EUnetHTA 21

Guidance Document

D7.1.1 – PRACTICAL GUIDELINE FOR INTERACTION BETWEEN HEALTH TECHNOLOGY DEVELOPER AND HTA BODIES

Part of D7.1 – Guidance for the interaction between HTA and HTD

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Document history and contributors

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

Associated HTAb & Stakeholders participating in public consultation

The draft deliverables of D7.1 were reviewed by associated HTAb and was open for public consultation between 20.07.2022 and 19.08.2022.

Associated HTA bodies who reviewed	Dachverband der Österreichischen Sozialversicherung, [DVSV], Austria Norwegian Institute of Public Health, [NIPH], Norway Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, [SESCS], Spain Regione Emilia-Romagna, [RER], Italy Health Information and Quality Authority [HIQA], Ireland Finnish Medicines Agency [FIMEA], Finland
Stakeholders who reviewed during public consultation	European Federation of Pharmaceutical Industries and Associations, Belgium F. Hoffmann-La Roche Ltd (Roche), Switzerland (head quarters) European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Belgium Medtech Europe (MTE), Belgium Intuitive, United states Verband Forschender Arzneimittelhersteller (vfa) e.V, Germany IGES Institut GmbH and HealthEcon AG (IGES LifeScience), Germany Ecker + Ecker GmbH (E+E), Germany Medtronic, Switzerland Takeda Pharmaceuticals International AG (Takeda), Belgium, Switzerland, pan-European operations European Union of General practitioners/ Family Physicians. UEMO, Belgium

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List of abbreviations

CEB	Consortium Executive Board
CHMP	Committee for Medicinal Products for Human Use
CSCQ	Committee for Scientific Consistency and Quality
EUnetHTA	European Network of Health Technology Assessment
F2F Meeting	Face to face meeting/ meeting with the HTD (and EMA) during JSC
HTA	Health Technology Assessment
HTAb	HTA bodies
HTAR	EU HTA Regulation – Regulation (EU) 2021/2282
HTD	Health Technology Developer
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
LoMI	List of Missing Items
MS	Member State
SOP	Standard Operating Procedure

1 GENERAL PRINCIPLES AND PURPOSE

1.1 General principles

During Joint Action 3 (JA3) procedures have been developed and tested regarding the interaction between Health Technology Developers (HTD) and Health Technology Assessment bodies (HTAb). When defining procedures for future interaction between HTD and HTAb, it is important to ensure the independence of the Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC) assessment teams. It also is important to ensure procedurally fair processes for HTD. In addition, it is important that the procedures are in line with the steps and timeline requirements as outlined in the Health Technology Assessment Regulation (EU) 2021/2282 (hereafter referred to as HTAR).

While this guidance follows the requirements as set out in the HTAR, the HTAR is not yet applied, therefore the EUnetHTA 21 Service Contract does not follow the same legal framework as the HTAR. Therefore, this guidance document describes in some cases the process for EUnetHTA 21 and the recommended process for under the HTAR. Chapter 6 will outline considerations and recommendations for the future process under the HTAR.

This guidance does not provide details on the duration of the steps mentioned for the JCA procedure, as the development of a timeline for JCA production are still ongoing.

1.2 Purpose and Scope

This document defines the objective and extent of any formal interaction between HTAb and HTD for JCA and JSC, based on requirements set out in the HTAR and experiences from EUnetHTA Joint Action 3.

This document does not describe the interaction with HTD as a stakeholder for EUnetHTA 21 deliverables, this is described in a separate SOP.

1.3 Relevant articles in Regulation (EU) 2021/2282

The HTAR specifies in a number of recitals and articles the interaction between HTD and HTA bodies. Table 1-1 shows which of these HTAR recitals and articles refer to JSC and/or JCA and in what stage of the production. For a complete overview, see Appendix 1.

