



eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

European HTA Collaboration Years 2009+

Proposal
November 2007

1. Introduction

In line with the Common Values and Principles¹ that underpin all European Union (EU) health care systems, health technology assessment is recognised as an essential element in improving the quality of healthcare across the different health systems in the EU.

The purpose of this document is to outline proposals for a successful, sustainable European health technology assessment collaboration building on the work of the EUnetHTA Project. This collaboration beyond 2008 is referred to as the 'EUnetHTA Collaboration'.

Health technology assessment (HTA) is a multidisciplinary field of policy analysis. It has been defined as a process that systematically assesses the medical, social, ethical, and economic implications of the development, diffusion, and use of health technology². In this context 'economic implications' implies assessment not only of the cost of a technology, but also its 'value for money' as determined by cost effectiveness or other economic modeling. The term 'health technology' covers a wide range of interventions used in health care and health promotion including methods for prevention, diagnosis, treatment and rehabilitation (such as vaccines, pharmaceuticals, medical devices, medical and surgical procedures), and the systems within which health is protected and maintained.

The overall aim of HTA is to systematically and objectively assess evidence to inform decision makers in their formulation of health policies and provide patients with equitable access to safe, effective, high quality health technologies that achieve best value.

¹ Official Journal of the European Union, C 146, Volume 49, June 22 2006

² www.inahta.org

In 2004, the European Commission (EC) and Council of Ministers targeted HTA as ‘a political priority...[recognising].... an urgent need for establishing a sustainable European network on HTA’³. After a call for proposals the European Commission committed to a three-year grant to support the EUnetHTA Project. The EUnetHTA Project began in 2006 and aims to establish an *effective* and *sustainable* European network for HTA that informs policy decisions. It is creating an open network, developing practical tools to share scientific evidence and frameworks for assessment among Member States. This cross border collaboration will help reduce duplication of effort, saving time and resources of Member States (MS) when health technologies are assessed for new or continued use in health care systems.

HTA is undertaken on a national or local level to *inform* health care policy and decision making. It does not mandate policies or decisions. However, the production of HTA can be coordinated at a European level, allowing decisions to be made by the Member States that take account of national differences and priorities, following the principle of subsidiarity. Thus, the contribution of European HTA collaboration does not interfere with the national responsibility and competence for organisation of healthcare systems.

Indeed, Member States have welcomed the work of EUnetHTA and actively supported its work to share information and provide frameworks to allow national/local adaptation of HTA. A total of 34 organisations are working in the EUnetHTA Project and a further 25 organisations are associated with the Project, from 27 European (24 EU) countries.

Halfway through the EUnetHTA Project, substantial methodological advances have been achieved, with the creation of a set of innovative tools that have been developed with wide stakeholder buy-in. This is the first time that an EU funded project has developed a suite of tools to facilitate the whole process of HTA. Achievements include publication of a comprehensive core HTA framework and the first core model for a medical device, an adaptation framework for local health care systems and a process for sharing horizon scanning information on emerging health technologies⁴. These practical tools will be developed further, through wide consultation and finalised by the close of the project in 2008. In addition to this planned work, the EUnetHTA Project has utilised its network to coordinate HTA work on an urgent and important health issue, namely HPV vaccination.

An overview of all the EUnetHTA Project workstreams is presented in Annex 1 and the current status of all activities can be found at www.eunetha.net.

Given the achievements of the EUnetHTA Project to date in creating tools that can add real value to cross-border HTA work including increased inter-agency collaboration on specific HTA projects, it is likely that the Project will be considered *effective*. This proposal outlines how the key goal of creating a *sustainable* (long-term) European collaboration for HTA can be achieved.

The active and enthusiastic participation of EUnetHTA Partners and calls for practical support for continuous collaboration that appeared as responses to the consultation process regarding “Community Action on health services” have encouraged

³ Executive Summary, Brussels, 30 November 2004, HLG/2004/21FINAL

⁴ http://www.eunetha.net/Communication/Press_Releases/First_results_delivered_by_EUnetHTA_report_from_the_EUnetHTA_workshop_June_17_Barcelona_Spain/

EUnetHTA Partners to consider the development of a sustainable collaboration after the end of the EUnetHTA Project in 2008. This includes recognition from Ministries of Health of the emerging added value of European collaboration on HTA and the intention to provide a single reference point/body on matters concerning the production and use of HTA in health policy in Europe.

