

WP1

Appendix 2

EUnetHTA Plenary Assembly meeting summary, May 24-25, 2012, Lisbon, Portugal

EUnetHTA Joint Action Plenary Assembly meeting
Lisbon, Portugal
May 24, 2012 13:00 – 18:00
May 25, 2012 09:00 – 15:00



Organised by: EUnetHTA Secretariat, Danish Health and Medicines Authority and INFARMED, Portugal
Address of the meeting venue: INFARMED, Parque da Saude de Lisboa, Av. Do Brasil, 53, 1749-004 Lisbon

Summary report

Agenda

Day 1 - May 24, 2012

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| 1. Opening | 13:00 – 13:10 |
| 2. EUnetHTA activities during the past year | 13:10 – 14:00 |
| - Key figures | |
| - Q&A based on written WP activity reports | |
| 3. Approaches to advance application of the EUnetHTA tools in daily HTA practice | 14:00 – 15:00 |
| - Information management system - new EUnetHTA websites | |
| - Feedback system to measure efficiency and implementation of EUnetHTA tools in Member States | |
| - Facilitation of use/integration of Core HTA information | |
| 4. EUnetHTA Elections 2012 – presentation of candidates and procedure | 15:00 – 15:15 |
| <i>Coffee break (elections)</i> | 15:15 – 15:45 |
| 5. Enhancing stakeholder involvement process | 15:45 – 16:45 |
| - Stakeholder Forum | |
| - SAGs and other forms of interaction | |
| - Stakeholder relations in a permanent network | |
| 6. Collaboration with the EU bodies, international networks | 16:45 – 17:00 |
| - Endorsement of the Memorandum of Understanding with INAHTA | |
| 7. EUnetHTA Evaluation (WP3) | 17:00 – 17:25 |
| 8. Announcement of Election results | 17:25 – 17:40 |
| <i>City guided tour followed by EUnetHTA JA dinner</i> | 19:00 – 22:00 |

Day 2 - May 25, 2012

1. EUnetHTA and permanent European network on HTA	09:00– 12:30
<ul style="list-style-type: none">- Commission update on current developments re: Article 15 implementation; ECORYS study- EUnetHTA strategy and business model: discussion and endorsement- structure, governance and management issues- financing streams	
<i>Coffee break</i>	10:30 – 11:00
<i>Lunch</i>	12:30 – 13:30
2. JA1 and JA2 - planning October-December 2012 overlap	13:30 – 14:30
3. Other issues and conclusion	14:30 – 15:00

Aric Ruether, who chaired the meeting, welcomed the participants to the EUnetHTA Joint Action Plenary Assembly meeting and thanked INFARMED for helping to organise and hosting the meeting. The President of the Executive Board of INFARMED, Prof. Jorge Torgal, addressed the audience highlighting the growing importance of the European network for HTA especially in the view of the growing need of an ever more accurate and high quality evaluation of the medical technology. Aric Ruether briefly presented the agenda of the meeting for approval.

EUnetHTA activities during the past year

Finn Børllum Kristensen and Julia Chamova presented the key figures, achievements and challenges in the EUnetHTA Joint Action during the past year (Appendix 1, slides 4-14). Finn Børllum Kristensen stressed the importance of defining the policies for the HTA Core Model for the future of EUnetHTA.

Finn Børllum Kristensen explained that the indicators and targets were presented in the form in which they are written in the grant agreement. He further posed a question to the LPs if the targets can be met by the end of the Joint Action 1. No indication of problems with meeting the targets were brought forward.

Finn Børllum Kristensen suggested that more focus on project management routines and approaches throughout EUnetHTA can assist in meeting the challenges. Project descriptions (protocols) and descriptions assist in implementing what the network is set up to do. Developing common standards for project work in EUnetHTA with more common understanding and approach to project work should be facilitated. Prioritisation of what to do – “do it later or leave it to others to do” – should be done. More focus should be put on the activities that are value-adding to the network and its partners.

Wim Goettsch commented that a more developed collaboration with industry should be welcomed and essential for further development and progress of the useful HTA cooperation in Europe. It is necessary to establish quicker and more effective communication routines with industry.

Elisabeth George remarked that some of the process developed in EUnetHTA can be assessed for further refinement and adjustment to meet tight deadlines (eg, number of questions to be answered when assessing drugs).

Luciana Ballini commented that a large network such as EUnetHTA will be able with time to produce a lot through sharing of the work load and specialisation (certain agencies/group of agencies producing certain output for the network (after agreeing on certain standards)). Francois Meyer commented that discussion of the scope of activities is important to identify which activities we indeed would like to continue and which can be delayed or not undertaken at all. In this discussion it is important to distinguish short-term (e.g., next 3 years of JA2) and long-term perspective. Long-term perspective includes the views and preferences of the

national decision makers – in addition to the network members – that will impact on the future of the network.

Wim Goettsch commented that the work associated with demonstrating the results of EUnetHTA to the world outside of EUnetHTA is time-consuming but very important to continue. Solutions should be sought to how this can be done more effectively.

Gro Jamtvedt asked if the additional activities that EUnetHTA is approaching to become or are involved in can be listed.

Finn Børlum Kristensen listed the following initiatives: Green Park collaborative initiative (piloting early advice guidelines for the developers of drugs based on regulatory, HTA and payer perspectives), various FP7 projects, ad hoc liaison with the Tapestry Network initiative, an ISG in HTAi about regulatory-HTA interaction, invitation to the specific countries activities (e.g., a conference in Moscow, Russia); DG SANCO-supported Joint Actions to liaise with.

Finn Børlum Kristensen concluded that the Executive Committee/WP1 will continue working on the challenges to find effective approaches to reach solutions that add value to EUnetHTA.

Approaches to advance application of the EUnetHTA tools in daily HTA practice

Finn Børlum Kristensen presented the agenda item highlighting an important role of the Information Management System that is being developed by EUnetHTA (WP6 led by KCE and co-led by DIMDI) (Appendix 1, slides 15-22). He commented that one of the reasons why the system is not yet utilised to its potential is that the staff of the EUnetHTA participating organisations still do not know what they can use this system for in their daily work.

Patrice Chalon introduced a EUnetHTA Tools flyer with short descriptions of each of the EUnetHTA tools. He further informed about the current efforts to improve the Information Management System (Appendix 2). Compliance with any browser, advice and involvement of the professional IT developers in the design of the public and intranet sites, better integration of the EUnetHTA tools hosted by tool developers into the IMS are among a few examples of improvements to be done by January 2013.

Claudia Wild informed that some of the agencies participating in WP7 Strand B introduced in their internal SOPs a requirement to consult the POP database when starting a new project. Access for the whole staff of partner organisations is a problem that WP7 is working on (in cooperation with WP6).

Wim Goettsch commented that it would be helpful to have information as a part of the POP database on the projects that are finalised .

Claudia Wild informed that this change had been implemented.

Kristian Lampe commented that access should be as technically easy as possible.

Julia Chamova commented that easy access should not negatively impact on the security and confidentiality that the system and agreed upon policies should guard as well.

Finn Børlum Kristensen asked if more frequent (even real-time) updates of the POP database would be technically possible to make in the future.

Alric Ruether invited the audience to comment on the issue of applying the HTA Core HTA information in the HTA processes of their organisations.

Finn Børlum Kristensen further asked how many institutions produce HTAs in-house and how many work on the basis of the submission files from the technology producers. He further asked if there are countries where the national legislation would prohibit using the HTA Core Model in local HTA production.

Gottfried Endel commented that in the field of pharmaceuticals the Austrian system has rather strict legal structures; it would require some adjustments in order to apply the core model structure. However, it is not impossible. WP5 is working on overcoming such constraints. WP4 developments can be used as they are in the local application. Due to the several fields where

the HTA Core model can be applied Austria will need adjustments in 3 regulatory schemes (screening, pharmaceutical and benefit schemes).

Sigurd Vitols commented that in SBU there will not be any problems in applying HTA Core Model.

Miguel Gomes confirmed that in Portugal there are no legal constraints; however, implementation in English language might require additional resources,

Luciana Ballini informed that the English language is used for writing reports in ASSR; therefore, there should not be a problem with sharing information in English through the HTA Core Model cards.

Mirjana Huic informed that the application of Core HTA structure is put in the guidelines for performing HTAs in Croatia. Some minor practical problems exist and can be overcome.

Finn Børlum Kristensen commented that the big pharmaceutical industry companies will soon start to realise that they move through the regulatory exercises and go into HTA and deal with 27 various requirements from 27 EU countries and they might see a benefit of and efficiency gains in using standard core HTA information produced as a “core” submission file that can be adapted/supplemented with additional information to meet local needs of specific country.

Alric Ruether commented that in Germany there are no regulatory obstacles to applying the HTA Core Model, however, the quality of information produced elsewhere is of the concern. He asked can we rely on information and quality of it if it is produced elsewhere?

Elisabeth George commented that the evidence requirements from the decision-makers across Europe should be looked at because any common submission developed in the collaborative way should meet all of these requirements. Review of the submissions can be performed using a common structure.

Paolo Siviero remarked that there is a problem with what kind of assessment one does. If it is a rapid assessment there are only 90 days – and using the HTA Core model to produce a rapid assessment, even in its current rapid structure, still takes a lot of time to complete. However, if we talk about the post-marketing assessment, the HTA Core HTA model is good and useful tool to apply. We really support an idea of standardisation, but we need to work more on developing tools that fit different purposes (and fitting the national and European requirements).

Luciana Ballini commented that the evidence requirements for decision-making may indeed present a real challenge in the sense of wide application of the HTA Core Model. Thoroughness of the evaluation might be perceived as being slow. We need to clarify how HTA is fitted into the decision-making process in different countries that will make a difference on application of the tools we develop. We should perhaps describe them in order to be aware and take into account when finding the ways of applying the tools.

Wim Goettsch commented that both the extended structure of the full HTA Core Model and the current way of collaborative production do not meet the needs of the rapid assessment process. The structure and the way of working together should be adapted to the practice and timeline of rapid assessments. He further welcome an idea of a pharmaceutical company producing a submission file structured as per the core HTA model that can be a basis for further work by the HTA agencies.

Kristian Lampe emphasised that currently he sees 2 types of projects 1) Core HTAs (project framework for collaborative work of 2-4 agencies - or even 10) to produce a large pool of information to be used later in various settings other than an original production setting and 2) a local project where you have to take into account your local production timeline. What we currently try to do is to build the system that supports both approaches, ie, if one wants to produce a comprehensive set of cards of Core HTA, one can do it as well as doing a rapid project selecting the cards that one wants to use.

Gro Jamtvedt informed that NOKC has started to produce more reports in English, initiated a collaborative project with FinOHTA applying the HTA Core Model, pilot projects applying the HTA Core Model are initiated. However, more experience is needed before the local production

process can be adjusted and all new projects be done based on the HTA Core Model. Thus application of the HTA Core Model is piloted in parallel with producing local reports according to the current production process.

EUnetHTA Elections 2012 – presentation of candidates and procedure

Finn Børlum Kristensen presented the development of the EUnetHTA partnership composition from the establishment of the EUnetHTA Collaboration in 2008 through time to Joint Action 2 (Appendix 1, slide 25). Julia Chamova briefly presented the election procedure and the list of candidates for election. Isaura Vieira and Anders Lamark-Tysse as well as Inge M. Skov were approved to be tellers supporting the election procedure.

The candidates briefly presented themselves/their organisations.

Enhancing stakeholder involvement process

Finn Børlum Kristensen introduced the agenda item on the stakeholder involvement process (Appendix 1, slides 32-40).

Alric Ruether opened the floor to stakeholders.

Andrea Rappagliosi commented that a letter from all organisations in the Stakeholder Forum had been addressed to the whole of EUnetHTA and the European Commission. He emphasised that it was a joint effort by all stakeholder groups participating in the Stakeholder Forum. Stakeholders are very supportive of the EUnetHTA activities and objectives. Developing effective approaches to avoid duplication of activities by all the concerned parties – including stakeholders – are welcome. The governance of the Joint Action 1 does not support this effort. More dynamic thinking about the level of involvement of the stakeholders is needed. He criticised the process of decision-making with regards to continuation of the current governance structure into the Joint Action 2 without consultation with or taking into account the past remarks from the stakeholders. He further commented that difficulties with recruiting the volunteers to the 2nd pilot in the REA of pharmaceuticals may be connected with the lack of accessible information on the lessons learned from the 1st pilot so that the potential volunteers can see if it is indeed valuable to spend resources on participation.

Christian Peters emphasised that it is in the stakeholders' interest that EUnetHTA guards its independency. The group of stakeholders is a very heterogeneous group.

Gordana Kalan Živčec stated that the network is absolutely needed for all involved; through the network the Member States can have access to a European HTA to bring to the national level. The network should be a reliable source of information in HTA.

Francois Meyer commented that the stakeholders letter states the general principles that we all share, without going into the level of specificity that would be expected after all the years of work put into developing a practice of stakeholder involvement in EUnetHTA. More concrete proposals are needed from all groups of stakeholders to be more practical and pragmatic to develop solutions.

Alric Ruether commented that concrete approaches and solutions to stakeholder involvement developed in EUnetHTA during the Joint Action 1 improved the transparency of the process if compared to a few years ago (eg, the introduction of Stakeholder Advisory Groups and regular Stakeholder Forum information).

Anders Lamark-Tysse thanked the stakeholders for their collective effort to develop a joint letter which is a positive development. He further reminded that the joint action proposals development follows a strictly defined process with tight deadlines set up by the European Agency for Health and Consumers. He welcomes the suggestion to be more concrete and specific in proposals on how to improve the stakeholder involvement process. This is very important also for the process of establishment of a permanent network on HTA in Europe. He would welcome proposals on how the Commission can facilitate a constructive role for stakeholders in the future network. That will assist the Commission in its dialogue with the Member States.

Andrea Rappagliosi responded that the different level of capacity and competence in HTA of stakeholder groups has not been taken into account up to now in the approaches to

stakeholder involvement that EUnetHTA has been using up until now. Adaptation of the practice to the needs of the stakeholders should be implemented.

