May 2020

PROCEDURE MANUAL
OTHER TECHNOLOGIES JOINT AND COLLABORATIVE ASSESSMENTS
MANUFACTURERS

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List of abbreviations

AT	Authoring Team
CET	Central European Time
COI	Conflict of Interest
COIC	Conflict of Interest Committee
CA	Confidentiality Agreement
DOI	Declaration of Interest
DOICU	Declaration of Interest and Confidentiality Undertaking. *Note: now split in to COI and CA.*
DR	Dedicated reviewer
EC	European Commission
HTA	Health Technology Assessment
JA3	EUnetHTA Joint Action 3
JA	Joint Assessment
PC	Patient & Consumer
PICO	Population/Intervention/Comparator/Outcomes
PM	Project manager EUnetHTA WP4 CoLP
OTJA/CAXX	Project Identifier: Other Technologies Joint/Collaborative Assessment XX
WP	Work Package

1 Objective of this Procedure Manual

This procedure manual is targeted at manufacturers who will be involved in a Joint or Collaborative Assessment (OTJA/OTCA) within Joint Action 3. It was compiled by the Austrian Institute for Health Technology Assessment (AIHTA), the Co-Lead Partner (co-LP) in EUnetHTA JA3 WP4 responsible for the overall coordination of the Other Technologies (OT) EUnetHTA Assessments.

This procedure manual is used as the basis for each OT Assessment. In section 2, project specific details, such as the composition of the Assessment team will be documented. Section 3 explains each step of the procedure. In Table 2, the current procedures, tools and templates that are the basis for each assessment are listed. When a procedure, tool and/or template is under development/revision, this is indicated.

Version History

Version	Date	Comment
V0.0	May 2020	Development of procedure manual. This version is subject to procedural changes and will be updated accordingly on a regular basis, therefore, this version should not be used as the final version by manufacturers.
V1.0	Date	Procedure manual updated with project specifics

2 Project Specific details

Assessment ID	Title	Manufacturer
OTJA/OTCA[XX]	[technology] for the [intervention] of [indication]	[name]

Assessment Team:

Role	Organisation (Country)	Comment (if needed)
Author	TBD	
Co-Author	TBD	
Dedicated Reviewer	TBD	
	TBD	
	TBD	
Observer (optional)	TBD	
Project Manager	TBD	Contact person e-mail:
	WP4 CoLP Other Technologies	e-mail: eunethta@aihta.at

3 Procedure, Tools & Templates Checklist

This section lists the procedures, tools & templates that have to be followed during OTJA/OTCA[XX].

3.1 Start-up Phase

The Joint/Collaborative Assessment process starts with the Topic proposal (either from the EUnetHTA partner organisation or the external stakeholder). To establish an assessment team, the Project Manager (PM) sends out a Call for Collaboration to all EUnetHTA WP4 other technologies partners. If the topic is proposed by an external stakeholder, the completed topic proposal template, including the following information, will be sent to the partners: name of the technology, brand name of product, name of the manufacturer, indication, rationale behind the proposal, description of the technology and mechanism of action, marketing authorisation status, proposed indications in the EU, description of the disease, specification of the population covered by the indication, EU clinical practice and comparators, and the suggested PICO for the assessment.
If the topic is proposed by a EUnetHTA partner organisation, the organisation specifies the proposed title, the draft PICO, the draft timelines, the rationale for the project, and the desirable qualifications in the assessment team.

The PM shares this procedure manual to inform the manufacturer about the procedures, tools & templates that are valid for the assessment. All relevant documents will also be shared with the manufacturer via e-mail. For further information about the submission templates and requirements, please see Table 2.

3.1.1 Selection of the Assessment Team

EUnetHTA follows a set of selection criteria when establishing the Assessment Team. Please visit our website for more details on the selection criteria. EUnetHTA cannot give details which organisations expressed interest in being part of the Assessment Team. Once the team is selected, each individual assessor and reviewer (as well as observers and the project manager) has to pass a Conflict of Interest examination. This can take up to 4 weeks.

The assessment team roles and their responsibilities are as follows:

- 1 Author organisation:
  - Leading role in both the scoping and assessment.
  - Responsible for the content-related process.
  - Ultimate responsibility for quality assurance.
- 1-2 Co-author organisations:
  - Support the author in all project phases.
  - Depending on the collaboration mode, responsible for preparing sections independently.
- 2-4 Dedicated Reviewer organisations:
  - Responsible for quality assurance by thorough review of the project plan and draft assessment.
  - Review of methods, results and conclusions based on the original studies included.
- OPTIONAL: Observer:
  - This role is specifically designed for partners new to EUnetHTA or who want to learn more about the Joint/Collaborative Assessment production process. Observers will not have an active role, but will have access to all the data.

