EUnetHTA 21

Guidance Document

D5.3.2 - Resourcing and maintaining HTAb technical expert working groups

(sub deliverable of D5.3)

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The work in EUnetHTA 21 is a collaborative effort. While the agencies in the Hands-on Group will be actively writing the deliverable, the entire EUnetHTA 21 consortium is involved in its production throughout various stages. This means that the Committee for Scientific Consistency and Quality (CSCQ) will review and discuss several drafts of the deliverable prior to validation. Afterwards the Consortium Executive Board (CEB) will endorse the final deliverable prior to publication.

External Stakeholder Contribution

The draft deliverable was reviewed by associated HTA bodies and was open for public consultation between 20.04.2022 and 20.05.2022.

Associated HTA bodies that reviewed the draft deliverable	Austrian Social Insurance [DVSV], Austria

Stakeholders that participated in the public consultation	European Union of General Practice Family Medicine UEMO,Belgium Lumanity,The Netherlands German Medicines Manufacturer´s Association (BAH), Germany Bayer AG. Germany EFPIA (European Federation of Pharmaceutical Industries and Associations), Belgium Eurordis – Rare Diseases Europe, France

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LIST OF ABBREVIATIONS

CA	Collaborative Assessment
CEB	Consortium Executive Board
COI	Conflicts of interest
COIC	Conflicts of interest Committee
CSCQ	Committee for Scientific Consistency and Quality
EUnetHTA	European Network of Health Technology Assessment
HaDEA	European Health and Digital Executive Agency
HTA	Health Technology Assessment
HTAb	HTA body
HTAR	HTA regulation
SOP	Standard Operating Procedure
ISN	Information Specialist Network
JA3	Joint Action 3
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
SSN	Statistical Specialist Network

1. BACKGROUND

The establishment of working groups (e.g., of information specialists and statisticians) from different health technology assessment bodies (HTAbs) to support HTA production teams was initiated in EUnetHTA Joint Action 3 (JA3). Besides improving the quality of joint assessments, the aim was to promote scientific exchange between European HTAbs with regard to HTA methods and other issues.

There is no standard definition of the term "technical expert". In the EUnetHTA 21 context, this term refers mainly to statisticians or information specialists, with the following experience as confirmed by their agency:

- Information specialist has experience in developing search strategies and conducting searches for HTAs, systematic reviews and / or other evidence syntheses
- Statistician has experience in statistical data analysis for clinical trials and epidemiological studies, meta-analyses and other evidence syntheses

However, if necessary, other roles may be added in the future.

Rather than the establishment of "informal" networks of technical experts from the different HTAbs, the guidance focuses on the formation of working groups including a limited number of highly trained experts delegated from HTAbs.

2. GENERAL PRINCIPLES AND PURPOSE

On 17 September 2021, the European Health and Digital Executive Agency (HaDEA) signed the "Service Contract for the Provision of Joint Health Technology Assessment (HTA) Work Supporting the Continuation of EU Cooperation on HTA" with the aim of supporting European HTA collaboration beyond May 2021, when the EU co-funded EUnetHTA JA3 work ended.

The EUnetHTA 21 consortium consists of 13 European national HTA agencies. Its work will build on the achievements and lessons learned from the EUnetHTA Joint Actions and focus on supporting a future EU HTA system under the HTA Regulation (HTAR), which is expected to become effective in 2025. The main objectives of this Service Contract are to further develop HTA methods and continue European HTA collaboration within the EUnetHTA network by producing a specified number of Joint Clinical Assessments (JCAs)/Collaborative Assessments (CAs) and Joint Scientific Consultations (JSCs).

This document addresses the following deliverables

- creation of a standard operating procedure (SOP) for the recruitment of technical experts to a formal network and establishing minimum requirements for technical experts for each project to be undertaken (JCA/CA and JSC); and
- design of a proposal for resourcing and maintaining technical expert networks (such as the ISN [Information Specialist Network] and the Statistical Specialist Network [SSN])

2.1. General principles

To ensure that joint work is of high methodological quality and reflects current standards, there is a need to establish HTAb technical expert working groups for information specialists and statisticians to

- **solve** general **common methodological problems** in information retrieval and statistics
- answer questions from the assessment teams and other bodies on an **ad-hoc basis**
- ensure that methodological expertise in **different areas** is covered (e.g. medical devices, pharmaceuticals, JSCs, emerging health technologies)
- give advice on **new topics** where methodological guidance is needed
- support the development and maintenance of **methods guidance**
- promote scientific **exchanges** between European HTAbs
- ensure that methodological expertise is available during assessments.