Table 1-1: Recitals and articles of the HTAR referring to interaction between HTD and HTA

JSC	
Selection of Health Technologies for JSC	Art 17 (1), (2): HTD may request JSC Art 17 (4): inform HTD about selection
Submission of information by HTD	Art 18 (2): submission of information by JSC
Conduct of JSC	Art 16 (1) and Art 18 (7): meeting with HTD during JSC
Share outcome of JSC with HTD	Art 19 (2), Art 30 (1c)
JCA	
Selection of Health Technologies for JCA/CA	Art 7 (1): Health Technologies subject to a JCA Art 8: Initiation of a JCA
Scoping process	Recital 25: inclusive scoping process Art 8 (6): Consider HTD input on PICO Art 10 (1): Inform HTD about final PICO & request submission dossier
Submission dossier	Recital 36: timeframe for JCA and deadline for submitting data Art 10 (2) (5), (6), (8): - Submitting of dossier

	- Check for completeness & inform HTD about continuation or discontinuation
Assessment process	Recital 36: timeframe for JCA production Art 11 (2): Interaction with HTD in case clarifying questions during JCA Art 11 (5): - Factual accuracy check by HTD of draft JCA report - HTD to flag which sections are confidential
Publication of JCA/CA	Art 12 (4): Inform HTD about publication final JCA
Secure system for data sharing	Art 30 (1c)

2 ACTORS AND THEIR SCOPE

2.1 HTA bodies & Secretariat

HTAb are responsible for conducting the JSC and JCA work. Therefore, this term refers to the JSC and JCA Assessor and Co-Assessor, Secretariat, the members of the Committee for Scientific Consistency and Quality (CSCQ), and the Consortium Executive Board (CEB) under the EUnetHTA 21 framework.

The Assessor and Co-Assessor are jointly responsible to prepare the JSC or JCA report and other respective tasks (such as the List of Issues for JSC and the consolidated PICO for JCA). The CSCQ reviews and validates the different documents at various stages. For JCA, the CEB endorses the final report before publication.

The Secretariat is responsible for all external communication, to ensure the independence of the Assessor and Co-Assessor. HTAb Assessor and Co-Assessor should have no direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat. In case the HTAb Assessor and Co-Assessor have clarifying questions, the Secretariat will liaise between them and the HTD.

2.2 HTD

For JCA, the HTD is requested to:

- Inform the Secretariat about the claimed indication/intended use,
- Inform the Secretariat about a contact person,
- Provide a submission dossier following the consolidated PICO(s) (Population, Intervention, Comparator(s) and Outcome(s)),
- Join the PICO information meeting (only for EUnetHTA 21),
- Perform a factual accuracy check of the draft JCA report validated by the CSCQ.
- In EUnetHTA 21, the HTD is requested to provide timely information and status updates on the regulatory process, and potential deviations in the regulatory timetable.

The Secretariat will inform the HTD about all timelines, procedural steps and deadlines before the start of the JCA process.

For JSC, the *JSC procedural guidance* published on EUnetHTA 21 and EMA websites[1] will be shared with the HTD. The Secretariat will inform the HTD about definite timelines, procedural steps and deadlines 1 month prior to the submission of the draft Briefing Book.

The HTD is not allowed to communicate directly with Assessors and/or Co-Assessors of JCA or JSC, nor interact with other HTAb about the ongoing JCA or JSC on a European level unless it is publicly available information. This is without prejudice to issues related to the national HTA process, such as additional analyses that were not part of the JCA submission. For any other communication, the HTD should liaise with the Secretariat.

For JSC, national consultations must be requested by the HTD directly from the relevant Member State (MS). JSC are at the discretion of HTD. A national consultation should complement and/or address context-specific issues related to the national HTA system of the specific MS (see also Article 16 (4) HTAR). Duplicated full scientific consultations at the national level (similar questions for the JSC and the national advice) are not foreseen according to the HTAR provisions. Clarification meetings on the national positions are exempted but should not re-address agreed on positions. When requesting a national consultation, the HTD must inform HTAb about the JSC/JCA that have taken place or are ongoing on a European level.

3 RULES OF THE COLLABORATION

3.1 Confidentiality

There will be no confidentiality agreement between the participating HTD and EUnetHTA 21, neither for a JSC process, nor for a JCA.

Detailed rules on confidentiality of submitted information by the HTD, are described in the process for commercially sensitive and academic-in confidence data (Part of D7.1 documents - D7.1.3 handling of commercially confidential information). Further information about the confidentiality, publication and citation policy of the submission dossier for a JCA can be found in the submission dossier requirements. The final submission dossier is published, together with the final JCA report.