3.1.2 Conflict of Interest and Confidentiality

EUnetHTA has a very strict Conflict of Interest (COI) procedure. Please find here further details on EUnetHTA's COI procedure. All participating individuals from the assessment team, the PM, SSO or replacement from the Secretariat, individual patients and healthcare professionals will have to sign our Declaration of Interest (DOI) and Confidentiality Agreement forms (previously called DOICU form). Due to this stringent policy, EUnetHTA cannot accept individual patients or healthcare professionals that are recommended by the manufacturer.

3.1.3 Announcement of Assessment Start

Once the assessment team is established and their COI is assessed, the start of the Joint/Collaborative Assessment will be announced on the EUnetHTA website (REA table) and on EUnetHTA social media.

- REA table: [technology] for the [intervention] of [indication]
- Social Media: "EUnetHTA is pleased to announce the start of the next Other Technologies Joint/Collaborative Assessment. OTJA/OTCA[XX] addresses [technology] for the [intervention] of [indication]."

3.2 Scoping Phase

In the scoping phase, the Authoring Team develops the Project Plan, which includes the PICO and general methods to be applied in the assessment. The Project Plan will be reviewed by the Dedicated Reviewers and external experts and is published on the EUnetHTA website.

3.2.1 PICO Survey

EUnetHTA aims to adopt a PICO applicable for most European countries. Therefore, the assessment team has to consider issuing a PICO survey to all WP4 OT partners in which they can indicate the relevance of the PICO proposed by the Authoring Team. The PICO survey is optional in Other Technologies.

The Authoring Team is responsible for the decision on the final PICO, but the aim is to include the scope of most of the partners. Please note that EUnetHTA will not share results of the PICO survey with external stakeholders.

EUnetHTA recently established a PICO Subgroup, which will discuss the need of a EUnetHTA guideline to develop a EUnetHTA PICO. Until such guideline is in place, it remains the responsibility of the Authoring Team to decide on the final PICO, using their assessor expertise and the input of the PICO survey, if applicable.

3.2.2 Stakeholder Engagement

EUnetHTA established a Task Group to develop recommendations for stakeholder engagement, focussed on patient organisations and healthcare providers.

3.2.2.1 Patients and/or patient organisations

Involvement is optional but encouraged in all EUnetHTA assessments. There are several patient engagement methods, from which the Authoring Team can choose one or more which fits best. For further information, please see EUnetHTA's recommendations for patient engagement in REAs.

- Open Call for Patient Input

The questionnaire is developed by EUnetHTA using the template created by HTAi Patient and Citizen involvement group. Only patient organisations are expected to complete the questionnaire and they are required to disclose information regarding their funding. Although the survey and other information is currently only available in English, submission in the national language of the authoring team is also allowed.

The open call for patient input is considered during the scoping phase of the assessment. The open call for patient input is issued on the EUnetHTA website and generally online for 1 month. It includes general questions on the disease and expectations or experiences with a health intervention/health technology. Once the call is online, the PM will announce the call using several strategies:

- Email to relevant patient organisations.
- Social media message to announce the open call.
- Share the open call for patient input with the HTA Network Stakeholder Pool.
- Ask the assessment team to disseminate the call in their national network.

- One-on-one conversation

This method allows asking more in-depth questions to one or more patients. The conversations are not primary research on patient perspectives, but performed to inform the assessment teams in the scoping phase. These conversations are usually held via telephone and should be conducted by an assessment team member who is experienced in interacting with patients.

- Group conversation

The group discussions are not intended as primary research on patient perspectives, but are performed to inform the assessment teams in the scoping phase. In a group discussion, a moderator will guide the discussion. Group discussions may be appropriate in specific situations, but due to resource implications for both patients and EUnetHTA partners, this should be done only for a limited number of assessments.

- Scoping e-meeting with patients

Individual patients or patient organization representatives can be invited to attend a scoping e-meeting, where the proposed scope of the assessment is discussed.

It remains the responsibility of the Authoring Team to decide on how to include the results of the different patient engagement method(s).