Finn Børlum Kristensen mentioned that the Directive 2011/24/EU mentions “appropriate stakeholder consultation”. EUnetHTA will follow the EU legislation, i.e., “appropriate stakeholder consultation”. The EUnetHTA practice was focusing on the “stakeholder involvement” and in comparison to other European initiatives has come rather far in the development of a practice. This will be continued - in terms of the governance structure - as agreed in Joint Action 1. Regarding the balanced representation and capacity to provide representation, different stakeholder groups have different abilities that EUnetHTA tries to address to the degree possible (e.g., industry has more means to provide input than the patient stakeholder group).

Kristian Lampe emphasised that all parties need to focus on finding practical solutions – we agree on the principles in general.

Francois Meyer commented that the existing organisational structure should be used more effectively in addressing the concerns and specific suggestions from stakeholders – the solution is not in adding additional layer to the organisational structure.

Julia Chamova suggested that a more active participation by the Stakeholder Forum representatives in suggesting agenda items for the Stakeholder Forum meetings would be one of the practical approaches to how stakeholders can bring forward their points for discussion and decision-making throughout the year.

Julia Chamova presented the proposals to enhance stakeholder involvement in the EUnetHTA Joint Action (Appendix 1, slide 41-42) for endorsement by the Plenary Assembly.

Wim Goettsch suggested shorter and more focused consultation periods when needed. The stakeholders need to organise themselves in order to respond to shorter and more focused consultation periods. The responsibility to organise within the group lies with the stakeholders. The final say will stay with the Plenary Assembly in cases of an inappropriate process of identification representatives of the stakeholder groups. The proposals were approved.

FBK presented the currently available information on stakeholder involvement in the permanent network (Appendix 1, slides 43-45).

Collaboration with the EU bodies, international networks

Finn Børlum Kristensen presented the priorities in collaborating with EU bodies and international organisations (Appendix 1, slide 46-47). Exploring the Innovative Medicines Initiative (IMI) was also mentioned as a priority.

The Memorandum of Understanding with INAHTA was endorsed by the Plenary Assembly.

Anders Lamark-Tysse commented that the names of the 4 recipients of the FP7 grants on HTA methodology will be shared with the Secretariat.

Wim Goettsch asked about the role of EUnetHTA in IMI? Is it a responsibility of a national organization to participate first? Shall we have memorandum of understandings with other international organisations like HTAi, ISPOR, Euroscan?

Finn Børlum Kristensen commented that if EUnetHTA is approached by these organisations, we should consider collaboration from the point of view that such cooperation will bring concrete, practical value to EUnetHTA activities. The Memorandum of Understanding with INAHTA was driven by the necessity to find practical solutions of cooperation around the HTA database and POP database.

Regarding the participation of EUnetHTA in IMI, it will not hinder individual countries' participation, but would be an opportunity to coordinate (when relevant and appropriate) a discussion within EUnetHTA of certain issues raised in the IMI.

Kristian Lampe asked if there are any plans of interactions between the Joint Actions supported by DG SANCO.

Anders Lamark-Tysse commented that this is a tricky issue. DG SANCO has an overview of the joint actions and at the level of the policy officer in the Commission they will try to have a targeted dissemination and establishment of contact between the joint actions. Health registries joint action has been asked to disseminate information to EUnetHTA.

Andrea Rappagliosi asked about the accountability system to the funding body for the permanent network on HTA.

Anders Lamark-Tysse responded that it is too premature to say as the funding modalities are not yet known. The 2014-21 “Health for Growth pProgramme” is proposed as the funding source for the network. The networks to be established under the Directive 2011/24/EU are a special, new kind of bodies that the Commission is to support. The Networks will serve the needs of the Member States, not the Commission's.

EUnetHTA Evaluation (WP3)

Eleanor Guegan presented the agenda point (Appendix 3).

Announcement of Election results

Anders Lamark-Tysse confirmed that there were 34 ballots delivered. Three people processed the ballots and delivered the summarised results to the Secretariat. Julia Chamova announced the results:

Thirty four organisations attended the Plenary Assembly. Thirty-four ballots were cast and considered valid during the election.

Plenary Assembly Chair – Mirjana Huic (31 votes)

Plenary Assembly Deputy Chair – Luciana Ballini (29 votes)

Both candidates accepted the election.

Executive Committee electable members: NICE (UK) – 30 votes, OSTEBA (Spain) – 26 votes, AHTAPol (Poland) – 20 votes, SNHTA (Switzerland) – 19 votes. AHTAPol, NICE and OSTEBA were elected to the Executive Committee.

Day 2 – May 25, 2012

EUnetHTA and the permanent European network on HTA

Anders Lamark-Tysse presented current developments with regards to Directive 2011/24/EU Article 15 implementation. (Appendix 4). He stressed that the Commission's objective for the transposition period is to have in place the formalities with regards to establishment of the European network for HTA. He informed that the Committee on cross-border health care is established to look after all the issues associated with the implementation of the Directive. The purpose of the HTA network (as well as the e-health network) is to support cooperation between the MS in the indicated areas, not the Commission's policy development. The rules of procedure to be developed by the network will be specifying how the work will be organised. If the formally nominated bodies to represent each member state in the permanent network would coincide with the bodies nominated to participate in JA2, then organisationally meetings of the permanent network could be linked to the existing EUnetHTA JA2 meetings. He also mentioned a consideration that the rules of procedure for the permanent network could be re-examined based on the JA2 experience.

Anders Lamark-Tysse further clarified that with regards to the stakeholder involvement in the permanent network it will be up to the network to decide on the final set-up of such involvement, but one could think that a specific body within the network's organisational structure might be established to take care of this (e.g., Stakeholder Forum).

Finn Børllum Kristensen presented the development timelines in relation to EUnetHTA and the establishment of the permanent network (Appendix 5). He underlined that when one talks about the future there are 2 parallel lines – overall strategic consideration of the EUnetHTA Collaboration itself for the future, and the preparation and thinking about how the formal permanent network could be set up and work. He assumed that the hopes of the Commission are that the Member States will nominate the organisations participating in the EUnetHTA Joint Actions to the permanent network.

Andrea Rappagliosi asked how the business model will be implemented.

Finn Børlum Kristensen responded that the business model was requested by the Executive Agency to be included as a deliverable of the current joint action. It has been a useful exercise to develop a business model proposal; it will be taken into the Joint Action 2 to be further developed. Specific input from all the stakeholder groups is welcome.

Andrea Rappagliosi further asked if the process described on page 6 of the Business Model (a fee structure for joint assessments) will be applied in Joint Action 2 pilots.

Finn Børlum Kristensen responded that it will not be applied for participating in pilots in the Joint Action 2.

Julia Chamova presented the proposed changes to the strategy document (Appendix 1, slides 52-53) An organisation can participate at different levels for different types of activities (e.g., it can participate at level 1 for one type of activity and at level 2 for the other type of activity).

Anna Zawada commented that the description fits better with AHTAPOL's understanding and asked if there would be benefits connected to participation at specific level? Level 3 – is it mandatory to re-use the information or is it sufficient only to produce?

Julia Chamova commented that further clarifications are needed on the minimum requirements and their connection to access to funds and any mandatory actions.

Elisabeth George asked if Level 3 is about exchange of value – if a partner contributes to a collaborative HTA project then they have the right to receive value as well (if a partner contributes, they can reuse as well) i.e., would this mean that if you contribute you can also have access to the information?

Julia Chamova commented that the secretariat will develop a table to match EUnetHTA tools and processes to different levels of involvement and present it to the Executive Committee and partners in general for review.

Isaura Vieira commented that varying levels of HTA development in countries will influence the level of their involvement in the network. If an institution decides to start activity at level 1 and then over time decides to move to a different level of activity – will it be possible (if they have enough capacity and they find they can move to the next level)?

Finn Børlum Kristensen responded that minimum requirements for participation should be defined, and then it is up to each institution to decide, e.g., in terms of using the HTA Core Model. The cards should be developed and fed into the system when access to the HTA Core Model On-line is granted. Use of EUnetHTA tools should be encouraged and facilitated.

Mirjana Huic suggested that activities at higher level should be encouraged and promoted. Otherwise there will not be sufficient core information produced to support national application.

Francois Meyer suggested that Level 3 formulation should be adjusted to include application of common standards and tools in national (regional) HTA production. "Re-use HTA information" - what this means in practical terms needs to be further defined.

Americo Cicchetti suggested that a definition of partner HTA organisations should be clarified further, with regards to the Collaborating Partners. In his view the parenthesis "(Basic, Committed, Advanced)" on page 3 of the strategy document should be removed.

Luciana Ballini supported adjustment of the formulation of Level 3 to include usage of tools at the national level. At the moment it is not yet clear how we involve people in work on the collaborative projects and what for. Her expectations for JA2 were: There will still be a lot of methodology ground to be covered. Principles of HTA research should be shared in a more open way – not as the "one and only way" of doing things, but by way of defining viable options suited for e.g., a rapid assessment – clarifying what kind of systems will better suit. Transparency into viable options would help a cross-border principle.

Finn Børlum Kristensen supported a proposed adjustment in the wording of Level 3 description reflecting the national level. It needs to be ensured that there is a link for producing information that can be shared – application of common standards and tools with the aim of supporting the production of the kind of information that can be re-used. Experience of e.g., WP5 shows us the option of a modular application the HTA Core Model depending on the needs and the technology at hand.

Kristian Lampe suggested further clarification of the purpose of levels and implications (financial implications? Administrative/governance implications?)

Anna Zawada commented that it was built into the design that an institution has some obligations and benefits if they participate in activities at certain levels.

Elisabeth George commented that a definition of the partner organisations is important. One size fits all model should be moved away from – tools should fit the real world processes in various HTA organisations. She further asked if the strategy document becomes superfluous if EUnetHTA becomes the permanent network. She commented that NICE does not produce HTAs, only commissions HTA work, so NICE cannot participate at either Level 2 or 3.

Anders Lamark-Tysse emphasized that the strategy document and discussions around it are very useful for the development of the permanent network.

Francois Meyer commented that if an organisation uses HTA to produce technology appraisals, rules and standards are applied through the guidance issued by the commissioning organisation on how HTA is to be performed.

Gro Jamtvedt asked what the implication and consequences of the levels are. Should all the tools be accessible to all partners – or is access connected to the level of collaboration?

Finn Børlum Kristensen responded that the tools are available to all EUnetHTA partners, however, the point is a matter of degree of usage of the tools and input back into the network systems. To make the tools available is not enough – one needs a common process that facilitates the use of tools. Development and application of common guidelines is another paramount example of collaborating: any institution can work at level 3 by participating in the development of shared guidelines for specific kinds of HTA research and revising their own guidelines for the production of HTA reports in their country to be aligned with common guidelines.

Gottfried Endel commented that levels are not intended to be an instrument for labeling the agency – what is expected as an added value at the European level should guide in understanding the levels. Different expectations as to the added value exist based on collaboration at different levels. This is a practical tool for structuring and clarifying the organisation of the involvement of partner institutions into network activities. He recommended a technical view on the classification.

Wim Goettsch commented that a core model for rapid REA is used in a “fit-for-purpose” way (eg. First 4 domains). He welcomed proposed levels as a very simple, useful system and supported suggestion on adjusting Level 3 formulation to include national application of tools. Those partners who do not do HTA themselves, but still commission the HTA work should look into the ways of how the developments and standards of EUnetHTA can be promoted for application by those they commission to do HTAs and how they can be involved in the development of standards.

Francois Meyer supported the view that the system of levels is useful. He further enquired about the Commission’s view on the utility of the levels system? Only explanatory purpose, or also to define the budget and to use as indicators of success?

Anders Lamark-Tysse responded that the system is useful to illustrate that the collaborative projects can take different forms, to show that it is feasible to work in very different ways. It is also helpful in engaging the national representatives to reflect on how their HTA process is organised in comparison with that of other countries. As indicated by Commissioner Dalli in the Gdansk conference, the more you engage in advanced cooperation, the more the EU should

support the learning curve because it is much more demanding not only to develop common standards and also to use them in collaborative projects and then translate them into national HTA reports. That is a big process. The levels might be used to evaluate the financial need for the network, however, no decision on that has been taken yet.

The Health for Growth programme will be the major source of finance for the network. There The HTA network is one of the priorities listed under the headline “stimulating innovation” . There is an expectation that the actual amount needed for the HTA network fits into this priority. It would be very difficult to see this system of levels be used as indicators of success. It will be rather based on the work plan evaluation and outcomes of the planned work. Evaluation would rather be based on activities planned and outcomes achieved. The work plan is to be proposed by the member states participating in the network and might need to be approved by the Executive Agency. However, no specific process has been discussed as the programme is not yet finalized.

Anna Zawada commented that it is necessary to consider the situation when the organisations that are still building an HTA capacity and might not be able to actively do something, produce something collaboratively but are in the need to use the results of the collaborative efforts.

It was agreed that the strategy document text should provide a clarification of the purpose of the levels. Usage of a more neutral word than “level” should be considered. This is a strategic, not operational document detailing the implementation process. The chair asked for endorsement with these remarks. There were no objections.

Julia Chamova presented new formulations of the vision, mission and values (Appendix 1, pages 54-56).

Following the discussion the following wording of the vision, mission and values were agreed and adopted:

Vision

EUnetHTA is a preferred facilitator of high-quality HTA collaboration in Europe. HTA agencies consider EUnetHTA an efficient way of collaborating.

Mission

To support collaboration between European HTA organisations that brings added value to healthcare systems at the European, national and regional level.

Through its activities, EUnetHTA

- supports efficient production and use of HTA in countries across Europe
- provides an independent and science-based platform for HTA agencies in countries across Europe to exchange and develop HTA information and methodology
- provides an access point for communication with stakeholders to promote transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations
- Develops alliances with contributing fields of research to support a stronger and broader evidence base for HTA while using the best available scientific competence..