3.2 Status of Outputs

Once the Health Technology is accepted by EUnetHTA 21 for a JSC or JCA, the process officially starts. As soon as the HTD has submitted their draft briefing book (for JSC) or the submission dossier (for JCA), the process cannot be terminated by the HTD. This means the documents submitted by the HTD cannot be withdrawn and the JCA or JSC process will continue also with publication of documents as required for the JCA or JSC procedure. However, the HTD should inform the Secretariat about any changes in the development plans that might have impact on the ongoing JSC or JCA. In the event that the HTD discontinues further product development or a previous study has not produced the desired results on which the questions of the JSC are based, the Secretariat shall be informed of the discontinuation of a JSC prior to submission of the final Briefing Book. In the event the HTD withdraws the product from the regulatory marketing authorisation process, if the HTD goes bankrupt or in case there is a negative outcome of the regulatory process, the JCA will be discontinued. In such event, there is no final JCA report and thus the submission dossier will not be published, however, the consolidated PICO(s) will be published without releasing commercially sensitive data.

[1] https://www.eunethta.eu/wp-content/uploads/2021/11/Guidance-on-parallel-consultation.pdf?x69613&x16454

Although information on previous JSC is required in the JCA submission dossier, no information on specific questions or national specifications nor the complete content of the JSC written recommendations can be published in the JCA report. Aggregated generic information on JSC can be content of an JCA report, e.g. whether the HTD deviated from the common recommendation of the JSC. For EUnetHTA 21, all documents submitted by the HTD, are stored internally on the respective SharePoint page[2] which all CSCQ members, appointed participants and Assessor and Co-Assessors have access to. For JCA, the CEB members will also have access to the documents submitted. For JSC, only the CSCQ members will have access. For all JSC and JCA, only individuals from the HTAb and any external experts who have signed the EUnetHTA Confidentiality Agreement will have access.

Both in EUnetHTA 21 as in the HTAR, the final submission dossier (for JCA) will be published together with the final JCA report. See D7.1.3 (guidance on handling confidential data) for further details. In EUnetHTA 21, re-use of the final JCA report will not be mandatory at the national level but is encouraged whenever possible.

Both in EUnetHTA 21 as in the HTAR, comments provided by the HTD during a factual accuracy check of the final draft JCA report will be made publicly available, together with the Assessor and Co-Assessor answers to the comments, once the final JCA report is published. The process for a factual accuracy check is further detailed in the guidance document for factual accuracy check (see the separate document D7.1.2)

[2] *Several security and Logging/Audit measures are taken, to ensure safe data storage on SharePoint, e.g. sharing of sites outside of existing accounts is disabled and is restricted to ony Azure AD registered members; Permission Matrix reports are automatically generated by means of SareGate on a regular basis for security control and auditing; and for all users that have access to the SharePoint, two-factor authentication is enabled.*

4 PROCESS

4.1 Joint Scientific Consultations

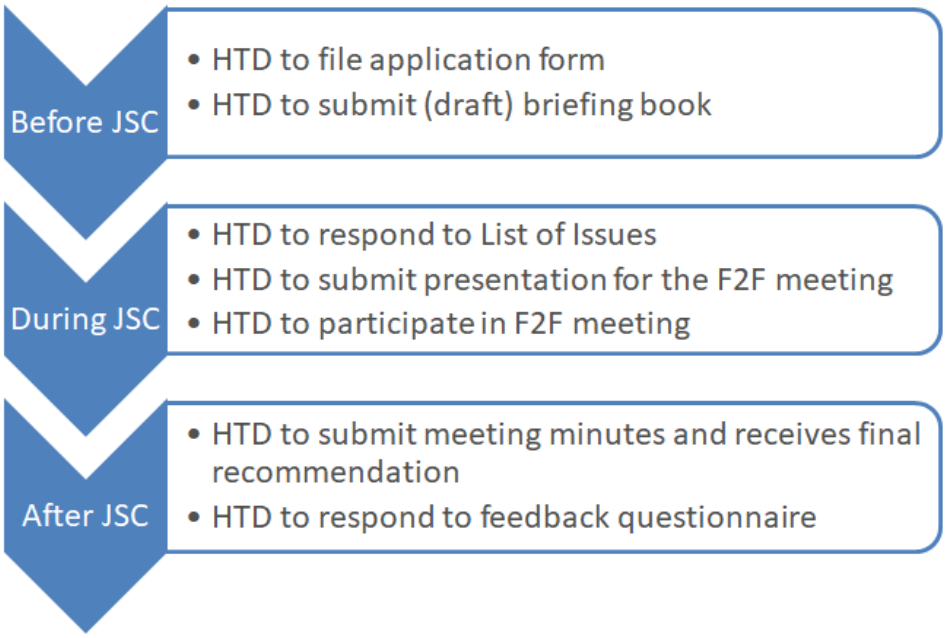

Figure 4-1: Process overview for JSC and Interaction between HTAb and HTD (for EUnetHTA 21 and HTAR)

For a more detailed process description, including timelines for the JSC production under EUnetHTA 21, please refer to the procedure guideline[3].