An HTA collaboration should advocate and facilitate robust, transparent analyses that will improve decision-making on the quality of national health care services, by creating faster access to safe, effective and efficient health technologies, balancing the needs and preferences of patients with the collective public need to use all health resources wisely.

This collaboration will provide a structured, systematic approach for provision of HTA information to policy and decision making at all levels in Member States. This can be achieved through mobilisation and reinforcement of the synergies between national/regional HTA organisations. Independent scientific advice, transparent analysis and respect to the principle of subsidiarity must be guaranteed, while keeping a non-prescriptive policy orientation.

These considerations have led to the development of this proposal document, which presents the vision, mission, aims and values of the 'EUnetHTA Collaboration'. It outlines key functions for the new collaboration and presents models of the organisational structure, governance mechanism and financing options. This proposal document will evolve as feedback is received from all stakeholders and as the EUnetHTA Project progresses to completion.⁵

2. Vision

The EUnetHTA Collaboration will contribute to high quality, safe, efficient healthcare for citizens across Europe through comprehensive, coordinated health technology assessment and provision of expert HTA input to inform health policies in Europe.

3. Mission

The mission of the EUnetHTA Collaboration is to support effective HTA collaboration in Europe that brings added value at the EU and national level by:

- building and supporting a permanent EUnetHTA Collaboration to facilitate the efficient use of HTA across Europe and support long-term strategic planning for the development of HTA taking account of emerging policy challenges,
- cross border collaboration to provide an access point for expert advice on HTA across Europe, thus providing a gateway to European HTA agencies,
- creating sustainable systems for knowledge sharing and provision of tools to assist HTA
 - amongst Member States, to allow HTAs to be shared and adapted for national use, thus supporting national processes and enhancing efficiency,
 - amongst stakeholders, to ensure that HTAs systematically cover a wide range of perspectives in their scoping, development and dissemination,

⁵ October 2007 – review by the EUnetHTA Steering Committee, followed by the external stakeholders' reflection process (November 2007) and further development of the consensus regarding the future of the EUnetHTA Collaboration in 2008 with presentation of the results of the development during the EUnetHTA Conference on November 20, 2008 in Paris (see www.eunetha.net for more information).

- developing alliances with contributing fields of research to support a stronger broader evidence base for HTA.

4. Aims

- The EUnetHTA Collaboration will contribute to improving health and the quality of health services by providing knowledge to facilitate the use of interventions that have been systematically and objectively assessed as effective taking account of the need to achieve best value within the healthcare system.
- As a long-term European collaboration with a nucleus of HTA organisations from the Member States, EEA countries and Switzerland, the EUnetHTA Collaboration will inform the field of health policy and practice, by facilitating an increasing volume of timely, high quality and relevant HTAs, reducing duplication of work and increasing quality of HTA methods.
- The EUnetHTA Collaboration will recognise and tackle barriers caused by language, variations in perceptions of terminology and facilitate national solutions to deliver context specific outputs in the most appropriate manner.
- The EUnetHTA Collaboration will have an efficient, financially sustainable organisational structure, serviced by a coordinating facility.

5. Values

The Partners in the EUnetHTA Collaboration will:

- be committed to improving the health of European citizens
- promote equity and best value
- assure quality through use of the best available evidence, common methodological and process standards and common review processes
- promote methodological and scientific independence thus contributing to high integrity
- aim at transparency of analysis and sharing of information
- be responsive to the needs of decision makers for timely, high quality HTAs on important health technologies
- appreciate the separation of the roles for the independent assessments resulting from an HTA and policy making decisions which are informed but not mandated by HTA
- maintain the independent role of each HTA Agency in the assessment of all evidence and conclusions

6. Key Functions

6.1. The framework to determine the key functions

The key functions of the EUnetHTA Collaboration have been determined by judging potential activities against:

- *users' perspectives*
- *the practical value* they provide
- *the unique value* they offer.