2.2. Purpose and Scope

The objective of this sub-deliverable is to complement the deliverable on "Procedural guidelines for appointing assessors and co-assessors" (D5.3.1) with a guidance on

- designing a proposal for resourcing and maintaining HTAb technical expert working groups

The scope of the guidance covers aspects of the proposed functioning of the HTAb technical expert working groups, including their sustainability, governance and their members' skills and roles. Whilst focusing on statisticians and information specialists, the proposed process could be applied to other HTAb technical expert working groups as necessary.

Further, this procedural guideline outlines how ad-hoc questions for the HTAb technical expert working groups could be organized.

As part of the HTAR implementation, "rules of procedure" should be established for the HTAb technical expert working groups, building on the present guidance document and providing further details.

3. ACTORS AND THEIR SCOPE

Table 1 presents the definitions of the main actors

Assessment team (JCA/CA)	An assessment team includes an institution for the role of assessor and another institution for the role of co-assessor. Both assessor and co-assessor can consist of multiple individuals from the respective institution.
CEB	The Consortium Executive Board (CEB) is the principal decision-making body of the EUnetHTA 21 Consortium. The CEB comprises representatives of each of the 13 consortium member organisations.
Coordination Group	The Coordination Group is defined as in REGULATION (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on Health Technology Assessment and amending Directive 2011/24/EU (Art. 3).
CSCQ	The EUnetHTA 21 Committee for Scientific Consistency and Quality (CSCQ) is in charge of the process that ensures the scientific consistency and quality of activities and deliverables covered by the EUnetHTA 21 service contract. The CSCQ is composed of representatives of all member organisations of the EUnetHTA 21 consortium and can convene in three different configurations (CSCQ JCA, CSCQ JSC and CSCQ Transversal).
EUnetHTA 21 Secretariat	The EUnetHTA 21 Secretariat consists of the ZIN Secretariat as consortium lead, the ZIN JCA Secretariat and the G-BA JSC Secretariat.
HTAb technical expert working group	An HTAb technical expert working group comprises a limited number of HTAb technical experts delegated from the HTAbs who are responsible for fulfilling the tasks of the working group for a defined period of time.
JCA/CA Assessor JCA/CA Co-assessor	The HTAb participating in JCA/CA production through their representatives are responsible for undertaking a single (or set of) task(s) and for the quality and timing of the task(s). During JA3, assessors and co-assessors were called authors and co-authors, respectively.
Joint work	Jointly produced clinical assessments, scientific consultations or other joint work that require the management of conflicts of interest.
Subgroup (of the Coordination Group)	Subgroups of the Coordination Group are composed of HTA authorities and bodies that provide adequate technical expertise for carrying out JCAs and JSCs. The members of the subgroup shall appoint their representatives, who shall have the appropriate HTA expertise, in the subgroups on an ad-hoc or permanent basis.

4. RESOURCING AND MAINTAINING HTAb TECHNICAL EXPERT WORKING GROUPS

4.1. Establishing HTAb technical expert working groups

Methods are continuously developing and experts must be aware of these changes. Furthermore, there must be agreements within the HTAbs on how to deal with certain methodological challenges in order to maintain consistency. To create a suitable framework for HTAb technical expert working groups, several sources were used (see Appendix 1).

Considering their profile and roles, the HTAb technical expert working groups could be part of the subgroup responsible for the development of methodological and procedural guidance as defined in the HTAR. Two dedicated working groups, one for statistics and one for information specialists, should be created when the Coordination Group forms the subgroup.