4.1.1 HTAb and HTD interaction before JSC starts

Application for JSC

Under the HTAR, it is envisaged that the Coordination Group shall publish the dates of request periods and state the planned number of JSCs for each of those request periods on the IT platform referred to in Article 30. At the end of each request period, where the number of eligible requests exceeds the number of planned JSCs, the Coordination Group shall select the health technologies that are to be subject to JSCs, ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3)).

Within EUnetHTA 21, the Secretariat published the dates of the request periods (Open Call for JSC) and stated the planned number of JSCs for each of those request periods on the EUnetHTA 21 website and via social media. Within the request period the HTD has to submit an application form (link on EUnetHTA 21 website) to the JSC Secretariat. The HTD receives a confirmation of receipt.

[3]https://www.eunethta.eu/wp-content/uploads/2022/05/External-Guidance-on-parallel-consultation_EMA_EUnetHTA21_2022-03-04_final_2.pdf

Selection of products for JSC

At the end of each request period, the CSCQ selected eligible applications which will be subject to JSC. The criteria for selecting eligible requests are publicly available[4] and are based on the criteria outlined in the HTAR and supplemented with additional prioritisation criteria for EUnetHTA 21.

At the end of the request period and following selection of eligible products applying the selection criteria stated in the Open Call for JSC, HTDs will be informed by the JSC secretariat/ the Coordination group (for the HTA R) whether they were selected for JSC. Where a request for JSC was refused, the HTD will be informed thereof and the reasons explained.

Submission of the (draft) Briefing book and check for completeness

The HTD must submit the briefing book[5] to the JSC secretariat according to the published timeline for the accepted time slot. The HTD receives a Written Request for Clarification if there are missing items in the draft Briefing book, e.g. explanations on the study design or missing supporting documents on endpoints. The Applicant sends the final version of the Briefing Book (a "track changes" version and a "clean" version) taking into consideration Written Requests for Clarification, if applicable.

4.1.2 HTAb and HTD interaction during JSC

List of issues

Approximately 30 days after submission of the final Briefing book the JSC secretariat will share the EUnetHTA 21 List of issues and the template for Applicant's Written Response, with the HTD. The HTD has to provide all introduced changes in a table format and to provide answers to "Issues to be addressed in writing only" to the JSC secretariat.

F2F - meeting

The HTD has to submit the slides that will be presented during the F2F meeting. In case of any questions the JSC secretariat will give feedback on structure of the slides prior to the meeting if they need modification in structure to be suitable for the F2F meeting. The slides should follow the PICO scheme according to the Questions in the Briefing book and present the issues from the lists of issues of the HTAb and EMA to be addressed by the HTD during the F2F meeting. The HTD has to take meeting minutes.

4.1.3 HTAb and HTD interaction after JSC

The HTD sends the F2F meeting minutes to the JSC secretariat. The meeting minutes will only serve as a tool of record and will not be commented on by EUnetHTA 21, nor will they be included in the final recommendations.

Final recommendations

After the F2F meeting the HTD can expect the final written recommendations according to the timelines in the procedure for JSC.

[4] https://www.eunethta.eu/jsc/

[5] the template can be found here: https://www.eunethta.eu/jointhtawork/parallel-consultation/

Evaluation

Participating HTD in a JSC are encouraged to submit their feedback on the procedure throughout the JSC production. After finalisation of the JSC, a feedback survey is sent to HTD by the JSC Secretariat.

