling" group of APs to mirror the Trio-Presidency structure of immediate past, present and ensuing EU Presidency country in order to work closely with Member States and the Council of ministers.

4.2. Management capacity

The Main Partner has an extensive experience in participating (HTA Europe, ECHTA/ECAHI) and managing (EUnetHTA) EU projects in the HTA field. The staff dedicated to the JA on HTA was already responsible for the EUnetHTA project management. Sixteen organisations participated in the EUnetHTA project as Associated Partners (APs) with 8 having been a Lead Partner in the EUnetHTA work packages. A work stream of collaborative development of a business model for sustainability beyond the current JA will be pursued by WP8 and serviced by the Coordinating Secretariat in close conjunction with WP1.

4.3. External and internal risk analysis and contingency planning

1	*Risk*	Change in key personnel in the Main Partner (MP), Lead Partners (LPs) and/or Associated Partners (APs)
	Contingency plan	Early development of and continuous monitoring of changes needed of a 3-year Work Plan to get new staff quickly integrated. Constant communication through WP1 on the progress in the individual WP will keep the personnel updated. The Standard Operating Procedures Manual produced by the Coordinating Secretariat will facilitate the rapid information of new personnel on procedures and details of the project.
2	*Risk*	Delay in reporting by APs
	Contingency plan	Early development of a strategy to require preliminary reporting 30 (or more) days prior to final reporting date. A separate consortium agreement will be developed for signature by all the Associated Partners of the JA to detail the responsibilities and repercussions of not performing according to the agreed-upon division of responsibilities.
3	*Risk*	Financial or management crises in one of the AP organisations
	Contingency plan	Strong central coordination with assistance of WP LPs, good internal communication and distribution of tasks among partner organisations should contain the risk of WPs becoming diverted from focus or timetable. Most partners have participated in several EU projects; many have been partners in the same EU projects and can substitute each other where appropriate and applicable. Most APs are public bodies that would allow for rapid crisis containment/management and access to human resources. WP 3 risk assessment and WP 1 risk management will be applied.

4	*Risk*	Major health emergencies affecting large populations
	Contingency plan	Possibly an early development of an emergency plan by the Executive Committee and constant monitoring of the public health situation for timely response and adjustment of work plans within the project in order to allow priority to immediate public health interventions. Online communication will allow uninterrupted communications even if face-to-face meetings become impossible.
5	*Risk*	Consensus between all JA APs cannot be reached on vital issues
	Contingency plan	Intensive work by the Executive Committee and the MP should be put into clarifying positions, regulatory and policy backgrounds for discrepancies. Consensus that will allow the network to move forward towards its objectives should be pursued while accepting that conditions for national implementation may differ.
6	*Risk*	No sustainability of European network for HTA secured beyond the JA
	Contingency plan	A Work Package is responsible for the development of a collaborative business model serviced by the Coordinating Secretariat. JA APs will work with their government (that nominated them for participation) to implement an agreed business plan while EUnetHTA collaboratively will work with the European Commission and stakeholders for the same goal.

Individual Work Packages Descriptions

WP1

Field in the Application Form	*Type of description, comments on the information to be provided*
Specifications	Title: Coordination
	Lead partner of the work package: National Board of Health of Denmark
	Starting date / Ending date: M1-M36
	Associated partners involved: KCE, DIMDI, ISCIII, THL, HAS, AGENAS, CVZ, AHTAPol, SBU, IPH-RS, NETSCC, LBI-HTA
Description of the work	Main partner (MP) answering to the Plenary Assembly (consisting of Associated Partners (APs)) and being a member of the Executive Committee (EC) (Consisting of Lead Partners (LPs) and 3 elected APs) will act as the contact for the Commission and APs for technical, administrative, financial matters & monitoring. WP LPs will be responsible for activities' coordination in the respective WPs and assist MP with timely reporting and providing any information on request. An SOP manual (with details on management/governance, procedures & forms) and a 3-year Work Plan will be developed and updated as needed. Reports to the Commission will be prepared to ensure rigorous quality assurance of the project. WP1 is responsible for organising 3 yearly Plenary Assembly (PA) and 6 WP1 meetings held in different MS. Representatives of the European Commission (DG SANCO, EAHC, DG RTD) and other relevant EU-bodies (eg, EMEA) will be invited as observers. The PA meeting will decide the JA's working and management plan, provide opportunity for JA participants to meet and strengthen JA dynamics. MP and the LPs in the framework of the Executive Committee will be responsible for potential conflict resolutions between the partners.
Specific objectives	N/A
List of deliverables linked to this work package	Interim and Final Technical and Financial reports from JA (M36)

Milestones produced by this work package	M3 First draft of SOP and 3 year. Work plan circulated M5 SOP and 3-year JA Work Plan approved by the Plenary Assembly M16 1st interim report to the Commission M28 2nd Interim report to the Commission

WP2

Field in the Application Form	*Type of description*, **comments on the information to be provided**
Specifications	*Title:* **Dissemination WP**
	Lead partner of the work package: Institute of Public Health of the Republic of Slovenia (IPH RS) *Co- Lead: Swedish Council on Technology Assessment in Health Care (SBU)*
	Starting date / Ending date: M1-M36
	Associated partners involved: SBU, HVB, NCPHP NBoH, MoH Spain, NSPH
Description of the work	WP2 will provide support in information sharing and dissemination of what is done in WP 4-WP8 with the aim of supporting HTA capacity building and application of EUnetHTA tools and processes in local HTA processes. The content of the dissemination materials will be developed in close collaboration with the Secretariat and WP1. Dissemination plan for the Joint Action will be built around 3-year Work Plans to be developed by each Work Package (to be presented at the first Steering Committee meeting in Ljubljana). Dissemination activities will be supported by a regular electronic EUnetHTA updates to EUnetHTA partnership and public e-news service. The perspective of the HTA users, i.e. those applying the results of HTA, will be a guiding principle in defining the JA's dissemination strategy. Partner organisations will have a defined role in promoting results at both European and national level. The communication strategy will include submission of articles to relevant journals/publications and presentations at international conferences (e.g., HTAi, Forum Gastein, ISPOR, DIA, EUPHA). The external and internal communication during the project and dissemination of the results will be facilitated by the web based information platform. This will make the project's products, progress reports, public EUnetHTA e-News, etc easily accessible via the project's website to the external audiences. The target audience in each individual case will dictate the choice of the nature of the particular communication channels. Liaising with other projects and initiatives, as well as EU bodies eg. EMEA, DG RTD, DG Sanco etc., will be established to avoid duplication of effort, ensure synergy, and exchange information. Toward the end of the project a public EUnetHTA JA event (conference/symposium) is envisioned where the JA results and next steps in further developing a sustainable European network for HTA will be presented and discussed. The event' proceedings will be widely disseminated through the EUnetHTA partners' network by electronic means. The target audience of dissemination activities will be representatives of HTA organisations, Ministries of Health and other health policy bodies (national/regional level), patient organisations, relevant EU bodies and projects, healthcare industry, relevant international organisations working in the field of healthcare policy and public health, and prominent healthcare professional organisations. The wide choice of the target audiences reflect

	the multidisciplinary character of HTA, but also the necessity to have a continuous support of the sustainable activities of the EUnetHTA Collaboration by the affected stakeholder groups. Close collaboration will be ensured with the Information Management System Work Package (WP6). WP2 in collaboration with WP6 will provide information support in developing stakeholder engagement activities. The EU-funding will be acknowledged in all communication materials. In order to foster the usage of EUnetHTA JA results and to inform the wider public of the project itself, WP2 will produce an informational video for distribution through the EUnetHTA website, and possibly though DG Sanco website and YouTube. The video will explain the aims and objectives of EUnetHTA JA and include 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 ca be achieved with the network. Moreover, EUnetHTA JA will develop input for Wikipedia, Medpedia and similar Internet resources.
Specific objectives	NA
List of deliverables linked to this work package	Communication and Dissemination Plan (M18)
Milestones produced by this work package	M2- project launch (making the project known to relevant target groups and stakeholders; website and press release) M3- Promotional leaflet for the project issued and 3-year work plan for EUnetHTA Communication M6 – Adapted public website and workshop/session at HTAi Conference M11 – Educational symposium at the ISPOR European Conference in Prague M22 – Session/workshop at ISPOR or EHFG conferences in Europe M36 – Final report on WP2 to contribute to WP 1 deliverable "Final Report"

WP3

Field in the Application Form	***Type of description*, comments on the information to be provided**
Specifications	*Title:* **Evaluation WP**
	Lead partner of the work package: NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)
	Starting date / Ending date: M1-M36
	Associated partners involved: none
Description of the work	The Evaluation work package includes actions undertaken to verify if the joint action is being implemented as planned, that it achieves its objectives, and that it is vigilant to emerging problems and subsequently corrective in its actions. It will assess the impact of the joint action on key secondary users of HTA information and policy makers. Ongoing responsibilities of project management, communication with the EU commission and monitoring, including progress against milestones, will be carried out by the main partner and Work Package 1. The Evaluation Work package will concentrate on supporting these activities by providing an audit function, overall evaluation, verification and feedback processes . Specifically the evaluation is designed to support the following questions: **Will the JA achieve its specific objectives, and ultimately did it?** **Will the JA achieve its overarching objective, and ultimately did it?** The approach is prospective, i.e. it follows an evaluation plan to be delivered during M1. The lead partner's guiding principles are to: 1. Prospectively support the achievement of objectives by being vigilant and corrective in action. 2. Retrospectively audit success and failure. 3. Generate maximum support for the work packages whilst actively seeking evaluation and monitoring solutions that minimise the burden. 4. Establish requirements and models for a sustainable Evaluation process beyond the JA. There are 3 aspects to successful and valuable evaluation: 1. Measurement processes: Baseline, success criteria, indicators and metrics, to establish on what terms activities are

	assessed. 2. Monitoring and vigilance process: To ensure there is timely and ongoing collection of information and that there is vigilance to emerging issues. 3. Feedback process: A mechanism for feed back from the ongoing evaluation processes to ensure it prospectively supports the achievement of the JA objectives and that there is appropriate corrective action when required.
Specific objectives	N/A
List of deliverables linked to this work package	A number of "internal" deliverables for WP3 are listed below. Only 1 deliverable, **ED2**, is to be put forward for the "specific" deliverables of the Joint Action. ED = Evaluation work package Deliverable

Ref	High Level Deliverable
ED1	Develop an evaluation plan including baseline evaluation, success criteria, indicators, metrics, timings and responsibilities.
ED2	**Document and implement ongoing monitoring, evaluation, feedback, and vigilance processes and systems (to include, interviews with LPs, annual evaluation reports, technical support, information gathering, and metrics).**
ED3	Progress reports issued at regular and key stages.
ED4	Evaluation of project completion for final reporting, including assessment of impact on secondary users of HTA information, and recommendations for the evaluation function for a sustainable EUnetHTA network from 2013.