Two main *users' perspectives* have guided the choice of key functions for the EUnetHTA Collaboration:

1. to be of high value to HTA producers in the current EUnetHTA Project
2. to effectively communicate with policy stakeholders e.g. Ministries/ Departments of Health.

The range of tools and services that the EUnetHTA Collaboration will offer will be of *practical value* to its members, funders and stakeholders.

A driving force when determining the functions for the EUnetHTA Collaboration is to reduce duplication of existing functions and ensure that the EUnetHTA Collaboration adds value. To achieve this, the range of services provided by existing HTA collaborative organisations will be considered; The EUnetHTA Collaboration will only provide functions similar to existing ones where *unique value* is provided.

6.2. The content of the key functions

6.2.1. Setting up and managing the HTA information system for Europe

Aims

The web-based HTA Information System of the EUnetHTA Collaboration will support knowledge management in HTA in the EU with focus on the needs and requirements of public HTA agencies and the collaborating Partners within the field of HTA. It will provide the basic functions to respond to information requests and support the production of HTA products.

Short description of the function

The functions included within the information system will facilitate information and communication requests both among members of the Collaboration and stakeholders. The starting point may be the prototype information system outlined in the EUnetHTA Project. This information system will be developed taking account of the strategic aims of the EUnetHTA Collaboration following feedback from all users of the system.

The following information may be included:

- Information on publications and ongoing and planned studies with protocols - additional metadata and extensions to the INAHTA HTA database in relation to HTA products
- Information resources, literature databases, search strategies, appraisal tools, reference handling tools etc.
- A database based on the system which is currently being developed and validated by the EUnetHTA project (EUnetHTA Card system) for common European HTA developments with connection to other HTA-databases
- A database including information for the adaptation of existing HTA products into different regional/national settings
- A database for monitoring upcoming or existing technologies
- A database of contact information of experts of topics relevant for HTA

6.2.2. Facilitating the development of HTA institutions

Aims

The main aim of this function is to support the continued development of HTA institutions across Europe not only in countries with limited experience in HTA or without institutionalised HTA but also in countries where an HTA unit or agency already exists. This support system will need to be sensitive to the special needs in different health care systems (public, insurance financed etc.)

Short description of the function

The general activities coordinated by the EUnetHTA Collaboration will provide models of best practice for the methodology and processes supporting HTA that could be used to develop new and existing HTA organisations. Specific activities that were not possible in the EUnetHTA Project could also be developed that provide support systems for those with little or no HTA capacity. These could include training activities about HTA and the EUnetHTA tools, provision of support to HTA producers within member agencies, facilitation of access to experts in different HTA topic areas throughout Europe and help in dissemination of products. The focus would be on practical functions of building capacity and knowledge.

6.2.3. Developing and improving common processes for performing and reporting HTA

Aims

Common processes for HTA will fulfil the following requirements:

- The EUnetHTA Collaboration will aim to be the point of reference for methodological issues regarding HTA in Europe:
 - Fostering standardisation of methods between member agencies
 - Developing methodological tools for all forms of HTA
 - Disseminating and implementing high standard methods for producing HTA among member agencies
 - Identifying methodological research themes
 - Facilitating peer review of the methodological quality of HTA reports.
- The EUnetHTA Collaboration will provide a library of tools to help members enhance quality of assessments, to share resources and to set up effective collaboration:
 - Providing tools for priority setting of topics to undergo HTA
 - Providing tools to produce or adapt HTA reports
 - Facilitating coordination for monitoring utilisation and effectiveness of new interventions in daily practice.

Short description of the function

This function will support new developmental work and maintain ongoing work on the tools. It will aim to bring the tools of the EUnetHTA Project into widespread use and assure HTA agencies, their funders and their users that HTA reports are timely, created according to high and internationally accepted standards, using efficient processes. It will also progress work that the EUnetHTA Project has piloted on HTA 'core models' and the 'adaptation toolkit' into mainstream processes. Ongoing work will include sharing of information, attendance at conferences, shared training programmes, staff exchange schemes etc. Developmental work will be focused around

particular projects, funded externally (e.g. EU's Research Framework Programme 7)⁶ wherever possible.

This function will also work with other HTA organisations to develop and raise standards, both in constituent disciplines of HTA (effectiveness research, economic evaluation, ethical evaluation and so on), and within international HTA activities (through INAHTA, HTAi, and other organisations). It will seek to add value by speeding up the processes for agreeing on and disseminating standards.

