EUnetHTA 21 Public Consultation Comments and Responses
of D5.2 JCA Assessment Report Template

Comments on the development of a guidance document instead of a template

The introductory section of the assessment report guidance describes the scope of the document. It clarifies that the document is the first component of the overall framework of guidance on the assessment report. As such, it is not a template aiming to provide detailed technical requirements for the assessment report. The guidance rather describes the general legal requirements laid down in the HTA R and provides a high level structure of the assessment report.

It seems that this scope of the document has not been sufficiently clear to all parties providing comments in the public consultation. This might partly be due to the fact that according to the project plan of this deliverable the development of a template was planned. However, it was decided to start with a general guidance to support the next steps of the implementation of the HTA R. The guidance document should inform the development of implementing acts according to the HTA R (Art. 26).

Various comments addressed the document as template of the assessment report, suggested a more detailed description of the content of the report and requested e.g.

- detailed requirements for the summary report
- specific tables (e.g. concerning the illustration of PICOs)
- specific background information (e.g. on epidemiology or regulatory procedures)
- inclusion of information not required according to the HTA R (e.g. about risks for medication errors)

Presentation of divergent scientific opinions

While part of the suggestions are helpful for the development of an assessment report template they are too specific for the high-level content of the guidance document. Therefore, these comments will not result in changes of the guidance but will be considered in the development of the assessment report template.

Comments concerning general methodological approaches and requests for details on methodological requirements

Some comments addressed general methodological approaches, e.g. the definition of the assessment scope including the PICO question(s), general approaches to different types of evidence or the harmonisation of assessment methods across Europe. These comments are out of scope of the assessment report guidance. General approaches to the JCA are laid down in the HTA R or are covered by other guidances (e.g. D4.2 Scoping process or D4.6 Validity of clinical studies).

Other comments asked for more details on methodological requirements, e.g. concerning

- information retrieval
- analyses of adverse events
- indirect comparisons

The assessment report guidance is not describing specific methodological requirements but is clarifying the principle that any assessment should be performed in conformity with the existing methodological guidelines in force at the time of the assessment. Limiting the description of methodological requirements to this principle approach seems appropriate in a general guidance. More details will be provided in the methodological guidelines themselves. The methodological guidelines are a more suitable format to specify detailed methodological requirements because they allow for adjustments over time which might become necessary due to future scientific developments of assessment methods.

Comments on the process of the JCA

Some comments reflected on processes of the assessment, e.g. on

- general timelines of the assessment process
- approaches to label changes during the assessment
- opportunities for HTDs to comment on the assessment report
- the timing of the publication of the assessment report
- an agreement on the use of evidence from outside submission dossier with the HTD
- the publication of names of involved assessors, experts and patients in the assessment report (with requests to publish or not to publish names)

- availability of multiple language versions of the summary report
- definitions of terms used in the HTA R (e.g. "other experts", or "further assessment")

These comments on the JCA process are out of scope of the assessment report guidance. The process of the JCA on a high level is laid down in the HTA R, further detail will be included in the Rules of Procedure of the HTA Coordination Group and in other guidances (e.g. D7.1 HTD Interaction or D7.2/7.3 Interaction with patient representatives and healthcare professionals).

Comments about the structure of the JCA report template, its length, and its readability

- Some comments suggested that the structure of the JCA report template and the Submission Dossier template should be identical.
- Some suggestions were made to limit the length of the JCA report template and to avoid duplication of information.

The Submission Dossier template forms the basis of the JCA report template but both templates have different aims and do not necessarily contain the same items. However, in order to optimise their use, the structure of the JCA report template follows the structure of the Submission Dossier template as closely as possible.

Readability, facilitating the understanding of the assessment and the re-use of the JCA report at national level are the main goals of this guidance so these will of course be pursued in the development of the assessment report template.

Comments on the wording of the JCA report template

- In agreement with the CSCQ, the word "disease" has been changed to "health condition".
- Regarding the suggestion to replace the word "should" with a stronger wording, the group decided not to make any changes to the guidance as the compulsory items will be mentioned in the implementing act.

Comments on the fact that the deliverable differs with respect to project plan

Cf CSCQ response regarding public consultation on the JCA report template.

Cf Secretariat response regarding an update of the project plan.

Points needing clarification

- The risk of bias refers to clinical trial data and evidence synthesis data.
- Both studies on the technology under assessment and studies used for indirect comparisons are to be included in the overview of included studies.
- Cf CSCQ response regarding the comment about early access programs.

Comment on missing elements

There were many comments on missing elements of the JCA not captured in the guidance including

- Involvement of external experts (patients, healthcare professionals and other experts) and reporting of their input
- List of definitions
- Justifications for methodological choices
- Unmet need
- Missing elements from the submission dossier
- Missing discussion/conclusion section
- Process timelines
- Differences in EUnetHTA21 template vs the template that will be used under the HTAR
- Summary for the public
- Discussion/conclusion section is lacking

The JCA report does not contain a conclusion section as in line with Article 9 of the HTAR the JCA reports shall not contain any value judgement or conclusions on the overall clinical added value of the assessed health technology and shall be limited to a description of the scientific analysis of the relative effects of the health technology and the degree of certainty of the relative effects, taking into account the strengths and limitations of the available evidence.

The Assessment Report Guidance is developed with the HTAR in mind. It is intended that this guidance will inform the relevant Implementing Acts. Therefore, specific recommendations for EUnetHTA 21 have not been made.

Information on the involvement of patients, clinical experts and other relevant experts is included in the General Information section of the guidance. Reporting of this input is outside the scope of the guidance but will be addressed in Deliverable 7.2. Although caregivers are not explicitly referred to in the Deliverable 5.2 guidance, their involvement in JCA is certainly possible and this is also covered in Deliverable 7.2

The JCA report will not address unmet need specifically as the purpose of the report is to provide a description of the scientific analysis of the relative effects of the health technology against the chosen parameters which are based on the assessment scope.

Information on previous JSCs should be included in the JCA report and this is now reflected in the guidance. Whether there will be sufficient capacity to ensure access to all HTD seeking JSC is outside the scope of this deliverable.

A list of abbreviations will be included in the guidance and template but it is not intended to provide definitions.

A summary report of the public is not required under the HTAR and will not be developed under this deliverable. However, this will be considered by the Coordination Group.