Milestones produced by this work package

Ref	Milestone Description	Month
EM1	Deliver ED1 an evaluation plan including baseline evaluation, success criteria, indicators, metrics, timings and responsibilities.	M1
EM2	Deliver ED2: Ongoing monitoring and evaluation processes and systems (to include publishing, technical support, information gathering, and metrics).	M6,M12, M18, M24, M30
EM3	Deliver ED3: Progress reports issued at key stages	M7, M13, M19, M25, M31
EM4	Deliver ED4: final evaluation reporting and recommendations for the evaluation function for a sustainable EUnetHTA network from 2013 onwards.	M36

WP4

Field in the Application Form	*Type of description*, **comments on the information to be provided**
Specifications	*Title:* **Core HTA WP**
	Lead partner of the work package: National Institute for Health and Welfare (THL), Finland *Co- Lead: Agenzia Nazionale Per I Servizi Sanitari Regionali (AGE.NA.S)*
	Starting date / Ending date: M1-M36
	Associated partners involved: LBI-HTA, GÔG, KCE, DIMDI, IQWIG, SDU, UTA, ISCIII, HIQA, AGENAS, THL, Regione del Veneto, SSD/MSOC, CVZ, AHTAPol, INFARMED, SBU, HVB, NBoH, IPH-RS, NICE, NOKC
Description of the work	**Context** WP4 aims at creating an easy-to-use online tool and service for producing and utilizing Core HTAs. The system is piloted by producing two concrete Core HTAs. **Objectives** STREAM A WP4 will build an online electronic tool and service that enable easy and effective use of the HTA Core Model. Relevant policies will be defined WP4 will supplement the current HTA Core Model with a new application for screening technologies. WP4 will consider input from WP5 and incorporates suggested changes into the HTA Core Model whenever feasible. WP4 will consider in more detail the adaptation of information contained in Core HTAs into local settings, using the Adaptation Toolkit (EUnetHTA/WP5, 2006-2008) whenever feasible. STREAM B Before starting the real production of Core HTAs Stream B will explore the participants' various ways of setting priorities to jointly agree on a common transparent method to select Core HTA topics Collaborative production models will be proposed and then tested during the production of the two core HTAs. A common method for involving any context-specific stakeholders' representatives will be also decided among participants in the framework of the EUnetHTA Stakeholder Policy, after an analysis of partners' stakeholder involvement practices. Two Core HTAs are produced using the new online Tool by clusters of agencies.

The experience from producing two Core HTAs by multi-national research groups is actively fed back to Stream A.

Organization

Stream A
All members are expected to participate in all tasks of the stream. Two of tasks, i.e. the development of the online tool and service and the development of a new screening application are divided among members.

Stream B
Each member agency of Stream B is expected to contribute in at least one - and preferably only in one - of the Core HTAs produced within the JA and in the preliminary work aimed at analysing and agreeing on topic selection and stakeholder involvement practices.

Tasks

STREAM A

- Development of Online Tool & Service for the HTA Core Model
- Development of policies to guide the utilization of the HTA Core Model and the aforementioned Tool & Service
- Development of a new application of the HTA Core Model on screening technologies
- Collaboration with WP5 to ensure that the methodological developments within relative effectiveness research are incorporated whenever feasible.
- Consideration of the adaptation of information contained in Core HTAs into local settings, using the principles and solutions of the Adaptation Toolkit (EUnetHTA/WP5, 2006-2008)
- Validation of the online Tool and Service and application on screening

STREAM B

- Analysis of HTA topic selection and priority setting processes among WP members
- Analysis of stakeholder involvement policies among WP members
- Consideration of collaborative models for producing Core HTAs
- Production of two Core HTAs
- Validation of the Core HTAs

	Communication plan WP4 members form the primary parties for collaborative work and consultations. Additionally, all other participants of the JA are called to participate in the work through providing feedback, particularly through the validation exercises. Key stakeholders are given a possibility to comment on the plans. The EMEA and DG Enterprise (WG on clinical investigation and evaluation) are recognized as particularly important parties that may share an interest in JA WP4 developments. Training in the use of the online Tool will be provided to the Core HTA producers in the March 2011 workshop. A Handbook for the Online Tool will be produced to allow wider use of the tool beyond the project participants. WP members' expertise and local knowledge will be used to inform national and regional health care actors on the Core HTAs and their main contents. ***Reporting*** A final report will be provided to WP1. Two Core HTAs will be published in the new online Tool & Service. Main results will be published as scientific articles.
Specific objectives	Develop a functional online Tool & service with defined policies for structured HTA information and Core HTAs, including testing with at least two topics.
List of deliverables linked to this work package	D4-1: An online tool and service for producing, publishing, storing and retrieving HTA information. The screening application of the HTA Core Model D4-2: A set of 2 Core HTAs. **Validation of deliverables** The online Tool and Service, the screening application of HTA Core Model, as well as the two Core HTAs are validated for local and European utility. The production of two Core HTAs provides a real-life testing experience of the new tool and service and enables further refinement of the tool and service.
Milestones produced by this work package	M9 Core HTA topics identified. M15 A new application of the HTA Core Model ready (on screening). M15 Start of Core HTA production. M36 Final versions of the online System and relevant processes and policies and final validated versions of the Core HTAs. M36 Final report on WP4 to contribute to WP 1 deliverable "Final Report"

WP5

Field in the Application Form	*Type of description*, **comments on the information to be provided**
Specifications	*Title:* **Relative Effectiveness Assessment (REA) of Pharmaceuticals**
	Lead partner of the work package: College voor Zorgverzekeringen (CVZ), Eekholt 4, Diemen, The Netherlands (LP) *Co- Lead:* Haute Autorité de Santé (HAS) Saint-Denis La Plaine, France (Co-LP)
	Starting date / Ending date: M1-M36
	Associated partners involved: CVZ (Netherlands) LP HAS (France) Co-LP NOKC (Norway) SDU (Denmark) HIQA (Ireland) AIFA (Italy) KCE (Belgium) IQWIG (Germany) GÖG (Austria) HVB (Austria) MoH (CZ) THL (Finland) VEC (Latvia) AHTAPol (Poland) SSD/MSOC (Malta) INFARMED (Portugal) SBU (Sweden) ESKI (Hungary) NICE (UK)
Description of the work	The WP focuses on the methodology for REA while exchanging information with EMEA.

	It is the task of WP5 to scientifically summarize the available methodology on REA and come to a common methodology that will closely relate to what is already happening in daily national and international practice. Therefore, the first phase of the WP will be an inventarisation (review) that should describe the current methodology that is used by the organisations in the member states that are nationally responsible for the assessment of the relative effectiveness, but also methodologies that are currently used in United States, Australia and Canada. The review is used to identify methodological issues related to REA and key points for improvement. Among the issues that should be addressed are: direct and indirect comparisons, generalisabilty/transferability, comparators, judgment criteria, clinical relevant treatment differences. In this phase the WP will also seek the input of academical institutions with specific expertise on these issues. On the basis of these results a REA model will be developed and subsequently adapted based on a pilot test with a number of pharmaceuticals. The medicines will be selected taking into account the work done by the PHARMA Forum (e.g the five molecules included in the work of the RE working group of the Pharma Forum). In the methodological guidance for the REA model, consideration will be given to the conditions under which REA are conducted. The WP suggests amendments to the EUnetHTA Core Model (WP 4) in order to develop an application incorporating REA issues.
Specific objectives	Develop principles and methodological guidance to improve the assessment of RE for pharmaceuticals.
List of deliverables linked to this work package	o A methodological guidance that will be appropriate for the assessment of relative effectiveness of pharmaceuticals. o A relative effectiveness assessment of a (group of) pharmaceutical(s) as a part of methodological guidance development and in line with the core-HTA development
Milestones produced by this work package	1. A review of available methodological tools for the assessment of relative effectiveness (M9); 2. A first concept of a model for relative effectiveness of pharmaceuticals including a methodological guidance (M18); 3. A pilot assessment with a (group of) pharmaceutical(s) using the concept model for the assessment of relative effectiveness (M27 and core HTA development; 4. A final model, adjusted for the results of the pilot, for the methodology of the assessment of relative effectiveness in line with the core HTA development (M36). 5. Final report on WP5 to contribute to WP 1 deliverable "Final Report" (M36)

WP6

Field in the Application Form	*Type of description*, **comments on the information to be provided**
Specifications	*Title:* **Information Management System**
	Lead partner of the work package: KCE, Belgium *Co- Lead:* DIMDI, Germany
	Starting date / Ending date: M1-M36
	Associated partners involved: CVZ (Netherlands) EMKI (Hungary) ESKI (Hungary) GÖG (Austria) HAS (France) HVB (Austria) ISCIII (Spain) LBI-HTA (Austria) NETSCC (UK) NIPH, (Slovenia) SBU (Sweden) THL (Finland)
Description of the work	**Context** EUnetHTA Project took place between 2006 and 2008. A members only website (MO site) was set up to support day to day work of the different work packages. Document or information sharing functionality was used by most partners, but communication functionalities (forum) were little used. The Project resulted in the development of a set of tools aimed at supporting the conduction of HTA studies and the reduction of duplication of effort between partners. The online tools with restricted access were developed by their respective work package, independently of the MO site, with own hosting and authentication system. This structure facilitates tools

development, but can present a barrier to their utilization.
The Project also identified the need of rapid dissemination of information between the members. This need was partly met by tools already existing outside EUnetHTA, but the up-to-dateness and completeness of those tools could be ameliorated.

