



eunethta

EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

EUnetHTA 21

Guidance Document

**D7.2 – GUIDANCE ON PATIENT & HEALTHCARE PROFESSIONAL
INVOLVEMENT**

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Disclaimer

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LIST OF ABBREVIATIONS

CEB	Consortium Executive Board
COI	Conflict of Interest
CSCQ	Committee for Scientific Consistency and Quality
D	Day (time during a procedure)
DOI	Declaration of Interest
ECA	EUnetHTA confidentiality agreement
EMA	European Medicines Agency
EPAG	European Patient Advocacy Groups
ERN	European Reference Networks
EUnetHTA	European Network for Health Technology Assessment
GDPR	EU General Data Protection Regulation
GRIPP2	Guidance for the Reporting of Patient and Public Involvement in Health and Social Care Research
GRIPP2-SF	GRIPP2 short form
HaDEA	European Health and Digital Executive Agency
HCP	Healthcare professional
HTA	Health technology assessment
HTAb	HTA body
HTAR	HTA Regulation (EU) 2021/2282
HTD	Health technology developer
JA	Joint Action
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
LoI	List of Issues
PICO	Patient population, Intervention, Comparator(s) and Outcome(s)
SOP	Standard operating procedure

1 GENERAL PRINCIPLES AND PURPOSE

On 17 September 2021, the European Health and Digital Executive Agency (HaDEA) signed a service contract for the provision of joint health technology assessment (HTA) work supporting the continuation of EU cooperation on HTA.

The EUnetHTA 21 work will build on the achievements and lessons learned from the EUnetHTA Joint Actions (JAs) and will focus on supporting a future EU HTA system under Regulation (EU) 2021/2282 (HTA Regulation, HTAR).

1.1 *General principles*

This guidance describes

- (1) The value of patient and healthcare professional involvement in HTA work for Joint Scientific Consultations (JSCs) and Joint Clinical Assessments (JCAs);
- (2) How patient and healthcare professional (HCP) input can be gathered;
- (3) When and how patient and HCP contributions can be used;
- (4) How patient and healthcare professional contributions should be reported.

1.1.1 **Relevant articles in HTA Regulation (EU) 2021/2282**

The articles from HTA Regulation (HTAR) (EU) 2021/2282 directly relevant to the content of this guidance can be found in [Appendix 1](#).

1.2 *Scope*

This guidance document provides a framework for the involvement of external experts in JSC and JCA as per requirements laid out in the HTAR. While the HTAR only defines the involvement of external experts, EUnetHTA 21 recommends a process for the involvement of stakeholders (i.e. patient organisations, HCP organisations) is also established. This recommendation is based on experiences from EUnetHTA Joint Action 3 and EUnetHTA 21, national HTA procedures as well as expectations and feedback received in public consultations.

To avoid confusion, the process for external experts and the EUnetHTA 21 recommended process for stakeholder involvement is separated. Nevertheless, the recommended processes should be read in conjunction.

The definitions and procedures described only inform the future European process under the HTAR. National definitions and procedures may be different. Although this deliverable only outlines the involvement of external experts and stakeholders in JSC and JCA, this should not replace or reduce the need for their involvement at national level in the JSC and JCA. However, the process for involvement of external experts and stakeholders on a national level remains the responsibility of the national HTAb.

1.3 *Objective*

This guidance document explains (1) the role of external experts (patient and clinical) during the production of JSCs and JCAs, (2) the recruitment of external experts, (3) the process for collecting their input, (4) the documentation of input in the JSC Final Written Recommendations or JCA reports, (5) the evaluation process for their involvement, and (6) describe the EUnetHTA 21 recommended process for stakeholder involvement..

The recommended processes can also be extended to allow for the involvement of other external experts in JSC or JCA outputs.

The document is primarily intended to provide a recommended process for external expert and stakeholder involvement for JSC and JCA to be conducted in EUnetHTA 21 and under the HTAR, although it may be informative for a wider audience of stakeholders such as HCPs, patients, payers, industry, HTAb, and regulatory agencies.

1.4 Preliminary work from EUnetHTA JA3

EUnetHTA JA3 established a task group on patients, consumers, and healthcare providers. The objective of the task group was to support the development of a process for patient, consumer, and healthcare professional involvement within EUnetHTA JA3 assessments and early dialogues, based on the procedures of national HTA agencies. This preliminary work was used as a basis for the processes described in this EUnetHTA 21 deliverable.

2 ACTORS AND THEIR SCOPE

2.1 Definition of external experts and stakeholders

2.1.1 External experts

As per Recital 45 of the HTAR “Patients, clinical experts, and other relevant experts should be selected for their subject matter expertise and act in individual capacity rather than representing any particular organisation, institution or Member State.”

In this deliverable, external experts are defined as *“individuals who are recruited based on their knowledge and expertise in a particular area. They speak in their own name and do not respond on behalf of an organisation, company or association, nor represent the general interest of a group affected by EUnetHTA 21 or the work under the HTAR. They should respond to specific questions or requests in the context of a joint production (i.e., JSC, JCA or methodological guideline) and provide insight from their perspective.”* External experts also have the opportunity to raise issues for discussion during a joint production.

External experts are individuals who have special skills or knowledge resulting from their experience or training.

External experts include clinical experts in the therapeutic area concerned, patients affected by the disease and other relevant experts, for example in the area of the type of health technology concerned or issues related to clinical study design.

Any external expert involved in a JSC or JCA, should have a European perspective, e.g., somebody who belongs to a European organisation or society, or is part of a European consortium on the topic, or can demonstrate European knowledge on the topic/therapeutic area (e.g., author of a clinical guideline).

2.1.2 Stakeholders

While the HTAR only defines external experts for the involvement in JSC and JCA, EUnetHTA 21 recommends that also stakeholders are involved. This deliverable defines stakeholders for the involvement in JSC and JCA as *“associations and professional actors who represent the general interest of groups affected by the objectives and achievements of EUnetHTA 21 and the future HTAR”*.¹

2.2 Definition of patients and patient representatives

Patients can be defined as *“People with a legitimate, personal interest in a health care issue (e.g., use of a health technology, healthcare services)”* (Menon and Stafinski 2011). Different groups of people can provide patient-based expertise in a JSC or JCA, possibly in different roles (as experts or as stakeholders). Depending on the group, a specific role and related activities could be defined.

To ensure consistent use in all EUnetHTA 21 outputs, [Appendix 2](#) provides a complete glossary of terms related to patients (e.g., patients, patient representatives, and patient organisations) to allow for a clear demarcation between the possible groups involved.

Where possible, **individual patients with collective experiential knowledge**, for example from participation in a patient organisation, should be targeted for contributions to EUnetHTA 21 joint production as external experts. These are patients with collective knowledge based on contacts and exchanges with multiple patients with experience of the condition. Patients who have been trained in scientific research and/or HTA might be able to communicate more easily with the HTA bodies (HTAb)

¹ The creation and establishment of the Stakeholder Network as foreseen by the HTAR (Art. 29) is the exclusive responsibility of the European Commission and is outside the scope of this guidance. Processes for involving stakeholders in EUnetHTA 21 work (excluding production of JCA outputs) via public consultations are described on the EUnetHTA 21 website). <https://www.eunetha.eu/public-consultation/>

and make the process more efficient, but it should not be a requirement for patients to have had training to become involved in a JSC or JCA.

Every effort will be made to involve the patient(s) themselves. In cases in which patients are less able to express themselves (e.g., children, condition inducing cognitive impairment) they can be supported by or represented by proxies (e.g., parents, informal caregivers) or patient representatives, ideally also with collective knowledge.

Patients, proxies or patient representatives invited to give input to JSCs or JCAs as external experts do not formally represent a patient association but may be members of one. When we refer to patient experts in this document, we mean patients acting as external experts.

EUnetHTA 21 recommends that in JCAs patient representatives can also provide input as stakeholders representing the interests of their patient association.

2.3 Definition of Healthcare Professionals

In this guidance, HCPs are defined as *“individuals with clinical expertise in a specific field and consolidated experience in clinical research and/or clinical practice, including general practitioners, medical specialists, nurses and others (e.g., pharmacists, physiotherapists, psychologists and dieticians)”*.