Comments on elements that should be avoided in JCA reports

- Duplication of information within the report
- Country-specific epidemiological data
- Information that could become outdated

Duplication of information within the report will be avoided as much as possible but in some cases duplication may be required for clarity.

Country specific (e.g. epidemiological data) will be avoided in the JCA report template whenever possible.

It is not possible to avoid inclusion of information that could become outdated as we consider that most information eventually becomes outdated.

Name organisation	Country
AstraZeneca	Europe Global
Bayer AG & Bayer Vital GmbH	Germany
EFPIA	Belgium
EUCOPE	Belgium
European Organisation for Rare Diseases (Eurordis)	France
European Union of General Practitioners/Family Physicians (UEMO)	Belgium
F. Hoffmann-La Roche Ltd (Roche)	Switzerland
German Medicines Manufacturer´s Association (BAH)	Germany
GSK	Headquartered in the UK, but local operating companies across Europe, therefore GSK is directly impacted by the HTA Regulation
IGES Institut GmbH and HealthEcon AG: "IGES LifeScience"	Germany
Lumanity	Lumanity is a global company with several European entities, including in Ireland and the Netherlands.
Lymphoma Coalition, Lymphoma Coalition Europe (LCE)	France
Medtronic	Switzerland
SKC Beratungsgesellschaft mbH (SKC)	Germany
Verband Forschender Arzneimittelhersteller (vfa) e.V.	Germany

EUnetHTA 21 Public Consultation Comments and Responses of D5.2 JCA Assessment Report Template

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Bayer A.Fraschke	general		When will the JCA report be shared with the HTD – simultaneously with the MSs or before? Will there be an opportunity for the HTD to review and comment on the JCA report before it is shared with the MSs?		
Bayer A.Fraschke	general		How long after the dossier submission can the assessment report be expected?		
Bayer M. Frick	general	57-67	Due to Regulation (EU) 2021/2282 (Art. 9.1) the JCA, and the JCA-report respectively, shall remain limited to description and must not contain value judgements. Though this in mentioned in general on page 6 line 57-67, the draft template does not have a format which emphasizes a clear distinction.		
Dr Daniel Widmer UEMO	General		Good document – no specific comments.	Dr Daniel Widmer UEMO	General
François Houÿez, EURORDIS	general		One part missing in the report is on the involvement of external experts and how they contributed to the JCA. A paragraph should be added that contains the information in Table 5-1: Template to report on patient and healthcare professional involvement of D7.2 –GUIDANCE ON PATIENT & HEALTHCARE PROFESSIONAL INVOLVEMENT		
François Houÿez, EURORDIS	general	216	The Summary Report should be made available in all EU languages.		
GSK	General	General	There is reference to the 'JCA report', 'summary report', 'assessment report' and 'report' through this document. Suggest clarifying what each of the reports are in a definitions section and ensure each phrase is referred to appropriately throughout the guideline.		
James Ryan AstraZeneca	General	General	Thank you for the opportunity to comments on this JCA Assessment Report Template. AstraZeneca supports the response from EFPIA.		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Matias Olsen, EUCOPE	General		When will the further components and guidance referred to in this document (e.g. the report, table and figure templates) be made available for public consultation?		
Mihai Rotaru, EFPIA	General		EFPIA recommends outlining general rules about the integration into the JCA/CA report of results based on information/data/analysis that might have been submitted (and accepted) during an ongoing assessment – that is after the submission dossier has been provided, but before the finalisation of the JCA/CA. For example, if a planned data cut was due to become available after the original submission date, but before draft report (or other agreed date), a process needs to be established to incorporate that data. *(Cf. EFPIA response to D5.1 consultation)*		
Mihai Rotaru, EFPIA	General		An adequate level of confidentiality is foreseen by the HTAR with respect to the JCA report, especially at Art 11.5, which ensures adequate protection of confidential data flagged by the HTD upon justification, including regarding third parties. EFPIA considers that the confidentiality of commercial information that might be included in the final JCA/CA report should be protected in the same way as protected by the Regulators according to: *EMA/HMA Guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application - release of information after the granting of a marketing authorisation*, 14 March 2021		

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			EFPIA therefore recommends considering the inclusion of mirroring provisions in the present guidance.		
Mihai Rotaru, EFPIA	General		EFPIA recommends that general guidance is provided on how the assessors and co-assessors are enabled to present and justify the scientific justification for their methodological choices and approaches in the JCA report. These approaches should not deviate from internationally/European-wide recognised guidelines.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	general		Comment: In the EUnetHTA 21 project plan, this sub-deliverable (D5.2) was announced as the assessment report template. However, the aim of the document published on 27-07-2022 only covers a description of the overall structure and general requirements for the assessment report. Hence, publication of the proposed assessment report template, which will be crucial for HTA according to Regulation (EU) 2021/2282, is still pending. In view of the limited time until Regulation (EU) 2021/2282 will be implemented and especially until the JCAs during EUnetHTA 21 are scheduled, adherence to deadlines and deliverable announcements are needed to create transparency, reliability and trust for all stakeholders. We recommend reviewing and if needed revising the naming of the pending sub-deliverables to ensure that stakeholders are correctly informed about the content of the upcoming public consultations and can prepare accordingly. In case the scope of a planned sub-deliverable change during its preparation, this information should ideally be made available to the stakeholder network before publication of the document draft. At the latest, the published document should indicate when the originally planned content will be available for public consultation.		