Objectives

Work package 6 (WP6) of the Joint Action on HTA aims at supporting the share of information, communication and experience. It will provide a single point of access to other WPs' tools, external information sources and training material. The Information Management System will support informed decision making; share of knowhow and knowledge; and development of capacity in countries where HTA is less established

Organization

WP6 Lead Partner (LP) will coordinate the WP during the whole period, provide policies, support and train users and manage the MO site. WP6 co-lead partner (CLP) will manage development, implementation and hosting of WP6 IT tools except for the MO site hosted by WP2 CLP (SBU). WP6 will work in close collaboration with WP3 LP for surveying users; and with WP2 CLP regarding the hosting and web mastering of the MO site. Associated Partners (AP) will serve as point of contact for their country and ensure good communication about the information system and provide feedback; LP from other WPs are APs of WP6.
Four face to face meetings will occur during the period. The first will be dedicated to selection of standards and preparation of the first users' survey. The second will be dedicated to the analysis of survey's result and resulting decisions. The third will prepare the final survey. The fourth meeting will be dedicated to global evaluation of WP6 and to the preparation of recommendations for the final report. All meetings will allow AP to provide direct feedback about the members only site and discuss the functionalities and possible enhancements.

Tasks

Tasks are distributed among the three years of JA. Here's a brief description:

- Provide a new version of the working space allowing groups to share documents and information. A mailing server will be provided to facilitate information exchange between members and archive discussions.
- Collaborate with developers from other WP to select standards for interoperability. This will result in the implementation of a centralized authentication system allowing single sign-on.
- Communicate with developers of external entities to select the best option that allow to enhance the efficiency of information dissemination.
- In close collaboration with WP3 LP, survey users to identify needs for and limits / barriers to information sharing and dissemination. Policies will be established concerning information exchange at EUnetHTA level. Processes will be provided describing the information exchange within EUnetHTA, but also with external entities.

	• Extend the development of the planned and ongoing projects database that was initiated by Project WP2. A document repository will also be set up to store supplemental material to reports provided by partners. A tool allowing to store and share information about policy decision will also be implemented. • Provide training and support for the Information management system and regular communication to ensure user awareness and know-how to use the tool.
Specific objectives	Provide contemporary tools and processes that facilitate the sharing of efforts; support collaborative working, and ensure rapid dissemination of HTA studies results within the EUnetHTA Collaboration.
List of deliverables linked to this work package	Information Management System (IMS) and the related documentation, processes and policies
Milestones produced by this work package	

M1	Starting date
M12	Members only adapted site
M18	Already existing EUnetHTA tools are accessible through the members only site with a single login and password
M24	processes and tools for rapid dissemination of HTA studies
M36	final report on WP6 to contribute to WP1 deliverable "final report"
M36	Ending Date

WP7

Field in the Application Form	***Type of description*, comments on the information to be provided**
Specifications	*Title:* **New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments**
	Lead partner of the work package: Haute Autorité de Santé (HAS) Saint-Denis La Plaine, France (LP) *Co- Lead:* LBI-HTA, Austria (Co-LP)
	Starting date / Ending date: M1-M36
	Associated partners involved: 1. CZ/ Czech Republic - Ministry of Health (Streams A and B) 2. DK/ Denmark - SDU, Centre for Applied Health Services Research and Technology Assessment, University of Southern Denmark (Stream B) 3. ES/ Spain - ISCII, Instituto De Salud Carlos III (Stream B) 4. FI/ Finland - THL, National Institute for Health and Welfare (Streams A and B) 5. HU/ Hungary - EMKI, Institute for Healthcare Quality Improvement and Hospital Engineering (Stream B) 6. IR/ Ireland - HIQA, Health Information and Quality Authority (Streams A and B) 7. IT/ Italy - AGE.NA.S, Agenzia Nazionale per i Servizi Sanitari Regionali (Streams A and B) 8. IT/ Italy – AIFA, Italian Agency for medicines (Stream A) 9. IT/ Italy - Regione Veneto (Streams A and B) 10. LT/ Lithuania - VASPVT, State Health Care Accreditation Agency (Stream A) 11. MA/ Malta - SSD/MSOC, Ministry for Social Policy, Strategy and Sustainability Division (Stream B) 12. NL/ Netherlands - CVZ, Health Care Insurance Board (Stream A) 13. PL/ Poland - AHTAPol, Agency for Health Technology Assessment (Streams A and B) 14. PT/ Portugal - INFARMED, National Authority of Medicines and Health Products (Streams A and B) 15. UK/ United Kingdom - NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre (Stream A) 16. UK/ United Kingdom - NICE, National Institute for Health and Clinical Excellence (Streams A and B) 17. NO/ Norway - NOKC, Norwegian Knowledge Center for the Health Services (Streams A and B)
Description of the work	**Context** Healthcare systems are confronted with a rising number of new technologies, often costly. Decisions around introduction and reimbursement must be made when the impact of these new technologies on health and on the healthcare system is uncertain.

Therefore, decisions about providing access to new technologies (based on HTA reports) may be linked to additional evidence generation requirements through conditional mechanisms. We refer to these mechanisms as *access with evidence generation* (AEG).

The definition of a new technology is challenging, but WP7 will address the timeframe starting with a technology reaching a late development stage or entering use outside an experimental context, and ending once member states have taken decisions on approval for use or reimbursement.

In Europe, HTA reports, decisions about providing access to, and additional data collection can be done in several countries within a short time window. This means that a lot of HTA-Knowledge is produced simultaneously, in different countries. A lot of duplication takes place and collaborations are still poor.

WP7 of EUnetHTA 2006-2008 developed 2 prototypes: 1) a web-based toolkit prototype to shared information on additional evidence generation; 2) information service to make the information gathered on new and emerging technologies available to a wider audience beyond regional or national decision makers. Based on this work, it is the general objective of WP7 to support collaboration on new technologies and to contribute to reduce duplication of work by:

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

Stream A

One simple way for European countries to collaborate on generation of additional evidence on new technologies is to share timely and useful information about additional data requirements, planned or ongoing prospective data collection. Based on EU Member States (MS) experiences (e.g. UK, France) and on the EUnetHTA project prototype (IT specifications defined), an operational web-based toolkit for a structured exchange and storage of information (database) on additional evidence generation on promising technologies will be developed. All EUnetHTA partners will be trained and invited to use the toolkit and they will be regularly informed about the database content.

A common dataset will be defined to provide meaningful and useful information on planned or ongoing prospective data collection. This information can be used to match additional evidence requirements and contribute to the gathering of a coherent and consistent data set between countries. Quantitative and global analysis of results may subsequently be possible.

Criteria to select new technologies for which additional evidence generation will be defined.

Stream B: The focus of Strand B is on new technologies, defined as "after market approval, but before general/broad reimbursement" and their assessment as decision support for reimbursement. WP 7 will collect information on ongoing and planned projects/assessments of new pharmaceutical and non-pharmaceutical technologies, synthesize the information electronically (in close cooperation with WP6) first in a excel list, later in a web-based-database, and will alert those working on identical or similar projects. WP7 will facilitate coordination of collaboration between those with similar topics, with the focus on non-pharmaceutical technologies.