HCPs give input to JSCs and JCAs as clinical experts. If a clinical expert is a member of a healthcare professional organisation or a clinical or learned society, the JSC or JCA team should be informed of this role. HCPs working for an HTAb (participating in HTAs and/or consultation), or a health technology developer (HTD) cannot be defined as clinical experts within the meaning of this document.

EUnetHTA 21 recommends, that for JCAs, HCPs can also provide input as stakeholders, sharing the views of their organisation (e.g., clinical society).

2.4 Value of patient and healthcare professional involvement

Patients and HCPs provide important knowledge about a disease and insights into treatment pathways. For JSC and JCA, it is important to consider the values of patients and HCPs and how these values are reflected (or not) by current treatments. For example, during a JSC input may help the assessment team to critically assess study designs, including aspects such as the selection of relevant outcomes linked to the direct and indirect impact of the disease and characterisation of the appropriate patient population. During the scoping process of a JCA, input may be used to support the development of the PICO (Patient population, Intervention, Comparator(s) and Outcome(s)). Input from patients and HCPs ensures the relevance, legitimacy and transparency of assessments and recommendations. Patients and HCPs bring different but complementary perspectives to HTA and their input is critical to the JSC and JCA process. Moreover, when taking part in HTA, patients and HCPs gain more understanding on how health technologies are assessed, which benefits transparency.

EUnetHTA 21 feels strongly that patients should have meaningful involvement in JSC and JCA. International evolution towards more patient involvement in HTA over the last ten year supports this position², which is also recognised in the HTAR.

The role of patients is of high importance, as they have specific knowledge and expertise to offer. Their expertise arises from their own lived experience and it can help assessors in understanding the context of the condition, the experience of patients living with the condition, the remaining unmet needs of patients despite current treatment management options and its impact on their lives. Moreover, their input might help assessors to contextualise the data provided by the HTD, and to understand whether and how the new technology would or would not help address the issues experienced by patients. It

² EUPATI (EUPATI Toolbox: <https://toolbox.eupati.eu/resources/guidance-for-patient-involvement-in-hta/>), HTAi ((Health Technology Assessment International) “Values and Quality Standards for patient involvement in HTA” (<https://htai.org/patient-and-citizen-involvement/>)), and INAHTA (<https://www.inahta.org/position-statements/>)

should be recognized that patients are in a different position than other stakeholders or external experts, especially when they are affected by the disease under consideration. To be physically, emotionally, and/or financially affected by a condition gives patients a different perspective to a problem, compared to stakeholders or external experts that are professionally or economically affected by the issue or have no direct experience with the disease under consideration.

HCPs also have specific knowledge and expertise to offer. For example, clinical experts having experience with patients in different stages of a disease and very diverse profiles, could share their knowledge on the long-term consequences of a disease or side-effect and the differential impact on patients with different co-morbidities, social gradients etc.

3 PROCESS FOR EXTERNAL EXPERTS

Input from individual external experts should be sought for each JSC and JCA. To assist the process, guidance for recruitment and selection is provided. If the JSC or JCA team is unable to recruit and select appropriate external experts, this should be explained in the JSC or JCA report. An effort should be made to identify external experts at the earliest possible time point to allow for adequate engagement.

This chapter will describe the rules of collaboration around confidentiality and conflict of interest, the procedures for selection and involvement of external experts in JSC and JCA.

3.1 *Rules of the collaboration*

3.1.1 Conflict of interest

Any external expert recruited for a JSC or JCA on the European level, must complete a DOI form. The DOI form will be evaluated by the EUnetHTA 21 Conflict of Interest (COI) Committee following the rules described in the guidance for DOI (D7.5 Procedure Guidance for Handling DOI and ECA forms) before the external experts become involved in the JSC or JCA. DOI information from external experts will remain confidential in EUnetHTA 21. Under the HTAR, declarations from external experts and any actions taken as a result shall be recorded in the summary minutes of meetings and in the outcome documents of the joint work in question (Article 5).

3.1.2 Confidentiality

External experts may receive access to certain JSC or JCA documents according to the needs of the Assessor and Co-Assessor (organisations responsible for developing and writing of a joint EUnetHTA 21 product). Further information can be found Table 5-1. They may only get access to these documents after their signed EUnetHTA 21 confidentiality agreement (ECA) form is approved by the Secretariat and after their DoI has been assessed by the EUnetHTA COIC.

The JCA report will remain confidential until publication of the final report at which time the ECA is lifted. JSC recommendations remain confidential after finalisation (i.e., there is no expiration date for the confidentiality agreement), and therefore external experts are not permitted to share any information as per the ECA. Information or feedback regarding their practical experience of being involved in a JSC (e.g. recruitment steps, time taken to prepare for meetings) can be shared, but this must be done without revealing the content of the JSC.

3.2 *Recruitment and selection of external experts*

Systematic recruitment of external experts is of outmost importance. Several recruitment strategies have been developed. After the identification process, selection will take place.

The role of stakeholder organisations in the identification of external experts is important. The EUnetHTA 21 Secretariat may approach relevant organisations (for example European patient organisations or European medical societies) directly via e-mail and ask for their support in finding external experts for a JSC or JCA. To identify relevant organisations, the following could be consulted (this list is not exhaustive):

- The EUnetHTA 21 Stakeholder Repository (only for EUnetHTA 21);
- The HTAR Stakeholder Network (once established);
- The clinical expert database (Section 3.2.2) or patient database (once created);
- European Reference Networks (ERN) and their respective European Patient Advocacy Groups (EPAGs);
- Existing databases or directories, such as Orphanet;
- Internet searches can identify relevant stakeholders and/or experts, for example, via the websites of hospitals or scientific publications and clinical guidelines.
- The European Medicines Agency (EMA) could be contacted for information on stakeholder organisations they work with or for individual experts in a particular area.

For a JCA, external experts can also be recruited via a public call for involvement on the EUnetHTA 21 website and social media channels. The EUnetHTA 21 website should log all active public calls. This approach is not possible for JSCs, as they are confidential in nature.

3.2.1 Dissemination of opportunities for involvement in HTA activities

To promote willingness to become involved, there are several ways to disseminate general knowledge about HTA work. One way is to actively participate in disease-specific conferences in the form of poster or oral presentations to raise awareness of what HTA work entails. Training opportunities for patients and clinical experts together with the EMA or other stakeholder organisations are pursued during EUnetHTA 21 to provide information about HTA activities and possibilities to engage in HTA processes.

3.2.2 Database of external experts

In order to be able to draw on a fixed pool of external experts in the future, a database should be created under the HTAR. Inclusion of an external expert in the database does not automatically result in acceptance of the external expert in a JSC or JCA as a selection process will have to be applied.

Development of an operational database similar to that of the EMA takes a lot of resources, also on the expert side to register via an extensive form. Based on our understanding of the EU General Data Protection Regulation (GDPR) regulation, it is unlikely this database including the registered experts can be transferred to the HTAR Secretariat. Therefore, it was decided to only provide recommendations for the database development and maintenance under the HTAR.

Registration form & GDPR compliance

To help define the needs for the external expert database under the HTAR, an informational interview was conducted with the EMA Public and Stakeholder Engagement team. The EMA allows individuals to register their interest in involvement in EMA activities via a web-based form.³ Similarly, the external expert database under the HTAR registration form should allow individual experts to register their contact details, area(s) of interest and the type of activity they would like to be involved in. To ensure GDPR compliance, specific GDPR information should be included on the sign-up page. Furthermore, in line with the EMA practices, it is recommended that the registered persons should be contacted by the HTAR Secretariat annually to confirm their information and that they want to remain on the database.