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Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	general		Comment: Overall, the published sub-deliverable does not contain the expected and needed specificity and clarity regarding the assessment report template. This is at least partially founded in the unexpected focus of the deliverable (see comment regarding the scope of this deliverable). Hence, the content is only of limited value for all stakeholders including HTA authorities. Therefore, the guidance should be further elaborated to provide more detailed information on the process of dossier assessment for all parties involved.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	general		Comment: Overall, a reasonable, comprehensive, and appropriate structure was chosen for the structure and content of the assessment report. Nevertheless, not all information requested in the dossier guideline appear in the guideline of the assessment report, e.g., the subitems of the characterization of the health condition and the aspect “Methods used in the development of the dossier content”. We recommend keeping the structures of the two guidelines identical to be able to clearly assign contents to each other. Furthermore, all parts that are requested in the dossier should be included in the assessment, otherwise, the question arises if these parts are essential and “needed by MS” in the first place.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D.	general		Comment: Many events can influence the course and outcome of a JCA: The submission dossier must already be handed in 45 days before the expected CHMP opinion and accordingly, the scoping process starts and ends even earlier. However, especially in orphan indications, late-stage label changes are possible, potentially influencing the relevant PICO		

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SKC Beratungsgesellschaft mbH			questions and MS needs after communication of the assessment scope to the HTD or even after submission of the dossier. Furthermore, the present draft deliverable allows the assessor to request additional data without any specification. However, due to very short deadlines, the newly requested information might not be available in time, which could negatively impact the assessment. Hence, we recommend to include a summary of the course of the project, where events similar to the ones given here as examples shall be mentioned, to provide completeness and transparency of the assessment process and report.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	general		Comment: Throughout the deliverable, the word „should“ is used to describe the required content of the assessment report. According to HTA Regulation (EU) 2021/2282 Article 8 (6) sentence 2 “the assessment scope shall be inclusive and reflect Member States’ needs in terms of parameters and of the information, data, analysis and other evidence […].” Hence, not only the submission dossier but also the assessment report shall meet the needs of every MS, so that the JCA can effectively be used on a national level. We recommend to review the requirement “should” regarding the content of the assessment report throughout the deliverable and replace it with a stronger wording where needed. Furthermore, we recommend to review whether all MS needs are already covered in the current version of the assessment report guidance, which strikes us as little detailed.		
Roche	General		For different kinds of sensitive information (e.g. commercial confidential information, development information, information from JSCs, individual patient data, investigator data, copyright protected publications) the European General Data Protection Regulation, proportionality		

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			considerations and the intellectual property rights of the HTD need to be taken into account. An elaborated and with the HTD agreed upon confidentiality framework is required. Appropriate data security measures need to be in place. Specifically, individual patient data listings or raw data are not needed as a mandatory component for the HTA assessment process and they fall within the scope of GDPR as personal data. There is no legal basis that justifies processing personal data for the European HTA assessment on EUnetHTA or Health Technology Assessment Regulation ("HTAR") level. Therefore this kind of information must **not** be included in the assessment report.		
Roche	General		This public consultation was announced and displayed as a public consultation for a template. However, the document under this public consultation is rather a high-level guidance describing the overall structure and the general requirements for the assessment report content. Important details, a set of table and figure templates and summary tables with how the assessment will be presented are missing. As a consequence this consultation will be closed, before important elements of the assessment report template are developed/finalised and presented to the public. Therefore, we ask EUnetHTA21 JCA secretariat to state when the actual dossier template will be publicly available for consultation, either specifying it in the introduction of the current guidance or updating the corresponding project plan, for full transparency and clarity towards the stakeholders.		
Roche	General		We think that the presentation of data in the assessment report should be done in a pragmatic manner and reflecting a consolidated European approach, instead of a simple additive inclusive scope to meet all the particular needs of each Member State. The assessment report template should		

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			be readable with a reasonable expenditure of time having a limited number of pages to remain sufficiently clear. In general the assessment report should be streamlined and avoid duplication of information/statements across sections.		
Roche	General		The current proposal for the assessment report is lacking a discussion/conclusion section. In order to to avoid duplication of work at Member State level, the JCA report should be based on explicit scientific judgements and conclusions on the quality and robustness of data in a disease and technology specific context, the patient and clinical relevance of outcomes measured, the validity and reliability of outcome measurement tools, statistical and clinical meaningfulness of differences in outcomes measured between intervention and comparator(s). The JCA report should provide an overall discussion and scientific conclusions on the health technology under assessment from an integrated European perspective.		
Roche	General		JCA report should not only include the objectives and methodologies used to gather input from patients and clinical experts but also, and importantly, a summary and the original answers of the input received and how the input was taken into consideration. This should be included in a specific section of the report dedicated to Patients and HCPs feedback.The individual answers from e.g. patients, clinical experts or transcripts from discussions, interviews, should be made available in an appendix, while protecting personal data according to GDPR.		
Roche	General		Whenever data/content included in the JCA report is not coming from the JCA core dossier submitted by the HTD (e.g. analyses or calculations not performed/included in the dossier by the HTD), the source should be cited. Furthermore, a mechanism should be in place to agree with the HTD about additional evidence to be included before		

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			publication of the assessment report.		
Roche	General		In some cases, there may not be neither direct nor indirect comparative evidence to respond to all PICO questions. A clear summary/table of which PICO questions could be answered or not based on available evidence submitted by the HTD will help set the scene at the start of the report. It should be made clear in the JCA report what, how and why evidence was submitted or not by the company, based on the information and justification included in the JCA dossier, particularly when the assessor/co-assessor disagrees with it in the JCA report. This should provide the full picture, otherwise it will be misleading.		
Roche	General		There is a genuine lack of information about the template itself and what applies under EUnetHTA21 and what under HTAR. To avoid confusion, clear and separate statements should be made in all instances about what is going to be the assessment report under EUnetHTA21 and what is EUnetHTA21's recommendation for the future assessment report to be carried under the HTAR (whether it is the same or different, and the respective reasoning behind such recommendations) or a separate document or appendix with the recommendations from EUnetHTA 21 to the Coordination Group for the future assessment report under HTAR should be developed.		
Roche	General		Currently a definition of complete information, data, analyses respectively a guidance about completeness/ incompleteness is lacking. It should be stated clearly in the assessment report when evidence for some PICOs defined by HTAb does not exist, not allowing the HTD to answer all research questions. Of note, as PICO(s) provides the basis and sets the framework for the JCA, the HTD must have the opportunity to comment. Based on the learnings from		

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			EUnetHTA JA3 as well as from national processes in various member states, the HTD should have the opportunity to discuss with the assessment team during the scoping phase (e.g. via a scoping workshop/meeting or any alternative way) about PICO survey results, data presentation requirements and potential methodological issues/challenges. The current proposal for the JCA assessment report includes a description of cases where insufficient evidence exists or insufficient evidence is not provided by the HTD. When the HTD shows that there is no adequate data available using appropriate methods compared to the case of non-existing evidence, the reasons should be explained in the assessment report.		
S. Walleser Autiero, Medtronic	general		It would be helpful for the process if standardized templates can be provided for the PICOs presentation		
Sebastian Werner vfa	General		The guidance includes a high-level structure of the JCA Report template and is only the first component of an overall framework in the assessment report. The complete framework is not described in this guidance. Further components such as the actual assessment report template, a set of table and figure templates further specifying technical requirements and supporting implementation of methodological guidance are missing. The missing elements complicate the response to the consultation. The vfa regrets that the public consultation was not possible including all the information.		