	WP7B will distinguish between "active" partners and "passive" partners. Active Partners will meet and "shape" the WP7B, be involved in the: • Development of electronic database according to needs • Selection of the category system for indexing studies • Development of a checklist for support of collaboration • Support (enforce?) collaboration themselves • Give feedback on LBI-HTA's work In WP7B, passive partners will be ALL EUnetHTA JA partners in the way of sharing the information on ongoing/planned projects and in being alerted on identical/similar projects. • Detailed specifications of IT tools to be developed for presentation at the 1st Steering Committee meeting. • Specifications of developing training capacity in applying EUnetHTA tools and processes (that are developed by WP7B) in everyday HTA practice will be developed for presentation at the 1st Steering Committee meeting. • The EUnetHTA JA will not duplicate, will make use of, and complement existing tools.
Specific objectives	**Development of HTA tools and methods:** • To develop of a web-based toolkit for structured exchange and storage of information on evidence generation on new technologies (Stream A). • To define an agreed dataset to facilitate exchange of information on planned or ongoing prospective data collection including pragmatic trials (Stream A). • To develop criteria to select new technologies for which additional evidence generation is important (Stream A). **Application and field testing of developed tools and methods:** • Test and implementation of a web-based toolkit for structured exchange and storage of information on evidence generation on new technologies. Each partner contributes with information on at least one new health technology (Stream A). • Test and validation of dataset on prospective data collection for 3 health technologies (Stream A). • Test and validation of criteria to select 3 new health technologies for which additional evidence generation is of

	importance (Stream A). • Real life support of information flow on new technologies prompting those where parallel assessments of same technologies are detected and alerting on opportunities for information sharing and closer collaboration (3 specific collaborations on new technologies coordinated). (Stream B)
List of deliverables linked to this work package	**Stream A** • M33 (main deliverable): Operational web-based toolkit including database containing all relevant information on evidence generation on new technologies of common interest to MS (research questions, reimbursement or approval decisions made in MS, planned, on going, available results of data collection, list of technologies for which AEG was required) (Stream A) • M18: Relevant dataset for exchange of useful information on prospective data collection published with examples of health technologies for which information was exchanged using the defined dataset. • M30: Publication of final version of criteria to select new technologies for additional evidence generation **Stream B:** • M2: Checklist for collaborations • M18: Electronic, web-based database on ongoing/planned studies (in cooperation with WP6) • M4, M7, M10, M13, M16, M19, M22, M25, M28, M31, M34: Quarterly communication protocols of information flow on ongoing/planned national assessments of same technologies based on database input, and personal comments of users.
Milestones produced by this work package	**Stream A:** • M1 to M4 review of published selection /prioritisation criteria for new technologies • M1-M12 survey on dataset on prospective data collection • M6: training to use toolkit prototype • M6 to M12 survey and Delphi method to identify a set of selection criteria • M10 to M18 Implementation of an operational web-based toolkit including database (e.g. user reminders, e-mail alerts, common password with the EUnetHTA members-only site in collaboration with WP6, etc.) based on feedback from EUnetHTA partners (on regular basis, by short questionnaires). • M13-M18 test and validation of dataset on prospective data collection for 3 health technologies

	• M 18: Key milestone: Relevant dataset for exchange of useful information on prospective data collection published with examples of health technologies for which information was exchanged using the defined dataset. • M14 survey results on selection criteria (first version) • M14 – M24 testing of selection criteria by WP7 partners to select 3 new health technologies for which additional evidence generation is of importance • M19-M33 upgrading web-based toolkit to integrate dataset on prospective data collection • M26 validation of selection criteria (second version) • M28 integration of selection criteria into the toolkit • M30 key milestone: publication of final version of selection criteria • M33 Operational web-based toolkit with all integrated functions based on feed back from EUnetHTA partners (on regular basis, by short questionnaires) • M36 Final report on WP7 to contribute to WP 1 deliverable "Final Report" **Stream B:** • M2: Draft Checklist for forms of different collaboration possibilities • M4: Determination of Category System (MESH, NLM) for categorizing ongoing/planned projects (discussion on development of the category system during WP6 first FTF meeting, Paris) • M13: Starting the development of the database of ongoing/planned assessments (with WP 6) • M1-M17: Developing a procedure for feeding the database, taking into account policies restrictions and interoperability with existing tools outside EUnetHTA (with WP 6) • M18: Key milestone: Database of ongoing/planned assessment is launched/released (with WP 6) • M1-M36: 12 x quarterly consolidation/ email requests of ongoing, planned assessments • M1-M36: 12 x quarterly update of ongoing, planned assessments list (later: database) • M1-M36: 12 x quarterly alerting on identical/ similar assessments • M1-M36: 11 x quarterly communication protocol + 1 final report/analysis report • M1-M36: 3 x coordination of 3 collaborations (by LBI-HTA, perhaps more by others) • M36: Database of ongoing/planned assessment is routine. From then on all EUnetHTA partners will keep their database information updated by themselves. • M36: Final report on WP7 to contribute to WP 1 deliverable "Final Report"

WP8

Field in the Application Form	*Type of description*, **comments on the information to be provided**
Specifications	*Title:* **Strategy and business model development**
	Lead partner of the work package: National Board of Health of Denmark
	Starting date / Ending date: M1-M36
	Associated partners involved: KCE, DIMDI, ISCIII, THL, HAS, AGENAS, CVZ, AHTAPol, SBU, IPH-RS, NETSCC, LBI-HTA. For the business model component on "facilitation of national strategies for continuous development and sustainability of HTA and HTA training and capacity building" GÖG, MoH Czech Republic, SDU, UTA, MoH Spain, NSPH), AIFA, Regione del Veneto, VASPVT, SSD/MSOC, NOKC (Norway) will be involved.
Description of the work	The business model development will take into account and incorporate the achievements of the EUnetHTA Project (2006-2008) and EUnetHTA Collaboration (that has been established and functioning since the end of the EUnetHTA Project) including the analysis of the already available shared HTA know-how and processes (Kristensen FB, Mäkelä M, Allgurin Neikter S, et al. European network for Health Technology Assessment, EUnetHTA: Planning, development, and implementation of a sustainable European network for Health Technology Assessment. *Int J Technol Assess Health Care*. 2009;25 (Suppl 2). The proposal for the EUnetHTA Collaboration and consequent developments eg, governance and organisational structure (annex Ia), specific "added value" contributions, financing mechanism, will provide a background for further development of the business model. The Stakeholder involvement policy will be developed and implemented as a part of this work. The Executive Committee supported by the Coordinating Secretariat (MP) will lead the business model development and stakeholder policy work to ensure its coherence with the processes and achievements in and across the JA Work Packages. Continuous dialogue with DG SANCO (and other EU institutions when relevant) will be ensured through regular communication (e-mail/telephone/e-meeting/meeting). Construction of a detailed business model for collaboration addressing the sustainability of the HTA collaboration within EU with the best structure chosen among possible structures will include the description of: - already available and shared HTA knowhow, procedures, tools, etc - proposed common/shared HTA processes, practices, methodology development and necessary supporting tools - facilitation in HTA training and capacity building activities connected to the process and tools employed in the collaboration

	- facilitation of national strategies for continuous development and sustainability of HTA - operational and management process - operational definition of stakeholders and process of engagement with them. - long term funding mechanism The WP8 will use public consultation to solicit input into the development of the business model from a wide audience of EUnetHTA JA target groups. WP2 will facilitate communication of the interim and final results of the development work – also through the Trio EU Presidency method of operation. A special line of activities targeting Training in EUnetHTA tools and facilitation of the national HTA strategies development will be coordinated in connection with current and future HTA capacity building initiatives within the yearly Work Programme of DG SANCO and DG RTD. Organisationally, for efficient project management purposes, WP8 activities will be coherently be managed with the WP1 activities.
Specific objectives	Development of a general strategy and a business model for sustainable European collaboration on HTA
List of deliverables linked to this work package	Stakeholder Policy (M10) Collaboratively developed business model for sustainability. (M24)
Milestones produced by this work package	M6 Governance and management structure in place M6 Stakeholder Forum established M13 Workshop on the facilitation of the national HTA strategies development M16 First drafts of the training and facilitation of the national HTA strategies development documents M18 first draft of the Business model ready for public consultation

4.4. TIMETABLE

M	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8
1	X	X	M	X	X	X	X	X
2	X	M	X	X	X	X	M	X
3	M	M	X	X	X	X	X	X
4	X	X	X	X	X	X	X	X
5	M	X	X	X	X	X	X	X
6	X	M	M	X	X	X	M	M
7	X	X	M	X	X	X	M	X
8	X	X	X	X	X	X	X	X
9	X	X	X	M	M	X	X	X
10	X	X	X	X	X	X	M	D
11	X	X	X	X	X	X	X	X
12	X	X	M	X	X	M	X	X
13	X	X	M	X	X	X	X	M
14	X	X	X	X	X	X	M	X
15	X	X	X	M	X	X	X	X
16	M	X	X	X	X	X	X	M
17	X	X	X	X	X	X	X	X
18	X	D	M	X	M	M	X	M
19	X	X	M	X	X	X	X	X
20	X	X	X	X	X	X	X	X
21	X	X	X	X	X	X	X	X
22	X	M	X	X	X	X	X	X
23	X	X	X	X	X	X	X	X
24	X	X	M	X	X	M	X	D
25	X	X	M	X	X	X	X	M
26	M	X	X	X	X	X	M	X
27	X	X	X	X	D/M	X	X	X
28	X	X	X	X	X	X	X	M
29	X	X	X	X	X	X	X	X
30	X	X	M	X	X	X	X	X
31	X	X	M	X	X	X	X	X
32	X	X	X	X	X	X	X	X
33	X	X	X	X	X	D	D	X
34	X	X	X	X	X	X	X	D
35	X	X	X	X	X	X	X	X
36	D	M	D/M	D/M	D/M	M	D/M	M

X - Work package duration (start to final months)
D - Month when deliverable will be produced
M - Month when milestone will be reached

