



**eunethta**  
EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

**Project Plan**

**5.3 PROCEDURAL GUIDELINES FOR APPOINTING ASSESSORS AND CO-ASSESSORS**

**Version 1.0 03/12/2021**  
Template version 1.0, 30 September 2021

## DOCUMENT HISTORY AND CONTRIBUTORS

Version	Date	Description
V1.0	03/12/2021	Final Project Plan

### Disclaimer

This Project Plan was produced under the Third EU Health Programme through a service contract with the European Health and Digital Executive Agency (HaDEA) acting under the mandate from the European Commission. The information and views set out in this Project Plan are those of the author(s) and do not necessarily reflect the official opinion of the Commission/ Executive Agency. The Commission/Executive Agency do not guarantee the accuracy of the data included in this study. Neither the Commission /Executive Agency nor any person acting on the Commission's / Executive Agency's behalf may be held responsible for the use which may be made of the information contained therein.

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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. For further information on stakeholder involvement in this deliverable, please see section 3.2.

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## LIST OF ABBREVIATIONS

CA	Collaborative Assessment
CEB	Consortium Executive Board
COIC	Conflict of Interest Committee
CSCQ	Committee for Scientific Consistency and Quality
EUnetHTA	European Network of Health Technology Assessment
HOG	Hands-on Group
HTA	Health Technology Assessment
HTAB	Health Technology Assessment Body
ISN	Information Specialist Network
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
SOP	Standard Operating Procedure
SSN	Statistical Specialist Network
ZIN	Zorginstituut Nederland

## 1 INTRODUCTION

In the technical offer, submitted on 04/05/2021, deliverables for the production of Procedural Guidelines for appointing assessors and co-assessors have been defined.

This Project Plan describes the objectives, approach and timelines for the deliverable D5.3.1 on procedural Guidelines for appointing assessors and co-assessors for JCAs and CAs. The roles “assessor” and “co-assessor” of JCAs / CAs are introduced by the Proposal for a Regulation of The European Parliament and of The Council on health technology assessment and amending Directive 2011/24/EU”. These roles are therefore similar to the author and co-author of relative effectiveness assessments produced under EUnetHTA JA3. The current project plan does not concern the roles of the scientific coordinator and rapporteur for joint scientific consultations (JSCs).

## 2 BACKGROUND

In JA3, JCA/CA teams were composed of partners volunteering for the different roles. A project manager was always dedicated to the assessment. An assessment team required the following roles: author and co-author (constitutes the authoring team), and at least two dedicated reviewers. Observer(s) could be added to the team for capacity building. This mode of collaboration was depicted in order to establish trust between the agencies, while gaining experience in differences or similarities of national HTA practices. In addition, this collaboration model allowed more agencies to become acquainted with EUnetHTA procedures, tools, and templates, and thus allowed for capacity building for future assessments.

In order to prioritise between partners, if needed, criteria for the selection of assessment teams have been developed in JA3. These criteria describe the competencies that should be covered within the assessment team and can be used when prioritisation is needed between partners.

The main criteria for the authoring team were:

- Availability during the timelines;
- Sufficient resources;
- No conflict of interest;
- Expertise in the disease area and health technology;
- Experience and/or knowledge of EUnetHTA procedures and methodology;
- Relevant expertise regarding information retrieval and statistical analyses within the authoring team;
- The agencies who participate in the authoring team should commit to use the assessment in the national setting;
- It is preferable to seek geographical spread.

The criteria are available on the website<sup>i</sup> and in Annex A-5.3.1-1. If no information specialist or statistical specialist can be found within the assessment team, the Information Specialist Network (ISN) or Statistical Specialist Network (SSN) can be contacted.

Experience of establishing assessment teams in EUnetHTA JA3 has shown that it was not always feasible to cover all aforementioned criteria. More specifically, these criteria as defined in JA3 were perceived to be difficult to meet by some national or regional agencies. Therefore, the selection criteria for appointing of assessors and co-assessors for JCA/CA should be examined. As a starting point, it should be further evaluated what difficulties former authoring teams of REAs have had in fully meeting the criteria set out by the EUnetHTA quality management system. From this, quality standards and support offers should be derived as to how these can be fulfilled in the future.

Other challenges were that not all national HTA agencies have dedicated information specialists in house, or statistical experts that can review advanced statistical methods or no experience with the GRADE methodology. Therefore, the creation of the ISN and SSN was crucial. There is no question that every authoring team needs an information specialist and statistical expert. An open point, however, remains the question of whether an ad-hoc involvement of a statistical expert from the SSN is sufficient or whether the availability of a statistical expert in the authoring team should be a mandatory

requirement. It also needs to be further explored how these expert networks can be involved in the assessments.