6.2.4. Providing the contact point for HTA in Europe

Aims

Developments in both HTA and in European health policy - particularly the development of the new European Union Health Strategy - make closer collaboration essential⁷. Policy may develop rapidly, so HTA agencies across Europe need to be able to respond flexibly and quickly, and to engage with various stakeholder groups. This function of the EUnetHTA Collaboration will facilitate communication among the European HTA producers and users, provide a discussion platform on the position of HTA in healthcare systems in Europe, and facilitate establishment of links with contributing to HTA fields of research.

Short description of the function

EUnetHTA Collaboration will be the HTA contact point in Europe through:

- serving as a focal point for advising on matters concerning the use of HTA in health policy in the EU
- promoting HTA as an input to decision-making processes in health care systems across Europe
- leading European cross-border collaboration on all aspects related to HTA
- supporting and improving communication about HTA activities in Europe

6.2.5. Piloting processes for core HTA information

Aim

This function will develop the processes for producing core HTA information. It will build on the EUnetHTA Project work to validate the core framework for HTA against two health technologies. The next steps of development will be to ensure clear processes are created for production of an increasing volume of core HTA information on specific technologies that can go into context specific HTAs produced by the members.

Short description of the function

The validated core framework, methodologies, domains, and instruments such as issues-cards will be used by volunteering members (subsets or all of them) when engaging in joint/common actions on identified HTA topics while sharing a shared workload. The volunteering members will pilot the feasibility of using a common

⁶ http://ec.europa.eu/research/fp7/understanding/fp7inbrief/home_en.html

⁷ http://ec.europa.eu/health/ph_overview/Documents/strategy_discussion_en.pdf

system for identification, prioritisation and selection of technologies for HTA and, possibly, for gathering primary research evidence to feed into HTA reports. Topics selected by a sufficient number of members will undergo HTA under a common project description that is linked up to context specific project descriptions in member organisations.

Quality assured common standards will be defined and the piloting phase will test if the intended benefits are increasingly documented in terms of indicators of high standards, less duplication, higher average speed of production, and cost-effective use of resources across the participating members.

When piloting production of the common core HTA information, benefit has to be demonstrated as the efforts invested in the function will develop and become a central function of the Collaboration.

6.3. Levels of collaboration

The key functions for the EUnetHTA Collaboration can be classified according to four levels of collaboration.

(Level 0):

- Basic level; sharing and exchange of information (on a voluntary basis). Currently existing HTA network organisations work on this level.

Level 1:

- Sharing and exchange of essential information on a mandatory and more committed basis

Level 2:

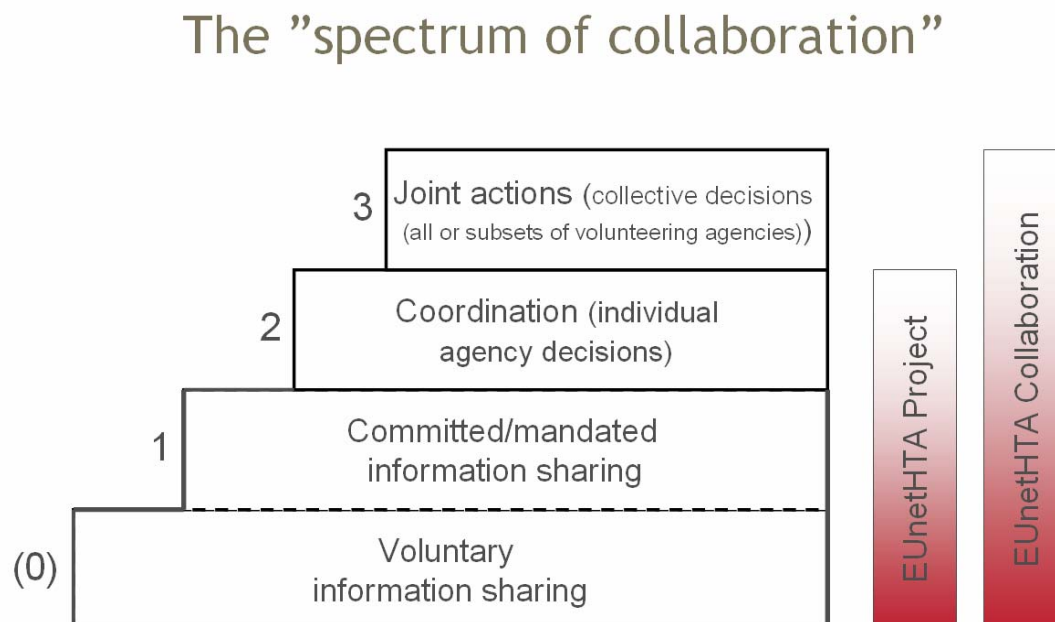
- more advanced and committed to collaboration in a harmonised manner; coordination of common activities where the EUnetHTA Collaboration members decide and implement HTA activities individually while applying common standards/tools at their own discretion.