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Sebastian Werner vfa	General		The JCA should address only contents with European focus. The characterisation of the relevant medical condition should include only information at the European level, e.g., no country specific epidemiological data.		
Sebastian Werner vfa	General		The summary report is foreseeable a very important part of the JCA report for Stakeholders in Europe. However, the guidance holds only few details about the structure and contents. The summary report should be further specified to ensure a readable overview of the assessment with sufficient detail and standardization of the format.		
Sebastian Werner vfa	General		The guidance should clarify which parts of the contents refer to EUnetHTA21 and which also refer to the HTAR.		
Sebastian Werner vfa	General		The report does not include a section where information about JSC can be found. The JCA report should provide information about whether a JSC was performed or not. This is especially important for HTD that might have not been granted the possibility of the JSC due to possible capacity limitations. The vfa strongly recommends that sufficient capacity be made available to ensure access for all HTD seeking advice in joint scientific consultations.		
Sebastian Werner vfa	General		The JCA report and summary should contain information about the specificities of the health technology regarding the evidence generation. These specificities can influence the assessment of relative effects and the degree of certainty. The JCA report therefore should contain information about the evidence generation considering the medical need situation in the disease area, the regulatory context (e.g.,		

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			accelerated approval) and the objective of the HTAR to improve patient access. The discussion of specificities of health technologies should include possible appropriate alternative evidence sources (e.g., clinical studies with the historic controls) where adapted methods are used for clinical assessment. The use of adapted methods for JCA of health technologies with specificities in their evidence generation is set by the HTAR. Therefore, the JCA report should contain information about the specificities of the health technology and the adapted methods that are used in their clinical assessment. (*"Methodologies for performing joint clinical assessments and joint scientific consultations should be adapted to include specificities of new health technologies for which some data may not be readily available. This may be the case for, inter alia, orphan medicinal products, vaccines and advanced therapy medicinal products." [HTAR, Recital 24])*		
Sebastian Werner vfa	General		The volume of the assessment report should be manageable and readable. However, reporting on the assessments of large numbers of PICOs using multiple methodological approaches (as expected by EUnetHTA21 Guidelines) is likely to result in a very large volume of reports with little clarity. Therefore, the vfa recommends limiting the number of PICO and methods through harmonisation of nationally differing research questions and methodological approaches. PICO definitions should follow a stronger European approach based on the European research question of the HTD, European evidence-based guidelines and a strong consistency of clinical exchangeability of comparators across Europe. A common European methodological framework should follow international standards of evidence-based medicine and should be based on predictable methodology with flexible,		

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			context specific approaches ensuring best fit for the data situation.		
Sebastian Werner vfa	General		The JCA report and the summary report shall present the results on relative effects and the degree of certainty of relative effects. The vfa recommends including a conclusive scientific statement about the degree of (un)certainty for individual outcomes and further cardinal points of the assessment. EUnetHTA21 and the CG should use its best endeavours to reach a consensus on this conclusive scientific statement. The assessment should follow international standards of evidence-based medicine and should be based on predictable methodology with flexible, context specific approaches ensuring best fit for the data situation. Consensus can best be reached based on a harmonised European methodological framework that is accepted by the Member States. This can promote consistent interpretations of the clinical data by HTA bodies across Europe and contribute to an improved patient access.		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	10-12	162-215 RESULTS GENERAL	**Comment:** DRAFT GUIDANCE: The draft guidance specifies which data should be reported in the dossier. E.g. Lines 172 to 176: „Information on the study design (e.g. on randomisation, blinding, or parallel observation; and inclusion and exclusion criteria) and on enrolled study populations (e.g. diagnosis, general severity of disease, and line of therapy) should be provided. The study interventions should be characterised and information on the course of the study (e.g. planned and actual follow-up times per outcome) should be presented."		

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			This is no comprehensive description of the characteristics to be described due to the inclusion of „e.g.“ in the definition. Such it leaves some variation to detail and content of reporting. **Suggestion:** Required characteristics should be clearly defined. Format of reporting should be open to the HTD and the HTD should also be allowed to directly integrate tables from clinical trial reports, as the timeline for the dossier compilation is extremely limited.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	5	48-55	Comment: In this draft sub-deliverable “guidance adopted by the CEB” is mentioned without specification which documents are referred to. Since further guidance is needed, information about when the respective documents will be published and if they will be available for public consultation is needed. We recommend specifying (outstanding) guidance documents by the CEB mentioned throughout the draft sub-deliverable including their planned publication date. The draft versions of these documents should also be made available for public consultation.		
S. Walleser Autiero, Medtronic	5, general	44-52	It is unclear if this ‘high-level structure’ will be combined with more detailed guidance on methods and content of the JCA report. As it stands currently this guidance is not informative and could be replaced with a flow chart or table that introduces the overall structure of a JCA. It is anticipated most of the content of this guidance will be repeated in the JCA report template.		
Bayer K. Eilermann	6	126 f	The guidance says that the assessment report should include information on the health technology under		

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			assessment, including the "registered European Medicines Agency (EMA) indication". The report should be based on the dossier submitted by the HTD. At the time of the dossier submission, the EMA approval process is usually not closed, so there may not be a final approved indication at that time. The indication wording may change from the time of dossier submission and final EMA approval. The guidance should clarify whether the HTD must provide an update of such information (if yes, with time frame) or whether the assessors retrieve final information on the approved health technology from the EMA.		
Bayer S. Caruso	6	73	There should be a clear timeline and a sufficient clock-stop in the process for the HTD to deliver any lacking data		
Bayer S. Caruso	6	80	what are the implications of such divergent scientific opinions?		
GSK	6	71-73	Please clarify the timing of any requests the assessors make to the HTD in order for the HTD to provide the additional details in time for incorporation into the JCA.		
Matias Olsen, EUCOPE	6	74-75	The input of caregivers should also be covered by this sentence. Add: "A summary of the involvement of external experts (patients, **caregivers,** clinical experts and other relevant experts) will be provided as part of the assessment report.".		
Mihai Rotaru, EFPIA	6	48-55	*"This guidance is the first component of the overall framework of guidance on the assessment report. […] Further components will comprise a template for the assessment report and a set of table and figure templates further*		