EUnetHTA cannot share any patient responses with the manufacturer, nor any early information on how the patient input will be used in the Joint/Collaborative Assessment report. However, the methods will be explained in the project plan and documented in the Assessment Report. Some guidance on how to make the input visible in the assessment report can be found in the Patient Input in Relative Effectiveness Assessments.

3.2.2.2 Healthcare Professionals (HCP)

EUnetHTA aims to involve two healthcare professionals in both the scoping and the assessment phase. Similar as for patient organisations, the PM will reach out to healthcare professionals and/or medical societies. HCPs also need to complete and sign Declaration of Interest (DOI) and Confidentiality Agreement forms, which need to be assessed by the COI Committee. EUnetHTA aims to make sure that participating HCPs do not have a conflict of interest in relation to the technology and comparator(s) assessed. Under exceptional circumstances (e.g. lack of available experts for a rare/ultra-rare disease), EUnetHTA may still seek the expert opinion of an individual with an existing CoI. However, in such cases the expert shall not have access to any project specific document requiring confidentiality and should only give advice on a predefined set of questions posed by the assessment team (see EUnetHTA Procedure Guidance for handling Declaration of Interest (DOI) and Confidentiality Agreement forms).
There are different methods on how HCPs can be involved in the scoping and the assessment phase (see document on Healthcare Professional Involvement in Relative Effectiveness Assessments). In the scoping phase they could be involved in a scoping e-meeting with the assessment team, review of preliminary PICO, receive predefined set of questions and/or review the draft project plan. The assessment team may ask scoping questions in order to help define the PICO and/or critical outcomes. In addition, the team may also ask the healthcare professionals questions throughout the assessment to answer a predefined set of questions and/or to review the draft assessment report.

The involved healthcare professional will be named on individual or institutional basis in the project plan and the assessment report. EUnetHTA will not inform the manufacturer about the selected healthcare professional prior to publication of these documents.

3.2.2.3 Manufacturers

EUnetHTA aims to involve the manufacturers of the assessed products. In Joint Assessments (JA) the involvement of manufacturers is mandatory; in Collaborative Assessments (CA) it is optional. The identification of manufacturers starts right after the assessment team is established. The PM follows the SOP on Identification of stakeholders to find and reach out to the respective manufacturers. The identified manufacturers are contacted and asked if they are willing to be involved. In case the answer is positive, the PM sends a Confidentiality Agreement form and the next steps are executed only upon return of the signed form. However, in case the manufacturer fails to respond to the request or the answer is negative, the product will still be included in the assessment.

Scoping F2F meeting or e-meeting with the manufacturer(s)

In CA, the team decides if they require a scoping (e-)meeting with the manufacturer(s) and discuss the form and possible dates of the (e-)meeting, if they do (if scoping (e-)meeting is held, please see the next paragraph for more information). If no scoping (e-)meeting with the manufacturer(s) is planned, the PM sends the preliminary PICO to the manufacturer(s) for comments. A comments form is included and the manufacturers have 5 working days to return their comments. The comments received from manufacturer(s) need to be answered by the author within the comments template and sent to the manufacturer(s) by the PM. If manufacturers have major objections to the answers provided, the author should discuss open issues with them. Consensus does not have to be reached with the manufacturer(s) and the authors have the final judgement on which comments should be included. Comments and answers provided on the preliminary PICO are not published on the EUnetHTA website.

In JA, the scoping (e-)meeting with the manufacturer(s) is mandatory. The aim of the meeting is to discuss the preliminary PICO and clarify questions from the authoring team to the manufacturer(s) (including submission dossier, potential fact check of the second draft of the project plan and the second draft assessment according to the fact check guidance). The manufacturers are also made aware of the EUnetHTA OT submission dossier requirements as published on the EUnetHTA website.The PM manages the relationship and communication with

the manufacturer(s) on behalf of the assessment team and informs the manufacturer(s) about the possibility for a scoping (e-)meeting. If the manufacturers accept the invitation, the PM creates a doodle survey to identify a suitable date. The PM monitors the answers and defines the time and place (face-to-face or online/telephone) for the meeting and the author prepares the agenda. The PM sends the scoping brief for the scoping meeting which includes location, contact details, participant list, agenda, preliminary PICO and timelines to the scoping (e-)meeting participants in due time (i.e. at least 2 working days in advance). Minutes are taken during the (e-)meeting and sent to the participants for approval.The minutes are not published on the EUnetHTA website.