Values

- European Union values for health systems (universality, access to good quality care, equity and solidarity)
- Efficiency in HTA production
- Sustainability of the healthcare systems
- The principle of subsidiarity of the European Union
- The use of best evidence, common methodological standards, trust and transparency

EUnetHTA finds it important to recognise and facilitate solutions to overcome barriers caused by language, variations in terminology, and culture.

Julia Chamova presented comments received from the 3 Stakeholder forum members (Appendix 1, p.57). She further presented the considerations of the Executive Committee with regards to the structure, governance and management issues and financial streams of the permanent network for HTA (Appendix 1, pp. 58-67).

Christoph Künzli commented that in 2004 the European network was thought to be wider than the EU countries, but now the development is that it is limited to the EU Member States.

Anders Lamark-Tysse clarified that the permanent network is a legal construction under the Treaty of the European Union. It follows from the Directive 2011/24/EU. Because it is an EU legal instrument that establishes it, it will be limited to those countries that implement this legal instrument.

Julia Chamova commented that it is necessary to ensure that the network has access to the competence and expertise that is available in Europe and might not be provided via the organisations nominated by the Member States to participate in the network. The contemplated Network Forum should be composed of all the participating organisations, not only the nominated partners. Those who would like to participate, have expertise and provide valuable input into the network should be given an opportunity to participate. There should be no exclusion but a different way to be included since the HTA network will have to follow the EU legal framework.

Americo Cicchetti commented that the Executive Committee has done a good job in designing the process and the future model. How will it be possible to obtain the support for those who will not be nominated by the ministry at the national level, e.g., by way of subcontracting agreements with the nominated organisations? Were there any considerations on a system of accreditation of the subcontractors at the network level as very different scientific contributions could be expected. Some institutions that use public resources have low or no conflict of interest. Minimum standards for involving such collaborators should be developed.

Wim Goettsch suggested that the Executive Committee should include the organisations that will lead the Activity Centers, not only the elected members, i.e., reflecting the current WP1 / Executive Committee structure.

Paolo Siviero commented that the relation between the activity centers and the Executive Committee and between the Executive Committee and the Network Assembly should be further detailed clarifying how this relationship and exchange of information should be organised and made transparent to all participants in the network.

Ingrid Rosian commented that somebody should be responsible for quality assurance.

Finn Børllum Kristensen commented that quality assurance would be probably asked by the Network Assembly but organised at the production level. Possibly there will be an activity center responsible for quality assurance issues.

Christoph Künzli asked if the legal entity issue was discussed and decided.

Finn Børllum Kristensen responded that no decision has been made with regards to establishing a legal entity. Julia Chamova further commented that it was recommended to consider establishing a legal entity and the Commission was asked to look into a legal framework and regulations with regards to this issue when establishing a permanent network under the Directive 2011/24/EU. Establishing a legal entity would be needed to handle a number of administrative matters (eg, receiving grants, fees, holding intellectual property rights).

Finn Børllum Kristensen mentioned that the consideration of the membership fee is legitimate as the network needs to ensure its viability and effective use of the public funds for its activities (e.g., which activities and how they will be supported).

Gordana Kalan Živčec commented that the issue of the holder of the intellectual property rights is important to clarify.

Eleanor Guegan presented the process of identifying a winner of the WP3 Evaluation prize for participation in the WP3 EUnetHTA participants surveys (Appendix 6). LBI has won the prize.

JA1 and JA2 - planning October-December 2012 overlap

Julia Chamova presented this agenda item (Appendix 1, pp. 68-70).

Francois Meyer informed that a pilot on early dialogue has started as a preparation for the work in JA2 WP7. Several voluntary HTA bodies will propose a process for a multi-HTA bodies early dialogue with the technology developers (2-3 pilots) as a preparation for the JA2. Seven to eight HTA bodies participate in the pilot, the Commission provides funding of travel for the participants.

Other issues and conclusion

Julia Chamova presented the agenda item (Appendix 1, pages 72-74).

Wim Goettsch commented that the number of participants in each Work Package should be manageable. Alric Ruether commented that it is the task for the Executive Committee to propose criteria for participation in the WP. The project management guidance mentioned by the Secretariat should assist in this matter.

During the discussion, it was clarified and agreed that a Co-Lead Partner organisation is a member of the Executive Committee having conditional voting rights when the Lead Partner is not present and delegates its voting right to the Co-lead Partner. The Lead Partner holds the responsibility for the whole of the Work Package.

INFARMED was thanked for the cooperation and assistance in organising the Plenary Assembly meeting. Alric Ruther was thanked for his two-year service as the Plenary Assembly Chair.

Anders Lamark-Tysse, in a personal remark to Plenary Assembly, thanked for the fruitful and learning experience of cooperating with EUnetHTA.

The meeting was adjourned at 14:30.

Participants List

As of May 25, 2012

EUnetHTA Partners:

Member	E-mail	Organisation	Country
Ingrid Rosian-Schikuta	Ingrid.rosian@goeg.at	GÖG-Gesundheit Österreich GmbH/Geschäftsbereich BIQG-Bundesinstitut für Qualität im Gesundheitswesen	Austria
Gottfried Endel	Gottfried.endel@hvb.sozvers.at	HVB, Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)	Austria
Claudia Wild	claudia.wild@hta.lbg.ac.at	LBI-HTA (Ludwig Boltzmann Institute of Health Technology Assessment)	Austria
Patrice Chalon	patrice.chalon@kce.fgov.be	KCE, Belgian Health Care Knowledge Centre	Belgium
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Mirjana Huic	mirjana.huic@aaz.hr	Agency for Quality and Accreditation in Health Care, Department for Development, Research and Health Technology Assessment	Croatia
Finn Børlum Kristensen Julia Chamova Inge M. Skov	fbk@sst.dk juch@sst.dk ins@sst.dk	DHMA, Danish Health and Medicines Authority	Denmark
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Kristian Lampe	Kristian.lampe@thl.fi	THL, National Institute for Health and Welfare	Finland

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Bence Nagy	Nagy.bence@eski.hu	GYEMSZI	Hungary
Patrick Moran	pmoran@hiqa.ie	HIQA, Health Information and Quality Authority	Ireland
Marina Cerbo Nicola Vicari	cerbo@agenas.it vicari@agenas.it	Agenda's, Agenzia Nazionale per i Servizi Sanitari Regionali	Italy
Paolo Daniele Siviero Agnese Cangini	p.siviero@aifa.gov.it a.cangini@aifa.gov.it	AIFA, Italian Medicines Agency	Italy
Luciana Ballini	luballini@regione.emilia-romagna.it	ASSR, Agenzia Sanitaria e Sociale Regionale. Regione Emilia Romagna (JA CP)	Italy
Elisa Boscolo	elisa.boscolo@regione.veneto.it	Regione del Veneto	Italy
Marco Marchetti Americo Cichetti	mmarchetti@rm.unicatt.it acicchetti@rm.unicatt.it	University Hospital "A. Gemelli" (JA CP)	Italy
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Juozas Galdikas	juozas.galdikas@vaspvt.gov.lt	VASPVT, State Health Care Accreditation Agency	Lithuania
Bernardette Rossi	bernardette.rossi@gov.mt	DPPM/SSD/MHEC Strategy Sustainability Division, Ministry for Health, the Elderly and Community Care	Malta
Wim Goettsch Sarah Kleijnen	wgoettsch@cvz.nl skleijnen@cvz.nl	CVZ, College voor zorgverzekeringen	Netherlands

Gro Jamtvedt	Gro.Jamtvedt@kunnskapssenteret.no	NOKC, Norwegian Knowledge Centre for the Health Services	Norway
Anna Zawada	a.zawada@aotm.gov.pl	AHTAPol, Agency for Health Technology Assessment	Poland
Isaura Vieira Miguel Gomes	isaura.vieira@infarmed.pt miguel.gomes@infarmed.pt	INFARMED, National Authority of Medicines and Health Products	Portugal
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Setefilla Luengo	sluengo@isciii.es	ISC III, Instituto De Salud Carlos III	Spain
Isabel Peña-Rey	ipenarey@msssi.es	Ministry of Health and Social Policies	Spain
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Andrew Cook Eleanor Guegan	andrewc@soton.ac.uk e.guegan@soton.ac.uk	NETSCC, NIHR Evaluation, Trials and Studies Coordinating Centre	United Kingdom
Elisabeth George	Elisabeth.george@nice.org.uk	NICE, National Institute for Health and Clinical Excellence	United Kingdom

EUnetHTA Associates:

Valeria Romano	valeria.romano@aress.piemonte.it	ARESS	Italy
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EU Institutions

Anders Lamark-Tysse	Anders-Lamark.TYSSE@ec.europa.eu	DG Sanco, European Commission	EU
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EUnetHTA Stakeholder Forum representatives

Andrea Rappagliossi	andrea.g.rappagliossi@gsk.com	EFPIA, European Federation of Pharmaceutical Industries and Associations	INDUSTRY
Christian Peters	Christian.Peters@bv.aok.de	ESIP, European Social Insurance Platform	PAYERS
Gordana Kalan Živčec	Gordana.KalanZivcec@zzs-mcs.si	CPME, Standing Committee of European Doctors	PROVIDERS

Apologies:

- SDU, Denmark
- DIMDI, Germany
- AETSA, Spain
- CAHIAQ, Spain
- UETS, Spain
- SLOVAHTA, Slovak Republic
- SNSPMS, Romania

WP1

Appendix 1 for Appendix 2



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EUnetHTA Plenary Assembly Meeting

May 24-25, 2012

Lisbon, Portugal

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu



Agenda – May 24, 2012

Opening	13:00
EUnetHTA activities during the past year	13:10
Approaches to advance application of the EUnetHTA tools in daily HTA practice	14:00
EUnetHTA Elections – presentations and procedure	15:00
<i>Coffee break</i>	<i>15:15</i>
Enhancing stakeholder involvement process	15:45
Collaboration with the EU bodies, international networks	16:45
EUnetHTA JA Evaluation	17:00
Election results	17:25
Social programme	19:00



Agenda – May 25, 2012

EUnetHTA and permanent European network on HTA 09:00

- Commission update on current developments
- EUnetHTA strategy and business model; discussion and endorsement
- Structure, governance and management issues, financing streams

Coffee break 10:30

Lunch 12:30

JA1/JA2 – planning October-December 2012 overlap 13:30

Other issues and conclusion 14:30



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EUnetHTA activities past year

Key figures; Q&A session

May 24, 2012



June 2011-2012

- 43 Partners
 - **25 EU MS, Croatia, Norway, Switzerland**
 - Slovakia, Romania (Czech Republic)
- 20 Associates
 - **11 EU MS, Serbia, Turkey, USA**
 - Russia



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June 2011-2012: JA Deliverables progress

- Online Tool and Service (*first pilot ready*)
- Core Model on Screening (*1st public draft*)
 - Policies for HTA Core Model ready for the Exec Comm review before the public consultation
- A set of 2 Core HTAs (*commenced: topic selection, domain teams, survey of manufacturers*)
- EVIDENT Database (*IT implementation*)
- Criteria to select new technologies for additional evidence generation (*final version ready for public consultation*)



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June 2011-2012: JA Deliverables progress

- Electronic POP Database (*1st version*)
- Quarterly communication protocol based on POP data (*ongoing according to schedule*)
- REA of Pharmaceuticals (*final publication scheduled for September 2012*)
- Communication and Dissemination Plan (*completed*)
- Business Model (*completed*)
- 2nd Interim Report (*submitted*)



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June 2011-2012: Activities and developments besides deliverables

Methods/tools/reports:

- Topic selection procedure for Core HTAs
- Background review on REA of pharmaceuticals
- HTA Core Model for rapid REA of pharmaceuticals
- Report on national HTA strategies
- Report on training needs followed by
 - **a training workshop on EUnetHTA tools**
- Early advice pilots
- Template for evaluation of the meetings



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June 2011-2012: Activities and developments besides deliverables

Communication:

- EUnetHTA Conference (Gdansk, December 2011)
- Informational Video
- LinkedIn group "HTA in Europe" (>600 members)

Collaboration with European/international institutions:

- EMA (improvement of EPARs)
- DG SANCO (Directive 2011/24/EU, Article 15 implementation: JA2 grant agreement)
- MoU with INAHTA



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June 2011-2012: Challenges

- Extensive coordination effort (large scale project, 40+ participants)
- Lack of defined procedures for managing certain situations (agencies' preferences, lack of expertise, staff turnover, etc)
- Lack of useful cooperation from industry (quality of requested information, refusal to get involved/cooperate)
- Short timelines to deliver results, limited resources vs. extensive workload (including managing public consultations and processing feedback) and time needed to reach common understanding in a multicultural environment
- Fast growing interest in EUnetHTA from external parties
- Additional tasks
- Staff turnover



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Grant Agreement - Indicators

Specific objective 1: Development of a general strategy and a business model for sustainable European collaboration on HTA

Indicator: Business model developed; **Target:** at least 70% of partnership expressed official support of the proposed model.



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Grant Agreement - Indicators

Specific objective 2: Development of HTA tools and methods

Indicators: 1. Recommendations on REA of pharmaceuticals identified and published. **Target:** publication of the recommendations in an international journal (submitted).

2. Core HTA Model on screening produced in an 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 online. **Target:** Every WP7 partner has contributed with at least one entry to the system.



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Grant Agreement - Indicators

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

Indicators: 1. Production of Core HTAs using the software tool and general use of the Core Model. **Target:** At least 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. **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. **Target:** at least 90% of partners has contributed with at least one entry to the information system.



How to meet the challenges?

- Improve project management routines and procedures throughout EUnetHTA ?
- Prioritize and delegate (share responsibility) ?
 - **activities and tasks that EUnetHTA is to take up are to be the most useful and value-adding for EUnetHTA partners (consider resources needed and expertise available!!!) ?**
- Less emphasis on quantity – more quality?





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EUnetHTA tools in daily practice

How to advance the application

May 24, 2012



EUnetHTA Tools in daily practice

- **IMS: new EUnetHTA websites**
- **Feedback system to measure efficiency and implementation in MS**
- **Facilitation of use/integration of Core HTA information**



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EUnetHTA Tools

Adaptation toolkit and glossary

Contact database

E-meetings

EUnetHTA Toolbar

EVIDENT Database

HTA Core Model

Members' Only Internet website

Members' Only Workrooms

News aggregator

POP Database



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Imagine you're a researcher, who works in a European HTA body, and you've just been given a new topic for an HTA project.....