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			specifying technical requirements and supporting the implementation of methodological guidance. " EFPIA welcomes the publication of the guidance as a first component of an overall Deliverable announced in the document (including a formal template, tables and figures template, and technical requirements). In that sense, EFPIA considers it essential to have a dialogue with EUnetHTA21 and the CEB over these further components once available. In particular, EFPIA wishes to highlight the importance of developing a JCA/CA Report Template (as well as tables and figures templates) that: ● reflects the content of the Guidance (including suggestions for improvement submitted in this response) ● allows the necessary flexibility to fit the presentation of the results with the specifics of the health technology under assessment.		
Mihai Rotaru, EFPIA	6	66-67	EFPIA suggests that the guideline should provide some examples of how this degree of certainty will be presented so that it is clear for all stakeholders. For instance, in Germany the "degree of certainty of the relative effects" is part of the overall additional benefit (ATV) assessment, which consists of two parts: the amount of the relative effects (i.e. extent of ATV like "minor", "considerable" etc.) and the here mentioned certainty (i.e. "hint", "indication" or "proof"). Therefore, the statement in these lines seems to be a contradiction to the statement in lines 61-62 that the JCA report shall be only of descriptive character and shall not contain value judgements or conclusions.		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru, EFPIA	6	68-73	"*The assessment report should be prepared on the basis of the dossier submitted by the Health Technology Developer (HTD). The dossier should contain complete and up-to-date information, data, analyses and other evidence submitted by the HTD to assess the parameters included in the assessment scope. Where the assessors consider that further specifications or clarifications or additional information, data, analyses or other evidence are necessary to carry out the assessment, the HTD should be requested to provide such additional details."* We suggest simplifying and clarifying the language to: "The assessment report should be prepared on the basis of the dossier submitted by the Health Technology Developer (HTD). The dossier should contain complete and up-to-date information, according to the submission template requirements and scoping process, as foreseen in the HTA Regulation"	Yes	
Mihai Rotaru, EFPIA	6	74	EFPIA recommends that a definiton of "other relevant experts" or at least an example be included in the guideline as well). *(Cf EFPIA response to D7.2 consultation)*		
Mihai Rotaru, EFPIA	6	74-75	*"A summary of the involvement of external experts (patients, clinical experts and other relevant experts) will be provided as part of the assessment report."* EFPIA is convinced that the incorporation of patients' and clinicians' views contributes to the quality of the assessment report. To this end, the involvement procedure shall be		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			appropriate in order to collect relevant and meaningful input (not limited to indirect interactions only). For the same reason, EFPIA recommends that the reporting clearly reflects both the procedural steps of the involvement and (whenever relevant) the full extent of the input provided. All stakeholders should have access to detailed comments done not only by clinician and patients but also by assessors during the final assessment meeting. *(Cf EFPIA response to D7.2 consultation)*		
Mihai Rotaru, EFPIA	6	76	The guideline should clarify what is the scope of 'additional evidence for further assessment' is. Considering that the JCA report is the conclusion of the European assessment, clarity should be provided if there is an expectation to outline additional evidence needs at national level, or for potential subsequent EU level re-assessments.		
Mihai Rotaru, EFPIA	6	76-77	EFPIA recommends providing further guidance on how the need for update would be reported, both in terms of format and with respect to the assessment scope and content/sections.		
Mihai Rotaru, EFPIA	6	78-81	*"Where a consensus cannot be reached, divergent scientific opinions, including the scientific grounds on which those opinions are based, shall be incorporated in the report"* EFPIA recommends that the guideline clearly outlines how Member States' diverging opinions and their scientific justifications are practically incorporated and presented in the JCA report. (For example: in what format those opinions will be included, considering that those might be content-specific or focused on general aspects).		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	6	68-71	**Comment:** DRAFT GUIDANCE: **„**The assessment report should be prepared on the basis of the dossier submitted by the Health Technology Developer (HTD)." „…should be based on the…" contradicts lines 69-71 where the draft guidance states „The dossier should contain complete and up-to-date information, data, analyses and other evidence submitted by the HTD to assess the parameters included in the assessment scope." In this case the assessment report „**must** be based" on the full dossier submitted by the HTA. As phrased now, the text could be interpreted as if the assessors are free to choose ("should") which part of the HTD dossier to consider. If the assessment report „shall not contain any value judgement or conclusions on the overall clinical added value", than it has to consider all facts and data submitted by the HTD. Everything less, i.e. any choice on consideration of specific data within the assessment scope would be a value judgement itself. **Suggestion:** „The assessment report is prepared considering the complete and information, data, analyses and other evidence submitted by the HTD to assess the parameters included in the assessment scope."		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	6	71-73	**Comment:** DRAFT GUIDANCE: „Where the assessors consider that further specifications (…) are necessary to carry out the assessment, the HTD should be requested to provide such		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			additional details." Preparation of additional data or analyses takes time. This should be taken into account and be reflected in the guidance. **Suggestion:** „Where the assessors consider that further specifications (…) are necessary to carry out the assessment, the HTD should be requested to provide such additional *details at the beginning of the assessment process, granting a reasonable timeframe for compilation of requested additional data.*"		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	6	69	Comment: The sentence "The dossier should contain complete and up-to-date information, data, analyses, and other evidence submitted by the HTD to assess the parameters included in the assessment scope." should not be addressed in this guidance but in the guidance D5.1 (Guidance on JCA Submission Dossier Template). Nevertheless, we welcome the usage of "should" as opposed to the wording "must" in deliverable D5.1. We recommend using the same recommendation grade in the dossier guidance as well as in the guidance for the assessment of the dossier. In general, the degree of regulation should be standardized between the different guidelines and words should be chosen carefully because they build the legal basis for the compilation and assessment of the dossier and therefore can have a high influence on MS' benefit resolutions.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp,	6	71-73	Comment: The wording „the HTD should be requested to provide such additional details" leaves room for the interpretation that - to the disadvantage of the HTD - no demand might be made. The assessor should be obligated to request additional		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH			details if needed. For this, however, the required details must be defined clearly in the scoping process. It must not happen that new requirements are defined afterwards, which are requested subsequently. Furthermore, the HTD must get a realistic chance (enough time e.g., 15 working days) for subsequent submission of required content. We recommend to reword the sentence and include the deadline to be given. Suggestion for rewording: "*[…] the HTD must be requested to provide such additional details as defined in the scoping process within 15 working days.*"		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	6	76-77	Original wording: „If required, the report shall specify the need for an update when additional evidence for further assessments becomes available." Comment: The wording „if required" does not provide any information regarding the criteria when a demand for additional evidence for further assessments can or will be made. To our knowledge, criteria and guidance clarifying when there is a need for an update can neither be found in the present sub-deliverable nor in any other deliverable published until now. Furthermore, it remains unclear what the consequences will be: Will the assessment be time limited? Does this mean that the HTA report requires all MS to set a time limit for their resolution on the additional benefit of the health technology? Would this be legally covered by Regulation (EU) 2021/2282? Or would this be a recommendation and MS themselves would decide whether to limit the duration of their regulation? Should the MS proceed differently, will another JCA be performed/an		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			update of the report be prepared? Would this then only be relevant to the MS with time limited resolutions? If it remains that an update of the report can be requested, we highly recommend to name the criteria and provide guidance for when an update will be considered "needed" and to elaborate on the consequences for the MS and HTD. Suggestion for inclusion: *"An update of the assessment report is considered needed, and additional information will have to be submitted by the HTD according to the following criteria:* •*[list of criteria that will lead to a need for an update]* •*[list of criteria clarifying the timing of a demand for further evidence]* *In case the additional evidence does not become available in the expected timeframe, the HTD can request an extension of the deadline up to 3 months before the deadline expires. An extension of the deadline will be granted, if it is justifiably and comprehensibly shown that the period of the time limit is not sufficient.* *In case an update of the report is needed, [name consequences for resolution on additional benefit]. In case contrary to expectations no additional evidence becomes available [name consequences]."*		
Roche	6	76-77	It should be made clear to the HTD what requirements need to be met to specify the need for an update of the assessment. Furthermore the need for and the scope of the additional evidence for an update of the assessment report must be discussed and agreed on with the HTD prior to the release of the JCA assessment report. Updates becoming already apparent during the assessment should be defined in the JCA assessment report to prevent heterogeneous definitions from member states.		

