EUnetHTA 21 Public Consultation & Responses
of the documents part of D7.1 on interaction between HTA bodies and Health Technology Developer

EUnetHTA 21 response to the public consultation comments on the draft practical guidelines under D7.1 (interaction between HTA and HTD)

- **D7.1.1 – guidance for the interaction between HTA and HTD**
- **D7.1.2 – procedure and framework for the factual accuracy check**
- **D7.1.3 – process for handling commercially confidential information**

EUnetHTA 21 wishes to thank the organisations and individuals who have responded to the public consultation of these practical guidelines. We have taken all comments into consideration. Due to the large number of comments received, we answer the comments on an aggregated basis instead of individually responding to each comment. Textual suggestions have been taken into account where possible but are not justified here. The comments are aggregated into general themes and the EUnetHTA 21 responses are found below each theme. Specific, unique comments were - however - answered in the comment table below. For abbreviations, we refer to the guideline.

ID number	Comment type	General response
1	Related to D4.2 (PICO)	Thank you for the comments on the scoping process. A relevant proportion of the comments have already been submitted to the consultation deliverable 4.2, which is why the current response is only condensed. The process for the scoping meeting is laid out under deliverable 4.2 and the public consultation comments on this deliverable are published. EUnetHTA21 will evaluate the feasibility and usefulness as a pilot within the context of EUnetHTA 21, to hold an information meeting. The benefit of this exchange will be evaluated at the end of the EUnetHTA 21 productions. <u>HTD involvement in the scoping and PICO development process</u> • The questionnaire for the PICO survey takes into account information provided by the HTD [Article 8(6)]; that is, information on the intervention to be assessed and the indication for which the HTD applied in the regulatory submission dossier (in the case of medicinal products) or the intended use according to the conformity assessment [in the case of medical devices (MD)]. This information is to be provided by the HTD upon request, before the beginning of the scoping process. <u>Breadth of the Scope for EU JCA</u> • Based on the HTA-R (article 8), the assessment scope should be inclusive and should therefore reflect Member States' needs. This means that the assessment scope is Member State driven and not dependent on data availability. Therefore, there is no formal limitation to only one PICO, and more than one could be requested, • We do not expect a situation in which the scope of a JCA comprises a very large number of PICO's. Typically, only a few different treatment standards across Europe exist (comparators). Some differences may occur due to different approaches of health care systems to the patients to be treated (populations). Which of these differences becomes relevant for any individual new technology to be assessed depends on the disease area or the current treatment landscape. Thus, we expect larger groups of MS using the JCA of a given PICO question to inform decision making in their health care systems. This constitutes a significant efficiency gain. • In case a specific PICO would only be relevant for 1 MS, the consolidation procedure already includes contact and discussion with the MS concerned to achieve the fewest number of PICO questions possible. A step

		introduced into the process is the explicit discussion of cases of PICO questions affecting only 1 MS in the validation meeting of the assessment scope. This will be an additional opportunity to clarify whether a certain information requirement might be covered at a national level or can be considered to be scientifically covered by other PICO(s). <u>More opportunity to interact with the assessor/co-assessor (via the Secretariat)</u> • In principle, the HTDs have the possibility to ask questions via the secretariat in case of ambiguities. If necessary, these questions will be forwarded to the assessment team. However, this contact is not limited to the PICO scheme and can also refer to questions about procedural steps or other topics. This possibility represents a common administrative standard that does not need to be set out in a general guideline. <u>Why no minutes taken. How does HTD get to know the PICO?</u> • The HTD will receive the consolidated PICO in a written form. • Since it is an informal internal HTA - meeting, no minutes will be taken by the Secretariat. However, the HTD is free to take notes for themselves. <u>Sharing of individual MS needs on PICO</u> In the PICO survey, a rationale for the specific PICO is not requested from the MS. In principle, the rationale for a MS PICO is the research question coming from their health care system. One example would be that relevant comparators are based on the treatment available in a MS. However, the scoping consolidation meeting offers the opportunity for assessors and co-assessors to clarify open questions. Mandatory use of the PICO that a MS provides in the PICO survey is not a (legal) requirement from the HTAR. The discussion on the national process is out of the scope of the HTAR and this guideline. It is up to the MS to decide how their input into the scoping process will affect their processes on the national level.
2	Good administration	
2. a	Fact check	Art 11 (5) states that the HTD shall not provide any comments on the results of the draft assessment. Please note that with regard to EMA procedures conclusions are drawn, which is not the case in EUnetHTA 21 or HTAR JCA reports. The purpose of HTA is different and the JCA reports do not include any conclusions; any conclusions or decisions are made on national level only. Therefore, only factual accuracy check related comments will be answered by assessor/co-assessor, since these are also in the scope of the HTAR. As indicated in the guidance (D7.1.2), all comments (also non-factual accuracy check related comments) including the answers from the assessor/o-assessor on factual accuracy check related comments will be published together with the final JCA report. No justifications on whether a comment was considered factual accuracy check related or not will be provided. However,