- How could you make practical use of EUnetHTA results if you wanted to look outside your country?



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EUneHTA - Windows Internet Explorer leveret af Sundhedsstyrelsen

http://www.sst.dk/English/EUneHTA.aspx

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EUneHTA



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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

Read more about
EUneHTA on www.eunetha.eu
EU-Commission-DG Sanco

EUneHTA – European network for HTA Joint Action, EU-grant no. 2009 2302

The purpose for a European co-operation on HTA is to find and develop an efficient and sustainable co-operation in the area of HTA. This co-operation is to lead to improvements on European, national and regional level.

The EUneHTA – Joint Action cooperation is to find solutions for a closer co-operation and to promote national solutions, in which context-specific reports contains relevant HTA-information, all created in joint action and complimented with national information.

The strategy for the co-operation consists of two closely connected objectives:

1. Development of methods in order to strengthen the effectiveness and visibility of HTA-cooperation in Europe.
2. Implementation of the tools, developed in the European Joint Action, on national, regional and local level.

Close interaction between the two objectives shall ensure that the needs of HTA-users within European Healthcare shall be meet. The goal for the Joint Action is to create a sustainable mechanism for exchange of reliable, timely, transparent and transferable information, which in the European countries may be used for HTA.

Welcome to **EUnetHTA Information System**

eunethta HOME ABOUT WORK AREAS RESOURCES CONTACT

JA WP6 Information Management System

Overview Document News Calendar Bulletin Board

Requirements: to fully use workrooms, Internet Explorer is required. [See more FAQs](#)

Work package presentation

Objective
[Read more](#)

Communication
Please use the mailing list EUnetHTA-WP6.

- To send a message to all WP6 participants (AP, CP), use this email address eunethta-wp6@googlegroups.com
- To get access to the mailing list, please contact **Patrice CHALON**
- List is not moderated; attachments are allowed

Coordination

-  **Patrice CHALON**, KCE (Lead Partner)

News

-  **3 years work plan Updated** (2010-12-17 08:53)
Patrice Chalon
-  **2nd face to face meeting (Brussels): summary** (2010-12-17 08:51)
Patrice Chalon
-  **1st face to face meeting (Paris): summary** (2010-04-18 12:32)
Patrice Chalon
-  **Communication at HTAi 2010** (2010-03-19 09:31)
Patrice Chalon

EUnetHTA - European network for Health Technology Assessment
Coordinating Secretariat, Telephone: +45 7222 8532, Fax: +45 7222 7411, eunethta@sst.dk

[Link to EUnetHTA public web site](#)

Internet 100%

LP=KCE, co-LP=DIMDI

Members Only | EUnethTA. - Windows Internet Explorer leveret af Sundhedsstyrelsen

http://www.eunethta.eu/Members_only/

Members Only | EUnethTA.

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HOME ABOUT WORK AREAS **RESOURCES** CONTACT

Tuesday, December 06, 2011

Welcome to the Members Only site of EUnethTA !

HOT topics:

- Learn how to update your profile with this webcast (requires Flash Player)
- Get a quick access to EUnethTA resources with the EUnethTA toolbar

Activities

- EUnethTA Joint Action on HTA 2010-2012 WP1 | WP2 | WP3 | WP4 | WP5 | WP6 | WP7 | WP8
- EUnethTA Collaboration 2009
- Overview of the Results of the EUnethTA Project 2006-08
- EU FP7 projects

Work areas (some with restricted access)

- My Workrooms
- Plenary assembly area
- Task Forces Work rooms
- Conference 2011 organizing committee
- Founding partners area
- Archive of the Project 2006-08 Members-only site

Communication tools

- EUnethTA Contact database
- EUnethTA Collaboration members Calendar
- EUnethTA Collaboration members News
- EUnethTA Members Update Newsletter
- EUnethTA e-meeting facility

EUnethTA Tools (some with restricted access)

- EIFFEL: Promising Technologies Database
- EUnethTA Glossary
- EUnethTA News aggregator
- EUnethTA Toolbar
- HTA Core Model
- Members-only site
- Planned & Ongoing Projects database**

Messages

Groups

Personal Contacts
Irina Cleemput
Julia Chamova

Contact database

Favourite pages

Fin Børlum Kristensen, MD, PhD
NBoH, Denmark

Edit contact info

EUnethTA - European network for Health Technology Assessment
EUnethTA Information System, eunethta@sst.dk

Link to EUnethTA public web site

Start | Trådløs netv... | Input from Pa... | Dokumenter | 6 Microsoft ... | 5 Internet ... | Microsoft Exc... | 3 Microsoft ... | GPC worksho... | 22:16

Resources | EUnetHTA, - Windows Internet Explorer leveret af Sundhedsstyrelsen

http://www.eunethta.eu/Members_only/Resources/

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RESOURCES

- Communication tools
- EUnetHTA Tools
- Library

Resources Home > Resources Bookmark this page

Welcome to the EUnetHTA Resources Centre!

Aim
The Resources Centre aimed at providing to EUnetHTA members a single place where they will find useful information and resources, including the EUnetHTA tools developed during the EUnetHTA project.

Contribution
The Resources Centre is maintained by KCE (**Patrice CHALON**). Content is provided by all EUnetHTA Members.

Published: June 15, 2009
Updated: August 18, 2010

EUnetHTA - European network for Health Technology Assessment
EUnetHTA Information System, eunethta@sst.dk

Link to EUnetHTA public web site

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Communication tools [Bookmark this page](#)

Home > Resources > Communication tools

EUnetHTA offers specific tools to facilitate communication within the Collaboration.

Contact database
The EUnetHTA Contact database provides email, phone and picture of colleagues.
[About](#) | [Consult the database](#)

MO Calendar
The MO calendar provides description of events organised by the different Work packages (face to face meetings etc) + registration form.
[About](#) | [Consult the Calendar](#)

MO News
The MO news list news provided by Lead partners; those news are included in the MO Newsletter by Secretariat.
[About](#) | [Consult the MO News](#)

MO site
The Members only site (MO site) is a private website restricted to EUnetHTA Partners and Associates.
[About](#)

Work rooms
A Workroom supports team working. Only members of the team can access the Workroom, all members of the team can create content in the

RESOURCES

- Communication tools**
- Contact database
- Calendar
- News
- Members only site
- Workrooms
- Inbox
- EUnetHTA Toolbar
- E-meetings
- EUnetHTA Tools
- Library

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EUnetHTA Elections 2012

May 24, 2012

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu



EUnetHTA Elections 2012

- **Plenary Assembly Chair and Deputy Chair**
Term: 2012-2014
- **Three Executive Committee Members**
Term: 2012-2013



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Chair / Deputy Chair Candidates

Chair:

- **Mirjana Huic**, Assistant Director and Head of Department for Development, Research and Health Technology Assessment at Agency for Quality and Accreditation in Health Care, Department for Development, Research and HTA, Croatia

Deputy Chair:

- **Luciana Ballini**, The leader of the Regional Observatory for Innovation research in Agenzia Sanitaria e Sociale Regionale (ASSR), Regione Emilia-Romagna, Italy



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Executive Committee Candidates

1. **SNHTA, Swiss Network for Health Technology Assessment, Switzerland** (represented by Urs Brügger)
2. **NICE, National Institute for Health and Clinical Excellence, United Kingdom**, (represented by Elisabeth George)
3. **AHTAPol, Agency for Health Technology Assessment, Poland**, (represented by Anna Zawada)
4. **OSTEBA, Basque Office for Health Technology Assessment, Spain**, (represented by Rosa Rico-Iturrioz)



Election Procedure

1. Nomination of 2 tellers amongst the Plenary Assembly participants
2. Vote casting during the coffee break 15:15-15:45
3. Vote counting 15:45-16:25
4. Results of the election 17:25



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Chair / Deputy Chair

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



Chair / Deputy Chair

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.



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Executive Committee

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 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 Executive Committee shall not contain more than 2 partners from one country.



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Enhancing stakeholder involvement process

May 24, 2012

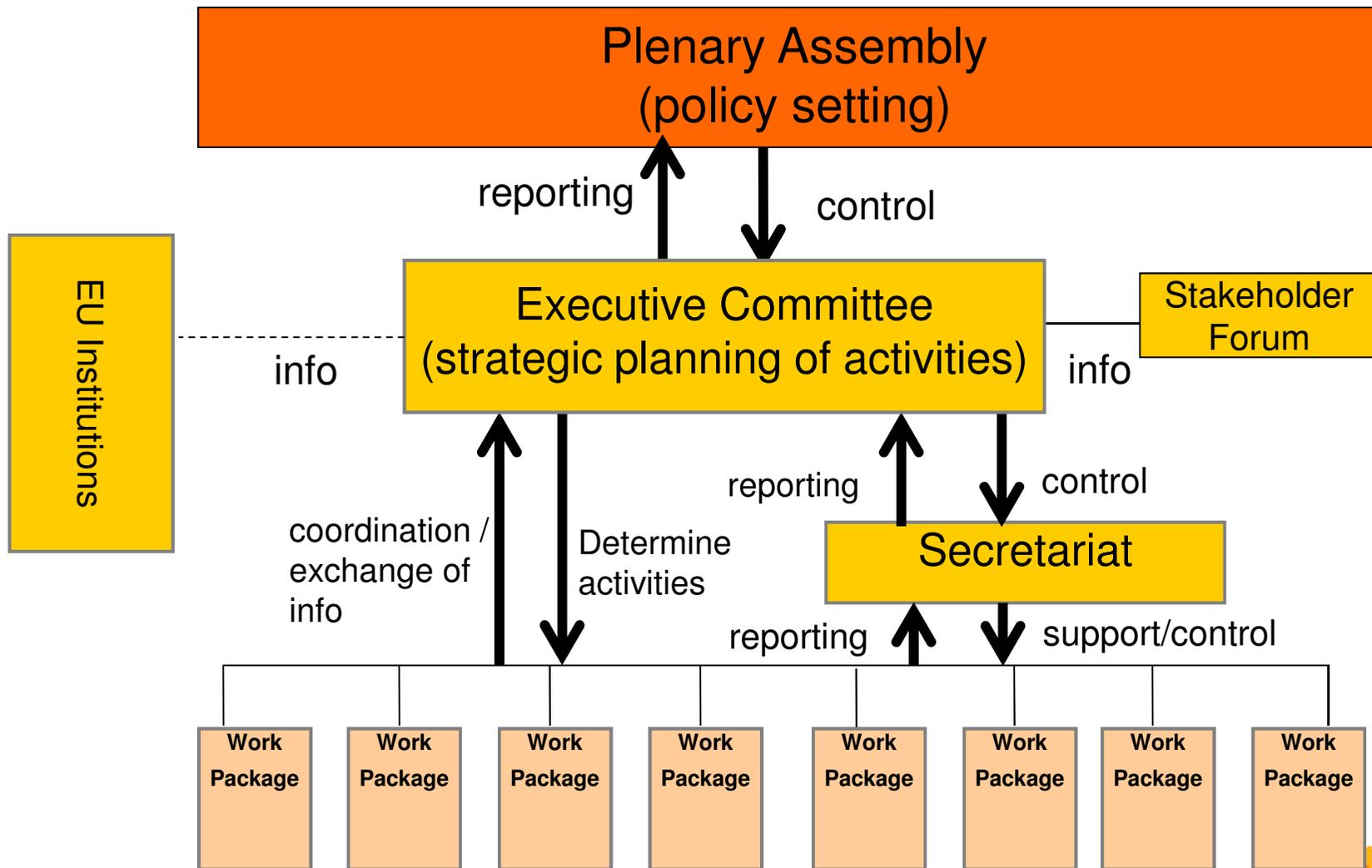


Stakeholder involvement

- Stakeholder Forum
- SAGs and other forms of interaction
- Stakeholder relations in a permanent network



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EUnetHTA Stakeholder Forum

Composition: European (international, national) umbrella organisations approved by PA

- **Aim:** to provide stakeholders with the opportunity
 - to participate as stakeholder representatives in the EUnetHTA Joint Action
 - to observe and comment on the EUnetHTA Joint Action work
 - to provide advice to overarching governance questions in the Joint Action and
 - to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Action



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Stakeholder Advisory Groups

- WP 4, 5, 7
- Stakeholder Forum members and participants
- Confidentiality undertaking
- Consultations on drafts



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EUnetHTA Pilots

- Contribution from the technology developers in concrete pilot work (eg, Core HTAs, REA of pharmaceuticals)
- Contribution from the Stakeholder Forum in early dialogue pilots



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Stakeholder Forum letter of April 26, 2012

- strengthening the role of the Stakeholder Forum. This pool of experts can be consulted and can provide advice according to the different perspectives and experiences represented, in addition to its role of receiving and disseminating information;
- increasing clarity with respect to the roles and responsibilities of all EUnetHTA bodies within the governance structure of the Joint Action, including the role of the Stakeholder Forum therein;
- securing timely, transparent and equitable access to the process and outputs of the Joint Action at all levels;
- adapting the forms of stakeholder involvement to the altered objectives and tasks of the Joint Action and future network;
- increasing stakeholder consultation on strategic issues (e.g. long- and short-term objectives and priorities);



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Stakeholder Forum letter of April 26, 2012

- acknowledging the different nature of the various stakeholders and the different kind of input they can provide both in terms of content and resources to contribute to the work of the Joint Action and facilitate their equal participation as necessary;
- exploring new forms of dialogue such as experts' meetings and other discussion fora not limited to written comments or responses to consultations;
- involving stakeholders early and providing them with adequate time to provide input.