It should also be discussed if the individual assessors and co-assessors of JCA/CA could have participated in the JSC of the product under assessment, as this could be seen as a risk for bias but potentially could also bring added value for the JCA/CA production.

Another issue that should be discussed is if one individual should be allowed to have multiple roles within one project (e.g. author/co-author and CSCQ member). Due to these challenges experienced in EUnetHTA JA3, it is important to revise the procedural guidelines for the appointment of assessors and co-assessors.

**Table 2.1. Existing EUnetHTA documents**

Title	Scope
EUnetHTA Standard Operating Procedure - Call for Collaboration and Formation of Assessment Team for PT and OT ( <a href="#">PT-01-CallCollFormAss</a> , <a href="#">OT-01-CallCollFormAss</a> )	<i>This SOP outlines the procedure of forming an assessment team, including the selection of an assessor and a co-assessor. The document can be used as a basis for developing the standalone guidance for selecting the assessor and a co-assessor; Annex 2 is especially relevant. Also, this SOP outlines the broader environment of the operations of the authoring team, so it can be used to ensure that the newly developed guidance will fit into the currently existing framework.</i>
<a href="#">EUnetHTA Recommendations for production process of Relative Effectiveness Assessments after Joint Action 3. May 2021</a>	<i>The document briefly discusses JA3 experience with setting up and using the ISN/SSN and therefore, it would be suitable to cover past expectations towards the operations of the Networks. The document also contains an explicit recommendation to maintain the Networks.</i>
EUnetHTA Standard Operating Procedure – Information retrieval ( <a href="#">OT-03-InfRetr</a> )	<i>This SOP describes how to plan, conduct, document and report information retrieval in the first draft of the assessment report. This SOP refers to the ISN and could be modified according to the results of D5.3.</i>
EUnetHTA Standard Operating Procedure – Review of Information Retrieval in the Project Plan by a Dedicated Reviewer (Information Specialist) ( <a href="#">OT-02-CheckInfRetrPP</a> )	<i>This SOP describes how to review the information retrieval methods reported in the first draft of the project plan. This SOP refers to the ISN and could be modified according to the results of D5.3.</i>
EUnetHTA Standard Operating Procedure – How to create an SOP ( <a href="#">QMS-00-CreateSOP</a> )	<i>This SOP should be followed when creating SOPs as planned.</i>
EUnetHTA Standard Operating Procedure – How to Maintain an SOP ( <a href="#">QMS-00-MaintainSOP</a> )	<i>This SOP should be followed when modifying SOPs as planned.</i>

### 3 OBJECTIVE AND METHODS

The objective of this deliverable is to:

- develop a list with minimum selection criteria for the appointment of assessors and co-assessors of JCA/CA
  - A clear distinction of tasks and responsibilities could be made between the different roles;
  - Also, the dedicated SOP as developed in EUnetHTA JA3 on establishing a team should be revised to reflect the updated selection criteria accordingly;
- facilitate the involvement of the ISN and SSN by:
  - Creating a SOP for the recruitment of technical experts to a formal network and establishing minimum requirement for technical experts for each project to be undertaken (JCA/CA and JSC); and

- Designing a proposal for sustaining and resourcing of technical expert networks (such as the ISN and SSN)

### **3.1 Methods to achieve the objectives**

For all of the objectives below the future EU HTA regulation will serve as the basis and the past JA3 experiences will be taken into account.

#### **3.1.1 Objective 1 – Revision of the selection criteria established in EUnetHTA JA3**

When fine-tuning the selection criteria for assessors and co-assessors, it is important that they are feasible but also clear enough and fulfill the quality standards to identify the best possible team for the JCA / CA. It is crucial to have a close collaboration with the hands-on groups on methodological development to ensure the selection criteria will request specific methodological expertise if that is needed for an assessment. In addition, close collaboration with the hands-on group on COI is needed to ensure that the selection criteria is linked to the transversal work on Conflict of Interest. In these discussions it can also be decided if coordinators or rapporteurs for JSCs can act as assessors or co-assessors for JCA/CA if the same product is under assessment and if an individual should be allowed to have multiple roles within one project (e.g. project manager and assessor/co-assessor).