In addition to usual contact information, the registration form should, at minimum, request the following information:

- Expert type (patient, patient representative, clinical expert)
 - If clinical expert: in what capacity/speciality (e.g., physician, nurse, pharmacist)
- Joint HTA activities the expert is interested in (JCA, JSC, receive information, comment on public guidelines or consultations)
- Disease / condition area(s) of interest
- Language spoken
- Member of association/organisation (patient or clinical) & name of the association
- Consent for data to be stored
- Previous experience or involvement in JSC or JCA, if any
- Any relevant training received, including the type of training and organisation/person that provided the training

The registration form should include a clear GDPR statement informing those who register that they agree to storage of their personal data and how the data will be used and who controls the information. The statement should indicate contact information and instructions for renewal or requesting removal from the database. As an example, the GDPR statement below was developed based on the statement provided by the EMA:

³ <https://fmapps.ema.europa.eu/stakeholders/signup.php>

“The HTAR Secretariat processes your personal data in accordance with [Regulation \(EU\) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data](#).

The Controller of your data is the European Commission who may be contacted through [\[insert e-mail address when created\]](#). The information that you provide will be used only for the purpose of informing and involving external experts and other interested parties in the activities under the HTAR. You will be asked on an annual basis if you wish to remain in the database, and to ensure your contact details and interests are up to date. Removal from the database can also be requested at any time by email to [\[insert e-mail address when created\]](#)

Further information on how your personal data are processed is provided in the specific privacy statement for this database published on website/IT platform to be created under the HTAR [\[include hyperlink once available\]](#)”

To populate the external expert database an open call could be published online informing patient and clinical experts that they can register for the external expert database and that this database will be used for identification of patient and clinical experts as needed for the joint activities (e.g., JSC, JCA) under the HTAR. Owing to GDPR compliance issues, registration in the database cannot be carried out on behalf of an individual.

A brief standard operating procedure (SOP) detailing the rules for maintaining and using the database should be created, covering at least the following points:

- Registration/how data is entered;
 - How data is maintained;
 - Annual renewal of data;
 - Automatic deletion of data;
- Who is responsible for entering and maintaining the data;
- Data usage;
 - Approved usage;
 - Track usage of the database in the dedicated activity log;
- Information on joint activities (e.g., JSC, JCA) the person has already participated in or reason why their participation may have been declined.

3.2.3 Selection criteria for external experts

Patients, clinical experts and other relevant experts should be selected for their subject matter expertise and act in individual capacity rather than representing any particular organisation, institution or Member State (Recital 45). However, external experts need to be able to contribute to the JCA and JSC and therefore it is not sufficient for them to have only a personal or national perspective.

After external experts have been identified, a selection process will start. Regardless of the number of external experts recruited, the Secretariat will apply a selection process according to the criteria listed below. These criteria are for guidance only and are not exhaustive. Furthermore, not all criteria need to be met in order for an external expert to be involved, this can be decided on a case-by-case basis and exceptions may be applied for (ultra) rare diseases. Criteria number two can be fulfilled by one of the sub-criteria.

1. Relevant expertise in and experience of the disease area/treatment area
2. Demonstrate broad European knowledge on the therapeutic area. Suggestions for how this broader perspective might be identified could be but are not limited to:
 - a. Member or associated with an EU organisation or society (e.g. (umbrella) patient organisation or medical society) or,

- b. Member or associated with a European consortium on the topic relevant to the JSC or JCA or,
- c. Author of a European clinical guideline,
- 3. Availability during the JSC or JCA activity.

Analysis of the DOI and ECA will be done by the appropriate governance body (in EUnetHTA 21 this is the COI Committee for the DOI form, and the Secretariat for the ECA form).

3.3 Involvement of external experts

Involvement is the term to be used in EUnetHTA 21 to refer to consultation with patients and HCPs in the context of JSCs and JCAs. External expert involvement follows the processes outlined in Sections 3.4 – 3.6, in accordance with the requirements as set out in the HTAR (see [Appendix 1](#) for the relevant articles).

3.3.1 External expert involvement

The EUnetHTA 21 Secretariat should explain the process in detail to the identified external expert, prior to their agreement to participate. Selected external experts will be supported by the (dedicated team at the) Secretariat throughout the JSC and JCA and will be provided with a contact to whom they can direct any questions at any time. After every verbal contact, the Secretariat will follow-up via e-mail with a short summary of the discussion.

Once selected, the Secretariat will reiterate or explain the process and associated objectives and expectations (including the format of the input) either verbally or via email, or both. Following assessment of the COI, the recruited external experts may be involved from the start of the process until completion of the JSC or publication of the JCA report. During the process, relevant documents and information (e.g., the briefing book for JSC) may be shared with external experts.

At the beginning of the procedure, the external experts involved also receive an overview of the expected dates and deadlines from the Secretariat. Prior to a scheduled interview (where one is planned), external experts receive the relevant input template to gain understanding of the scope of the interview and what is expected of them. The summary of the interview will be shared with the interviewee for them to verify the content is an accurate reflection of their views. Alternatively, the input template can be completed by the external expert as a written statement.

3.4 Time points and methods for involvement of experts

Input from external experts should be sought for each JSC and each JCA. If a JSC or JCA team is unable to obtain this input, it should be explained in the JSC or JCA report.

The different EUnetHTA 21 products (JSC vs. JCA) require input at different time points in the process. The options for external expert involvement in EUnetHTA 21 production activities are described in Table 5-1. The potential methods that can be used for each step in the procedure are shown. The procedures described for external expert involvement may apply both to EUnetHTA 21 and the HTAR.

A detailed visualisation of the different points in time and process phases in which inputs are collected is shown in [Error! Reference source not found.](#) and [Error! Reference source not found.](#)

3.5 Reporting on external expert involvement

Owing to legal constraints in some member states, patients acting as external experts will not be named individually; instead, the type of patient expert involved will be reported (see [Appendix 2](#)). On agreement with the clinical expert, the clinical expert may be named in the participant table in the JSC or JCA report. If the clinical expert does not want to be named, a general description of the type of expert could be added, such as “clinical professional, working at a hospital in country X”.

To adequately reflect patient and HCP involvement, the method and timing of involvement should be described in the JSC or JCA report.

The report should present the input, based on responses from input templates, individual interviews or group discussions. Expert input obtained via the input templates will be published in the Annex of the JSC or JCA report. In the case of patients acting as external experts, no personal details will be published.

The principles of the international consensus-based Guidance for the Reporting of Patient and Public Involvement in Health and Social Care Research (GRIPP2)⁴ are used by EUnetHTA 21 to guide the reporting on patient and healthcare professional involvement in JSCs and JCAs. Since a description of patient and HCP involvement is not the primary focus of JSC and JCA reports, the GRIPP2 short form (GRIPP2-SF) (see **Error! Reference source not found.**, can inform the content for the JCA report template (D5.2) and JSC written recommendation template (D6.2/6.3).

3.6 Proactive evaluation mechanism for external experts

To ensure that external expert involvement is appropriate, timely and meaningful for all partners, an active feedback mechanism was developed. Feedback is active in the sense that it is sought in the form of a questionnaire at the end of the external expert involvement in an EUnetHTA 21 JSC or JCA process. Questionnaires include questions on whether the participant understood their role in the JSC or JCA, overall satisfaction with the process, feedback on documents used during the process and suggestions to improve the process. In addition, participants are encouraged to provide feedback to the relevant Secretariat at any time during the process or after their involvement. Results from the questionnaires as well as other comments on the process will be used to further refine the process and associated guidance documents.

The feedback questionnaire can be found in [Appendix 3](#).

⁴ Staniszewska S, Brett H, Simera I, et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research. *BMJ* 2017;358:j3453. <https://doi.org/10.1136/bmj.j3453>

4 PROCESS FOR STAKEHOLDERS

While the HTAR only defines the involvement of external experts, EUnetHTA 21 recommends a process for the involvement of stakeholders (i.e. patient organisations, HCP organisations) is also established. This recommendation is based on experiences from EUnetHTA Joint Action 3 and EUnetHTA 21, national HTA procedures as well as expectations and feedback received in public consultations.

Involvement of patient and HCP organisations in HTA enables the perspective of the wider community of patients and healthcare professionals across the EU to be represented. In addition, patient and HCP organisations also play an important role informing their membership about HTA, and encouraging engagement in HTA processes, as well as providing training to their members. They may also assist the EUnetHTA 21 Secretariat in identifying external experts.