		to ease the process i.e. to facilitate the distinction if a comment is factual accuracy check related or not, and in case of any issues related to confidentiality highlighted by the HTD during the factual accuracy check, a body or committee (on the level of the JCA subgroup) will be proposed and added as a recommendation. However, answers should be provided by the assessor/co-assessor on the relevant comments. Please also see answer regarding "6 Confidential information (related to D7.1.3)" below.
2a1	Extent scope of fact check	The interpretation of data is a scientific exercise performed by assessor/co-assessor based on relevant methodology and it refers to data presentation, description and summary of the report. It is an objective review of the evidence with a presentation of the results and the associated uncertainty. In the factual accuracy check e.g. any potential errors from transferring data from the submission dossier to the JCA report can be highlighted. The questions in the checklist cover the scope of the factual accuracy check and should facilitate the factual accuracy check by the HTD. The application of the methodology in the respective JCA report is up to the JCA assessor/co-assessor. The draft JCA report will be reviewed by HTAb experts and is aimed to ensure methodological soundness of the report. Please see D4.7. Assessment of high-risk medical devices for the different review steps. The factual accuracy check is only applicable to the draft JCA reports (no other documents), since it includes relevant information from the submission dossier as provided by the HTD. This is also foreseen as such in the HTAR.
2. b	Time window	While we acknowledge the difficulty with the time windows provided, we have to work with clear and strict time constraints provided in the HTAR. However, all deadlines (receipt of PICO, submission of dossier, check of completeness of the dossier, start of assessment, factual accuracy check period) will be shared with the HTD at the start of the process so that appropriate planning can be put in place. EUnetHTA 21 has set up another hands-on group to discuss and further develop the JCA timelines for medicinal products. Until this group has reached a consensus, we are not able to amend the current guideline. The HTAR does not define working days or calendar days, and therefore the working assumption is they work in calendar days. Therefore, this cannot be changed in the EUnetHTA 21 deliverables In relation to the differences in timelines for JCA between medicinal products and medical devices this is specified in the HTA R text and therefore is outside of the scope of this deliverable.
2. c	good administration – interaction national level during JCA/JSC	The HTD should not communicate with national HTAbs about the JCA during an ongoing JCA to ensure an unbiased assessment. MS should not accept national consultations at the same time as JSCs on the same questions, as the responses to the JSC should not differ. This is without prejudice to issues related to the national HTA process, such as additional analyses that were not part of the joint assessment. For all other communications, the HTD should contact the

		Secretariat.
2. d	Direct interaction with assessor and co-assessor	If the (co-)assessor need to interact with the HTD, because of clarifying questions, they are invited to share these with the Secretariat. The Secretariat will then liaise with the HTD and share the respective information with the (co-)assessor. No direct interaction on the JSC or JCA with the assessor and co-assessor is allowed, as this is important to guarantee the independence of the (co-)assessor team and to ensure a fair process to all JSC/JCAs.
2. e	good administration – hearing after JSC or JCA	As both the JCA and JSCs aim to provide an objective review of the evidence with a presentation of the results and the associated uncertainty and in the case of the JSC clear objective advice, it would not be appropriate to provide subjective commentary alongside nor a hearing before or after publication. The factual accuracy check does allow appropriate recourse where errors may arise. After the publication of a JCA, EUnetHTA 21 has an error reporting procedure in place. The Coordination Group will have to decide and investigate if such process also will be applied under the HTAR
3	JSC	HTA agencies should align on a consolidated recommendation The aim of the CSCQ JSC and later the JSC subgroup will be to take into account all the needs of the member states and, if possible, to find compromises in the requirements for a clinical trial. However, the aim of a JSC is also to make a fair recommendation on what might be expected in a JCA based on the different PICO requirements of the MS. Therefore, national recommendations will also be included in the JSC. Updates to the procedures and templates are expected in 2023, which will include recommendations for the HTA R.
3a	National consultations	MS should not accept national consultations at the same time with an ongoing JSCs on the same questions, as the responses to the JSC should not differ whether it is a national or a joint scientific consultation. This is without prejudice to issues related to the national HTA process, such as additional analyses that were not part of the joint assessment. For all other communications, the HTD should contact the Secretariat. If there is not enough capacity for a JSC, there are independent opportunities for national consultation. However, it is not possible for individual member states to obtain the views of other MS, to seek European expertise from clinical experts and patients, or to provide other information on the specific European procedure,
3b	Update to procedural guidance	For all comments that refer to exact timelines and procedural steps, EUnetHTA 21 refers to the respective deliverable (D6.4) of the JSC. Comments will be taken into consideration for the next revision of that guideline.
3c	Capacity	EUnetHTA 21 has no influence on what capacities will be available for JSC under the HTAR. Selection criteria should enable a fair selection of candidates to be made in the event of too many applications without causing unequal treatment. How possible follow-up questions or consultations could be organised unter the HTAR, cannot yet be foreseen. However, the interest is recognised and will be taken into account as a recommendation for the processes under the HTAR in order to develop them further in the course of the project. In this respect, these comments do not lead to any changes in the guideline. Rejected candidates will receive a justification as to why a rejection was made in the corresponding Open call. The