Level 3:

- highest level of collaboration; all or subsets of volunteering members collectively decide and engage in joint/common actions sharing workload in a harmonised manner whilst using common standards and tools

The EUnetHTA Collaboration will operate on Level 0-2 and aim to gradually collaborate at Level 3. Figure 1 illustrates the “spectrum of collaboration”:

Figure 1.



The five key functions suggested for the EUnetHTA Collaboration (as outlined in Section 6.2) can be distributed among the three levels of collaboration.

Figure 2. Clarification of functions

		Key functions	
Levels of collaboration	Level 3. Joint/ common actions	4. Providing the contact point for HTA in Europe (all EUnetHTA Collaboration member agencies)	5. Piloting processes for common core HTAs (all EUnetHTA Collaboration member agencies or subsets of volunteering agencies)
	Level 2. Coordination	2. Facilitating the development of HTA institutions	3. Developing and improving common processes for doing and reporting HTA
	Level 0/1. Sharing information	1. Setting up and managing the HTA web-based information system for Europe	

7. Organisational and Governance Structure

7.1. Background

The outcomes and the practical solutions developed by the EUnetHTA Project will lay a foundation for the success of the EUnetHTA Collaboration. In the meantime, feedback is being sought from a broad range of stakeholders on the draft deliverables of the EUnetHTA Project and internal evaluation of the work processes and collaboration experience is done according to plans.

The current experience suggests that to ensure continuity of work, the plans for a Collaboration must be ready for implementation when the EUnetHTA Project is finalised. If a long-term Collaboration is not created, although the tools created by the EUnetHTA Project will be publicly available, it is unlikely that they will be developed further or used in a more harmonised/transparent manner. Furthermore, planned processes such as the HTA information system for Europe, monitoring emerging technologies and educational activities will not take place.

In order not to lose momentum in the coordination of HTA in Europe by the end of the EUnetHTA Project, the Partners will clarify the mandate of a long-term EUnetHTA Collaboration with funders, the European Commission and major stakeholders which will, in turn, underpin the choice for the appropriate organisational structure of the EUnetHTA Collaboration. In the meantime it is important to draft proposals for an organisational structure of a sustainable collaboration for HTA across Europe to facilitate discussion.

7.2. Initial considerations for an organisational structure of the EUnetHTA Collaboration

The national and regional HTA agencies (from the European Member States, non-EU EEA countries (Norway, Iceland, Lichtenstein) and Switzerland) will comprise the *nucleus* (core group) of the EUnetHTA Collaboration. The nucleus agencies have the task of producing HTAs to be fed into policy and decision making within their specific health policy and organisational settings. The proposed criteria to be eligible for being a member of the core group includes production of HTA as a part of the organisation's mandate and public financing of all or the majority of the operations.

The nucleus will have a *shell* around it, which will comprise the institutions (e.g., university departments, research institutions, academia, and international organisations in HTA) that contribute to the production of HTA and the development of HTA methodology.

The structure of the EUnetHTA Collaboration will also include a Stakeholder Forum to promote an open exchange of views on e.g. the application of HTA in Europe.

The majority of Partners in the EUnetHTA Project agree that the EUnetHTA Collaboration should be an organisation with a legal entity. To determine the optimal organisation, the following partly overlapping options will be explored:

- part of the European Commission
- an independent organisation with formal links to the European Commission
- a membership organisation of institutions / organisations.