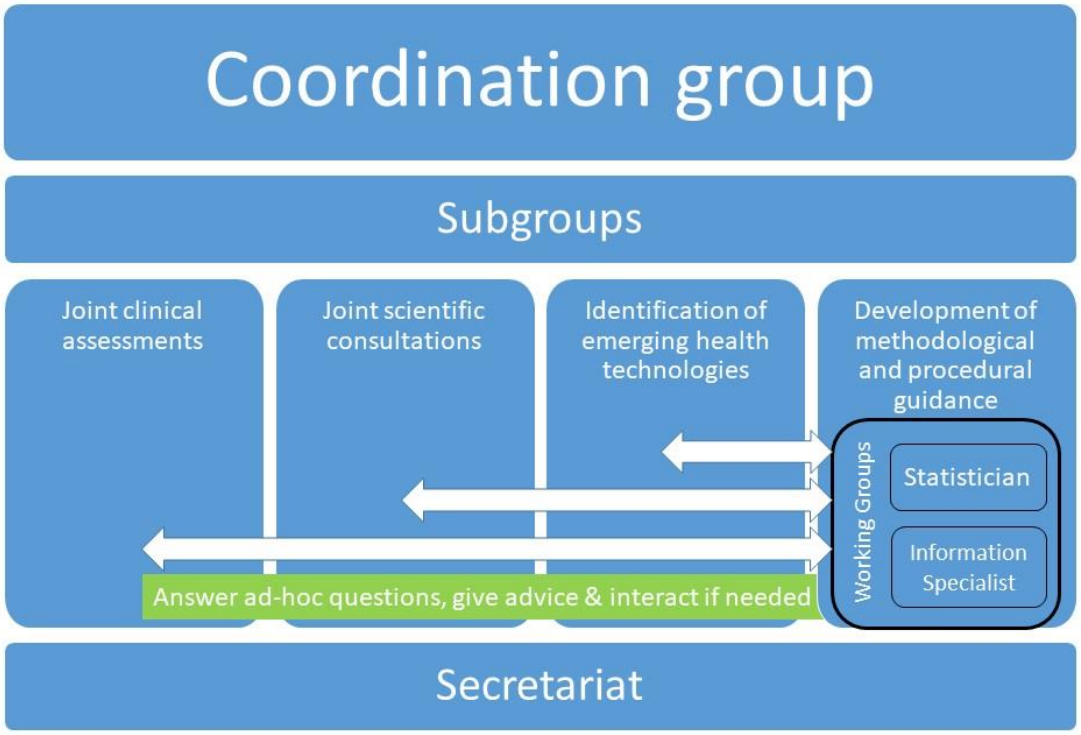

Figure 1: Suggested integration of the HTAb technical expert working groups within the HTAR governance

4.2. Structure and tasks of HTAb technical expert working groups

There should be one HTAb technical expert working group for each field (e.g., statistics, information retrieval). Each HTAb technical expert working group comprises 5-10 highly experienced experts with a wide range of expertise, who are delegated from the HTAb and who are responsible for fulfilling the tasks of the working group for a defined period of time. It is recommended that a relevant number of the HTAb technical expert working group members should be senior technical experts. This formal group is given a mandate and clear responsibilities, as well as structures such as the designation of a chair/co-chair and regular and ad-hoc meetings. Observers from HTAbs are accepted in HTAb technical expert working groups for further training purposes.

The HTAb technical expert working group is involved in the development and maintenance of all methodological guidelines relevant to its area of expertise, as requested by the Coordination Group or designated subgroups. It additionally can provide input to specific methodological queries arising during the course of a specific JCA or JSC. The decision-making bodies (Coordination Group, subgroups)

should receive input from the HTAb technical expert working groups when reviewing relevant methodologies.

General or technical questions and tasks arising, for example, from the assessment teams or subgroups should be processed by the HTAb technical expert working groups.

Table 2: Structure and tasks of HTAb technical expert working groups

Structure
• One HTAb technical expert group for each field (e.g. statistics, information retrieval) • 5-10 members from various HTAbs, headed by chair/co-chair. • Specific expertise and experience in the area of interest. • Nomination for a certain period of time (e.g. 3 years). • Working group composition agreed by Coordination Group / subgroup, for example.
Tasks
• Preparation, review and update of guidelines, templates and concept papers. • Provision of responses to methodological queries (e.g. ad-hoc queries from JCA/CA, JSC and other bodies). • Promotion of exchange between HTAb technical experts. • Facilitation of further training.

Since the involvement of HTAb technical expert working groups in ad-hoc questions is a regular occurrence and may also be relevant for EUnetHTA 21, the corresponding process for assessment teams is outlined in Appendix 2. In addition, other bodies (e.g. Coordination Group or subgroups) could contact these HTAb technical working groups to answer ad-hoc questions.

4.3. Resourcing HTAb technical expert working groups

The HTAb technical expert working groups can only function if they are provided with sufficient financial and human resources. According to the HTAR (Article 27), the European Union ensures the funding of the work of the Coordination Group and its subgroups, including the funding of the development of methodological guidance. The funding of HTAb working groups may be part of the funding of the methodological and procedure subgroups. When implementing the HTAR it should be ensured that this funding will be made available.

5. IMPLEMENTATION IN EUNETHTA 21

This proposal describes the requirements and implementation of HTAb technical expert working groups within the framework of the HTAR.

For EUnetHTA 21, it has to be verified whether the funding of the specific project work (e.g. answering ad-hoc questions) is possible within the existing budgets. The further development of the HTAb technical expert working groups can be ensured, at least in part, through the Deliverable D5.3. The amount of resources still available for this purpose also needs to be determined.

6. BIBLIOGRAPHY

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APPENDIX 1: INFORMATION SOURCES

The following sources were used to create a suitable framework for HTAb technical expert working groups.