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			In cases where additional evidence is required a meeting between the HTD and the assessment team and/or the project manager must be considered.		
S. Walleser Autiero, Medtronic	6	70-74	We recognize that as HTD we hold considerable knowledge and understanding of the technology and its evidence, and would therefore see the relevance to provide as much information as possible in the dossier, and any further additional details requested by the assessor if available. It should be noted however that as HTD we might not have all the information available eg on clinical evidence, in particular i fit is relating to in-confidence information eg from co-funded 3rd party sponsored studies.		
Sebastian Werner vfa	6	68-71	*"The dossier should contain complete and up-to-date information, data, analyses and other evidence submitted by the HTD to assess the parameters included in the assessment scope."* EUnetHTA21 needs to clarify what facts or circumstances lead to an incomplete dossier. Definitions should be available.		
Sebastian Werner vfa	6	74-75	*"A summary of the involvement of external experts (patients, clinical experts and other relevant experts) will be provided as part of the assessment report."* The input of patients, clinical experts and other relevant experts is of great importance and should be comprehensively documented, incl. how the input was used in the assessment. A summary in the JCA report should be extended by further documentation which should hold all the answers and transcripts of the experts input and information about how the input was used in the report. Transparency about this involvement is of great importance.		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Sebastian Werner vfa	6	76-77	*"If required, the report shall specify the need for an update when additional evidence for further assessments becomes available"* It should be clarified which facts or circumstances might lead to updates. It should be also clarified how these updates are integrated into the assessment report.		
Sebastian Werner vfa	6	78-81	*"To finalise the JCA, the report shall be endorsed by the CEB by consensus. Where a consensus cannot be reached, divergent scientific opinions, including the scientific grounds on which those opinions are based, shall be incorporated in the report and the report shall be deemed endorsed."* The JCA report shall be endorsed by consensus. Where a consensus cannot be reached divergent scientific opinions should be included in the report and the report shall be deemed endorsed. At the same time, it should be ensured that the JCA report contains and clearly articulates the "favoured scientific opinion". This is especially important for conclusive scientific statements about the degree of (un)certainty for individual outcomes or other cardinal points of the clinical assessment. Consensus on scientific aspects in the JCA, such as validity and the degree of certainty can best be reached based on a harmonised European methodological framework that is accepted by the Member States. This can promote consistent interpretations of the clinical data by HTA bodies across Europe and contribute to an improved patient access.		
Matias Olsen, EUCOPE	7	90	We suggest adding a brief description on the current standard of care indicated to treat the medical condition and recommendations from clinical guidelines.		

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François Houÿez, EURORDIS	8	118-121	Question whether “disease” is the appropriate term, or if “condition” would apply, as in paragraph title. S syndromes or symptoms can also be treated. The condition etiology and physiopathology should also be explained, when know.		
François Houÿez, EURORDIS	8	134-136	The method of administration, dosage and duration of treatment, and concomitant treatment and/or intervention if any are best described and kept up to date in the Product Information as published by the EMA and il all EU languages. Reference to the EMA website relevant page where Product Information is published should appear.		
François Houÿez, EURORDIS	8	139-142	Other important characteristics for pharmaceuticals are 1/ medicine for paediatric use (PUMA), 2/ medicine with orphan medicinal product status, with significant benefit over existing treatments if the case.		
GSK	8	Section 2.2.1	It could be relevant to add any special storage conditions to the characteristics of the health technology.		
GSK	8	Section 2.2.2	For vaccines, this can include need for thawing, reconstitution and packaging (multi-dose vials) that can have an impact on implementation and wastage. Suggest adding these examples.		
GSK	8	136	Please clarify the meaning of “intervention” in the wording “…concomitant treatment and/or intervention if any”. Is “intervention” referring to something different to the I in PICO? If so, should re-word to avoid confusion.		
Matias Olsen, EUCOPE	8	118 – 121	More details details on the epidemiological data to be described should be provided (i.e., geographical coverage, global level, European level, or Member State level).		
Matias Olsen, EUCOPE	8	122-132	This should include a short description of the clinical pathway in the different countries, i.e. relevant comparators and unmet need of patients, caregivers and health systems as per the input of the relevant stakeholders in the “Characterisation of the medicinal product / medical device		