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Specific suggestions

Composition of Stakeholder Forum:

- Increase the number of organisations per stakeholder group from 4 to 6
- Remove a 2-tier system of members and participants, ie, allow all eligible organisations be SF members
- Introduce a rotation system of stakeholder group representation at the meetings (to ensure a fair and balanced opportunity for influence among the stakeholder groups)
 - **Alternative:** charge the stakeholder group members to organise themselves for the participation in the meetings (with the maximum number of participants per stakeholder group limited to 6)



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Specific suggestions

- Introduce new forms of stakeholder involvement (in addition to SF and SAGs) – eg, expert meetings
- Consider earlier involvement of stakeholder expertise and allow an adequate time to provide input (ie, longer consultation period)



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Stakeholder relations in a permanent network

Article 15, Directive 2011/24/EU:

1. The Union shall support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology assessment designated by the Member States. ...

That network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and **appropriate stakeholder consultations**.



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Stakeholder relations in a permanent network

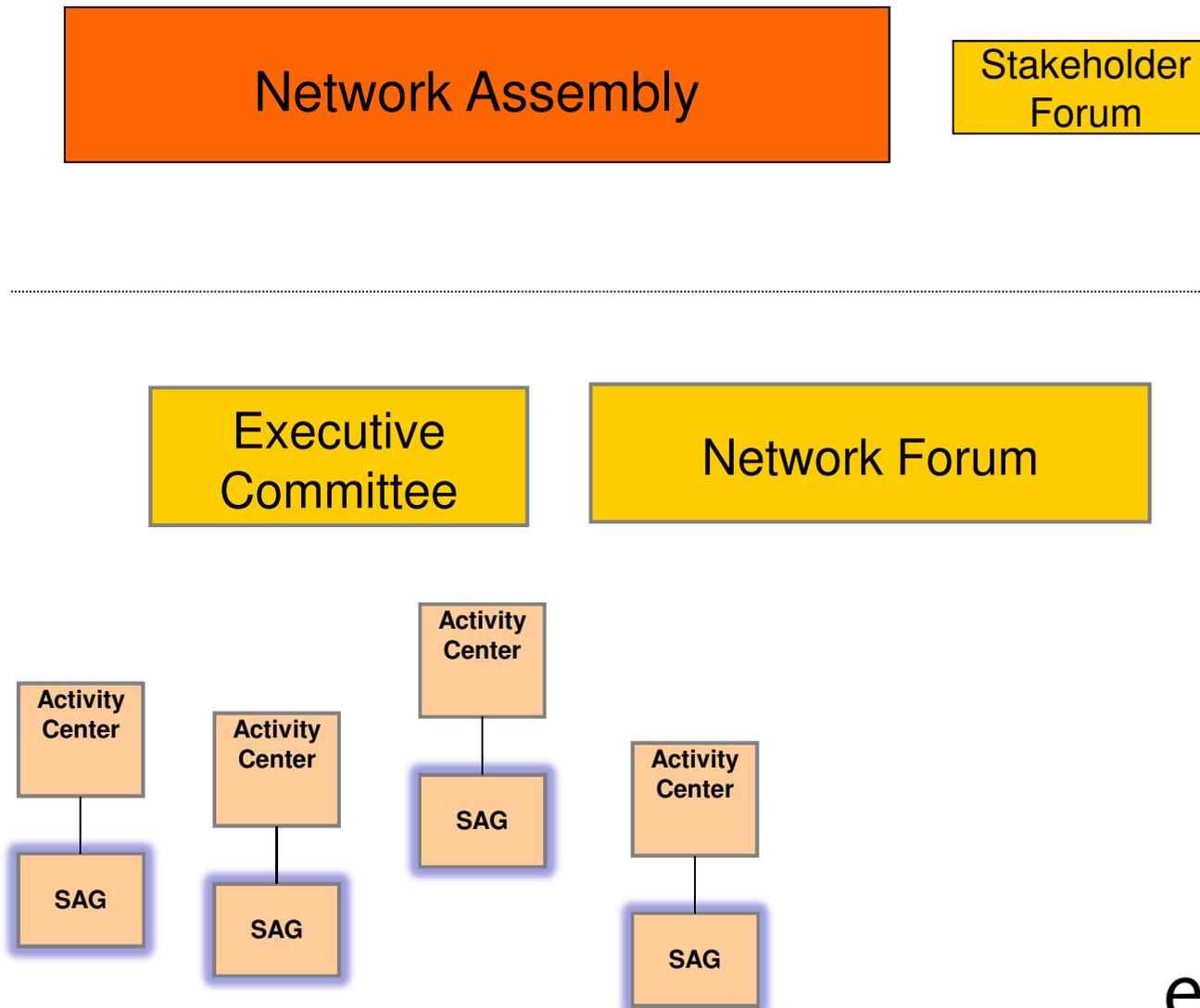
Stakeholder Forum (connected to the Network Assembly) - "*governance level*"

Involvement of stakeholder expertise in the specific activities (based on a "SAG model") – "production level"



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GOVERNANCE
LEVEL

PRODUCTION
LEVEL



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Collaboration with the EU bodies, international networks

May 24, 2012



Priorities

- **Cooperation with DG SANCO, EMA, DG RESEARCH, CIE**
 - More formal agreements on cooperation to be put in place
- **Cooperation with INAHTA**
 - Memorandum of understanding for endorsement by the EUnetHTA Plenary Assembly



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EUnetHTA Evaluation

May 24, 2012

EUnetHTA Joint Action 2010–2012 | www.eunetha.eu





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Election results

May 24, 2012





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EUnetHTA and permanent European network on HTA

May 25, 2012

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu



EUnetHTA and permanent European network on HTA

- Commission update on current developments
- EUnetHTA strategy and business model: discussion and endorsement
- Structure, governance and management issues
- Financing streams



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EUnetHTA strategy and business model: discussion

- Levels of involvement
 - EUnetHTA tools and services should be matched to every level of involvement in the network
- Vision, mission, values (*to make it more concise and straightforward*)
- Stakeholder Forum comments
- Business model: factual corrections (*EIFFEL, database of impact assessment*)



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Levels of involvement - new

European network for HTA – levels of involvement

Level 1 (entry level): Sharing and exchange of information and methods (within the agreed EUnetHTA framework)

Level 2: Development of common generic guidelines for HTA

- Piloting standardisation of the guidelines' use at the national level (within defined time lines, with access to resources supporting such piloting and with a requirement to report on the experience)

Level 3: Application of common standards and tools in collaborative HTA projects with re-use of HTA information at national level

ta

Vision

To be the high-quality, preferred facilitator for HTA collaboration in Europe. HTA agencies consider EUnetHTA an efficient and attractive way of working.



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Mission

To support collaboration between European HTA organisations that brings added value to healthcare systems at the European, national and regional level.

Through its activities, EUnetHTA

- supports efficient production and use of HTA in countries across Europe
- provides an independent and science-based platform for HTA agencies in countries across Europe to exchange and develop HTA information and methodology
- provides an access point for communication with stakeholders to promote transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations
- Develops alliances with contributing fields of research to support a stronger and broader evidence base for HTA.



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Values

- European Union values for health systems (universality, access to good quality care, equity and solidarity)
- Efficiency in HTA production
- The principle of subsidiarity of the European Union
- The use of best evidence, common methodological standards, trust and transparency
- Appropriate stakeholder consultation

EUnetHTA finds it important to recognise and facilitate solutions to overcome barriers caused by language, variations in terminology, and culture.



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Stakeholder Forum comments: AESGP, EFPIA, Eucomed

- Learning from the experience of JA1 to guide adjustments in the organisational and governance structure of JA2
- Consideration of differences between medicinal products and medical devices to ensure adequate evidence generation and in early dialogue pilots
- Consideration of different expertise and experience of representatives of different stakeholder groups
- Welcome
 - **further efforts to refine the roles and tasks of the Stakeholder Forum and SAGs to increase the relevance of HTA**
 - **To further develop procedures for appropriate stakeholder consultation**
- Take into consideration ECORYS study results and DG SANCO public consultation on the modalities of stakeholder consultation
- Apprehension with guidelines – to be commonly designed and adopted
- Outcomes of the European collaboration to be implemented at the national level



Permanent European network on HTA

- Structure, governance and management issues
- Financing streams



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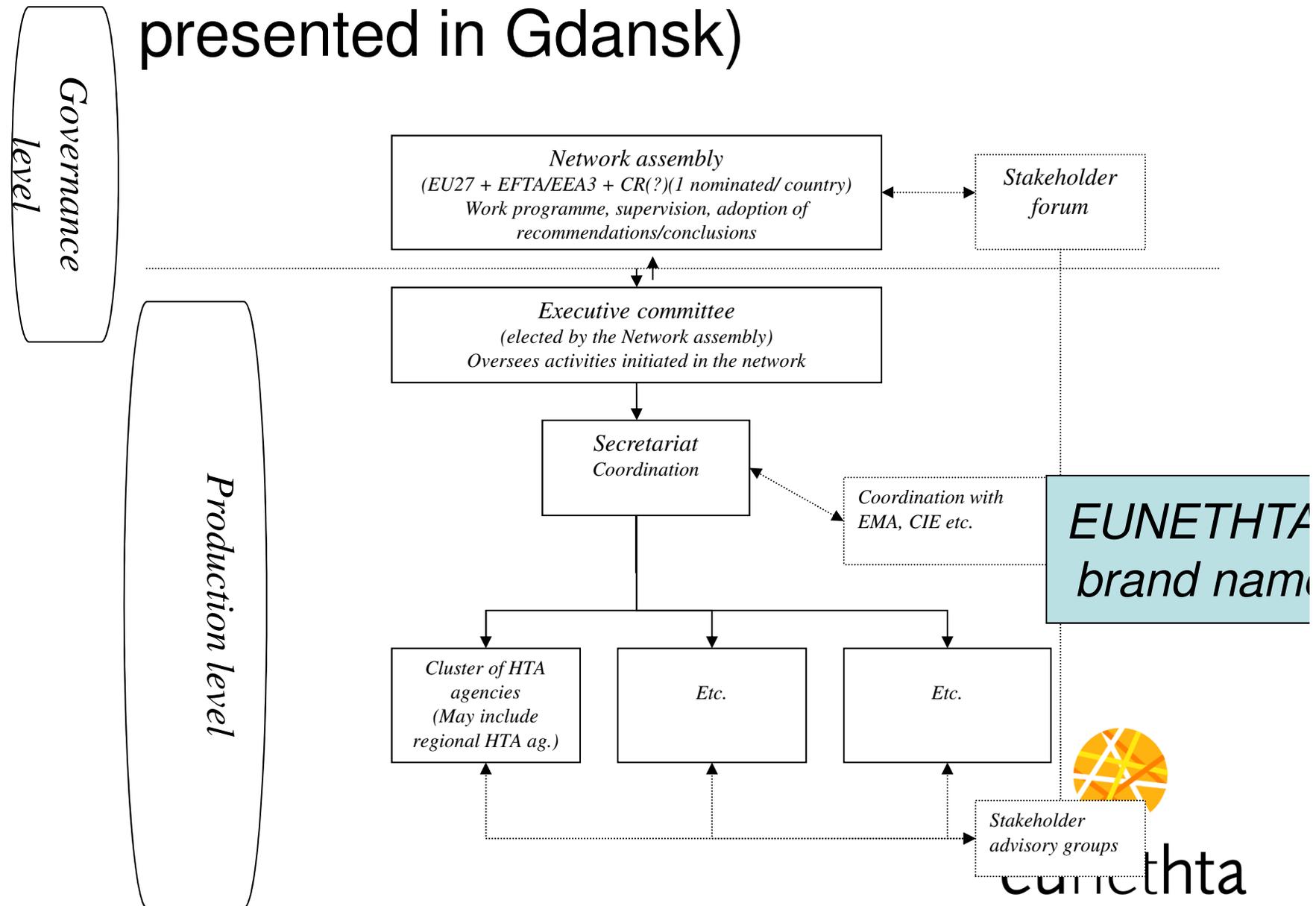
Permanent European network on HTA

- Presented and discussed in Gdansk
- Discussed at length by the Executive Committee at its last meeting in Rome (April 18-19, 2012)

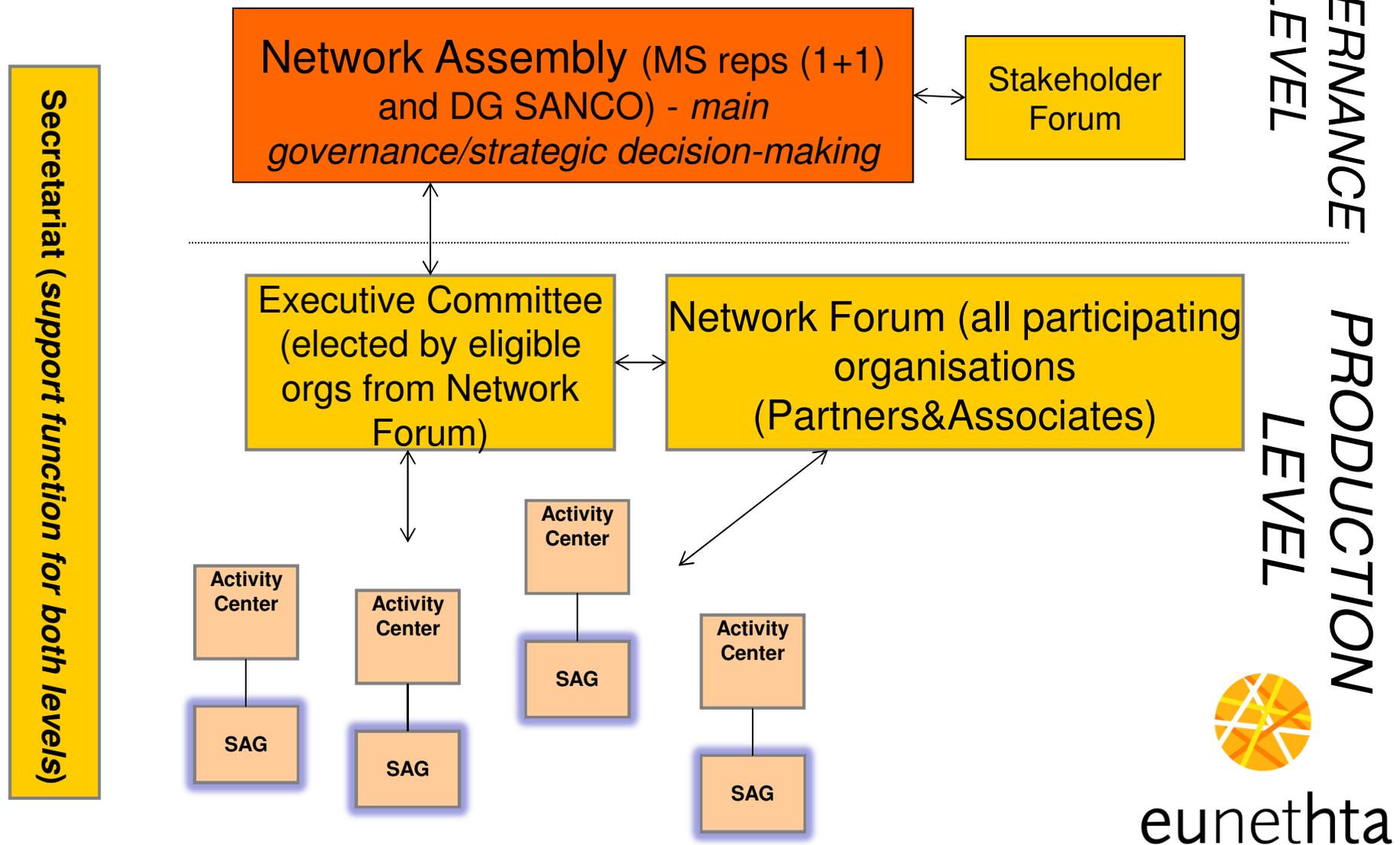


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Possible governance structure (as presented in Gdansk)