4.2 Joint Clinical Assessments

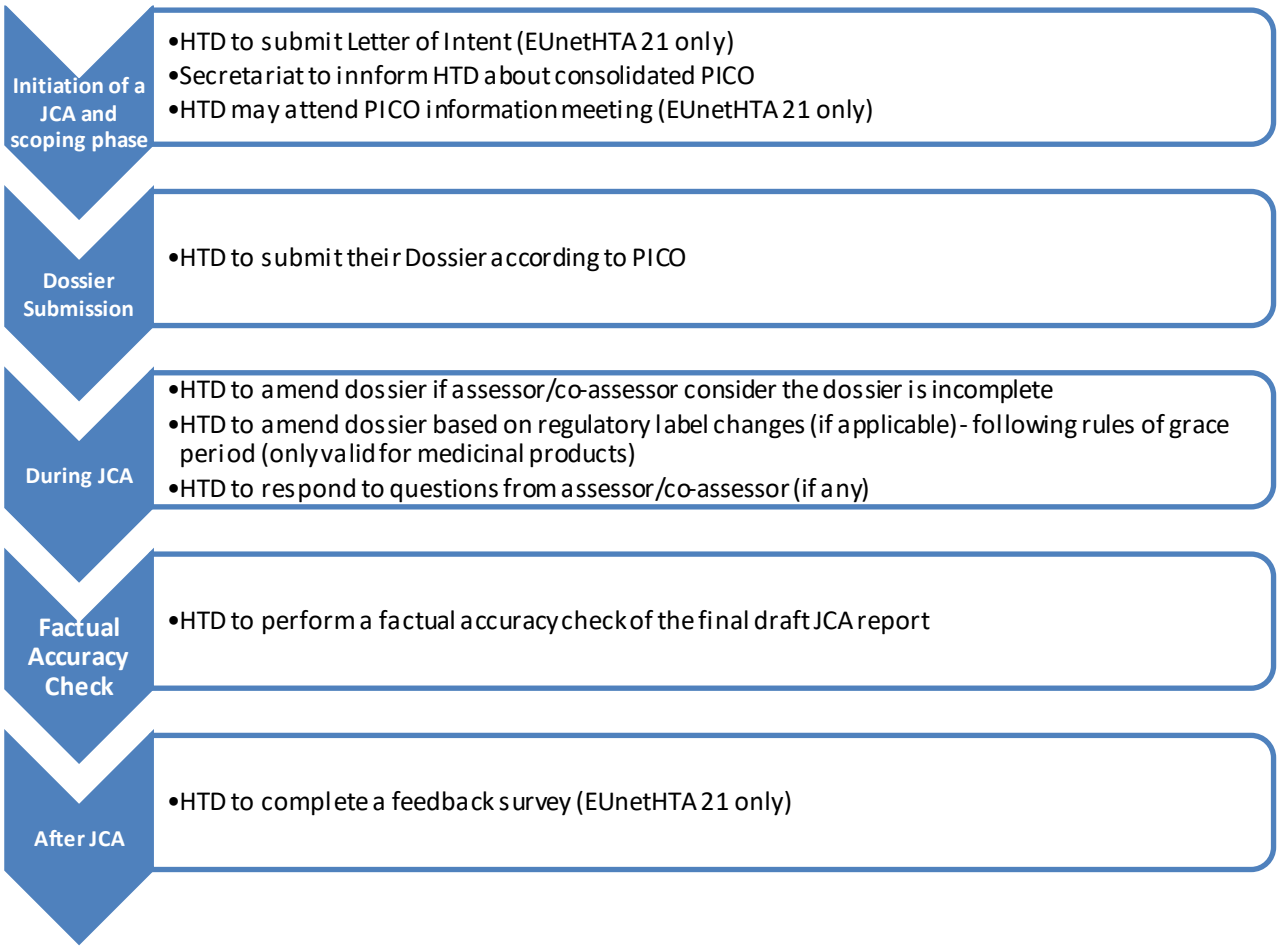

Figure 4-2: Process flow for JCA and interaction between HTAb and HTD (for EUnetHTA 21 and HTAR)

4.2.1 Initiation of a JCA and Scoping phase

Selection of Health Technologies for JCA

Under the HTAR, article 7 defines the health technologies eligible for a JCA. For medicinal products, there is no additional selection process under the HTAR. For medical devices and in vitro diagnostic medical devices the selection will follow the criteria of the HTAR article 7.4. Specifications on the operationalisation of the selection process for Medical Devices JCA, see deliverable D4.7.3 and D4.7.4.

During EUnetHTA 21, the HTD is expected to submit a signed Letter of Intent, in which they indicate their intent to participate in a JCA. Submission of a Letter of Intent does not automatically lead to acceptance of the technology for a JCA in EUnetHTA 21. The Secretariat will inform the HTD once their technology is accepted for a JCA in EUnetHTA 21.

In the Letter of Intent, the HTD is requested to state the contact person for the JCA process, the indication applied for in the regulatory submission dossier or the intended use according to the conformity assessment (hereafter referred to as claimed indication or intended use), and the anticipated regulatory pathway.