EUnetHTA 21 recommends that stakeholders are only involved in JCAs. For JCAs, an online questionnaire can be administered to obtain stakeholder input using the dedicated stakeholder input templates. Stakeholders are informed of the claimed indication, but all other information in the dossier remains confidential until the JCA report is published. For JSCs, stakeholders are not involved for confidentiality reasons.

4.1 *Rules of the collaboration*

4.1.1 Confidentiality

No confidential information will be shared with stakeholders during their involvement in a JCA

4.1.2 Conflict of interest

Patients and healthcare professionals who contribute as stakeholders to a JCA are required to provide information regarding their organisation's funding as part of their submission via the respective input template. This information will be included, with their submission alongside the JCA report.

4.2 *Recruitment and selection of stakeholders*

Systematic recruitment of stakeholders is of outmost importance. The recommended mechanisms for recruiting stakeholders is largely identical to the recruitment mechanisms for external experts are largely identical. After the identification process, selection will take place.

The EUnetHTA 21 Secretariat may approach relevant organisations (for example European patient organisations or European medical societies) directly via e-mail and ask for their involvement in the JCA. Please see section 3.2 for a suggested list of organisations that could be consulted.

For a JCA, stakeholders can also be recruited via a public call for involvement on the EUnetHTA 21 website and social media channels. The EUnetHTA 21 website should log all active public calls. This approach is not possible for JSCs, as they are confidential in nature.

4.3 *Involvement of stakeholders*

Involvement is the term to be used in EUnetHTA 21 to refer to consultation with stakeholders in the context of JSCs and JCAs.

4.4 *Time points and methods for involvement of stakeholders*

EUnetHTA 21 recommends that stakeholder input is sought for every JCA. If a JCA team is unable to obtain this input, it should be explained in the JCA report.

A detailed visualisation of the different points in time and process phases in which inputs are collected is shown in [Error! Reference source not found.](#) and [Error! Reference source not found.](#)

4.5 Reporting on stakeholder involvement

A list of all stakeholder organisations that participated in the JCA should be reported. See Appendix 4 - Participant table JSC or JCA report for an example.

To adequately reflect patient and HCP involvement, the method and timing of involvement should be described in the JCA report.

The report should present the input, based on responses from input templates. Stakeholder submissions will be published alongside the JCA report, as well as details on funding of the organisation will be published.

4.6 Proactive evaluation mechanism for stakeholders

To ensure that stakeholder involvement is appropriate, timely and meaningful for all partners, an active feedback mechanism was developed, similar to the mechanism that is in place for external experts. See Section 3.6 for further details.

The feedback questionnaire can be found in [Appendix 3](#).

5 EUNETHTA 21 RECOMMENDED COMBINED PROCESS

While the HTAR only defines the involvement of external experts, EUnetHTA 21 recommends a process for the involvement of stakeholders (i.e. patient organisations, HCP organisations) is also established. This recommendation is based on experiences from EUnetHTA Joint Action 3 and EUnetHTA 21, national HTA procedures as well as expectations and feedback received in public consultations.

In this chapter, we describe the process currently applied within EUnetHTA 21. Therefore, in this chapter, the external expert and stakeholder involvement procedures are combined. EUnetHTA 21 recommends this process also to be applied under the HTAR.

The EUnetHTA 21 recommended options for external expert and stakeholder involvement in EUnetHTA 21 Joint Production activities are described in Table 5-1. The potential methods that can be used for each step in the procedure are shown as well.

A detailed visualisation of the different points in time and process phases in which inputs are collected is shown in [Error! Reference source not found.](#) and [Error! Reference source not found.](#).

Details on how the input received should be documented in JCAs and JSCs can be found in Section 3.5 (for external experts) and Section 4.5 (for stakeholders).

5.1 Overview of external expert and stakeholder involvement in EUnetHTA 21 production outputs

Table 5-1. Overview of external expert and stakeholder involvement in EUnetHTA 21 production outputs

Time point for involvement	Purpose	Stakeholder or expert	Level	Method(s)	Information provided to the external expert/ stakeholder
Joint Clinical Assessment (JCA)					
Online submission during the scoping process	<p>Input from patients used to obtain information on living with the disease; expectations for new treatment, etc.</p> <p>Input from patients and healthcare professionals used to support development of the consolidated PICO(s)</p> <p>This information is obtained well-before the JCA scoping starts⁵ so that HTA bodies who do not have a national procedure in place can still benefit from stakeholder-level patient and healthcare professional input.</p>	Stakeholders (patient and healthcare professional)	European	Online submission using the relevant stakeholder input templates	Indication under review
<i>Input during PICO development at a national level *</i>	<i>Depending on national procedures</i>	<i>Depending on national procedures</i>	<i>National</i>	<i>National procedures</i>	<i>As per national requirements</i>
Input during the scoping process	Input from patients and clinical experts is used to support development of the consolidated PICO(s). Input may be shared with national HTA bodies	External experts (patient and clinical)	European	Includes written statement or interview** using relevant external expert input templates and meeting participation	Indication under review. This occurs early in the scoping phase, so no draft PICO is available
Draft JCA report	Answer specific questions from the Assessor/Co-Assessor	External experts (patient and clinical)	European	Relevant individual questions, interviews if necessary	Depends on the mode of involvement, but could be specific information needed to understand the context of a question

⁵ The external expert input templates will be used 1–3 months before the scoping process of a JCA starts. The process to collect this input will last for about 1 month.

Joint Scientific Consultation (JSC)					
Ideally before List of Issues, but at the latest before the Face-to-Face meeting	Obtain information on living with the disease; expectations for new treatment etc. or getting input following the PICO scheme	External experts (patient, clinical)	European	Written statement or Interview using external expert input templates View draft List of Issues and respond to specific questions e.g. regarding the HTD development plan Participate in meeting with EMA, HTAb and HTD (Face-to-Face meeting) View Final Written Recommendations	Provide the briefing package or relevant sections of the package
<i>Input during consultation process to form national position *</i>	<i>Input from patients used to obtain information on living with the disease, expectations for new treatment, etc.</i> <i>Input from patients and healthcare professionals used to support position of the HTAb in a JSC</i>	<i>Experts and/or stakeholders (depends on the national procedure)</i>	<i>National</i>	<i>National procedures</i>	<i>As per national requirements</i>

Abbreviations: EMA=European Medicines Agency; HTA=health technology assessment; HTD=health technology developer.

* note: the shaded areas represent national involvement that could be carried out on the national level, according to national procedures. If a national HTAb sought the contribution of national experts and stakeholders this input should be reflected in the individual position of the HTAb in a JSC, and in the national PICO for JCA. In contrast to the involvement of European experts, the views of individual national experts or stakeholders are not directly included in the JCA report/annex or in the Final Written Recommendation/annex to the JSC.

** note: an interview will take place between the external expert and Assessor/ Co-Assessor/ Secretariat. After the interview, a summary is shared with the external expert for their validation of the content.