Possible governance structure (Exec Comm discussions April 2012)



Permanent European network on HTA: **governance level**

Network Assembly:

- for MS participation (1 vote per country, 1+1 representation (technical+political); members to be regularly informed on activities at production level
- strategic/endorsing role (eg, approving the output of the network – but not single HTA reports!; approving annual plans and reports, etc)
- Meeting once a year
- Role of the Commission – provider of services and financing, co-chairing the Network Assembly; facilitator in cooperation on stakeholder involvement



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Permanent European network on HTA: **production level**

General:

- Participation at the production level should reflect the HTA organisation at national level (eg, more than 1 organisation can be nominated with maximum number of nominated organisations)
- Clear distinction of the roles and decision-making power of the Network Assembly ("governance level") and the Executive Committee ("production level")
- Of utmost importance is to clarify WHAT is to be done by the network to develop HOW it will be governed and managed



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Permanent European network on HTA: **production level**

Network Forum:

- Composed of the organisations participating in the network (“partners and associates”)
- Purpose:
 - to provide an opportunity for regular network-wide scientific discussions and exchange of experience
 - discuss the key scientific and working process issues in order to
 - advise the Executive Committee



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Permanent European network on HTA: **production level**

Executive Committee:

- Composition decided by elections from the organisations nominated to participate in the permanent European network
- Main executive body of the network with a direct link/reporting to the Network Assembly:
 - preparation and managing implementation of the work plan, developing strategy proposals, performance overview of the activities, etc



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Permanent European network on HTA: **production level**

Activity Centers:

- Some work process and scientific decision-making to be delegated to the AC – while Network Forum will discuss the key scientific and working process issues
 - Decisions with the consequences for the whole of the network should be brought up in the Executive Committee
- Activity to be decided and approved by the Network Assembly as a part of the annual work plan (higher level decision-making)



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Permanent European network on HTA: **general**

- Financing of the network at the EU level will come from the "Health for Growth" programme (2014+; 7-year budget period)
 - Eligibility criteria to receive EU aid will be as is in joint actions
 - Some specific activities might be financed through other sources (eg, FP7, etc)
- Establishing a legal entity for administrative purposes (eg, receiving grants, holding intellectual property rights)
- Fee for service, membership fee (for non-nominated organisations (Associates))



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JA1 and JA2 – planning

Oct-Dec 2012 overlap

May 25, 2012



JA 1 and JA2 overlap

- From October 1, 2012 a cost recording system that identifies the costs for JA1 and JA2 SEPARATELY should be in place! The reporting of the activities should also be done separately (time sheets, etc)
- Sept 2012 – Secretariat will inform on the format for JA1 final reporting
- January 15, 2013 – WP final reports for JA1 and AP financial statements
- **October – December** – development of the JA2 3-year Work Plan
 - WP1 meeting in Copenhagen in January 2013
- March 2012 – Plenary Assembly meeting (endorsement of the 3-year Work Plan)
- **October-December** Conflict of interest declaration to be completed by all the individuals working in EUnetHTA JA2 Partner and Associate organisations. Procedure to handle the conflict of interest to be discussed and developed by the Executive Committee.
- **HOWEVER, October 2012 – JA2 WP4 and WP5 should have a project description in place (WP5 milestone M3; WP4 milestone M8)**
- **October-December – putting the new JA2 information platform in place**
- **January – new JA2 web platform goes live!**



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Stakeholder Forum in JA1 and JA2

- Current Stakeholder Forum is working until the end of JA1 (ie, December 31, 2012)
- Stakeholder Forum for JA2 – operational from January 2013
 - October 2012 – open call for expression of interest to participate in the Stakeholder Forum; to be announced on the EUnetHTA website
 - Current members to apply if wishing to be considered for participation in JA2 Stakeholder Forum



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Other issues and conclusion

May 25, 2012



Other issues

EUnetHTA Associates (recommendation of the Executive Committee):

- Continue with the policy of inclusiveness based on the availability of expertise and value that the applying organisations bring to EUnetHTA
 - Access to a wider pool of expertise and competence in Europe and world-wide
- Mode of involvement could be via
 - Contribution to WP activities (project-based)
 - Performing general tasks that are not tied to specific WP (task-based, eg, POP database, Evident database, etc)
- Secretariat to develop further criteria for assessing and accepting applicants to become Associates
 - Including considerations of the financing sources



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Other issues

Health programme Joint Actions brochure (EAHC):

- EUnetHTA members' assistance with **identifying examples of EU Member States' uptake of the results/ outcomes of the Joint Action activities for national Health Programmes/Policies development.**
- Secretariat will send an e-mail to EUnetHTA members next week (week 22) with a request and a deadline for responding by June 10.



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Other issues

Clarification of the status of the Co-Lead Partners in the governance structure:

- WP Lead Partners are “full members” of the Executive Committee having 1 voting right. The Co-LPs are **members of the Executive Committee** having **conditional** voting rights when the “full member” is not present and delegated its voting right to the Co-Lead Partner.



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WP1

Appendix 2 for Appendix 2



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Plenary assembly, face to face meeting

IMS – New Websites

Patrice Chalon

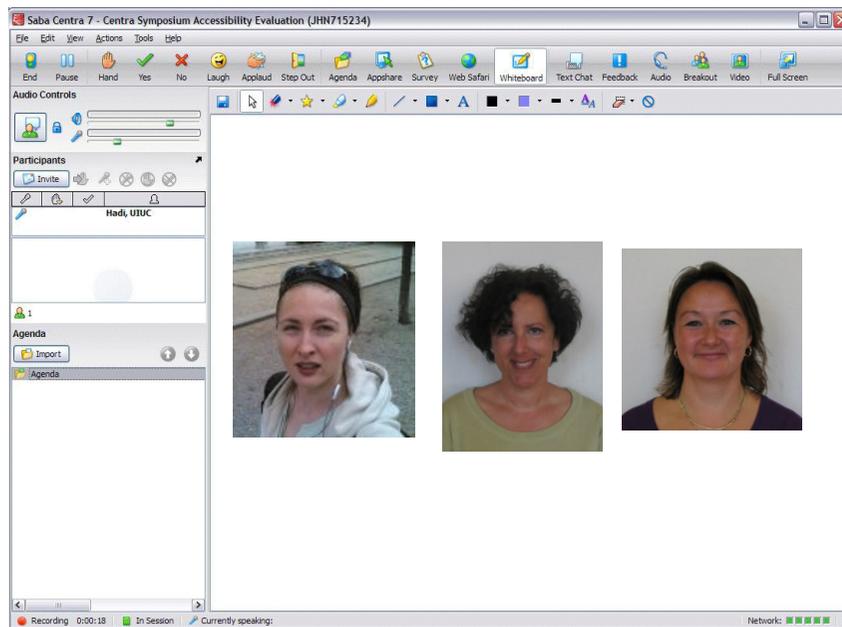
2012-05-24/25, Lisbon, Portugal



JA2 Websites: Project description

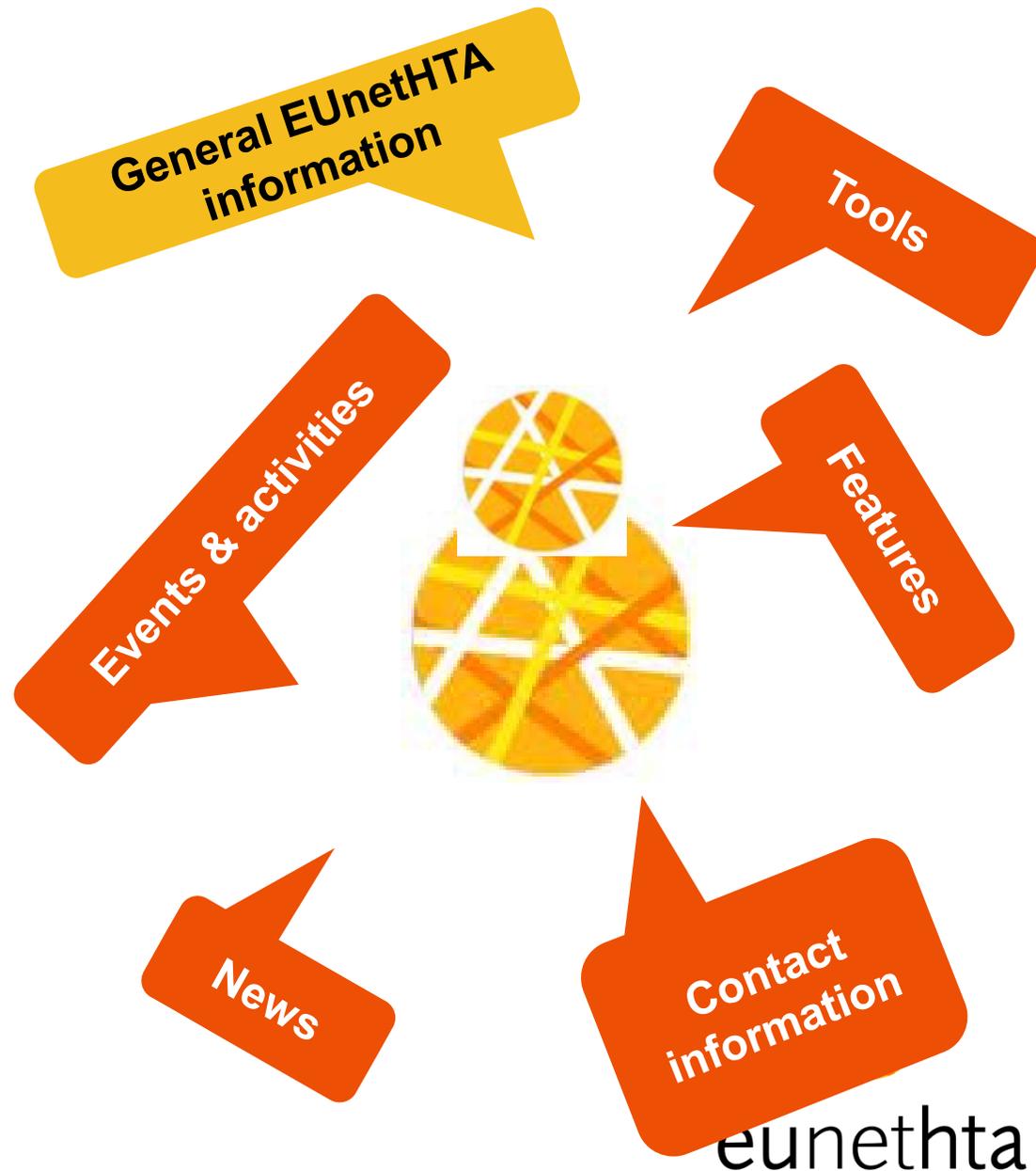
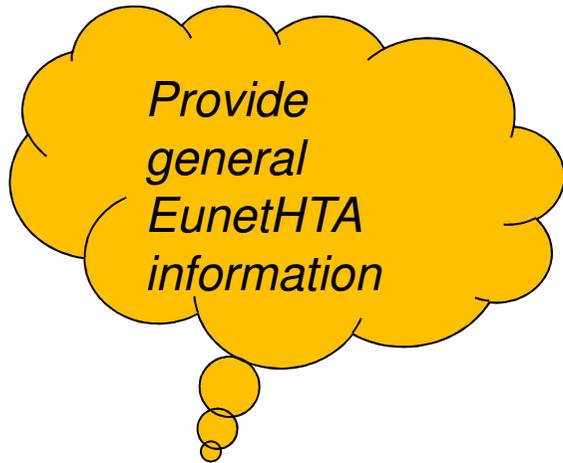
	Description
Tasks achieved	<ul style="list-style-type: none">• Surveys and interviews• Requirements synthesised & analysed• Technical options identified for Website and Intranet / workrooms / project management + basic tests• Preliminary contacts with potential furnishers (technical information)• 1st meeting task force: agreement on strategy• 2nd meeting task force: tender