The EUnetHTA Collaboration will comprise the following entities:

- A *Steering Committee* with responsibility for governance functions, either including all member organisations (nucleus and shell) or only including nucleus members. In either case only nucleus members would have voting rights (one vote each).
- An *Executive Committee* to undertake management functions if the number of nucleus members is too large, e.g. 12. The Executive Committee will be elected by the Steering Committee and thus for time periods the remaining nucleus members will only be part of the governance and not the management function.
- A *Secretariat* to perform the coordinating functions containing employed staff accountable to the Executive Committee.

For the Secretariat, a variety of alternatives will be considered:

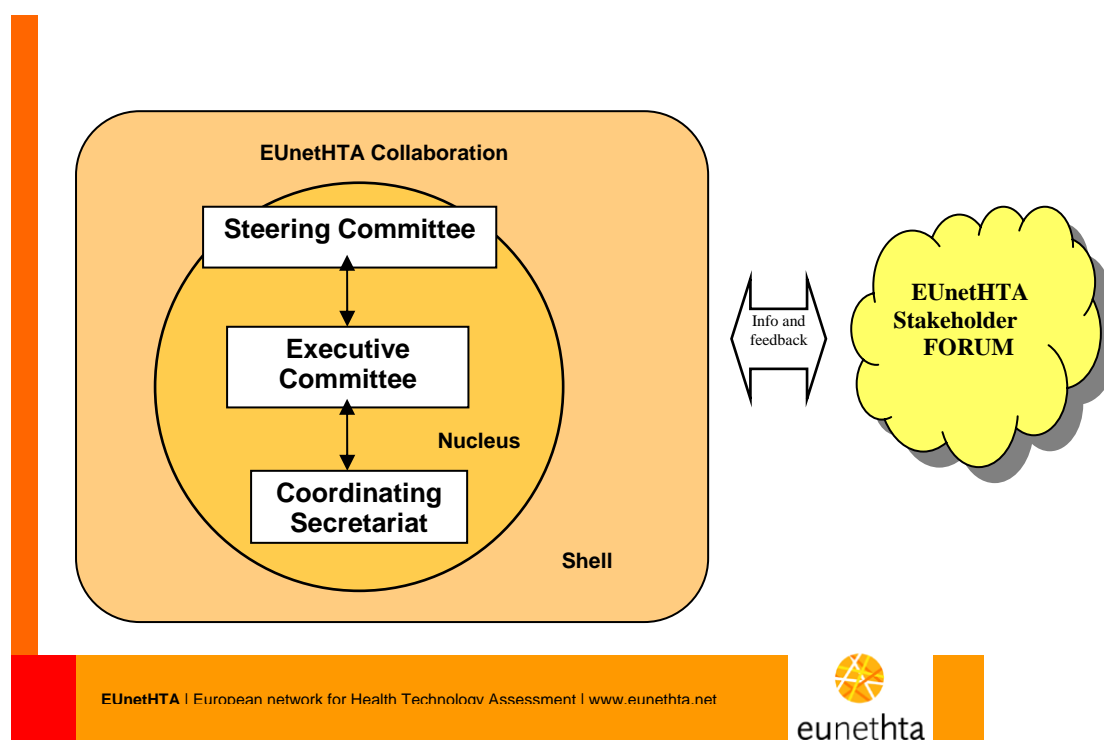
- The Secretariat is a new legal entity, and the Secretariat staff, including a director, are employed by a new legal entity as permanent staff (ie, as for EUnetHTA Collaboration). The Secretariat could rent office space permanently in one existing member organisation. Being director, manager or member of the board in one of the EUnetHTA Collaboration member organisations should be incompatible for managing the Secretariat.
- The Secretariat is a new legal entity, and the Secretariat staff, including a director, are employed by a new legal entity as permanent staff (ie, as for EUnetHTA Collaboration). The Secretariat uses completely independent accommodation. Being director, manager or member of the board in one of the EUnetHTA Collaboration member organisations should be incompatible for managing the Secretariat.
- Placing the Secretariat in member organisations for 3-5 year periods. This would mean that the Secretariat is a function of its current host organisation and staff are employed by that organisation but funded by the EUnetHTA Collaboration. After each period of 'contract', a decision is made about which organisation is next to host the Secretariat or it could remain with the current host. Another alternative could be a compulsory rotation of the Secretariat around all member organisations. Being director, manager or member of the board in one of the EUnetHTA Collaboration member organisations should be incompatible for managing the Secretariat.
- Selecting one organisation to be the long-term hosting organisation for the Secretariat. Staff are clearly identified as EUnetHTA Collaboration staff with a manager/director reporting to the Executive Committee. Staff will be formally employed by the host organisation but funded by the EUnetHTA Collaboration. Being director, manager or member of the board in one of the EUnetHTA Collaboration member organisations should be incompatible for managing the Secretariat.