Submission of PICO(s) & Request Submission Dossier

Both under the HTAR and EUnetHTA 21, as per Art 10 (1) of the HTAR, the Secretariat informs the HTD about the consolidated PICO(s) for the JCA and requests a completed submission dossier as per the

PICO(s) by a specified deadline. The HTD has to submit their JCA dossier, after the consolidated PICO(s) has been submitted to the HTD.

PICO information meeting (only EUnetHTA 21)
In EUnetHTA 21, the HTD is invited to join a PICO information meeting, in which the assessor and co-assessor present the consolidated PICO(s). The purpose of this meeting is to provide the HTD with information on the consolidated PICO(s), and is not a meeting to discuss submission requirements. There is no provision to amend the EUnetHTA 21 consolidated PICO(s) at this point, and no final decisions will be taken during the PICO information meeting. No minutes will be published or shared with the HTD after the meeting, nor will the meeting be recorded.

4.2.2 Submission Dossier for a JCA

Receipt of Submission Dossier & check of completeness
Both under the HTAR and EUnetHTA 21, the Assessor and Co-Assessor perform a technical completeness check after receipt of the submission dossier and the Secretariat performs a procedural completeness check. The HTD has to submit a dossier according to the scope (I.e. consolidated PICO(s)) of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)). In case the HTD does not submit data for a PICO, the HTD has to explain thereof otherwise the dossier has to be declared incomplete. A list of missing items (LoMI) will be shared with the HTD by the end of this check. The time for providing the amended dossier responding to the LoMI depends on the JCA procedure (i.e. medicinal products or medical devices).

In case the HTD does not provide the amended Submission Dossier by the deadline, or the Submission Dossier is still considered incomplete by the Assessor and Co-Assessor in consultation with the Secretariat, the Assessor and Co-Assessor will discuss with the relevant governance bodies (In EUnetHTA 21: CSCQ and CEB; under the HTAR: JCA Sub-Group and Coordination Group) if they can proceed with the JCA or whether the JCA should be discontinued.

For medicinal products only: Given the publication deadline specified in the HTAR, the JCA process does not have clock-stops. However, a grace period to amend the Submission Dossier is allowed if CHMP opinion differs from what was anticipated and only to those sections impacted by the CHMP opinion. The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat. During the grace period the Assessor and Co-Assessor will update the PICO.

Formal interaction with HTD during the JCA
As per Art. 11(2) of the HTAR, interaction with the HTD should be possible at any time during preparation of the JCA in case the Assessor and Co-Assessor consider that further specifications or clarifications or additional information, data, analyses or other evidence are necessary in order to carry out the assessment. In this case, the Secretariat reaches out to the HTD with a formal request to provide such information, data, analyses or other evidence. Depending on the type of request, a deadline to provide the requested information will be communicated.

As outlined in Art. 11(2) of the HTAR, where new clinical data becomes available during the assessment process, the HTD concerned shall proactively inform the Coordination Group about this indicating anticipated timelines when it will become available. Within EUnetHTA 21, this means that the HTD shall inform the Secretariat.

The Secretariat is responsible for communicating any questions from the Assessor and Co-Assessor to the HTD, requesting the required input from the HTD and sharing the received input with the assessor and Co-assessor.

4.2.3 Factual accuracy check of JCA by HTD

For more information on the factual accuracy check, please see the document D7.1.2 Procedure and Framework for the Factual Accuracy Check

4.2.4 HTA and HTD interaction after JCA

Publication of a JCA

Once the final JCA report, submission dossier and answers/comments from the factual accuracy check are published, the Secretariat shares the link[6] with the HTD.

Evaluation (EUnetHTA 21 only)

Participating HTD in a JCA are encouraged to submit their feedback on the procedure throughout the JCA production. After each JCA is finalised, a survey is sent to HTD

Error reporting procedure (EUnetHTA 21 only)

In case potential errors are identified in a EUnetHTA 21 JCA report after its publication, EUnetHTA will start the error reporting procedure. The person reporting the error is requested to reach out to eunethta@zinl.nl, and state the following:

- Your affiliation and contact details;
- Specifically describe the potential error you discovered (mention the title of the report (and the project ID), state both the page number and the specific sentence, and mark the error);
- If applicable, please also submit a reference to a source where the correct information can be found.

More information can be found here.

5 PRACTICAL ISSUES

5.1 Contact Points (EUnetHTA 21 only)

The JCA Secretariat (JCA_Secretariat@zinl.nl) is the primary point of contact for the HTD for JCA on medicinal products and medical devices.