Surveys & interviews



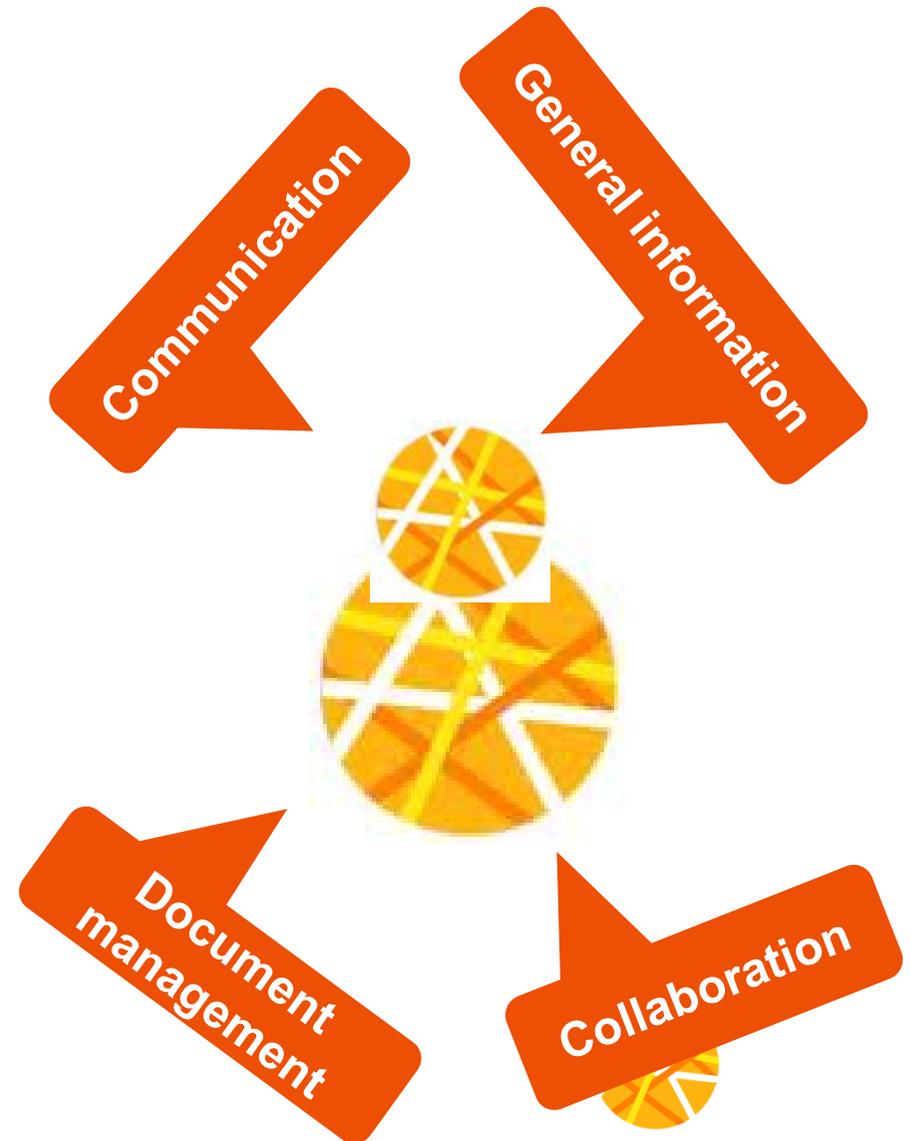
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Public site



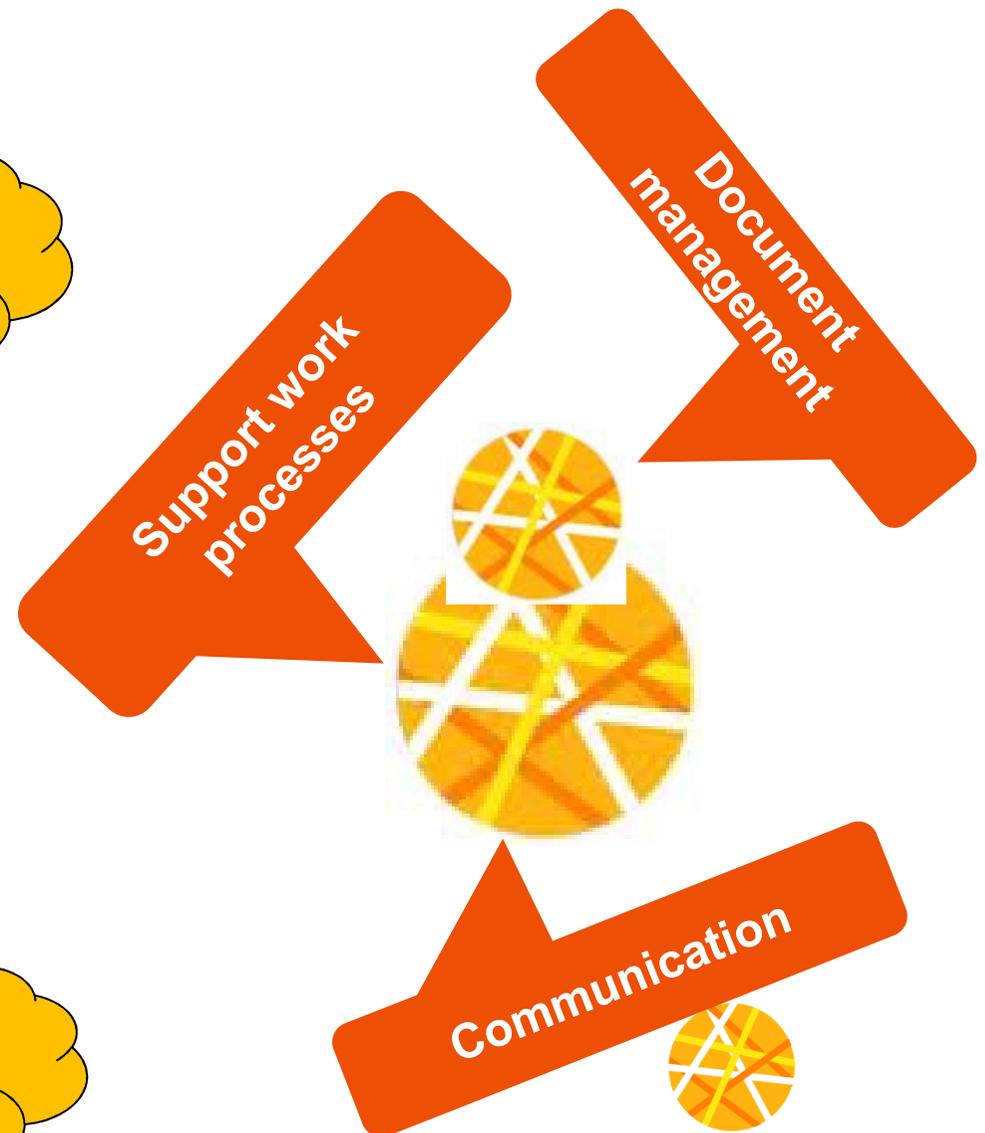
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Intranet



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Work rooms



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Analysis

*Overlap
Public site
& intranet*

*Overlap
intranet &
workrooms*

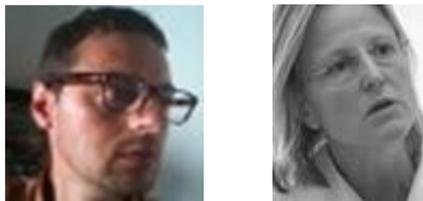
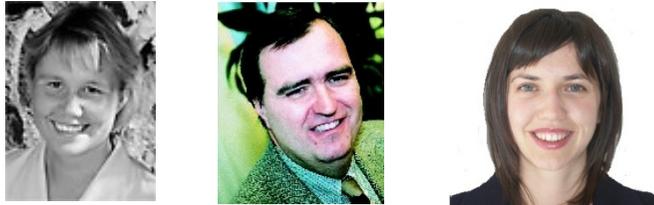
*More
information
for public
site*



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Task force

APRIL
26



Public site

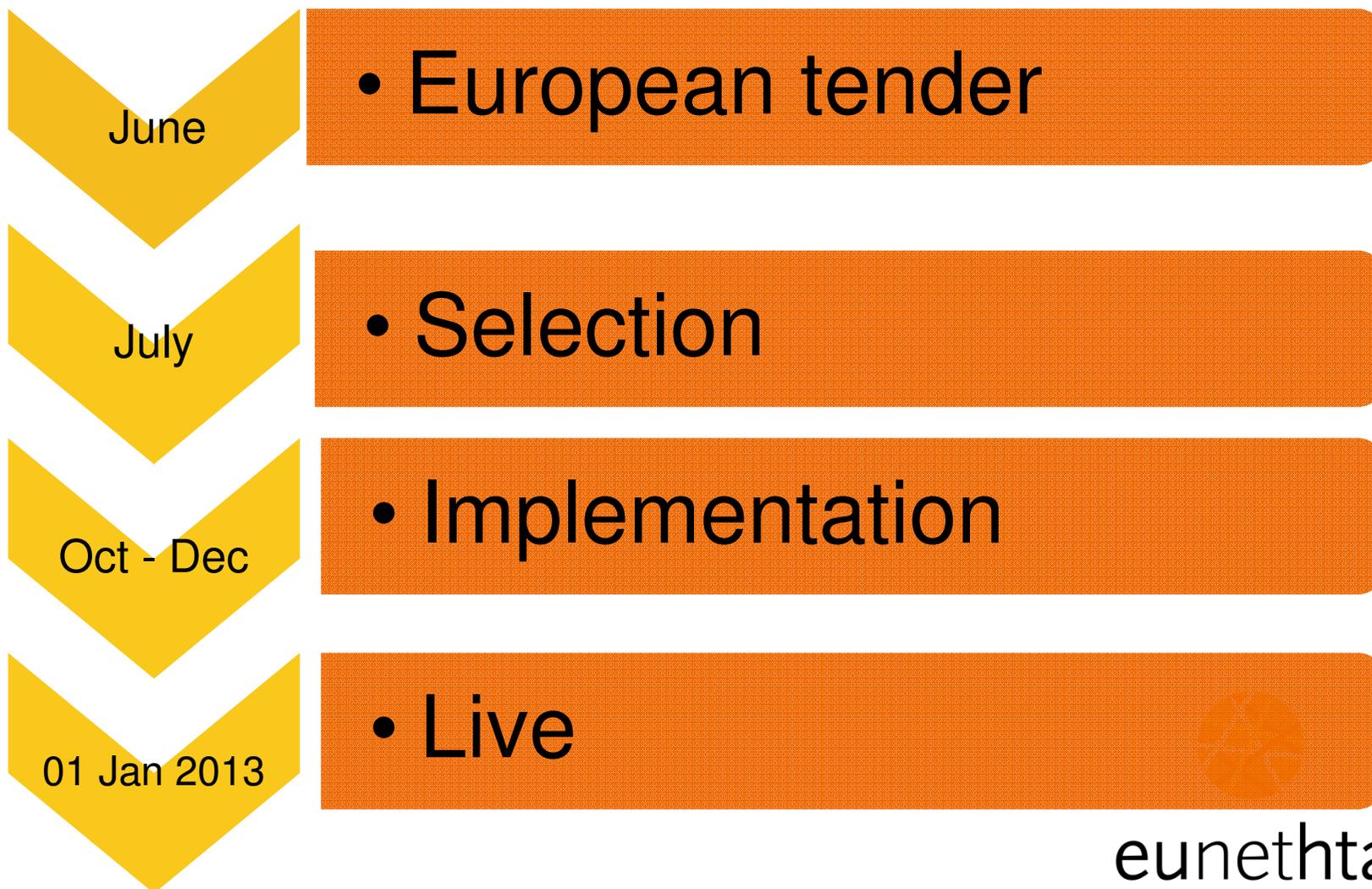
- FEDICT Fast2Web

Intranet

- Includes workrooms
- European tender 

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NEXT




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JA2 Websites: participants

KCE



Gudrun Briat, Patrice Chalon, Carl Devos, Kirsten Holdt Henningsen

Secretariat



Julia Chamova, Naomi Dayan, Inge Merete Skov

Task Force



Susanne Eksell, Gottfried Endel, Judit Erdos, Eleanor Gueguan, Wim Goettsch, Sarah Kleijnen,



Peter Kraemer, Leena Raustia, Ingvil Sæterdal, Sorin Stanel, Claudia Wild,



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WP1

Appendix 3 for Appendix 2



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*National Institute for
Health Research*

Participants' Survey 2012

Response so far.....

Dr Eleanor Guegan

NETSCC, UK

Plenary Assembly, 24-25 May 2012, Lisbon





Muito obrigado!



"Promover a Saúde Pública."



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PA 2012 Evaluation survey

The form is in your pack – please complete it before you leave!