The Steering committee would decide on the hosting organisation. The selection (call for tender) process would depend on the final funding and legal basis for the permanent secretariat function, practical, and other determinants. A performance evaluation mechanism should be put in place to ensure quality of the provided coordination services.

A *Stakeholder Forum* will perform an advisory role. The EUnetHTA Project has identified the following stakeholders:

- National/regional policy makers
- Policy makers at hospital level
- Patient organisations
- Health care professionals
- Industry.

Figure 3. Organisational model



When considering organisational models it is important to recognise that the real benefit of the Collaboration depends on the motivation and commitment of the Partners. This will be reflected in creating efficient processes that add value through synergy, for which there is buy-in from all members of the EUnetHTA Collaboration and that encourage a consistent approach to assessment across Europe that takes account of the national context.

8. Funding

The costs associated with each of the five proposed functions of the EUnetHTA Collaboration will be determined as the EUnetHTA Project draws to a close and the

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mandate of the EUnetHTA Collaboration is clarified. Presently, it is clear that it will be necessary to obtain secure, long-term public funding from one or more sources to ensure the sustainability of the EUnetHTA Collaboration. The organisational model employed will influence the most appropriate funding sources.

Appendix 1.

Overview of EUnetHTA Project workstreams

Work Package	Specific Objectives	Deliverable
1. Coordination	To establish the organisational and structural framework for the network with a supporting secretariat	The EUnetHTA organisational structure including a supporting Secretariat Final report from the project EUnetHTA conference presenting the project results
2. Communications	To effectively disseminate and handle HTA results, information sharing and coordination of HTA activities through the development and implementation of elaborate communication strategies and description of Clearinghouse functionality	Website/Information platform Communication strategy A clearinghouse functionality - detailed identification of the clearinghouse needs of different target groups and consecutive structure development to be ready for practical application after 3 years EUnetHTA conference presenting the project results
3. Evaluation		Internal evaluation of the project Framework for external evaluation
4. Common core HTA	To produce generic Core Models for HTAs on two essential categories of health technology questions: interventions and treatment, as well as Core HTAs on selected topics for each category	Core HTA structure/model 2 pilot examples of Core HTAs for different types of questions (e.g. diagnosis and treatment) A handbook on Core HTA.
5. Adapting existing HTAs from one country into other settings	To develop and implement generic tools for adapting assessments made for one country to new contexts	A web based toolkit for adapting Core HTA results from existing HTAs into other contexts including a HTA Glossary of adaptation Applicability testing of core information from 2 existing HTA reports in various national environments using the toolkit
6. Transferability of HTA to health policy	To develop and implement effective tools to transfer HTA results into applicable health policy advice in the Member States and EU – including systems for identification and prioritisation of topics for HTAs and assessment of impact of HTA advice	EUnetHTA Open Forum for stakeholders to exchange views and expectations/feedback on HTA A book containing a systematic overview of the HTA & healthcare policy links in selected Member States & EU representing different health systems, remuneration systems, etc

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7. Monitoring development for emerging new technologies and prioritisation of HTA	To develop effective monitoring of emerging health technologies to identify those that will have the greatest impact on health systems and patients	A prototype of a structured information service on high volume, costly, rapidly developing, emerging technologies A set of monitoring tools for emerging/new technologies
8. System to support HTA in Member States with limited institutionalisation of HTA	To establish a support system for countries without institutionalised HTA activity	Handbook on HTA organisations. The handbook will compile the results and information extracted from the review and the survey of HTA organisations