4.5. Collaborating Partners

Austria AU	University of Health Sciences, Medical Informatics and Technology	Uwe Siebert	Public-health@umit.at	Eduard-Wallnoefer-Center 1 A-6060 Hall i. T. Austria
Belgium BE	NIHDI, National Institute for Health and Disability Insurance	Francis Arickx	francis.arickx@riziv.fgov.be	Tervurenlaan 211 1150 Brussels Belgium
Denmark DK	IRF, Institute for Rational Pharmacotherapy	Marianne Møller	mam@dkma.dk	Axel Heides Gade 1 2300 Copenhagen Denmark
Denmark DK	Dept of Health Services Research and HTA, Centre for Public Health, Central Denmark Region	Mette Kjoelby	Mette.kjoelby@stab.rm.dk	Olof Palmes Allé 17 DK-8200 Aarhus N Denmark
Denmark DK	DSI, Danish Institute for Health Services Research	Henrik Hauschildt Juhl	hhj@dsi.dk	Dampfaergevej 27 – 29 2100 Copenhagen Denmark
Spain ES	AETSA, Andalusian HTA Agency	Belen Corbacho Aurora Llanos Sandra Flores	belen.corbacho.ext@juntadeandalucia.es aurora.llanos.ext@juntadeandalucia.es sandra.flores.sspa@juntadeandalucia.es	Edificio Renta Sevilla, 2ª planta. Avda Innovación s/n 41020 Seville Spain
Spain ES	CAHTAR, Catalan Agency for HTA and Research	Montse Moharra	mmoharra@aatrm.catsalut.net	Roc Boronat 81-95 08005 Barcelona Spain
Spain ES	UETS, HTA Unit, Agencia Laín Entralgo	Juan Antonio Blasco	juan.blascoa@salud.madrid.org	GRAN VIA 27 28013 Madrid Spain
Spain ES	AVALIA-t, Galician Agency for HTA	Leonor Varela	leonor.varela.lema@sergas.es	Edificio administrativo San Lázaro s/n 15781 Santiago de Compostela Spain

Spain ES	OSTEBA, Basque Agency for HTA	Jose Asua	jasua-osteba@ej-gv.es	Donostia-San Sebastián 1 E-01010 Vitoria-Gasteiz Spain
Ireland IR	NCPE, National Centre for Pharmacoeconomics	Lesley Tilson	ltilson@stjames.ie	St James's Hospital, James's St, Dublin 8 Ireland
Italy IT	ARESS, Agenzia Regionale per i Servizi Sanitari (Piedmont Health Care Agency)	Dr. Bertetto Oscar	oscar.bertetto@aress.piemonte.it	Corso Palestro 3 10122 Turin Italy
Italy IT	ASSR, Agenzia Sanitaria e Sociale Regionale Regione Emilia Romagna	Roberto Grilli	rgrilli@regione.emilia-romagna.it	Via Aldo Moro 21 40127 Bologna Italy
Italy IT	Laziosanità – Agenzia di Sanità Pubblica, Regine Lazio	Paolo Giorgi Rossi	giorgirossi@asplazio.it	Via di S. Costanza, 53 I 00191 Rome Italy
Italy IT	REGLOM-DGSAN - Regione Lombardia Direzione Generale Sanita	Michele Tringali	michele_tringali@regione.lombardia.it	Via Pola 9/11 20124 Milano Italy
Italy IT	University Hospital "A.Gemelli"	Marco Marchetti	mmarchetti@rm.unicatt.it	Largo Francesco Vito, 1 00168 Rome Italy
Slovenia SI	Agency for Medicinal Products and Medical Devices	Stanislav Primožič	stanislav.primozic@jazmp.si	Ptujska ulica 21 SI - 1000 Ljubljana Slovenia
Sweden SE	TLV, Tandvårds- och läkemedelsförmånsverket / Dental and Pharmaceutical Benefits Agency	Lisa Landerholm	lisa.landerholm@tlv.se	Box 55, 171 11 Solna Sweden

Switzerland CH	SNHTA, Swiss Network for HTA	Christoph Kuenzli	christoph.kuenzli@bag.admin.ch	c/o Swiss Federal Office of Public Health Health and Accident Insurance Medical Technology Unit Schwarzenburgstrasse 165 CH - 3003 Berne Switzerland
Serbia	Quality unit, Ministry of Health of Serbia	Dr Dragana Atanasijevic	dragana.atanasijevic@zdravlje.gov.rs	Dr Subotica 5 11 000 Belgrade Serbia
Turkey	KDTD Turkish Evidence-Based Medicine Association	Dr. Rabia Kahveci	rabiakahveci@gmail.com	Aşağıöveçler 2. Cadde no: 33/3 Öveçler 06460 Ankara Turkey

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EUnetHTA Collaboration Organisational Structure 2009 - 2012
Governance Guiding Principles

0. Conditions for the development of Governance Guiding Principles

The EUnetHTA Collaboration was established in November 2008 by a group of 25 Founding Partner organisations from 13 EU Member States, Norway and Switzerland upon completion of the EUnetHTA project (2006-2008) responding to the need expressed by the EU Member States to establish a sustainable network for health technology assessment. The founding partners formed the EUnetHTA Collaboration to implement the EUnetHTA Collaboration Proposal of June 16, 2008, which was developed during the project and unanimously endorsed.

In December 2008 the DG SANCO of the EU Commission called upon the Member States to consider which public body would be best placed to represent their Member State in the Joint Action on HTA which is part of a DG SANCO Work Plan 2009 and which is aiming at "building on the expertise already developed in the field of HTA, ensuring the continuation and development of HTA in the EU, including work on relative effectiveness of drugs". A Joint Action for HTA preparatory meeting of appointed bodies and ministries of the EU Member States and EEA/EFTA states was held in Brussels on February 20, 2009. This meeting called upon EUnetHTA Collaboration to take a Joint Action process between Member States and the Commission forward, and National Board of Health of Denmark was appointed to be the coordinator.

On February 27, 2009 the formal call for proposals (including for Joint Actions) was issued by the Executive Agency for Health and Consumers.

The aim of these guiding principles is to constitute the self governance of EUnetHTA Collaboration to make structures, rights and duties of the network and its members transparent.

The purpose of the proposed organisational structure is to support and balance

- the functions/Work Packages of the EUnetHTA Collaboration and requirements and rules laid down for the Joint Action on HTA
- strong governance based on shared responsibility and timely and effective decision-making and implementation
- focus on rapid progress and practical orientation allowing cultural and contextual flexibility
- long-term viability, overall value and utility of the EUnetHTA Collaboration activities.

The Governance structures and principles are applied to the functioning of the EUnetHTA Collaboration in :

a) 2009, key activities of which will focus on coordinating the consolidation of the products, processes and the collaboration that has resulted from the EUnetHTA project, some activities extending from the EUnetHTA project work packages and preparation of the application to the Joint Action mechanism;

b) 2010 – 2012, the timeframe of the Joint Action.

1. Aims and Governance Structures of EUnetHTA Collaboration

1.1 EUnetHTA Collaboration Mission

The mission of the EUnetHTA Collaboration is to support effective HTA collaboration in Europe that brings added value at the European, national and regional level

1.2 Aims

Work emerging from the EUnetHTA Collaboration aims to:

- assure quality through use of the best available evidence, common methodological and process standards and good review processes
- promote methodological and scientific independence thus contributing to high integrity of HTA products
- make analyses transparent and facilitate sharing of information
- be responsive to the needs of decision makers for timely, high quality HTAs on important health technologies
- maintain the independent role of each HTA Agency and institution in the production and use of assessments of evidence and conclusions
- promote information about frameworks for national stakeholder engagement in HTA, including with consumers
- be inclusive and share information to ensure that all relevant information is included in HTA
- support advancements both in research and in medical care.

The EUnetHTA Collaboration will recognise and facilitate solutions to overcome barriers caused by language and variations in perceptions of terminology and will facilitate national solutions to deliver context specific reporting in the most appropriate manner.

1.3 EUnetHTA Collaboration – Participants and Governance bodies

EUnetHTA Collaboration activities are carried out by the following participants and supported by governing structures of the network as described below.

1.3.1 Participants

a) **EUnetHTA Collaboration Partners**

- The Founding Partners[1] of the EUnetHTA Collaboration and
- Other publicly funded organisations from the EU Member States, EEA and EFTA countries that produce or contribute to HTA and are nominated by the respective Ministries of Health to participate in the Joint Action

can become EUnetHTA Collaboration Partners. For clarity and transparency, the mandate of each Partner organisation and a link to health policy in its country setting have to be described in detail. The official status of the organisation as being nominated by the Ministry of Health should be confirmed every 3 years.

[1] Organisations that sent to the EUnetHTA Secretariat by November 20 2008 a Declaration of Intent to establish the EUnetHTA Collaboration and that contributed financially to its operation in 2009 shall be deemed to have founded the EUnetHTA Collaboration and as such shall be Founding Partners.

The EUnetHTA Collaboration partner must follow the formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement). The formal requirements and limitations on the participation in the Joint Action are to be observed (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action).

b) **EUnetHTA Collaboration Associates**
Non-for-profit organisations that produce or contribute to HTA and are willing to be actively involved and provide scientific input in the activities of the EUnetHTA Collaboration. The expression of interest will be considered on their experience and competence. The status of the EUnetHTA Collaboration Associate is granted by the Executive Committee and confirmed yearly on the basis of the continuous active input of the organisation to the activities of the EUnetHTA Collaboration.

c) **Lead Partner Organisations:** Partners participate in the activities of the EUnetHTA Collaboration organised into functions/Work Packages (Figure 1). Each function/Work Package is led by one function/Work Package Lead Partner organisation. In exceptional cases approved by the Plenary Assembly, a function/Work Package can have a co-Lead Partner. The organisations interested in leading a function/Work Package have to ensure that their professional resources, competences and qualifications as well as financial resources are sufficient to perform the function/Work Package Lead responsibilities.[2]

The number of functions/Work Packages is subject to changing needs and priorities of the EUnetHTA Collaboration and is suggested by the Executive Committee for the decision by the Plenary Assembly.