- Review of documents prepared during JA3 and published articles on the collaboration of information specialists in Europe [1]

Interview with the EUnetHTA Secretariat

- To learn more about the Secretariat's work regarding the SSN, an online meeting was held in which we were updated on the procedure so far, including the experience gained, and provided with internal documents.

Interview with stakeholders from the European Medicines Agency (EMA)

- We screened documents by the EMA on its "Biostatistics Working Party" and other working parties [2-4] and held an online meeting with EMA stakeholders on 22 November 2021 to learn more about the structure and tasks of the working parties.

Cochrane Methods Group

- The Cochrane Methods Group is another multi-national group working on health care issues. We therefore examined its structure and tasks in more detail [5].

Input from HTAbs

- A meeting with the EUnetHTA21 consortium and associated HTAbs took place on 3 December 2021. We informed them about our work and asked them to respond to questions by 31 December 2021. The question as to whether other technical experts (excluding information specialists, clinical experts, patients and healthcare professionals) should be organised centrally was answered by only a few HTABs: (medical editors: 2x, experts in ethical, legal, and environmental aspects: 1x, public health experts: 1x).

APPENDIX 2: INVOLVEMENT OF HTAb TECHNICAL EXPERT WORKING GROUPS FOR AD-HOC QUESTIONS

Even though an assessment team consists of the experts required, methodological questions can arise that should not be addressed solely within the assessment team. In such cases, the HTAb technical expert working groups should be contacted and solutions found by consensus. These groups may answer questions arising in individual assessments on an ad-hoc basis.

The collaboration process is outlined in Figure 2; however, details of the procedure, responsibilities and timelines should be developed when the HTAb technical expert working groups have been established.

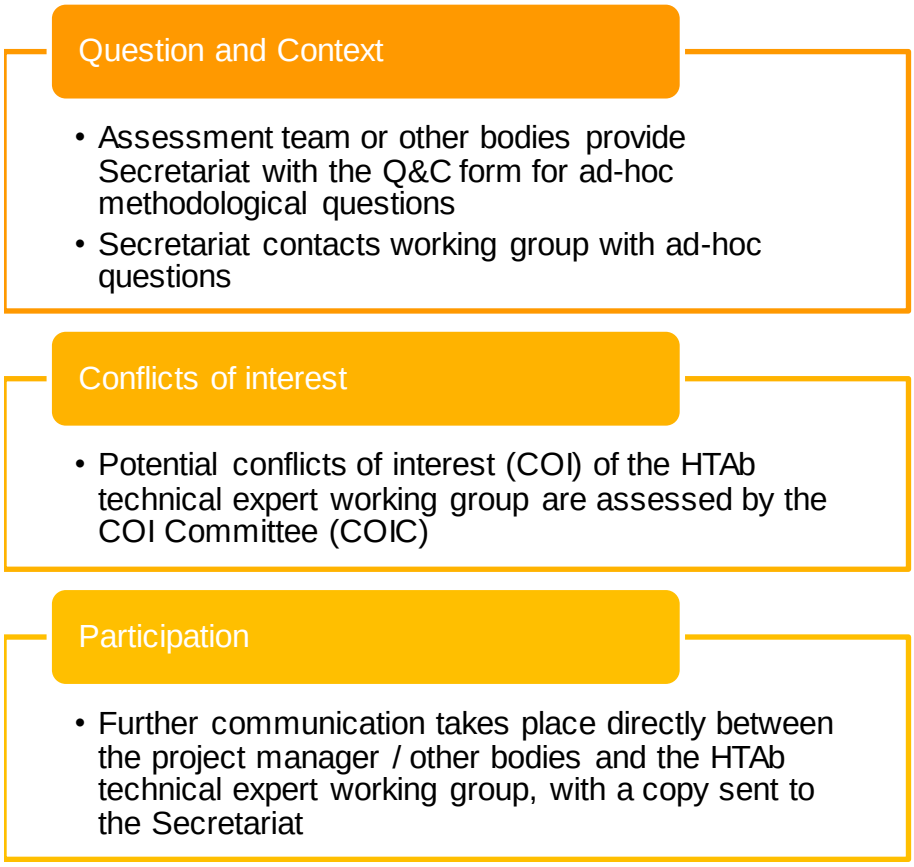

Figure 2: Process flow for involvement of HTAb technical expert working groups for ad-hoc questions

Q&C Form for ad-hoc methodological questions within assessments

- Assessment ID
- Type of assessment (JCA, JSC, emerging health technologies, medical devices, pharmaceutical products, voluntary cooperation on HTA etc.)
- HTA agencies / other institutions involved so far
- Research question/ topic
- Parties involved
- Estimation of time needed
- At what stage is the project now?
- Overall timelines for the project
- E-mail address for further contact
- Detailed description of the support needed