5.2 Timing and process phases for involvement

5.2.1 JSC time points for involvement

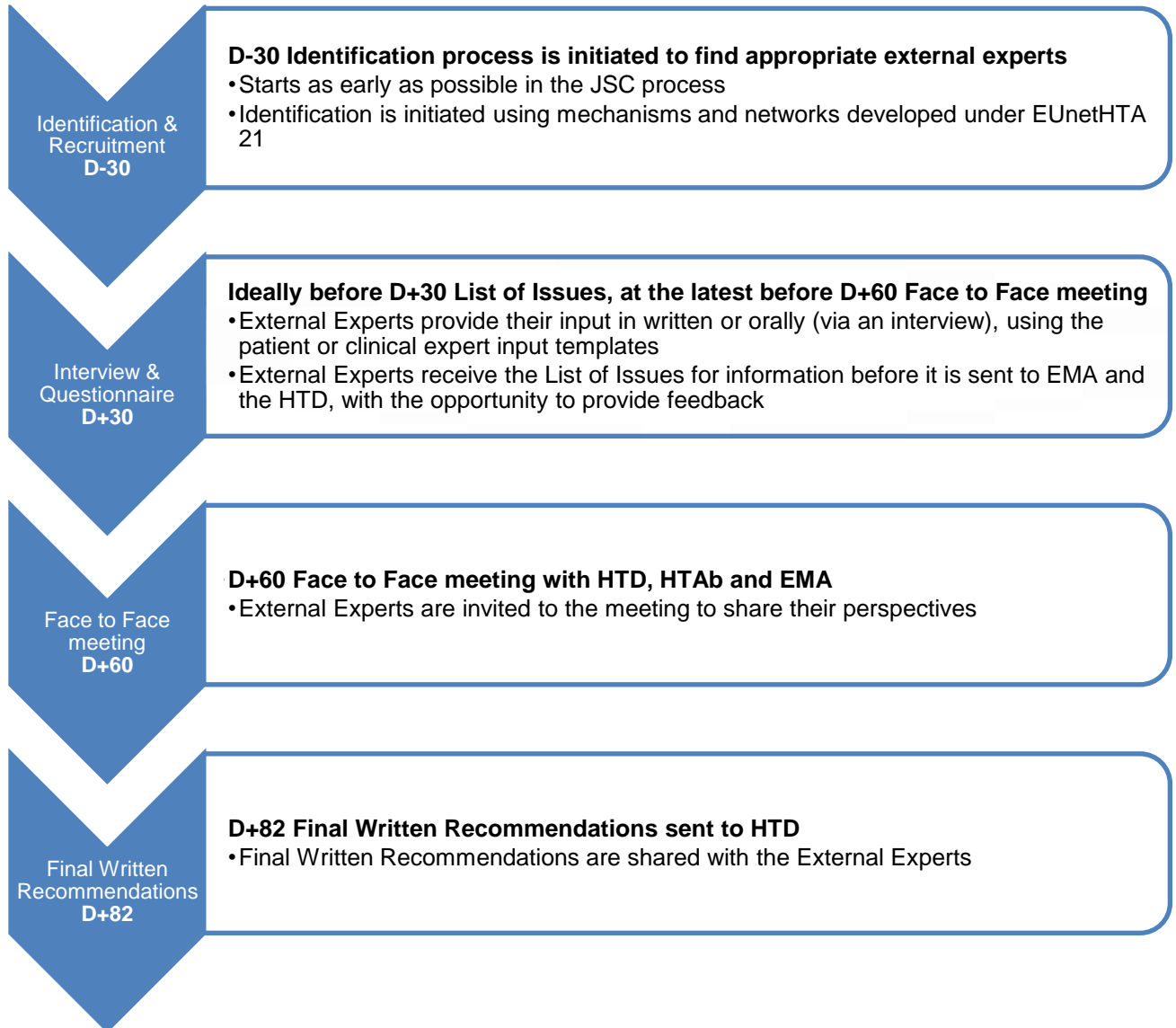


Figure 5-1. Time points for involvement in the JSC process (under EUnetHTA 21 and the HTAR)

5.2.2 JCA time points for involvement

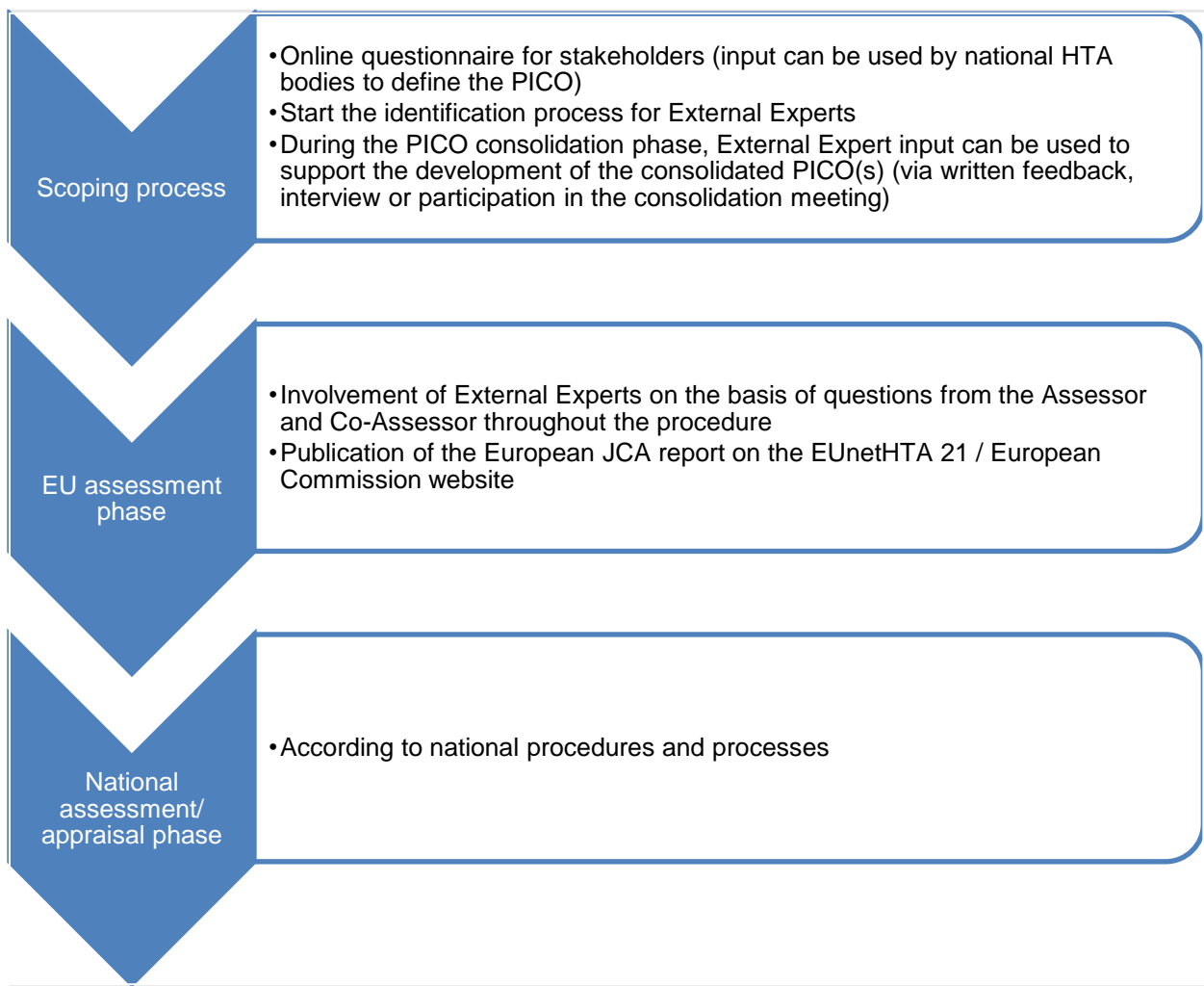


Figure 5-2. Time points for involvement in the JCA process (under EUnetHTA 21 and the HTAR)

Table 5-2. Template for reporting on patient and healthcare professional involvement

Report section		Items to report in JSC and JCA reports	Examples
Aim	Report the aim of patient and HCP involvement	Use a standard sentence	<p>Possible examples of standard sentences to be developed:</p> <p>For example: “External experts and stakeholders were consulted early in the JCA scoping process, before a consolidated PICO was developed.” and “Clinical experts were consulted to define the relevant clinical questions regarding the intervention being assessed.”</p> <p>“Patients were consulted to provide insights on living with the disease/condition and to describe advantages and disadvantages with existing treatments and expectations for new treatments.”</p> <p>and/or</p> <p>“Patients were consulted to support the interpretation of the effects of the intervention on the patient-relevant outcomes.” and “Clinical experts were consulted to support the assessment of the clinical relevance of the measured effects of the intervention.”</p>
Contributor table	Provide transparency on which (type of) external expert or stakeholder was involved	<p>Patients involved as external experts are by default not named individually, but a description is provided.</p> <p>Patients speaking on behalf of a patient organisation should be included by their organisation/affiliation and country.</p> <p>Clinical experts have the option to be named individually or not, with their affiliation and country.</p> <p>HCPs speaking on behalf of a HCP organisation or a clinical society should be included by their organisation or clinical society and country.</p>	See Appendix 4
Results of the patient and HCP involvement	Provide a clear description of the methods used to	<p>Who:</p> <ul style="list-style-type: none"> - Clinical expert, patient + type of patient (see Appendix 2 for an overview of the types) 	<p>If relevant for patients, provide a general description:</p> <ul style="list-style-type: none"> - having collective knowledge on the disease (yes/no) - having knowledge on experiences with the technology under evaluation (either self or knowledge obtained from other patients) (yes/no)