1.3.2 Governance bodies

a) **The Plenary Assembly** is comprised of the head of each of the EUnetHTA Collaboration Partner organisations or a person appointed by the head (one representative per Partner organisation). The Chair of the Plenary Assembly is elected by the members of the Plenary Assembly.

b) **The Executive Committee** is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat and elected representatives from three Partner organisations which do not have the function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Leader and the Secretariat Manager) and the Chair of the Plenary Assembly. The Chair of the Executive Committee is appointed by the members of the Executive Committee.

c) **The Secretariat** is comprised of the Secretariat Director, Secretariat Manager and other staff members assisting with the administrative and financial management matters (administrative assistant, financial assistant, financial manager).

d) **Stakeholder Forum** is formed to ensure the transparent engagement with stakeholders and comprised of but not limited to representatives from the European umbrella organisations representing interests of the following stakeholder groups:

1. Policymakers at regional/national/hospital level
2. Patient organisations
3. Healthcare professionals
4. Payers (statutory health insurance)

[2] A process of identification, approval and dismissal of the Lead Partner organisations should be developed.

5. Industry
6. Health related media

The specific composition of the Stakeholder Forum is suggested by the Executive Committee for discussion and approval by the Plenary Assembly. To maintain the effectiveness of the Stakeholder Forum, each stakeholder group should not be represented by more than 4 different European umbrella organisations. The participation in the EUnetHTA Stakeholder Forum is at the invitation of the EUnetHTA Executive Committee. The EUnetHTA Executive Committee develops and applies Stakeholder Forum Membership criteria to identify and invite organisations for participation in the Stakeholder Forum. Each stakeholder organisation holds a position in the Stakeholder Forum for 3 years.

The Plenary Assembly has the final decision-making power regarding issues of the stakeholder involvement in the EUnetHTA Collaboration.

2. Rights and obligations of the EUnetHTA Collaboration participants.

2.1 Rights and obligations of Partners

Each Partner shall actively participate in the EUnetHTA Collaboration activities and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time all of its agreed upon obligations. Partners shall

- promptly notify the function/Work Package Lead Partners and Secretariat of any significant problem and delay likely to affect the progress within the function/Work Package or the success of the EUnetHTA Collaboration and

- inform the Secretariat of relevant communications they receive from third parties in relation to the EUnetHTA Collaboration activities.

A Partner should designate an individual to be an official representative of the organisation who will have a right and obligation to represent an official position of this organisation in any policy- and decision-making process in the EUnetHTA Collaboration eg, at the Plenary Assembly meetings. In case of a Partner being involved in a number of distinct activities of the EUnetHTA Collaboration, a Partner has to indicate the official representative of the organisation for the general EUnetHTA Collaboration activities, and can designate several representatives to be involved in various specific activities of the EUnetHTA Collaboration.

Partners may use the title "EUnetHTA Partner" or "Partner of the European network for Health Technology Assessment (EUnetHTA)" and the official EUnetHTA logo for their websites or for specific correspondence, presentations and the like in relation to EUnetHTA .

Each Partner organisation shall endeavor to be represented at Plenary Assembly meetings, and shall have one voting member at each meeting.

Each Partner organisation shall have full access to the tools and information published within the EUnetHTA Information Management System. The degree of access to specific areas devoted to ongoing work (so-called Workrooms) is governed by the rules developed and agreed by the Executive Committee.

Any Partner may resign at any time (subject to formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement. The formal requirements and limitations on

the participation in the Joint Action are to be observed (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action).

Any Partner may be required to resign by a vote of three-quarters of the Partnership (subject to consideration of the formal legal requirements of the Joint Action on HTA when applicable (including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action). In case a Partner nominated by the Ministry of Health, the Plenary Assembly's request for resignation of the Partner in question will be brought to the attention of the respective Ministry of Health to identify further appropriate procedural steps.

A Partner must follow the formal legal requirements of the Joint Action on HTA when applicable (see Appendix 1 for the description of the responsibilities of the beneficiaries under the Joint Action Grant Agreement) including the rights and responsibilities detailed in the consortium agreement for implementation of the Joint Action.

2.1.1 Acting on behalf of EUnetHTA

Each Partner shall inform the Secretariat of any occasion if their representatives act as a EUnetHTA Partner or on behalf of EUnetHTA (e.g. when giving presentations, writing communications on EUnetHTA) for coordination and documentation purposes.

In cases when a EUnetHTA Partner is invited to participate in various projects or other activities "on behalf of EUnetHTA", its role and responsibility as "EUnetHTA representative" would be limited to

- informing the EUnetHTA Secretariat of such involvements,
- providing information to EUnetHTA (through the EUnetHTA Secretariat) on the developments in the new project that the EUnetHTA Partner considers relevant and important for EUnetHTA,
- providing information about the developments within EUnetHTA

EUnetHTA Collaboration assumes no responsibility for the actions of the EUnetHTA Partners participating in the projects not directly initiated by the EUnetHTA Collaboration.

The EUnetHTA Partner cannot express views and take positions on issues "on behalf of EUnetHTA" unless a clear consent of the EUnetHTA Executive Committee is sought and received by the EUnetHTA Partner in advance.

The views and statements expressed by the EUnetHTA Partner without the prior consent of the EUnetHTA Executive Committee are the sole responsibilities of this EUnetHTA member and do not reflect the views of EUnetHTA. EUnetHTA assumes no responsibility for the contents of such views or statements.

2.2 Rights and obligations of Associates

Each Associate shall actively participate in the EUnetHTA Collaboration activities and undertake all reasonable endeavours to perform and fulfil promptly, actively and on time all of its agreed upon obligations. Associates shall

- promptly notify the function/Work Package Lead Partners and Secretariat of any significant problem and delay likely to affect the progress within the function/Work Package or the success of the EUnetHTA Collaboration and
- inform the Secretariat of relevant communications they receive from third parties in relation to the EUnetHTA Collaboration activities.

An Associate should designate an individual to be an official representative of the organisation who will have a right and obligation to represent an official position of this organisation in general EUnetHTA Collaboration activities. In case of an Associate being involved in a number of distinct activities of the EUnetHTA Collaboration, an Associate has to indicate the official representative of the organisation for the general EUnetHTA Collaboration activities, and can designate several representatives to be involved in various specific activities of the EUnetHTA Collaboration.

Associates may use the title "EUnetHTA Associate" or "Associate of the European network for Health Technology Assessment (EUnetHTA)" and the official EUnetHTA logo for their websites or for specific correspondence, presentations and the like in relation to EUnetHTA.

Any Associate may resign at any time and maybe required to resign by a vote of here-quarters of the Partnership.

Each Associate can participate in the meetings of the Plenary Assembly and be represented by one member of its organisation, but shall have no voting rights.

Each Associate shall have access to the EUnetHTA Information Management System. The degree of access is governed by the rules developed and agreed by the Executive Committee.

2.3 Obligations of the Function/Work Package Lead Partners

Function/Work Package Lead Partners are responsible for the organisation of activities and management of their respective function/Work Package, including provision to the Secretariat of the information on the function/Work Package work plans, their implementation updates and results for inclusion in the annual report, participant organisations' lists and consultation with the Secretariat and other Lead Partners on major function/Work Package implementation issues that have implications for the overall functioning of the network. Any additional responsibilities of the Lead Partners are to be described in detail in the EUnetHTA Collaboration Standard Operating Procedures (SOP) Manual.

Lead Partner organisations are members of the Executive Committee. In cases of co-leadership of a function/Work package, the Lead Partner of the function/Work Package is the full member of the Executive Committee having 1 voting right. The Co-Lead Partner can act as an alternate and is allowed to attend the Executive Committee meetings without having voting rights, except when the "full member" is not present and delegated its voting right to the Co-Lead Partner.

2.3 Functions of the governance bodies[3]

2.3.1 Plenary Assembly

The Plenary Assembly is EUnetHTA's major governing and policy setting body. It is comprised of the head of each of the partner organisations or a person appointed by the head (one representative per organisation).

The Plenary Assembly takes a strategic overview of the work of the EUnetHTA Collaboration including functions such as:

a. approving the composition of the Stakeholder Forum and its chair
b. deciding by majority vote (1 voting right per partner) on strategic matters relevant to the development of the sustainable European network for HTA including changes in governance and organisational structure

[3] See Appendix 2 Organisational Structure Grid

c. deciding on the Functions/Work Packages and their Lead Partners
d. monitoring / supervising the progress of the network and performance of the Executive Committee and the Secretariat
e. elect the non-function/Work Package members of the Executive Committee
f. facilitating the Secretariat and the Executive Committee with the execution of its coordinating tasks
g. approving strategy, work plans, an annual report, budgets
h. advising on future developments
i. admitting new partners / exclusion of partners

Delegates of the European Commission may additionally participate in the Plenary Assembly meetings but have no voting right. Observers can be invited to Plenary Assembly meetings to counsel the Plenary Assembly but have no voting rights.

Decisions are taken by majority vote of Plenary Assembly members, in case of ties, the decision by the Plenary Assembly Chair prevails. Plenary Assembly chair exercise his/her voting rights only in case of ties.

The Plenary Assembly convenes once a year in a face-to-face meeting. Extraordinary meetings can be called subject to recommendation of the Executive Committee or on request from at least 1/3 of the Plenary Assembly members[4]..