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Stakeholders' survey



29 May 2012!

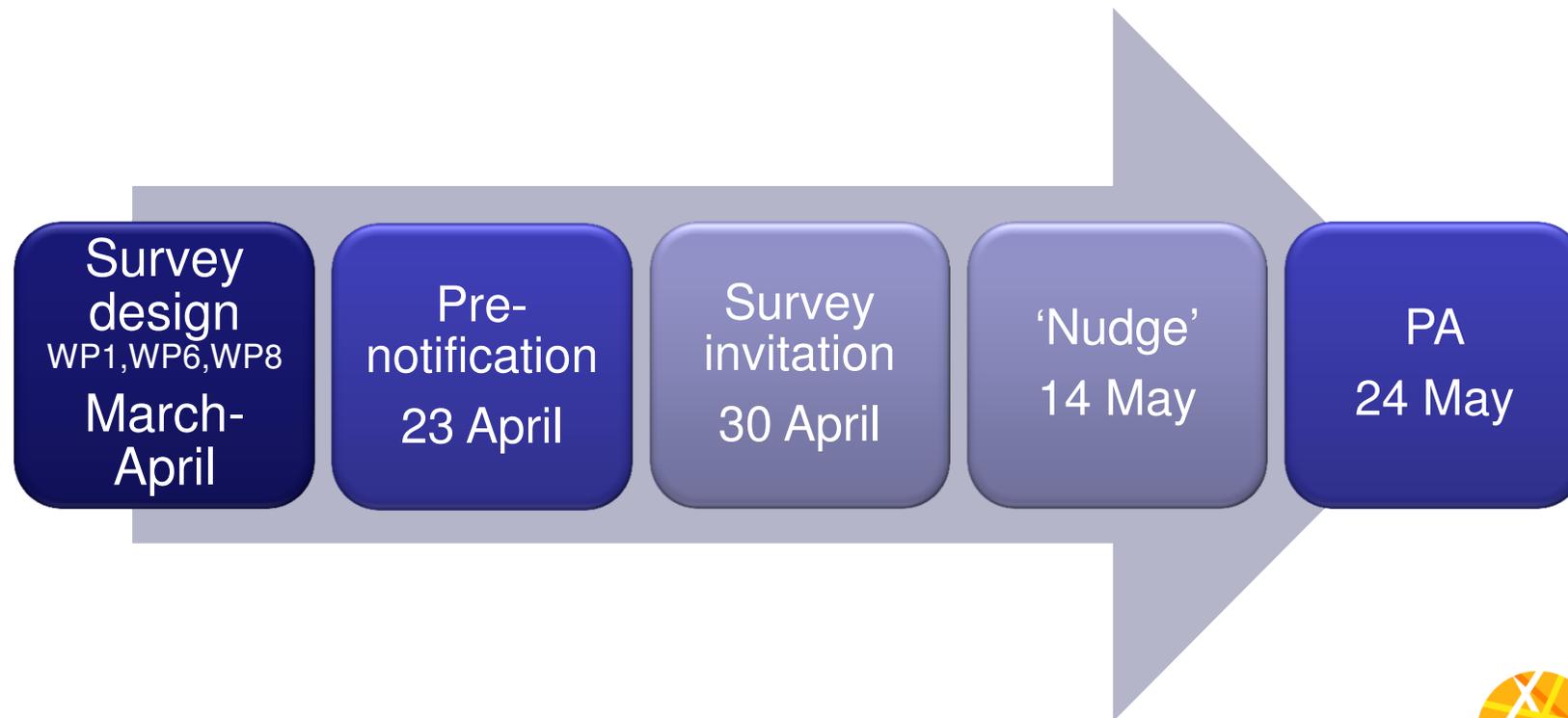


Apologies for missing logos that were unavailable on the internet



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Participants' 2012 Survey timeline



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Response so far



151 from 212 responded 21 May



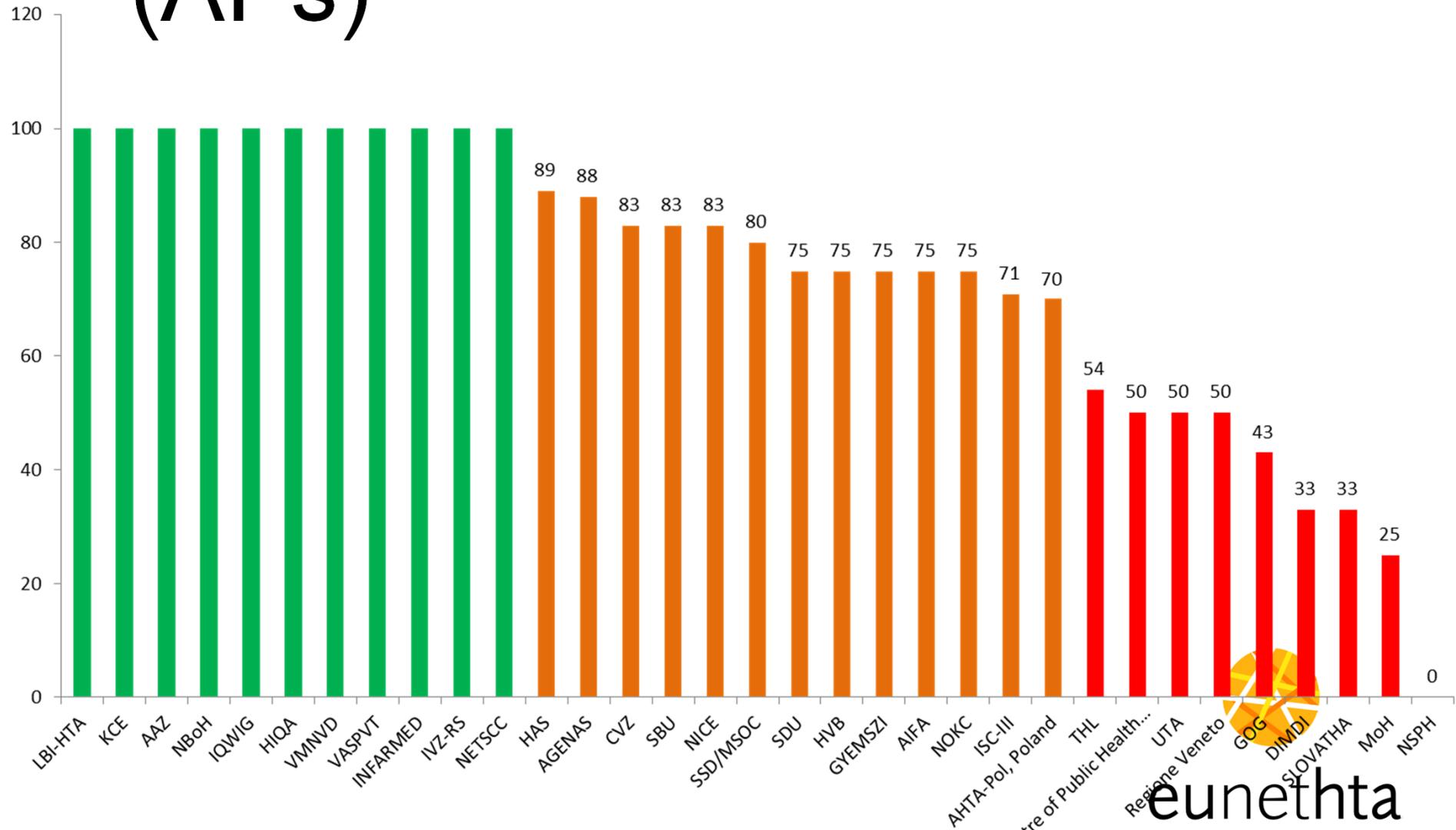
Respondent Certificates

- **All respondents by 21 May have a certificate**
- **Folders available for each organisation.....**

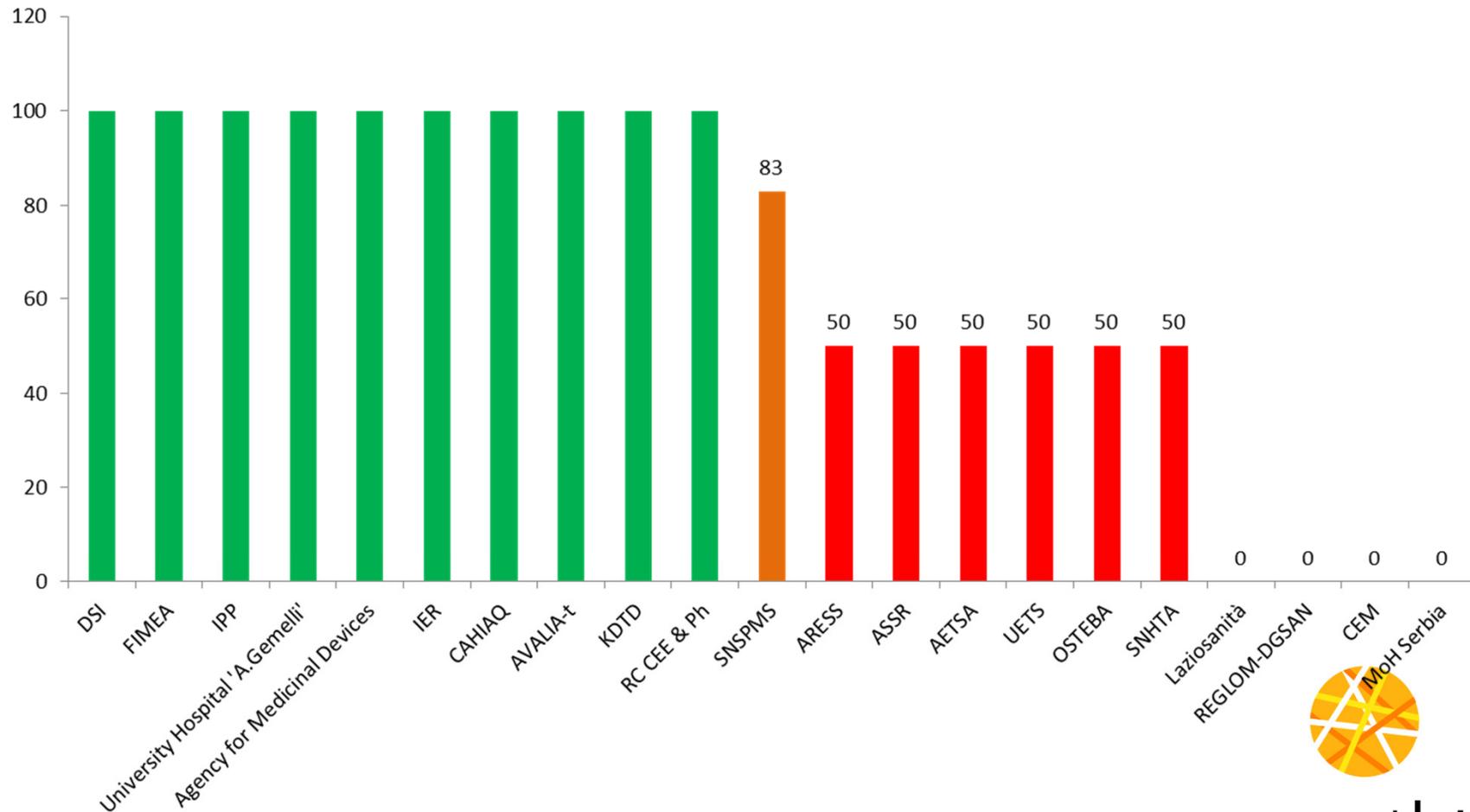


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Organisational response (APs)



Organisational response (CPs)



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Who hasn't yet responded?

- **5/49 here!**      
- **Reminder to be emailed – 28 May**
- **Please complete your survey**
- **Please encourage your organisation & WP colleagues to complete it too**



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Prize!
To be continued...



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WP1

Appendix 4 for Appendix 2



Establishing a permanent European HTA network

**EUnetHTA Plenary Assembly
25 May 2012
Anders Lamark Tysse, DG Sanco**



State of play – Directive 2011/24/EU

- ❑ **Entry into force:** 24 April 2011
- ❑ **Transposition period:** 30 months (**25 October 2013**)
- ❑ **Bilateral discussions** with 27 Member States:
 - COM questionnaire on the transposition of the measures provided for in the Directive (May – October 2011)
 - COM bilateral visits in all 27 Member States (2011 – 2012) to discuss particular issues related to transposition
- ❑ **Committee on Cross-Border Healthcare**
 - **Formal forum** created by the Directive where all 27 MS meet regularly to discuss and vote on implementing acts
 - Has already voted on the draft act setting up the eHealth network, which is now formally established.





Ongoing activities - HTA

- Kick-off meeting in Gdansk December 2011
- Spring: Bilateral meetings with interested Member States
- March-June: Ecorys study on alternative models for hosting the HTA network (governance, synergies, costs)
- May-July: Stakeholder consultation on the modalities of stakeholder consultation in the HTA network



Ecorys study

- Feasibility study necessary as future network is eligible to Union aid
- Ecorys will consider alternative hosting of the secretariat (Commission services, Member State, other)
- The study serve as a background document for future decision-making possible scenarios



Stakeholder consultation

The network shall consist of members appointed by the Member States, however...

- its work "...shall be based on [...] appropriate consultation of stakeholders..." (Article 15.1)
- and Union aid may be granted to the network "...in order to [...] facilitate the consultation of stakeholders on the work of the network..." (Article 15.2(e)).
- Stakeholder consultation necessary to ensure that also stakeholders outside EUnetHTA and its Stakeholder Forum have a chance to provide input



Stakeholder consultation (ii)

Duration: 2 May – 1 August

Purpose:

- Map *interest* and *capacity* of stakeholders
- Get input on possible ways/methods to consult stakeholders on the HTA network's activities
- HTA agencies can reply – see section 4 of the questionnaire





Next steps

- A consultation summary and the Ecorys study will serve as background papers for the Committee on Cross border Care
- The Committee will discuss the HTA network autumn/winter 2012/2013 (start 18 September), and vote on a draft Commission decision spring 2013
- The Commission aims at formally adopting the implementing act before 25 October 2013
- Member States will then be asked to appoint their representatives to the HTA network



Next steps (ii)

- The Network will convene and adopt its own Rules of procedure.
- If overlap with EUnetHTA members, meetings should be linked to existing EUnetHTA meetings
- Should the network's scope and working methods be re-discussed based on JA2 experience???





Access to the stakeholder consultation

http://ec.europa.eu/health/technology_assessment/consultations/cons_hta_network_en.htm



WP1

Appendix 5 for Appendix 2



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NHS

*National Institute for
Health Research*

Participants' Survey 2012

Prize giving ceremony!!

Dr Eleanor Guegan

NETSCC, UK

Plenary Assembly, 24-25 May 2012, Lisbon

EUnetHTA Joint Action 2010–2012 | www.eunethta.eu





Prize!



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Winning rules



- **100% response rate**
Before PA in 2010, 211 & 212
THEN
- **Time of last responder**
FOR
- **Organisations at PA 2012 (to be able to collect prize)**



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100% response rate

Before PA in 2010, 211 & 212



- LBI-HTA (n=3)
- KCE (n=4)
- AAZ (n=1)
- NETSCC
- University Hospital “A.Gemelli” (n=4)
- Agency for Medicinal Products and Medical Devices, Slovenia (n=2)
- AVALIA-t (n=2)



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Time of last responder



• LBI-HTA	02.05	09:44
• KCE	14.05	16:18
• AAZ	18.05	08:17
• Uni Hosp	03.05	08:49
• Agency for medicinal products, Slovenia	16.05	12:19
• AVALIA-t	21.05	12:27



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Congratulations!!



HBI-LTA – Ludwig Boltzmann Institute, Austria



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