	involve the patient and/or HCP	<ul style="list-style-type: none"> - Number of patients/clinical experts involved - Number of stakeholder organisations involved 	<ul style="list-style-type: none"> - Country <p>If relevant for clinical experts:</p> <ul style="list-style-type: none"> - Clinical experience with the disease - Clinical experience with the technology under evaluation <p>For stakeholder organisations:</p> <ul style="list-style-type: none"> - Health conditions represented by the organisation (or remit of the organisation)
	Recruitment (see Section 3.2 and 4.2)		Describe how (according to what criteria) external experts and/or stakeholders were identified and recruited.
	Why/for what specific purpose (Table 5-1)		<p>Describe the purpose of the involvement:</p> <ul style="list-style-type: none"> - To obtain information on living with the disease; expectations for new treatments - To support the development of consolidated PICO(s) - To provide input for the JCA report - To assess the relevance of ethical and social aspects - To answer research questions related to patient aspects ...
	When		See Chapter 5
	How were the patients and healthcare professionals involved (Methods column in Table 5-1) What was actually done (Section 3.3 and 4.3)		<p>Online submission</p> <p>Interview</p> <p>Written participation</p> <p>Participation in [specify: F2F, PICO consolidation, other] meetings</p>
Results from the patient and clinical expert involvement	Report the results of patient and healthcare professional input in the PICO definition.	Input description	<p>The complete external expert input to be included as annex to the JSC and JCA report, without modifications.</p> <p>The complete stakeholder submissions to be published alongside the JCA report, without modifications.</p>
	Comment on the extent to which patient and healthcare professional input was used in the JSC or JCA overall.	Explain how the results of the patient and healthcare professional involvement were used/implemented,	
Reflections/critical perspective	Comment critically on the patient and healthcare professional involvement experience.	Discuss aspects of the validity and reliability of the results, based on, e.g., the number of experts and stakeholders included and their level of collective knowledge and COI status.	Mention the number of experts/stakeholders involved, geographical representation, etc. For patients, state whether they had collective knowledge or were speaking from individual experience.

6 PRACTICAL ISSUES

6.1 *EUnetHTA 21 and HTAb*

HTAb are responsible for conducting JSC and JCA work. Therefore, this term refers to JSC and JCA Assessors and Co-Assessors, the CSCQ, CEB and Secretariat.

The Secretariat is responsible for all external communication, and liaises between the JSC and JCA Assessors and Co-Assessors and the external experts involved at the European level. If an interview is conducted with an external expert, the Assessor and Co-Assessor are responsible for conducting the interview and incorporating the input received into the JSC or JCA. For methods that do not have a direct interaction with an expert, the Assessor and Co-Assessor are responsible for incorporating the input received into the JSC or JCA.

Potential interaction with patients and/or clinical experts at a national level is outside the scope of the HTAR and therefore remains the responsibility of the relevant HTAb.

6.2 *Contact points*

- External experts from the database should always be contacted by the JSC or JCA Secretariat;
- The Secretariat is the central contact point for questions from stakeholders and external experts;
- The Assessor and Co-Assessor take the lead for interviews.

6.3 *Other*

To be covered in the future: methodological experts.

7 RECOMMENDATIONS FOR THE HTAR

In this chapter we list a number of recommendations to be considered for the HTAR.

7.1 *Expert and stakeholder input in Joint Work*

While the HTAR only defines the involvement of external experts, EUnetHTA 21 recommends a process for the involvement of stakeholders (i.e. patient organisations, HCP organisations) is also established. This recommendation is based on experiences from EUnetHTA Joint Action 3 and EUnetHTA 21, national HTA procedures as well as expectations and feedback received in public consultations.

It is critical that for every JSC and JCA appropriate input from patients and HCP is sought.

7.2 *Central department for external involvement*

It is recommended that in the future a dedicated external expert and stakeholder involvement structure is set up, to have a centralised department to maintain the databases referenced in this document and to recruit external experts and stakeholders in collaboration with JSC and JCA Assessor and Co-Assessors. Such structure could also be involved in training for HTAb, to ensure consistency in incorporating stakeholder and external expert input in a JSC and JCA. A similar structure exists within the EMA to assist external expert and stakeholder involvement in their products.

7.3 *Refine processes and create SOPs*

As experience is gained, feedback from stakeholders, experts and assessors should be considered in order to refine processes and ensure input from HCPs, patients and other relevant experts is meaningful and has impact.

All processes and responsibilities related to stakeholder and external expert input in JSC and JCA should be detailed in SOPs. This guidance focuses primarily on patients and healthcare professionals. However, further processes around the involvement and reporting of input from other relevant experts may need to be developed as experience is gained.

7.4 *Training and dissemination*

The following is recommended for dissemination and training purposes for external experts:

- Opinion-forming congresses on the respective diseases in Europe should be regularly reviewed following calls for submissions to ensure that EUnetHTA 21 can participate;
- Training opportunities for patients and HCPs together with EMA should also be considered to inform about HTA activities and possibilities to engage in HTA processes;
- Any training and dissemination activities should also focus on the patient perspectives that are likely to be under-represented in HTA;
- All information/templates should be in accordance with good practice of digital health literacy and we will refer to the Web Content Accessibility Guidelines and underline the need to ensure that all sighted users can read the material (e.g., high colour ratio, ability to change font size, not use colour alone to impart information);
- Under the HTAR, a notification system should be set up on the EU level to alert about the published annual work plan. This would allow stakeholders to plan their resources

Training for the Secretariat and HTAb on patient involvement methods and practices should also be considered, especially training for the Secretariat and HTAb in patient interviewing techniques.

7.5 Database

For the expert database, it is recommended that experiences from EMA are considered regarding the registration form and database maintenance. Among the additional points to be confirmed are the following:

- Data ownership should be at the Secretariat of the European Commission;
- Where is the data stored;
- Who has access to the database:
 - How is it populated;
 - Who can access/modify/manage the data it contains;
 - How is maintenance arranged;
 - Can individuals listed in the database see, modify and/or delete their own information? This would require a system for which a personal account needs to be set up before entering information. The database should be capable of automatic updating when any modifications occur;
- A relational database management system allowing connection to other databases (COI and ECA, Medical Subject Headings, etc.) to avoid duplication of information stored in different areas.
- Furthermore, to ensure a diverse list of individuals and to avoid the same experts always being involved the database registration process must be prominent and straightforward.

7.6 Inclusiveness

To ensure inclusiveness, templates to be used by patients for their involvement in a JSC or JCA should be in lay language and translated into the official EU languages. In addition, the possibility of accepting patient input in all official EU languages should be considered, as not all patients are able to communicate sufficiently in English. However, this does mean that translation services should be available to ensure that the patient input is available in English for the JSC/JCA (Co-)Assessor.

To ensure inclusion of patients who are less able to express themselves (for example patients with cognitive impairment or children), it should be investigated how to adjust the process (e.g., facilitation for eliciting their input, adapted input template) to fit their needs.

The patient input template should either be adapted to be relevant for in vitro diagnostics, or a separate template should be developed.

Furthermore, the current template is not dedicated to caregivers directly (they complete it when they are a proxy); however, in the future, inclusion of questions dedicated to caregivers (or the creation of a separate template for caregivers) should be considered to capture their views and input too.

Finally, under the HTAR, it should be investigated how fair remuneration procedures can be put in place for external experts.

7.7 Considerations for the implementing acts

When defining the implementing acts for stakeholder and external expert involvement in JSCs and JCAs, an outstanding question is the number of external experts to involve in a JSC or JCA. If there are too few experts, this can impact the applicability of the information, while a greater number of experts puts constraints on resources.