In order to reach this objective, a possible guiding principle is to review the feedback from JA3 (i.e. follow-up interviews) and carry out desk research on already published HTA reports to see if every role has been filled appropriately during the assessment procedure. The experience of finding an assessment team of the EUnetHTA Secretariat can be incorporated. The SOPs "Call for Collaboration and Formation of Assessment team" (for PT and OT) will be updated accordingly based on the outcomes of the review.

#### **3.1.2 Objective 2 – Develop a SOP for the recruitment of technical experts to a formal network, establishing minimum requirements for expertise and design a proposal for sustaining and funding of these networks**

In order to develop a SOP for the recruitment of technical experts to a formal network, past experience with the involvement of such experts needs to be evaluated. In addition, e.g. a survey can be conducted to determine whether there are other technical experts for which networks need to be established.

In terms of sustaining and funding of such networks, multiple options need to be developed acknowledging that there is a solidarity between HTA bodies (HTABs), yet the contribution of the expert can vary between assessments, depending on the actual task. When discussing the sustainability of the networks, issues related to the governance, involvement and further training<sup>ii</sup> should also be addressed.

As a practical approach, e.g. a survey would be feasible to depict the expectations of EUnetHTA Partners towards the involvement of external expertise to see if those can be fulfilled, or internal capacity building is expected.

### **3.2 Stakeholder inclusion**

EUnetHTA 21 Stakeholder Pool is composed of HTA bodies (HTAb) outside of EUnetHTA 21 consortium, as well as stakeholder groups on patients, health technology developers (HTD), healthcare professionals (HCP), payers, and regulatory agencies from the EU/EEA countries.

Non-consortium HTAb (i.e. those not part of the EUnetHTA 21 consortium) who will be involved in the future subgroups of the HTA Regulation, should participate in the development of this project in order to ensure the deliverables are applicable to all European HTAb. They should be consulted at the beginning of the project. Additionally, they will be invited to review, at the same time as the Committee for Scientific Consistency and Quality (CSCQ), the 1st draft of the deliverable and the pre-final draft that will be submitted for public consultation.

Other members of the EUnetHTA 21 Stakeholder pool will also be involved in this project. Their involvement will include, at minimum, participation in an informational kick-off meeting and regular stakeholder fora. They will also be invited to contribute to the work through public consultation.

## 4 ORGANISATION OF THE WORK

### 4.1 Mode of collaboration and frequency of meetings

The work will be distributed evenly between the agencies of the hands-on group (HOG). All HOG members will review each other's work prior to review by the CSCQ. The HOG will appoint one agency to interact with the three CSCQ configurations and the CEB.

The HOG will have meetings/email updates when needed, but at least bi-weekly meetings, to update each other on the progress. In addition, when needed, the HOG will also have regular meetings with the other relevant HOGs.

### 4.2 Timelines

**Table 4.1. Timetable**

Deliverable	D5.3.1 – Procedural guidelines for appointing assessors and co-assessors		D5.3.2 – Technical expert networks	
	Start date	End date	Start date	End date
<b>Project duration</b>	15/11/2021	03/06/2022	15/11/2021	29/07/2022
<b>1st Draft deliverable</b>	15/11/2021	17/12/2022	15/11/2021	26/01/2022
<b>Public consultation</b>	07/03/2022	05/04/2022	20/04/2022	20/05/2022
<b>Validate final version deliverable (CSCQ)</b>	17/05/2022		12/07/2022	
<b>Endorsement final version deliverable (CEB)</b>	01/06/2022		27/07/2022	
<b>Estimated finalisation date of the deliverable *</b>	03/06/2022		29/07/2022	

\*publication date may fluctuate depending on the outcome of the Consortium Executive Board endorsement

## 5 REFERENCES

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- <sup>i</sup> European Network for Health Technology Assessment, Joint Action 3: Recommendations for production process of Relative Effectiveness Assessments after Joint Action 3. Available at: [https://www.eunetha.eu/wp-content/uploads/2021/06/Recommendations-for-production-process-after-Joint-Action-3\\_WP4\\_May-2021.pdf](https://www.eunetha.eu/wp-content/uploads/2021/06/Recommendations-for-production-process-after-Joint-Action-3_WP4_May-2021.pdf) [date last accessed: 9<sup>th</sup> of July, 2021]
- <sup>ii</sup> Waffenschmidt S, van Amsterdam-Lunze M, Gomez RI, Rehrmann M, Harboe I, Hausner E. Information specialist collaboration in Europe: collaborative methods, processes, and infrastructure through EUnetHTA. *Int J Technol Assess Health Care*. 2020 Oct 21;37:e20. doi: 10.1017/S0266462320000732. PMID: 33081862.