The JSC Secretariat (EUnetHTA21-JSC@g-ba.de) is the primary point of contact for the HTD for JSC.

5.2 Other

A secure system will be used for data sharing between HTD and EUnetHTA 21, in the form of a secure e-mail system, Eudralink or through SharePoint.

[6] Under the EUnetHTA 21 framework, the report will be published on the EUnetHTA 21 webpage and that link will be sent to the HTD. According to the HTAR Art. 12 (4): The Commission shall publish, [..] the procedurally compliant reports [...] on the publicly accessible webpage [...] and shall inform the HTD of the publication.

6 FUTURE CONSIDERATIONS FOR THE HTAR

- Appoint a dedicated Project Manager per JSC and JCA
- A secure data sharing system has to be used
- A JCA manual for HTD should be developed. This manual should explain the JCA process, the binding timelines for the specific JCA, and which (version of the) tools, guidances and guidelines and templates are binding to the specific JCA. Use a tool to confirm and keep track of tools, templates, procedures and guidance that are applicable for the specific JSC and JCA
- Consider using a form by which the HTD can provide information on the following:
    - the contact person for the JCA process,
    - the claimed indication/intended use
    - the anticipated regulatory pathway and respective timelines
- Discuss if new evidence can be accepted during an ongoing JCA and if so, define a process for submission of this new evidence during an ongoing JCA
- Investigate the need for an error reporting procedure

7 APPENDIX 1 – LIST OF HTAR ARTICLES AND RECITALS RELATED TO THIS DELIVERABLE

Recitals	Text	JCA or JSC
25	The assessment scope for joint clinical assessments should be inclusive and should reflect all Member States' needs in terms of data and analyses to be submitted by the health technology developer.	JCA
32	The obligation on Member States not to request at national level any information, data, analyses or other evidence which has been submitted by health technology developers at Union level reduces, where health technology developers comply with information submission requirements laid down pursuant to this Regulation, the administrative and financial burden on them which would result from being confronted with multiple and divergent requests for information, data, analyses or other evidence at Member State level. **That obligation should however not exclude the possibility of Member States asking health technology developers for clarification about the submitted information, data, analyses or other evidence.**	
36	The timeframe for joint clinical assessments for medicinal products should be fixed, as far as possible, by reference to the timeframe applicable to the completion of the centralised marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure that joint clinical assessments could effectively facilitate market access and contribute to the timely availability of innovative health technologies for patients. Health technology developers should therefore respect the deadlines established pursuant to this Regulation when submitting the requested information, data, analyses and other evidence.	JCA
39	In order to facilitate the process of preparing joint clinical assessments, health technology developers should, in appropriate cases, be afforded the opportunity to engage in joint scientific consultations with the Coordination Group in order to obtain guidance on the information, data, analyses and other evidence that are likely to be required from clinical studies. Clinical studies comprise clinical trials of medicinal products, clinical investigations required for the clinical evaluation of medical devices and performance studies required for performance evaluations of in vitro diagnostic medical devices. Given the preliminary nature of the consultation, any guidance offered should not be legally binding either on the health technology developers or on HTA authorities and bodies. Such guidance, however, should reflect the state of the art of medical science at the time of the joint scientific consultation, in particular in the interest of patients	JSC
Article		
1 (b)	This regulation establishes: a mechanism which lays down that any information, data, analyses and other evidence required for the joint clinical assessment of health technologies is to be submitted by the health technology developer only once at Union level;	JCA
Art 8 (6)	The designated subgroup shall initiate a scoping process in which it identifies the relevant parameters for the assessment scope. The assessment scope shall be inclusive and reflect Member States' needs in terms of parameters and of the information, data, analysis and other evidence to be submitted by the health technology developer. The assessment scope shall include in particular all relevant parameters for the assessment in terms of: (a) the patient population; (b) the intervention or interventions; (c) the comparator or comparators; (d) the health outcomes. The scoping process shall also take into account information provided by the health technology developer and input received from patients, clinical experts and other relevant experts.	JCA
Art 10 (1)	The Commission shall inform the health technology developer of the assessment scope and request the submission of the dossier (first request). That request shall include the deadline for submission as well as the dossier template pursuant to Article 26(1), point (a), and refer to the requirements for the dossier in accordance with Article 9(2), (3) and (4). For medicinal products, the deadline for submission shall be at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use referred to in Article 5(2) of Regulation (EC) No 726/2004.	JCA
Art 10 (5)	Where the Commission finds that the dossier fails to meet the requirements laid down in Article 9(2), (3) and (4), it shall request the missing information, data, analyses and other evidence from the health technology developer (second request). In such a case, the health technology developer shall submit the	JCA