Location	Face-to-face or online (if face-to-face, usually at the author's premises)
Attendees	Author, Co-Author, manufacturer(s), Project Manager
Objective	To discuss the preliminary PICO and clarify questions from the Authoring Team to the manufacturers (including submission dossier, potential fact check of the second draft of the project plan and the second draft assessment according to the fact check guidance).
Preparation - Scoping Brief	The PM will share the preliminary PICO with the manufacturer(s) at least 2 working days in advance of the scoping meeting. The PM will share questions from the team to the manufacturers in advance, provided they are available.

Factual Accuracy Check of the draft project plan

Each Authoring Team decides whether they want to include a factual accuracy check in their assessment. Such checks in the process have been established as good practice.

The factual accuracy check takes place in parallel with the external review of the draft project plan and takes 5 working days. Comments submitted after the deadline or in a different format will not be considered. The manufacturer can only comment on fact-related typos/mistakes (e.g. numbers). Please follow the guidance/checklist as presented in Table 2.

Only comments within the scope of a factual accuracy check will be considered and answered by the Authoring Team. Comments that, according to EUnetHTA, do not belong to a factual accuracy check, will not be considered nor answered by the Authoring Team. The comments made by the manufacturer and the answers of the AT to the comments will be published on the EUnetTHA website at the same time EUnetHTA publishes the final project plan.

3.2.3 Submission Requirements & Citation/Publication Policy

EUnetHTA published the submission requirements in September 2019. This document outlines EUnetHTA's publication and citation policy. In December 2019, information was added to clarify the publication and citation policy and to clarify GDPR compliance. The manufacturer(s) should only provide non-confidential information that can be used for the production of the EUnetHTA assessment report. The EUnetHTA submission dossier is shared with the assessment team and will be published without redaction and alongside the final REA assessment report on the EUnetHTA website. The requirements can be found here.

3.2.4 Submission Dossier

The use of the Submission dossier is optional in CA and mandatory in JA. In CA, the assessment team discusses if they would require the use of the dossier. The use of the submission dossier is not applicable if the technology assessed does not specifically involve the use of a medical product for example when evaluating screening, dental or psychological interventions. Similarly, the submission dossier is not required if manufacturers indicate that they will not submit the required information for the HTA.

The author identifies questions relevant to the assessment and according to the final PICO (or at least after feedback was received from the external experts) and deletes the non-relevant sections from the submission dossier template (Medical Devices Template). According to the Submission requirements document, the questions related to the CUR and TEC domains are required along with other questions selected by the authors. The co-authors verify the selection done by the authors.

The current versions can be found in Table 2.

3.2.5 Submission Timelines

The PM sends the submission dossier template to manufacturers and asks them to complete it within 30 working days according to the included draft PICO question. The PM also makes the manufacturer aware of the EUnetHTA OT Submission Requirements and include the link to the published document on the EUnetHTA website.

The manufacturers submit the completed submission dossier directly to the PM within the 30 working days and the PM sends it to the author once received from the manufacturers.

The author checks the completeness and the appropriateness of the information included in the submission dossier. The author prepares open questions for clarification (if applicable) and sends them to the PM. The PM sends the questions to manufacturers and collects their answers. The manufacturers need to answer within a given timeline, usually 10 working days.All requested content needs to be completed. Once the Submission Dossier is submitted, the manufacturer is not allowed to provide any additional or supporting information, unless requested by the Authoring Team.

3.3 Assessment Phase

For the assessment report, the ultimate responsibility to make decisions lies with the authoring agency. In case of major disagreements within the Assessment Team, the EUnetHTA Senior Scientific Officer or his/her replacement will mediate the discussion.

3.3.1 Methodological Guidelines

Please see an overview of all Methodological Guidelines that are applicable for the Joint/Collaborative Assessment in Table 2.

3.3.2 Factual Accuracy Check of the draft assessment

Each Authoring Team decides whether they want to include a factual accuracy check in their assessment. Such checks in the process have been established as good practice.

The factual accuracy check takes place in parallel with the external review of the draft assessment report and takes 5 working days. Comments submitted after the deadline or in a different format will not be considered. The manufacturer can only comment on fact-related typos/mistakes (e.g. numbers). Please follow the guidance/checklist as presented in Table 2.

Only comments within the scope of a factual accuracy check will be considered and answered by the Authoring Team. Comments that, according to EUnetHTA, do not belong to a factual accuracy check, will not be considered nor answered by the Authoring Team. The comments made by the manufacturer and the answers of the AT to the comments will be published on the EUnetTHA website at the same time EUnetHTA publishes the final report.