The Plenary Assembly shall elect a Chair and a Deputy Chair from among its members by the absolute majority of its members on the basis of individual merits, and not as representatives of their respective organisations for the period of 2 years, not to serve for more than two terms in the same function, commencing the day following the annual Plenary Assembly meeting. Representatives of the Lead and Co-Lead Partner organisations are not eligible to run for the Plenary Assembly Chair/Deputy Chair position.

The Chair of the Plenary Assembly ensures an optimal liaison between the Plenary Assembly and the Executive Committee and is a non-voting member of the Executive Committee. Plenary Assembly Chair oversees that the Executive Committee and the Secretariat actually operate in such a way that the Plenary Assembly's opinion is sought whenever it should be sought and that the Plenary Assembly's decisions are taken into account and implemented by the Executive Committee and Secretariat. S/he has the internal task of motivating partners to participate in general and in the long term and facilitating efforts of seeking funding for the EUnetHTA Collaboration activities.

The procedure for the election of Chair shall be as follows:
The vote for the election of Chair shall be taken by an absolute majority of the Plenary Assembly voting members present and by secret ballot. Several rounds of election take place in case when more than 2 candidates are nominated for the same position and when no candidate receives an absolute majority of votes in the first round of election.

Nominations for Chair shall be submitted either by the candidates themselves or by other members of the Plenary Assembly to the secretariat no later than 3 weeks before the start of the Plenary Assembly meeting at which the election is to take place. The Secretariat shall send the nominations so received to the members of the Plenary Assembly no later than 10 working days before the Plenary Assembly meeting at which the election is to take place. Candidates shall submit a statement in support of their candidature at the time of the nomination.
Two tellers shall be designated amongst the members, observers or the secretariat to assist in the counting of the vote.

[4] considerations to be given to the funds availability to hold extraordinary meetings

An individual may be nominated for both Chair and Deputy Chair. If a nominated candidate is elected Chair, the nomination for Deputy of this individual will automatically become non-eligible. If two or more candidates receive the same number of the majority votes for the same position, the next round of election takes place where the members cast votes only for the candidates that received the equal majority vote in the first round. Rounds will run until one of the remaining candidates receives simple majority of favourable votes of the Plenary Assembly members. In case of two remaining candidates receiving equal amount of votes, the election shall be suspended and the Plenary Assembly shall seek an agreement to enable new nominations and the process shall resume if possible during the same meeting of the Plenary Assembly. In such case, new nominations can be made during the meeting.

The Deputy Chair shall be elected following a procedure identical to that of the Chair.

The Deputy Chair shall automatically take the place of the Chair if he/she is prevented from attending to his/her duties.

2.3.2 Executive Committee

The Executive Committee is the major executive body responsible for coordinating the activities, implementing policy decisions and managing the affairs of the EUnetHTA Collaboration. It is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat and elected representatives from three Partner organisations which do not have the Function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Director and the Secretariat Manager) and the Chair of the Plenary Assembly. The Executive Committee shall not contain more than 2 partners from one country. An organisation-member of the Executive Committee should designate an individual to be an official representative of an organisation on the Executive Committee who will represent an official position of an organisation in any decision-making process of the Executive Committee, and a substitute in cases of unavailability of the official representative.

The electable members of the Executive Committee are elected for the period of 1 year, not to serve for more than 2 consecutive terms in the same function. The function/Work Package Lead Partners serve 3-year terms.

The Executive Committee is responsible for supervising performance and monitoring the EUnetHTA Secretariat.

The Executive Committee is responsible for:

a. appointing the chair of the Executive Committee
b. supervising the Secretariat in implementing the work plan
c. develop strategy for approval by the Plenary Assembly
d. preparing work plans and monitoring outcomes
e. preparing suggestions for the changes in the governance and organisational structure for approval by the Plenary Assembly
f. reviewing the performance of the Collaboration
g. in charge of the information exchange with the Stakeholder Forum and other identified strategic external parties
g. reviewing finances
h. being accountable for the performance of the EUnetHTA Collaboration to the Plenary Assembly.

The representatives from the three Partner organisations which do not have the function/Work Packages lead responsibility and are willing to serve on the Executive Committee are elected by the Plenary Assembly at the Annual Meeting.

The procedure for the election of electable members of the Executive Committee shall be as follows:
The vote for the election Executive Committee member shall be taken by a simple majority of the Plenary Assembly voting members present at an annual meeting and by secret ballot. The election is EUnetHTA Collaboration partner organisation-based, ie each EUnetHTA Collaboration partner organisation has 3 votes to be cast for up to 3 organisations running for elections (1 vote only per 1 running organisation).

The declaration of interest to serve on the Executive Committee shall be submitted by the candidate organisations themselves to the Secretariat no later than 3 weeks before the start of the Plenary Assembly meeting at which the election is to take place. The Secretariat shall send the declarations so received to the members of the Plenary Assembly no later than 10 working days before the Plenary Assembly meeting at which the election is to take place. Candidate organisations shall submit a statement in support of their candidature at the time of the nomination which should present the organisation's ideas for networking, integration and collaboration along the cross-functional (Work Plan based) activities.
Two tellers shall be designated amongst the members, observers or the secretariat to assist in the counting of the vote.

The 3 organisations that receive the highest number of votes will be elected.

If two or more candidate organisations receive the same number of the majority votes, the next round of election takes place where the members cast votes only for the candidate organisations that received the equal majority vote in the first round. In each round, each EUnetHTA Collaboration Partner can cast 1 vote per running organisation (the total number of cast votes per EUnetHTA Collaboration Partner not to exceed the number of positions to be filled). Rounds will run until all the places on the Executive Board are filled.

The Chair of the Executive Committee is appointed by the members of the Executive Committee.

The regular meetings of the Executive Committee are convened monthly by the means of web-based conferencing solutions. There shall be at least one meeting per year with attendance of the members of the Executive Committee in person. The reports from the Executive Committee meetings are made available to the Plenary Assembly members.

Each member of the Executive Committee is authorized to exercise one (1) vote with respect to each matter to be decided upon by the Executive Committee (the Secretariat has one (1) vote (to be cast by the Director of the Secretariat (in case of absence, the Manager will have the vote); the Chair of the Plenary Assembly is a non-voting member of the Executive Committee).

2.3.3 Secretariat

The Secretariat is the executive body acting under the supervision of the Executive Committee and assisting the Executive Committee in implementing the policy decisions. It is comprised of the Secretariat Director, Secretariat Manager and other staff members assisting with the administrative and financial management matters (administrative assistant, financial assistant, financial manager).

The Secretariat supports partners in conducting the routine EUnetHTA management affairs and is responsible for:

a. coordination function

b. communication
c. financial management
d. development of strategy in coordination with the Executive Committee
e. preparation of Work Plan
f. Organising the Plenary Assembly and the Executive Committee meetings

The Secretariat must follow the formal legal requirements of the Joint Action on HTA when applicable.

The work of the Secretariat is led by the Director who works under the supervision of the Executive Committee and is co-responsible together with the Executive Committee for implementing the EUnetHTA Collaboration policy decisions. The Director acts as a facilitator of close coordination between functions/Work Packages with special emphasis on the HTA work content, is given the responsibility to facilitate the promotion of EUnetHTA in relation to a range of "external" entities, organisations and processes, and is expected to act on behalf of EUnetHTA with obligation to report and ensure approval of the Executive Committee on major strategic issues in situations when the Executive Committee cannot be directly involved.

The work of the secretariat is coordinated by the Secretariat Manager who works under the supervision of the Secretariat Director and in close cooperation with the Executive Committee members and EUnetHTA Collaboration partners. The Manager is responsible for managing the day-to-day activities and for operations management of the EUnetHTA Collaboration. The Manager is reporting to the Executive Committee and the Secretariat Director.

2.3.4 Stakeholder Forum

Stakeholder Forum is formed to ensure the transparent engagement with stakeholders and comprised of representatives of the identified stakeholder groups with broad and balanced representation including European umbrella interest organisations. The Stakeholder Forum receives information on Joint Action developments, globally and on every function/Work Package and provides comments on them to the Executive Committee.
A Stakeholder involvement policy is to be developed to support an effective EUnetHTA Collaboration information exchange with the Stakeholder Forum.

3. Governance Guiding Principles and Structure

- The Plenary Assembly is comprised of the head of each of the partner organisations or a person appointed by the head (one representative per organisation). It decides on the overall development of the EUnetHTA Collaboration based on input from the Secretariat and the Executive Committee. The Executive Committee is comprised of the representatives of the function/Work Packages Lead Partner organisations, the Secretariat, elected representatives from three Partner organisations which do not have the function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Director and the Secretariat Manager) and the Chair of the Plenary Assembly. The Executive Committee shall not contain more than 2 partners from one country. The Executive Committee acts on behalf of, and is subordinate to the Plenary Assembly.

- The function/Work Package Lead Partners make decisions in daily network work in their functions/Work Packages.

- The function/Work Package Coordination and the function/Work Package Communication/Dissemination[5] are supporting functions facilitating effective operations of the whole of the EUnetHTA Collaboration

- When decisions within functions/Work Packages have significant implications for other functions/Work Packages, the Lead Partners of the functions/Work Packages affected and the Secretariat should be consulted. If the parties can't find a satisfactory agreement, the Secretariat should be involved and the Executive Committee should make a decision.