	requested information, data, analyses and other evidence in accordance with the timeframe established pursuant to Article 15.	
Art 10 (6)	Where, after the second request referred to in paragraph 5 of this Article, the Commission deems that a dossier was not submitted in a timely manner by the health technology developer, or attests that it fails to meet the requirements laid down in Article 9(2), (3) and (4), the Coordination Group shall discontinue the joint clinical assessment. If the assessment is discontinued, the Commission shall make a statement on the IT platform referred to in Article 30, justifying the reasons for the discontinuation and shall inform the health technology developer accordingly. In the case of discontinuation of the joint clinical assessment, Article 13(1), point (d), shall not apply.	JCA
Art 10 (8)	Without prejudice to paragraph 7, where a joint clinical assessment has been re-initiated, the Commission may request the health technology developer to submit updates of previously provided information, data, analyses and other evidence.	JCA
Art 11 (2)	Where the assessor, with the assistance of the co-assessor, at any time during the preparation of the draft reports, considers that further specifications or clarifications or additional information, data, analyses or other evidence are necessary in order to carry out the assessment, the Commission shall request the health technology developer to provide such information, data, analyses or other evidence. The assessor and the co-assessor may also have recourse to databases and other sources of clinical information, such as patient registries, where it is deemed necessary. Where new clinical data becomes available during the assessment process, the health technology developer concerned shall proactively inform the Coordination Group.	JCA
Art 11 (5)	The draft reports shall be provided to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies in accordance with the timeframes established pursuant to Article 15. The health technology developer shall also signal any information it considers to be confidential and justify its commercially sensitive nature. The health technology developer shall not provide any comments on the results of the draft assessment.	JCA
Art 12 (4)	The Commission shall publish, in a timely manner, the procedurally compliant reports endorsed or re-endorsed by the Coordination Group on the publicly accessible webpage of the IT platform referred to in Article 30(1), point (a), and shall inform the health technology developer of the publication	JCA
Art 16 (1)	The Coordination Group shall carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for a given health technology. Those consultations shall facilitate the generation of evidence that meets the likely evidence requirements of a subsequent joint clinical assessment on that health technology. The joint scientific consultation shall include a meeting with the health technology developer and result in an outcome document that outlines the scientific recommendation made. Joint scientific consultations shall in particular concern all relevant clinical study design aspects, or clinical investigation design aspects, including comparators, interventions, health outcomes and patient populations. When carrying out joint scientific consultations on health technologies other than medicinal products, the specificities of those health technologies shall be taken into account.	JSC
Art 16 (3)	The joint scientific consultation outcome document shall not give rise to any legal effects on Member States, the Coordination Group or the health technology developer. Joint scientific consultations shall not prejudice the joint clinical assessment which may be carried out on the same health technology.	JSC
Art 17 (1)	For health technologies referred to in Article 16(2), health technology developers may request a joint scientific consultation.	JSC
Art 17 (2)	Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency. In such a case, the health technology developer shall make the request for scientific advice to the European Medicines Agency when submitting the request for the joint scientific consultation. Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel. In such a case, when submitting the request for the joint scientific consultation, the health technology developer may make the request for a consultation with the expert panel, where appropriate.	JSC
Art 17 (4)	Within 15 working days after the end of each request period, the Coordination Group shall inform the requesting health technology developer whether it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons, having regard to the criteria laid down in paragraph 3.	JSC

Art 18 (2)	The health technology developer shall submit up-to-date documentation containing the information necessary for the joint scientific consultation, in accordance with the requirements set out pursuant to Article 21, point (b), in the timeframe set out pursuant to Article 3(7), point (f).	JSC
Art 18 (7)	The designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and patients, clinical experts and other relevant experts.	JSC
Art 19 (2)	The Commission shall send the joint scientific consultation outcome document to the requesting health technology developer at the latest 10 working days after it has been finalised.	JSC
Art 30 (1c)	a secure system for the exchange of information between the Coordination Group and its subgroups with health technology developers and experts participating in the joint work referred to in this Regulation, as well as with the European Medicines Agency and the Medical Device Coordination Group;	JCA/JSC