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			under assessment" section.		
Matias Olsen, EUCOPE	8	133-137	We suggest adding use in special populations and contraindications.		
Mihai Rotaru, EFPIA	8	117-121	EFPIA recommends that the guidance provides additional clarity regarding the presentation of this data. Considering that the JCA report will summarize evidence from the submission dossier, and will be EU-wide in scope, the presentation of this data will be EU-wide and not country specific for each individual country. In addition, this section doesn't mention a description of the disease burden and the unmet medical need, as mirrored in the requirement for the submission dossier. EFPIA recommends that these descriptions should be included in the final JCA report as well.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	8	124-125	Original wording: *"Describe in a tabular listing the characteristics of the intervention and comparators should described in a tabular listing, including, if applicable, the following information: […]"* Comment: Due to the incorrect sentence structure, the meaning of the sentence is not clear. We recommend rephrasing the sentence: Suggestion for rewording: "*Describe in a tabular listing the characteristics of the intervention and comparators including, if applicable, the following information: […]*"		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp,	8	125-129;132-133	Comment: This paragraph states, that the composition of the medicinal product / medical device can be named in the assessment report. However, it is not specified, to what extent the		

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Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH			composition of the medicinal product / medical device might be listed. This leaves the HTD uncertain, to which extent critical confidential information of the product / device may be published. The presented information should not exceed the information presented in the SmPC. Moreover, the need for publishing the exact composition of the medicinal product / medical device for the assessment remains unclear.		
Roche	8	112-115	In order to increase the transparency of the process the paragraph on the general information on the joint clinical assessment should also include the names of assessors and co-assessor as well as the names from the members of the HTAb technical expert working groups which worked on the JCA. To comply with data privacy laws names of patients, clinical experts and other relevant experts must not be disclosed.		
Roche	8	117	The brief summary of the disease must also include an overview of the burden of the disease, a description of current clinical practice and unmet medical need at a pan european level.		
Roche	8	118	The depiction of the prevalence and incidence of a health condition should be on a European-wide basis only. The additional description of differences between European countries does not give any additional value to the European perspective of the assessment report but increases the volume of the assessment report unnecessarily.		
Roche	8	129	The information on ongoing early access programs in the European Union does not impact EU-level JCA. In fact, this information increases the volume of the assessment report unnecessarily. Therefore, we propose to completely delete		

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			this information.		
Roche	8	140	It is unclear why information on other licensed indications is relevant for a present assessment report. In fact, this information increases the volume of the assessment report unnecessarily. Therefore, we propose to completely delete this information.		
S. Walleser Autiero, Medtronic	8	129	Description of the characteristics of the technology. One of the characteristics to be described is “monitoring required” to me this appears a bit vague. If this is relating to post market vigilance, then this should be clearly specified.		
Sebastian Werner vfa	8	118	“*Here a brief summary of the disease should be given, including its prevalence or incidence*.” As the JCA report contains a European HTA assessment, it should be specified that prevalence incidence refers to European scope. We suggest adding *“its prevalence and incidence at European level”*.		
Sebastian Werner vfa	8	124-125	“*Describe in a tabular listing the characteristics of the intervention and comparators should described in a tabular listing, ...”* We suggest deleting the half sentence “should described in a tabular listing”.	x	
Sebastian Werner vfa	8	140	“*For pharmaceuticals, the regulatory status of market authorisation (MA) should be provided, such as other licensed indications, […]”* There is no obvious relevance of other licensed indications here for the JCA. This part should be deleted.		
Suzette Matthijsse	8	124-125	“Describe in a tabular listing the characteristics of the		

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Lumanity			intervention and comparators should described in a tabular listing" to "Describe in a tabular listing the characteristics of the intervention and comparators"		
Suzette Matthijsse Lumanity	8	129	Does the requirement to describe ongoing early access programs include national level programs as well?		
François Houÿez, EURORDIS	10	162-165	Some data that could be used by the HTD are not necessarily available to the HTD. Data can be managed by third parties, universities, databases, foundations etc… Hence, evidence / analysis that are requested by HTA might not be made available to the HTD. In such circumstances, what are the provisions for EUnetHTA21 or the HTA Cooperation to obtain access to the data and/or conduct the analysis themselves?		
Matias Olsen, EUCOPE	10	177-178	Please clarify if 'Risk of Bias' sections refer to clinical trial data as well as evidence synthesis data. We suggest adding which method/check list to use to assess the Risk of Bias.		
Prof. Matthias P. Schönermark, M.D., Ph.D., Dr. Laura Könenkamp, Ina Berger, Pharmacist, Lynn Bordt M.Sc., Svenja Sake, Ph.D. SKC Beratungsgesellschaft mbH	10	160	Comment: We agree that "The assessment will be done in conformity with the existing methodological guidelines in force at the time of assessment." However, the content of the guidelines cannot be assessed conclusively because not all documents are available yet. We recommend referring to the relevant documents, which provide information supplementary to sub-deliverable D5.2. This would provide guidance for the HTD on which analyses to present and for HTA bodies on which analyses to accept.		
Roche	10 11	167-168 194-199	It should be specified whether the overview of all included studies/ the availability of evidence only refers to studies		

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			which include the medicinal product under assessment or also studies which were used for indirect comparisons, when applicable.		
S. Walleser Autiero, Medtronic	10	152-155	It is not clear how the degree of certainty of relative effects should be presented. Clear guidance on how this should be evaluated and presented is needed to make this meaningful and consistent.		
S. Walleser Autiero, Medtronic	10	162-165	Besides guidance on how the information retrieval should be described, to ensure quality of the evidence review and ultimately the JCA, it would be required to determine detailed methods for literature review including systematic search and selection, reporting and quality assurance.		
Sebastian Werner vfa	10	149-151	*"The JCA should be performed according to the assessment scope identified by the MSs and agreed upon by the CEB. The assessment scope including the PICO question(s) should be presented*." The JCA report should include a transparent documentation of the assessment scope, incl. the responses of the MS to the PICO survey. A fair procedure must include the opportunity of the HTD to comment on the PICO of the assessments scope and to justifiably deviate from it. For these cases the JCA report should report the PICO of the HTD and the reasons. Further, it should be clarified whether this procedure will also apply under the HTAR.		
Sebastian Werner vfa	10	149-151	*"The JCA should be performed according to the assessment scope identified by the MSs and agreed upon by the CEB. The assessment scope including the PICO question(s) should be presented*." The JCA report and the summary report should contain a		