- When the Secretariat considers it necessary the Executive Committee should be consulted / make decision with the Secretariat

- When the Executive Committee cannot / should not make the decision, the Plenary Assembly should be involved

- The Executive Committee supervises the Secretariat on a continuing basis

- The Plenary Assembly receives regular updates in order to be able to guide the EUnetHTA Collaboration through transparent delegation

- Implementation is a responsibility of the appropriate decision maker with the partners involved

Figure 1 (next page)

[5] Joint Action framework terminology (Dissemination Work Package)

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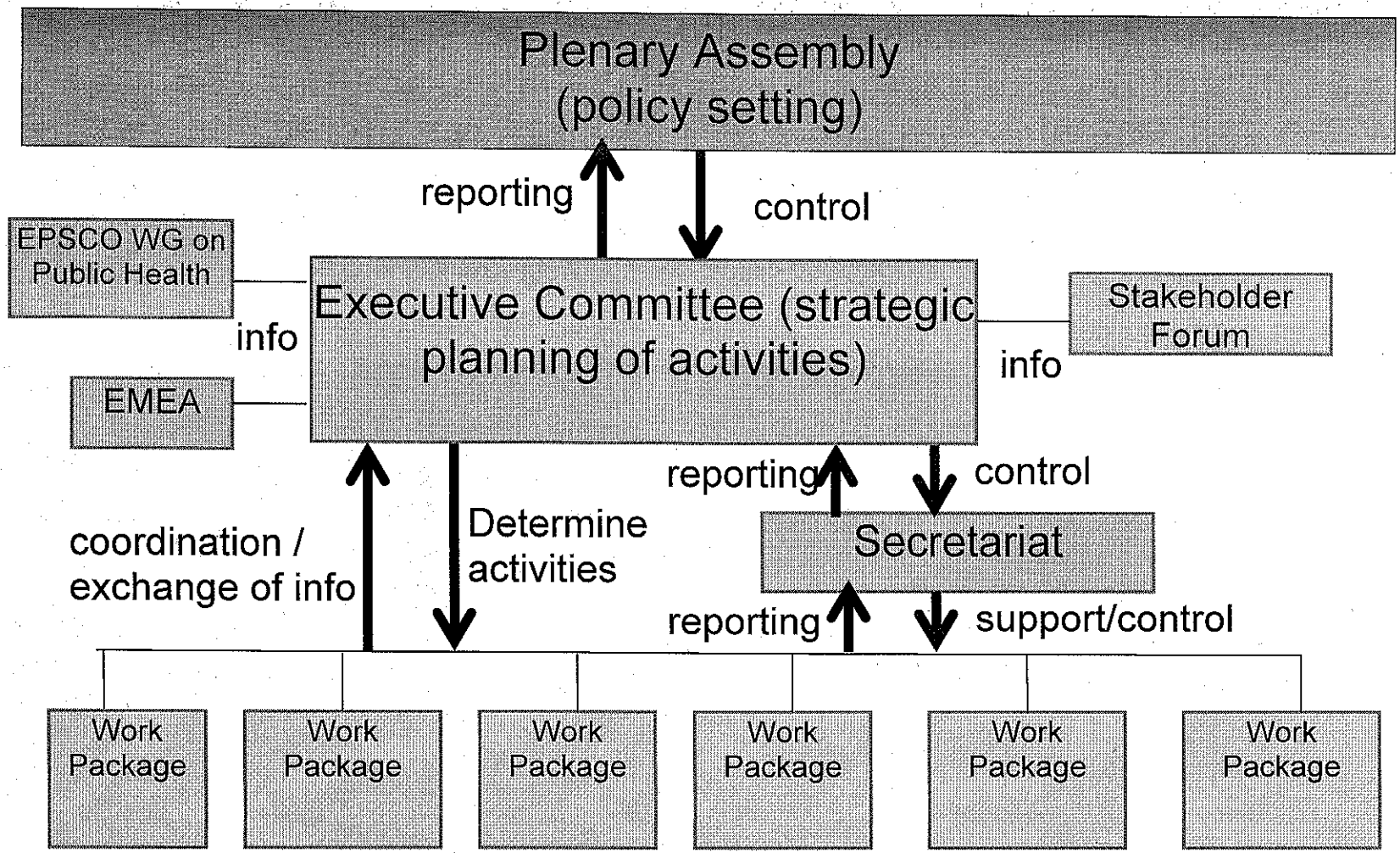
Figure 1. EUnetHTA Collaboration Organisational Structure 2009-2012



Appendix 1

Excerpt from the Grant Agreement for Joint Action – Article I.3 **ARTICLE I.3 – ROLE OF THE BENEFICIARIES**

I.3.1 The co-ordinator shall 'inter alia':

a) have full responsibility for ensuring that the action is implemented in accordance with the agreement;

b) be the intermediary for all communication between the co-beneficiaries and the Executive Agency in accordance with Article I.8. Any claims that the Executive Agency might have in respect of the agreement shall be addressed to, and answered by, the co-ordinator, save where specifically stated otherwise in the agreement;

c) be responsible for supplying all documents and information to the Executive Agency which may be required under the agreement, in particular in relation to the requests for payment. The co-ordinator shall not delegate any part of this task to the co-beneficiaries or to any other party. Where information from the co-beneficiaries is required, the co-ordinator shall be responsible for obtaining and verifying this information and for passing it on to the Executive Agency;

d) inform the co-beneficiaries of any event of which the co-ordinator is aware that is liable to substantially affect the implementation of the action;

e) inform the Executive Agency of transfers between items of eligible costs, as provided in Article I.4.4;

f) make the appropriate arrangements for providing the financial guarantee or the joint guarantee of the beneficiaries participating in the action, when requested, under the provisions of Article I.5;

g) establish the payment requests on behalf of the beneficiaries, detailing the exact share and amount assigned to each beneficiary, in accordance with the agreement, and in particular the estimated eligible costs as foreseen in Annex II, and the actual costs incurred. All payments by the Executive Agency are made to the bank account(s) referred to in paragraph 1 of Article I.7;

h) where designated the sole recipient of payments on behalf of all of the beneficiaries, ensure that all the appropriate payments are made to the co-beneficiaries without unjustified delay in accordance with paragraph 3 of Article I.7 and shall inform the Executive Agency of the distribution of the Community financial contribution between the co-beneficiaries and of the date of transfer;

i) be responsible, in the event of audits, checks or evaluations, as described in Articles II.20 and II.6, for providing all the necessary documents, including the accounts of the co-beneficiaries, the original accounting documents and signed copies of sub-contracts, if any have been concluded by the beneficiaries in accordance with Article II.9.

I.3.2 The co-beneficiaries shall 'inter alia':

a) agree upon appropriate arrangements between themselves for the proper performance of the action; *[The beneficiaries are deemed to have concluded an internal co-operation agreement regarding their internal operation and coordination.*

The co-operation agreement shall include all aspects necessary for the management of the beneficiaries and the implementation of the action;]

b) forward to the co-ordinator the data needed to draw up the reports, financial statements and other documents provided for in the agreement including its Annexes;

c) ensure that all information to be provided to the Executive Agency is sent via the co-ordinator, save where the agreement specifically stipulates otherwise;

d) inform the co-ordinator immediately of any event liable to substantially affect or delay the implementation of the action of which they are aware;

e) inform the co-ordinator of transfers between items of eligible costs, as provided in Article I.4.4;

f) provide the co-ordinator with all the necessary documents in the event of audits, checks of evaluations, as described in Articles II.20 and II.6.

Full text of the Grant Agreement for Joint Action :

http://ec.europa.eu/eahc/documents/health/calls/Model_Grant_Agreement_Joint_actions.pdf

Appendix 2 Organisational Structure Grid

	Main purpose	is comprised of	Positions	Main tasks / Responsibilities
Plenary Assembly	Principal policy setting body	head of each partner organisation (1 representative per partner organisation)	- Chair - Members	- Approving the composition of the Stakeholder Forum and its chair - deciding by majority vote (1 voting right per organisation) on strategic matters relevant to the development of the sustainable European network for HTA including changes in governance and organisational structure. - deciding on the functions/Work Package and their Lead Partners - monitoring / supervising the progress of the network and performance of the Executive Committee and the Secretariat - elect the non-function/Work Package members of the Executive Committee - facilitating the Secretariat and the Executive Committee with the execution of its coordinating tasks - approving strategy, work plans, an annual report, budgets - advising on future developments - approving changes in the governance and organisational structure - admitting new partners / exclusion of partners
Executive Committee	strategic leadership/main executive body	representatives of the function/Work Package Lead Partner organisations, the secretariat, 3 elected Partner organisations and chair of the Plenary Assembly (non-voting). Shall not contain more than 2 partners from one country.	- Chair - Members	- Appointing the chair of the Executive Committee - supervising the Secretariat in implementing the work plan - develop strategy for approval by the Plenary Assembly - preparing work plans and monitoring outcomes - preparing suggestions for the changes in the governance and organisational structure for approval by the Plenary Assembly - reviewing the performance of the Collaboration - in charge of the information exchange with the Stakeholder Forum and other identified strategic external parties - reviewing finances - being accountable for the performance of the EUnetHTA Collaboration to the Plenary Assembly.

	Main purpose	is comprised of	Positions	Main tasks / Responsibilities
Secretariat	operational leadership	a director, a manager and staff members	- Director - Manager - Staff	- coordination function - communication - responsible for the financial management - develops strategy in coordination with the Executive Committee - prepares work plan - organisation of the Plenary Assembly and the Executive Committee meetings
Stakeholder Forum	information exchange	representatives of relevant stakeholder groups	- Chair - Members	- receives information on EUnetHTA Joint Action developments, globally and on every function/Work Package and provides comments on them to the Executive Committee