3.4 Publication

The final publication date for the Joint/Collaborative Assessment report will be communicated in the final Project Plan, which will be published on the EUnetHTA website. The publication of the final assessment report will be announced via email to the Assessment Team, healthcare professionals, the manufacturer, patients/patient organisations (if applicable) and to EUnetHTA partners. In addition, the publication of the final assessment report will be shared on the EUnetHTA website, LinkedIn, and Twitter.

3.4.1 Error Reporting and Correction Procedure

In case the manufacturer identifies a factual error in the published Joint/Collaborative Assessment report, EUnetHTA will start an error reporting and correction procedure. By means of this procedure, EUnetHTA will assess the (impact) of the error and decides whether the report needs to be updated. The process description is available on the EUnetHTA website.

4 Joint/Collaborative Assessments - Timelines

Table 1: Indicative timeline for Joint/Collaborative Assessment

Milestone	Responsible	Timeline
Call for Collaboration	WP4 Co-LP OT PM	2-3 weeks
Establishment of the assessment team (institutional level only)	WP4 Co-LP OT PM	5 working days
Receipt of Scoping Brief (in case of scoping (e-)meeting)	manufacturer	At least 2 days prior to scoping (e-)meeting
Receipt of and commenting on the preliminary PICO (in case of no scoping (e-)meeting)	manufacturer	Receipt after returning the signed confidentiality agreement, 5 working days for commenting
Scoping (e-)meeting	PM+AT+manufacturer	Approx. 3 hours
Factual accuracy check of 2nd draft project plan	manufacturer	5 working days
Submission Dossier completion	manufacturer	30 working days
Check for completeness and clarity of the Submission Dossier	AT	10 working days after receipt of Submission Dossier
Provide missing items/comment on request from check of completeness and clarity	manufacturer	Within 5 working days after receipt of request
Factaul accuracy check of 3rd draft assessment	manufacturer	5 working days
Publication final JA/CA report and Submission Dossier (if requested in CA) and factual accuracy check (if requested)	PM+AT	

*Please note that project specific timelines might deviate from the indicated timeline above.

5 Appendix – Table of Tools, Templates, and Procedures

Table 2 – overview of tools, templates and procedures

Tools/ template/ procedure		Version	Status
Topic Proposal template	To be shared via e-mail upon request by the manufacturer.	2.0	
Submission Requirements	The submission requirements – other technologies can be accessed here .	2.0	Updated, published in December 2019
Submission Dossier Template	The version is called: "EUnetHTA-Evidence Submission Template – MedDEv- short" and "EUnetHTA Evidence Submission Template – MedDev – long" and can be accessed here	Dec 2016	
Factual Accuracy Check guidance	To be shared via e-mail at time of the fact check phase.	1.0	
Methodological Guidelines	Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness	2.0; 2019	
	Endpoints used for Relative Effectiveness Assessment: Clinical Endpoints	2.0; 2015	
	Endpoints used for Relative Effectiveness Assessment: Composite Endpoints	2.0; 2015	
	Endpoints used in Relative Effectiveness Assessment: Surrogate Endpoints	2.0; 2015	
	Endpoints used in Relative Effectiveness Assessment: Safety	2.0; 2015	
	Endpoints used for Relative Effectiveness Assessment Health: related quality of life and utility measures	2.0; 2015	
	Comparators & Comparisons: Criteria for the choice of the most appropriate comparator(s)	2.0; 2015	
	Comparators & Comparisons: Direct and indirect comparisons	2.0; 2015	Update expected on the indirect comparisons part; to reflect reporting of ITC and NMA
	Levels of Evidence - Applicability of evidence for the context of a relative effectiveness assessment	2.0; 2015	
	Internal validity of randomised controlled trials	2.0; 2015	
	Internal validity of non-randomised studies (NRS) on interventions	1.0; 2015	
	Meta-analysis of diagnostic test accuracy studies	1.0; 2014	
	Therapeutic medical devices	1.0; 2015	
	Personalised Medicine and Co-Dependent Technologies	0.1; 2015	
	Methods for health economic evaluations - A guideline based on current practices in Europe	1.0; 2015	
	Critical assessment of clinical evaluations	-	Concept - Planned publication: 2021
	Critical assessment of economic evaluations	1.0; 2020	