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			summary (incl. table), how PICO questions were addressed by the HTD based on the available evidence. This summary would provide a readable overview of the assessment's evidence situation with explanations. It is important to include a default position with this information in the JCA report for readability. This is important, as in some cases the HTD might not be able to answer all PICO questions by direct or indirect comparative evidence.		
Sebastian Werner vfa	10	158-161	*"Furthermore, the results sections will provide an assessment of the methods used by the HTD in the submission dossier, as appropriate. The assessment will be done in conformity with the existing methodological guidelines in force at the time of assessment."* The HTD is expected to address PICO questions with a possibility of multiple methods according to EUnetHTA21 Guidelines. However, these guidelines do not contain information about their acceptability. For HTD is it unclear how the assessment of EUnetHTA21 is performed, especially which methodological analyses of the HTD dossier might be chosen by EUnetHTA21 for the JCA or whether all of them are transferred into the JCA report. Principles should be clarified according to which analyses of the HTD dossier are selected for the JCA report. The vfa recommends addressing all the data analyses in the JCA report.		
Sebastian Werner vfa	10	167-168 194-195	It is unclear whether this overview only includes studies of the medicinal product within the label population or also additional studies which might be required to perform an ITC. Please specify.		
Suzette Matthijsse	10	156	Could you please clarify how the degree of certainty of		

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Lumanity			relative effects will be assessed?		
Suzette Matthijsse Lumanity	10	158	What happens if the HTD developer submits information using methods which are not in conformity with the existing methodological guidelines?		
Suzette Matthijsse Lumanity	10	164	How will it be identified whether or not all relevant studies have been identified? Will separate searches be run? What will happen if relevant studies have been missed?		
Suzette Matthijsse Lumanity	10	172	It may be useful to also report information on: - Whether the study supports application for marketing authorisation - Location where the trial was carried out (country and care setting) - Dosing schedule of trial drugs and/or device version and usage protocol - Concomitant medications permitted and disallowed - Pre-planned subgroups and stratification factors Planned statistical analyses		
François Houÿez, EURORDIS	11	196	How is “relative safety” defined and measured? Safety is a two-dimension parameter, it includes both the frequency of side-effects (identified or potential risks), and their severity. The easiness of use and the potential for medication errors could also be compared.		
GSK	11	183-184	Please clarify that each relevant comparator will be denoted by <x-1>, <x-2> etc to tie in with subsequent sections of this document.		
Mihai Rotaru, EFPIA	11	180(-215)	With regards to the section 4.3 (Study results on relative effectiveness and relative safety) EFPIA considers that it is worth avoiding unnecessary repetition and complexity in the presentation of the results. To this end we recommend that if one patient population represents a subset of another patient population, this should be reflected as a “Sub-PICO” of the latter, rather than a separate research question. This should ensure that effects		

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			in subsets vs full population are analysed, interpreted, and presented in conjunction. *(Cf EFPIA response to D4.2 and D5.1 Guidance)*		
Mihai Rotaru, EFPIA	11	196-197	Although indirect comparison is mentioned in the relative efficacy and safety sections, we would recommend creating a specific subsection (heading) in order to give more weight to the text (similar to sub-section 'studies')	Yes	
Natacha Bolanos, Lymphoma Coalition	11	191-192	**Patient characteristics** One of the key issues with clinical trials from a patient perspective is that the recruitment criteria oftentimes does not accurately represent the patients and/or patient population who are optimal candidates for receiving the treatment/therapy, if approved and for marketing authorisation and/or reimbursement. Therefore, with respect to application in a real-world setting, we question how the documentation might further or better integrate the comparability of patient characteristics between treatment groups, in the included studies and among the real-world patient characteristics.		
Matias Olsen, EUCOPE	12	222-223	The summary table content is not specific, we recommend further specifying the contents of the table.		
Matias Olsen, EUCOPE	12	224	A summary of the interactions with the HTD should also be included, and the involved Assessors (HTA bodies) should also be mentioned.		
Mihai Rotaru, EFPIA	12	216-224	EFPIA considers that the guideline should provide additional clarity whether the summary report is intended either as an JCA report Executive Summary" or as a document for the public (similar to the EMA "Medicine Overview", former "EPAR for the public").		

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			EFPIA considers that the assessment report should be accompanied by a document intended to inform the public about its contents and that the Executive Summary can fulfill that role. However, more details should be provided to define it, as that would be an actual and relevant section of the JCA report. While recommending that detailed guidance and a formal template are outlined for such a "summary report for the public", we recognise some of the challenges that come with this exercise: the choice of a user-friendly format, definition of the level of detail allowed to explain complex information to non-specialists, an appropriate balance between scientific and plain language. Therefore, we also recommend involving and consulting the public (and especially patient and clinicians) in the very process of shaping such document.		
Roche	12	217 -224	The summary report might become a very important part of the assessment report per se given the European Commission's intention to translate it in all European languages. It would be desirable to translate the complete assessment report in all european languages to facilitate the uptake. The current proposal for the summary report has a very limited amount of information. The complete template for such a report should also be subject to a public consultation. Therefore, we ask EUnetHTA21 JCA secretariat to state when the actual executive summary template of the assessment report will be publicly available for consultation.		
Natacha Bolanos, Lymphoma Coalition	16	393	**Time points for involvement**		

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			In our experience, it is critical to determine timelines relative to the involvement of clinical experts and patients, patient advocates, and patient organisations. This is especially important during the scoping and EU assessment stages for clinical experts. As we believe it is key that clinicians have sufficient time, given the demands on their respective calendars, to ensure they are ideally situated to become involved in a substantial way, there needs to be a minimum time defined for time points of involvement. Further, as we believe speedy evaluations may jeopardise efficiency and/or accuracy of external stakeholder participation and reviews, we propose that the process pursue and achieve a reasonable balance between the need for efficient and timely evaluations, and the time demand placed on clinicians that may impede involvement.		