

EUnetHTA 21 Public Consultation

Comments should be submitted not *later than 30 August 2022, 23:59 CET*

**D4.3.1 Practical Guideline Direct and Indirect Comparisons,
D5.2 JCA Assessment Report Template,**

D7.2/3 Guidance and template for the interaction with patient representative, healthcare professional and other experts *(please note this consists of four templates)*

Please use this form for submitting your comments and share your completed comment form to JCA_Secretariat@zinl.nl prior to the deadline (30 August 2022, 23:59 CET). When submitting your comment form, please include “**EUnetHTA 21 – Public Consultation – D4.3.1, D5.2.1 or D7.2/D7.3**” in the subject line of your e-mail.

Please carefully read the principles for public consultation [here](#), prior to your review, as these are binding for our process.

We kindly ask you to:

1. Submit one consolidated response per organisation; in a word-file
 - a. PDF files will not be accepted;
2. Complete the first table; if this table is not completed, the input will not be considered by EUnetHTA 21;
3. Put each new comment in a new row;
 - a. Please be clear about the context of your comment and if possible, provide a suggestion for rewording;
 - b. Please consider the [HTA Regulation \(EU\) 2021/2282](#) when reviewing the document and when you provide comments;
 - c. Please consider the corresponding project plan when commenting. Comments that refer to matters out of the scope of the deliverable may not be considered by EUnetHTA 21.
 - d. Please do not provide linguistic comments, as the document will undergo language editing prior to finalization;
4. Insert the page number and line/section number on which your comment applies. If your comment relates to the document as a whole, please put ‘**general**’ in this column;
5. Provide a description of your comment as specific as possible and preferably also provide a suggestion for rewording. If you wish to draw our attention to published literature, please supply the full reference;
6. Add rows as needed.

NB: All comments received within the deadline of the consultation and following the correct format will be published on the website, together with the final deliverable. Only comments eligible for consideration will be answered by EUnetHTA 21. The answers will be made publicly available as well. EUnetHTA 21 may decide to rank the comments received on importance.

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Please complete this table. If this is not completed, your comments will not be considered.

Name organisation & abbreviation	Irish Platform for Patient Organisations, Science & Industry (IPPOSI)
Country	IRELAND
Contact details (name & e-mail address) – this information will not be published	Derick Mitchell, CEO dmitchell@ipposi.ie 77 Camden St. Lower Dublin D03P973

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Is your comment an editorial comment?
	<i>Insert your name and organisation</i> <i>Please repeat in each row</i>	<i>Insert 'general' if it relates to the whole document</i> <i>Please don't put 'p' before the number</i>		<i>Please insert each new comment in a new row.</i>	<i>Please indicate with 'x' if your comment is an editorial comment.</i>
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	6	119	We suggest amending this wording to “Patient and healthcare professionals provide important knowledge about the disease, treatment processes, treatment outcomes, adherence issues and unmet medical need.” - this wording indicates the additional areas they contribute to, and emphasizes that not only they “can”, but that they “do” provide such knowledge. There are several other places in this section where “can” is used, which could suggest something is optional. The necessity of patient involvement at both the EU and member state levels should come through in all the language used. This is in line with the language used in Articles 11.4 (JCA) and 18.6 (JSC) of the new HTA Regulation.	
D7.2 Guidance and template for	IPPOSI	8	206 – 218	We agree that confidentiality is critical in the process. The confidentiality section makes it very clear that documentation and	

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the interaction with patient representative, healthcare professional and other experts				communications are kept secure and that the JCA report remains confidential until published.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	8	206	We recommend that EUnetHTA takes the initiative to have a separate section to address confidentiality for stakeholders involved (in this case, patients and healthcare professionals). This section will help outline how information provided by patients, patient advocate groups, clinicians and other healthcare professionals will be stored safely, and not be released without further permission. These additional details will ultimately promote trust, engagement, and involvement in HTA.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	8	229-236	We underline the importance of supporting high quality national processes to evaluate possible conflicts of interest among proposed patient experts and clinical experts (in line with EUnetHTA Guidance) in order to avoid differing interpretations across the region and introducing any suspicion or mistrust among Members. It could be helpful to include the details of how national compliance (or non-compliance) with the Guidance is monitored, and addressed.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	8	229-236	We believe it is important that all DOIs be made publicly available, and that the mechanism to do this be created on the EUnetHTA 21 website as a priority.	

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D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	9	243 – 367	We agree that the process of recruitment of stakeholders and external experts and further involvement should be clear and appropriate. We believe that membership of the HTAR Stakeholder Network should remain open indefinitely - building trust and facilitating a diverse pool of stakeholders and external experts to continuously enter the health technology assessment space.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	9	243 – 367	We suggest that where possible efforts should be made to launch public calls for participation in JCAs on a dedicated webpage to allow patients and their representatives to regularly visit the site and self-nominate. A list of opportunities could also be circulated to a self-subscribing mailing list.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	9	243	We recommend EUnetHTA considers adding a separate section at the beginning of Section 4 - Process - where considerations about diversity, equity, and inclusion are emphasized. We believe that the process of stakeholder engagement should not only lay out the technical process of engagement, such as timing, documentation and dissemination, but rather advocate an open, transparent, diverse, inclusive and equitable environment throughout the engagement process.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	9	243	We recommend that an evaluation of the diversity of the patients and representatives contributing to JCAs should be conducted annually.	