It is recommended that the relevant implementing acts clarify that Article 11(4) (see [Appendix 1](#) for the full article) refers to all types of European involvement described in this deliverable that provide opportunities for input from external experts to draft JSC and JCA reports. It is not interpreted as meaning involvement in a review of a draft JSC or JCA report, as this brings challenges regarding confidentiality and timing. The appropriateness or relevance of such a review is also questionable, as it cannot impact the JSC recommendations or the JCA PICO or results of the JCA report at this point.

A key part of patient and HCP involvement in JCA takes place at a national level, when a PICO survey response is prepared (see deliverable 4.2 for further information). It is recommended, that a process to

support and encourage national external expert and stakeholder involvement therein is set up, as well as guidance on how to request and analyse information on potential COI, particularly for those HTAb that do not have their own patient and or healthcare professional involvement procedures.

8 RELATED DOCUMENTS

- JA3 Recommendations for Patient Involvement in REA;
- JA3 Recommendations for Healthcare Professional Involvement in Relative Effectiveness Assessments;
- JA3 Patient Questionnaire Template;
- EUnetHTA 21 Procedure Guidance for Handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms;
- EUnetHTA 21 Declaration of Interest (DOI);
- EUnetHTA 21 Confidentiality Agreement (ECA);
- EUnetHTA 21 Patient expert and stakeholder input templates
- EUnetHTA 21 Clinical expert and HCP input templates

APPENDIX 1 - HTAR RECITALS AND ARTICLES RELEVANT FOR THIS DELIVERABLE

(Rec 45)	Item 45 of the preamble of the HTA Regulation states that: “In order to ensure that joint work is of the highest scientific quality and reflects the state of the art, external experts with relevant in-depth specialised expertise should provide input on joint clinical assessments and joint scientific consultations. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts on, for example, the type of health technology concerned or issues related to clinical study design. European Reference Networks could also be used as source to identify those experts and access relevant knowledge in specific therapeutic areas. Patients, clinical experts and other relevant experts should be selected for their subject matter expertise and act in individual capacity rather than representing any particular organisation, institution or Member State.”
JCA	
Art 5(5)	Patients, clinical experts and other relevant experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.
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.
Art 11 (4)	The subgroup shall ensure that patients, clinical experts and other relevant experts are involved in the assessment process by being given the opportunity to provide input on the draft reports. Such input shall be provided within the framework and the timeframe set out pursuant to Article 15(1), point (c), and Article 25(1), point (b), and the procedure adopted by the Coordination Group, and shall be made available in a timely manner to the Coordination Group via the IT platform referred to in Article 30.
Art 25 (1)	The Commission shall adopt, after consulting all relevant stakeholders, by means of implementing acts , general procedural rules: (a) ensuring that the members of the Coordination Group, its subgroups, as well as patients, clinical experts and other relevant experts take part in joint clinical assessments in an independent and transparent manner, free from conflicts of interest; (b) on the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts in joint clinical assessments at Union level.
JSC	
Art 18(6)	The designated subgroup shall ensure that patients, clinical experts and other relevant experts are given an opportunity to provide input during the preparation of the draft joint scientific consultation outcome document.
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
Art 20(1) (b)	Implementing act: After consulting the Coordination Group, the Commission shall adopt, by means of implementing acts, detailed procedural rules for: (a) ...; (b) the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts in joint scientific consultation;(c) ...

APPENDIX 2 - GLOSSARY ON PATIENTS

Different groups of people that can bring in patient-based expertise in a JCA or JSC, possibly in different roles (as experts, as patient advocates, as healthcare users). Depending on the group, a specific role and related activities could be defined. (Cleemput, Dauvrin et al. 2019) All groups of people included in the glossary are part of the “patient community”, which is an overarching term covering individual patients, patient representatives (including family and carers), patient advocates and patient organisations (PARADIGM 2020).

Group	Sub-group level 1	Sub-group level 2	Definition	Role
Patients			<p>People with a legitimate, personal interest in a health care issue (e.g., use of a health technology, healthcare services). (Menon and Stafinski 2011)</p> <p>A person who uses, is affected by, is entitled to or is compelled to use a health service. (Consumer HTA glossary)</p> <p>A person, presenting with clinical signs or not, who consults a physician. (HTA Glossary English Editorial Board)</p>	Please refer to the respective sub-group level.
	Patients with experiential knowledge		<p>Patients with a valuable experiential knowledge about a specific illness or condition or treatment. (Facey, Boivin et al. 2010) They encompass individuals with a specific condition or having recovered from a specific condition, or having experience with the healthcare system (e.g., through pregnancy and delivery). Even if patients are newly diagnosed and therefore do not have experiential knowledge about a disease, they can have valuable insights into the diagnostic procedure. Hence, patients do not have to be long-term patients.</p>	Patients are recruited for their experiential knowledge, when involved in a JCA or JSC.
		Individual patients with individual experiential knowledge	<p>Patients who can, but not necessarily, belong to or representing a patient association or other organised form of patient representation</p> <p>“A person with lived experiences of the health condition. Patients can bring a detailed knowledge of the experience of living with the health condition, including its burden on daily life, the diagnostic process, and currently available treatment(s) (if any treatment is available).”(EUnetHTA 2018)</p> <p>Experience may relate to the entire lifecycle of the patient, including phases of the disease/conditions and/or outcomes the patient is no longer experiencing now and/or treatments patients have received in the past.</p>	Individual patients with individual experiential knowledge convey lived experiences from the perspective of one affected person.
		Individual patients with collective	<p>Patients with collective knowledge based on contacts with other patients, and exchanges with multiple other patients with experience with the condition or treatment under consideration, either through a</p>	Individual patients with collective experiential knowledge can present the experiences of other affected persons in a collected form.

Group	Sub-group level 1	Sub-group level 2	Definition	Role
		experiential knowledge	<p>patient association or through an informal gathering of patients (e.g., as moderator of a Facebook group or spokesperson of a group of people).</p> <p>“They can share the experiences of other patients based on their personal interactions (EUnetHTA 2018)</p> <p>NB: These patients do not formally represent a patient association</p>	They can provide a richer contribution compared to individual patients with individual experiential knowledge.
		Trained patient	<p>Experts with individual or collective experiential knowledge who are trained or have expertise in scientific approaches for policy research (trained or acquired through frequent involvement in research projects) (NN)</p> <p>They understand the scientific language, know what is expected from them in the process of the research project, know how to accurately respond to queries and give input.</p>	Training might facilitate better communication with researchers and make the research process more efficient., but care should be taken that it does lead to ‘distancing’ from the patient group the patient expert is representing
Patient representatives			<p>People who do not necessarily have the health problem, but speak on behalf of patients with a specific health condition. Depending on the context, this could also be people who bring the collective voice of specific, affected communities. (Canadian Institute of Health Research 2014)</p> <p>Patients acting as patient representatives, to represent the views of a particular group of patients or survivors. (EUnetHTA 2018)</p> <p>A person or organisation who/that is actively involved with others and presents the perspectives and concerns of a group of patients. (HTA Glossary English Editorial Board)</p>	<p>Patient representatives can make a significant contribution to understanding patients’ perspectives, especially in a context where patients are unable to communicate their values, needs, and preferences. (OHTAC Public Engagement Subcommittee 2015)</p> <p>It is important that they are clear about whom they represent, and the basis for their knowledge of patient perspectives.” (EUnetHTA, 2018. Patient Input in Relative Effectiveness Assessments -Updated: 29.05.2019)</p>
	Representatives of individual patients	Relatives or informal caregivers (e.g. caregivers, parents of a sick child)	<p>Representatives of individual patients with experiential knowledge that are unable to express themselves.</p> <p>“An individual patient’s caregiver is a person with experience acting in a primary care role for people living with a health condition. As with patients, caregivers may also act as representatives for a particular group of caregivers. Caregivers can:</p> <ul style="list-style-type: none"> • Bring second-hand knowledge about what it is like to live with the health condition, including its burden on daily life, the diagnostic process and currently available treatment(s). • Share first-hand knowledge about being a caregiver and/or guardian for individuals with the health condition” (EUnetHTA 2018) 	

Group	Sub-group level 1	Sub-group level 2	Definition	Role
	<p>Representatives from patient associations (patient advocates)</p>		<p>Patient associations are:</p> <ul style="list-style-type: none"> - not-for profit organisations which are patient-focused, and whereby patients and/or carers (the latter when patients are unable to represent themselves) represent a majority of members in governing bodies. (EMA 2005) - entities that produce and mobilise knowledge about a condition (experiential and credential knowledge) to make things happen in their disease area”.(Rabeharisoa, Moreira et al. 2013) They have a membership of individual patients and/or relatives and/or informal caregivers. Representatives of patient associations are often advocates, defending the interests of the patient population they represent, but they can also contribute to a research process by bringing in the collective patient perspective, rather than their own exclusive experience, because they can consult their membership. (Perlmutter, Roach et al. 2015) - formal gatherings of specific patient groups (e.g., cancer survivors, haemophilia patients) (and professionals) aiming at advocating, supporting and promoting patient issues and rights. <p>The size, the degree of formalisation, the presence of health care professionals and the objectives –among others– vary from association to association. Patient associations usually concern a specific disease, health condition or symptom.</p> <p>Patient advocates speak on behalf of a patient organisation. They are closely involved with patients and are able to voice any concerns and views of a patient group.</p>	<p>Representatives of patient organisations (patient advocates) can, in case they have collective experiential knowledge, contribute to JCA and JSC with perspectives of patients with a specific condition.</p> <p>Representatives of patient associations can also help identify patients to act as external experts with collective experiential knowledge.</p>
	<p>Patient umbrella organisations</p>		<p>Regroup numerous patient associations and aim at advocating for patient rights from a general perspective – without referring to a specific disease, health condition or symptom. Patient umbrella organisations can also represent patients for whom no association exist. It should be noted that not all patient associations are members of a patient umbrella organisation.</p>	<p>Patient umbrella organisations can contribute to JCA and JSC with perspectives of patients in general. Especially in the European context, patient organisations can represent the interests of all European patients in the most comprehensive way.</p> <p>Can potentially identify patients to act as external experts with collective experiential knowledge</p>

Group	Sub-group level 1	Sub-group level 2	Definition	Role
	Representatives of healthcare consumers		Representatives of health care consumers in general, including people who cannot be regarded or would not regard themselves as being patients (e.g., pregnant women, people undergoing screening or vaccination).	<p>The representation of healthcare consumers is organised differently in different member states. e.g., in Belgium, sickness funds claim to be healthcare consumer representatives). In France, a subdivision of the consumer association focusses on healthcare and defending the healthcare consumers' interests.</p> <p>If a JCA or JSC would benefit from contributions of healthcare consumer representatives, it could be more relevant to collect these via the stakeholder consultation approaches described in D8.6.1., as it is more difficult to identify specific experts with collective experiential knowledge on topics that would require such contributions (e.g., screening or vaccination programmes),</p>
Citizens			Individuals selected to represent the interests of the wider community.	<p>Consultation of citizens as experts is less likely to be applicable to JCA and JSC.</p> <p>Can be involved to learn about the aspects that are relevant for the society as a whole, but this is a different kind of perspective which might require a different approach</p>
	Consumers' organisations		"Not-for -profit organisations which defend and promote the general interests of European consumers - citizens as purchasers or users of goods and services" (EMA 2005)	

APPENDIX 3 - EUnetHTA 21 Evaluation Questionnaire for stakeholder and expert involvement in production activities

1. In which of the below procedures were you involved in?

- Joint Scientific Consultation
- Joint Clinical Assessments

General feedback on the procedure

2. Did you understand the general objective of the EUnetHTA 21 procedure?

- Yes, completely
- Mostly yes
- Mostly no
- No, not at all

If no, please explain:

3. Did you understand your role in the EUnetHTA 21 procedure?

- Yes, completely
- Mostly yes
- Mostly no
- No, not at all

If no, please explain:

4. Do you think you had enough opportunities to give input?

- Yes, completely
- Mostly yes
- Mostly no
- No, not at all

If no, please explain:

5. Do you feel that your input was taken into account?

- Yes, completely
- Mostly yes
- Mostly no
- No, not at all
- Not sure

If no, please explain:

6. Do you feel that your input had a meaningful impact in the procedure?

- Yes, completely
- Mostly yes
- Mostly no
- No, not at all
- Not sure

If no, please explain:

7. How do you feel about your interaction with EUnetHTA overall?

- Very satisfied
- Satisfied
- Neither satisfied nor dissatisfied
- Dissatisfied
- Very dissatisfied

Additional comments:

Feedback on documents used during the process

8. Did you give input as a

- Patient stakeholder
- Patient expert
- Healthcare professional stakeholder
- Clinical expert
- Other expert (please provide details)

Questions 8 & 9 if answering as a patient stakeholder

9. Did you find the EUnetHTA 21 Stakeholder Patient input template (insert link) helpful in preparing you for your involvement in the assessment?

- Very helpful
- Helpful
- Not very helpful

10. Were there any questions you felt were missing from the template?

- Yes
- No

Questions 10 & 11 if answering as a patient expert

11. 10. Did you find the EUnetHTA 21 Individual Patient Expert input template (insert link) helpful in preparing you for your involvement in the assessment?

- Very helpful
- Helpful
- Not very helpful

12. 11. Were there any questions you felt were missing from the template?

- Yes
- No

If yes, please explain: ...

Questions 12 & 13 if answering as a healthcare professional stakeholder

13. Did you find the EUnetHTA 21 Healthcare Professional Stakeholder input template (insert link) helpful in preparing you for your involvement in the assessment?

- Very helpful
- Helpful
- Not very helpful

If “not helpful”, please explain.

14. Were there any questions you felt were missing from the template?

- Yes
- No

Questions 14 & 15 if answering as a clinical expert

15. Did you find the EUnetHTA 21 Clinical Expert input template (insert link) helpful in preparing you for your involvement in the assessment?

- Very helpful
- Helpful
- Not very helpful

If “not helpful”, please explain.

16. Were there any questions you felt were missing from the template?

- Yes
- No

If yes, please specify

Questions 16-18 for all participants

Process improvement

17. Do you have any suggestions to improve external participant involvement in a EUnetHTA 21 assessment?

18. Was your involvement useful to you? (e.g., did you gain new knowledge or have a positive experience)

19. Would you consider participating in a EUnethTA assessment again?

Yes

No

If no, please explain: ...

APPENDIX 4 - PARTICIPANT TABLE JSC OR JCA REPORT

It is important to transparently show which input has been sought during the production of a JSC or JCA. The table will be added by the Secretariat after the 'participants' overview. Please note that external expert input is anonymised when referenced in the JSC Final Written Recommendations or JCA report.

As a general guidance:

- HCPs and patients that were involved as stakeholders in a JCA should be named by their organisation/affiliation and country;
- Upon agreement, the clinical expert may be named individually, with their affiliation and country. If the clinical expert does not want to be named, the clinical expert can be named on an institutional level or more generally the type of expert could be described;
- Patients that participate as an external expert are not named individually due to legal constraints, but a description is provided (including country).

Text in orange is guidance for the JSC or JCA team and text in between square brackets should be completed or selected so that it matches the approach for the JSC or JCA.

Table A 1 – Contributor table to be included in JSC Final Written Recommendations or JCA Report

Contributor	Patient or healthcare professional (HCP)	Organisation or individual	Type of involvement <i>The text provided are just examples, please complete as appropriate.</i>
Stakeholders	Patient and health care professional (HCP)	<i>List all stakeholders/ organisations that participated in the JCA. They should be named on an individual level:</i> [name organisation], [abbreviation], [country]	Participated in the open call for input
External expert	clinical expert	<i>Before naming an external expert, it should be confirmed the external expert is in agreement with this.</i> [name individual], [organisations], [country]	Answered specific questions during the joint production
	Patient	<i>Individual patients should not be named, due to legal constraints, but a general description could be provided:</i> [select one or modify descriptions: <i>Patient living with the condition; carer – parent of a child living with the condition;</i>], [country]	<i>select the method that reflected the involvement for this JSC/JCA:</i> [JSC: Approach 1, 2 or 3] [JCA: Participated in an interview during the scoping phase; participated in the scoping meeting]