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D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	9	244	Emphasizing that the process is transparent will facilitate information sharing among key stakeholders. We believe having a section to address the inclusive and friendly environment will make sure all parties in the HTA process be respectful and accountable for their activities.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	11	313-317	You may already be aware that EUPATI maintains a network of patient experts. It may be worthwhile for EUnetHTA to include a reference to EUPATI Connect (https://connect.eupati.eu) and liaise with EUPATI to investigate an efficient way for patient experts to be included in the database.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	11	319	It would be useful to provide an explanation of how the data are preserved and kept. A flowchart may be useful for describing the process covered in the SOP.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	12	372	Typo (for JCA and JCA) presumably (For JCA and JSC)	
D7.2 Guidance and template for the interaction	IPPOSI	13	384	It would be worthwhile to collect data on unmet medical needs when collecting stakeholder information.	

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with patient representative, healthcare professional and other experts					
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	16	393	The fourth bullet point in the scoping process section refers to the potential for clinical expert input. However, it makes no specific reference to the potential for patient expert input - even though page 13 line 384 seems to indicate that there is potential for both clinical and patient expert input at this stage. This needs to be amended.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	16	393	The language used in the EU assessment phase appears quite vague in terms of its commitment to involve patients. We suggest that the term 'the ad hoc involvement of 'european' expert' be improved for clarity purposes and the term patient expert should be included.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	16	406-407	We suggest amending this sentence to "... to adequately reflect patient and healthcare professional involvement the method and timing of involvement, <u>as well as the extent to which patient and healthcare professional influenced the JSC or JCA overall</u> , should be described in the JSC or JCA report." We realize the inserted phrase is mentioned in the table, but feedback on the results of patient involvement has often been neglected in the past and should be emphasized here.	
D7.2 Guidance and template for the interaction with patient representative, healthcare	IPPOSI	19	429	We would support some transparency around the evaluation of patient involvement and we would recommend that an annual report include aggregated data from the stakeholder and expert questionnaires.	

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professional and other experts					
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	21	506-511	We believe that much greater consideration needs to be given to HTAR Article 11 which calls for the involvement of patients and other experts in the assessment process. We believe a more robust patient involvement framework is needed for the assessment stage of the JCA process. At a minimum, we consider it appropriate that a number of patient experts attend and observe the process of drafting the JCA report. This could be taken a step further whereby 1-2 patient experts could be invited as co-assessors from the start and invited to follow the process from beginning to end. We would also consider it appropriate that the draft JCA be open to comment from patient experts and stakeholders for a period prior to publication. The final JCA report would detail how any feedback during this consultation period was considered.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	22	513-514	We agree a process to support and encourage national expert and stakeholder involvement should be set up. Patient Involvement experiences vary across Member States and it is important that we start to harmonise this where we can to avoid inequalities around opportunities to input and participate.	
D7.2 Guidance and template for the interaction with patient representative, healthcare professional and other experts	IPPOSI	25	539	Appendix 2 - Patient Representative and Patient Organization are defined- and are listed in the first summary paragraph. but patient advocate (listed 3 times throughout the guidance) is not defined in the glossary anywhere. It would therefore be helpful to provide a definition for patient advocate or include patient advocate in the patient representative's definition.	
D7.3 Individual Patient Expert Input Template	IPPOSI	general		The template provides a thorough introduction and overview, and the questions include detailed prompts. This can be very helpful to users,	

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for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)				but it may be worthwhile to consider the tradeoff between detailed prompts and user-friendliness.	
D7.3 Individual Patient Expert Input Template for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)	IPPOSI	general		It would be helpful to provide a clear statement on the template regarding the confidentiality of information collected.	
D7.3 Individual Patient Expert Input Template for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)	IPPOSI	1	25-37	In this section it states that individuals may add issues that are not covered in the prompts. Given the extent of the texts in the prompts, it may be worthwhile to add this information in other sections of the document as well.	
D7.3 Individual Patient Expert Input Template for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)	IPPOSI	4	72	It is notable that the term “quality of life” is not used in this section. This may be worth adding to the prompts.	
D7.3 Individual Patient Expert	IPPOSI	8	103	Informing individuals how all the information collected from the template will be used would be beneficial. In particular, the inclusion	

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Input Template for Joint Clinical Assessments (JCA) and Joint Scientific Consultations (JSC)				of this 'summary section' without additional information may raise concerns that only this section will be used or will be of primary interest?	

Please add extra rows as needed.