		relevant explanations of the criteria can be found on the EUnetHTA 21 website and are continuously being refined. It is defined in the HTAR that "The Coordination Group shall publish the dates of request periods and state the planned number of joint scientific consultations for each of those request periods on the IT platform". Thus, it is intended to select the applications in the scheduled administration slot. An Open Call serves to improve and streamline the organisation of the corresponding administration. In order to avoid duplication of work and to minimise the administrative effort required to update the same information in different places, these issues are not included in this guideline.
3d	Minutes	It is not intended to correct the minutes of the HTD, with some exceptions, if the contents contradict the advice to a considerable extent. The final written recommendations are validated by the respective committees and correspond to the agreed opinion of EUnetHTA 21. This is not the case for the minutes of the HTD, they cannot be validated by the HTAb.
4	Secretariat	We agree that the secretariat will play an important role under the future HTAR however the matter of the secretariat is described in the HTAR and is to be established by the EU Commission and therefore is outside of the scope of this deliverable. We have added additional detail on the role of project manager and secretariat although it is recognised that under the HTAR only a secretariat is described in the text of the regulation.
5	Editorial/ linguistic	Thank you for pointing out editorial and linguistic errors. Where appropriate, they have been amended.
6	Confidential information (related to D7.1.3)	We wish to clarify, as also stated in the guidance document, that all involved individuals from the HTA bodies, Secretariat, and external experts will have to sign a confidentiality agreement (to be assessed and approved by the Secretariat/independent body/ Conflict of Interest Committee [under the HTAR the governance has to be further defined]) before they can participate and receive any information on the JSC or JCA. As stated in the guideline the HTD shall signal any information it considers to be confidential and justify its commercially sensitive nature when they submit the submission dossier and during the factual accuracy check of the JCA report. Therefore, at two points in the process, the HTD has the option of either defining confidential information in advance and marking it for the JCA report, if it contains any confidential information. The assessment teams are responsible for reviewing the HTD's comments on the factual accuracy and on confidential information and, in the event where redaction of confidential information is proposed by the HTD, reporting this back to the relevant committee (in EUnetHTA 21: CSCQ- JCA; under the HTAR this could be the JCA subgroup (TBD by the Coordination Group). Although generally the information on methodological and clinical aspects should not be considered confidential, EUnetHTA 21 recognises that in exceptional circumstances this information could be subject to redaction prior to publication. These issues should be scrutinised and a decision should be made by the relevant committee as to whether the report should be published with redactions or whether the HTD should be contacted again by the HTAb for further justification and exchange with the HTD, as to whether the definition of commercially confidential information

		applies. The process was further refined in section 4. For the future HTA system, a legal mechanism will be established to request the relevant information from regulators to ensure a proper HTA JCA. However, In EUnetHTA 21 information is needed from the HTD. Such information will not be published before the product is authorized. Timelines of the regulatory process and changes to the label are aspects that are content of the EPAR or publicly accessible information and cannot be considered confidential at the time of publication of the JCA. We wish to clarify that EUnetHTA 21 will not release clinical study reports. The EMA publishes the clinical data submitted by pharmaceutical companies to support their request for marketing authorisation, and which are assessed by the CHMP. EUnetHTA 21 will in those cases, in which the relevant clinical data are not in the publishable submission dossier but are relevant for an unbiased JCA, extract information from clinical study reports. Publication of clinical data or methodological aspects cannot be prevented by labelling them as academically confidential. The reason that these data are then no longer available for scientific publication is an individual interest that is overruled by public interest. This view is supported by the ICMJE statement. Furthermore, congress organisers should be actively made aware of this view if a contrary view is expressed. Academic in confidence data must be distinguished from actual commercially confident data.
6a	Individual patient data (IPD)/ GDRP	Some comments address the issue of a potential request for patient-specific data. In the context of a JCA, no data is required that would allow the identification of individual patients. No lists of patient data or other information that could lead to the identification of individuals are required. Specifications regarding the submission dossier are outside the scope of this guideline and we refer to the relevant deliverable 5.1 submission dossier. Clarifications have been made to the text.
6b	Update on regulatory status	there is only one comment addressing, therefore this issue was answered in the comment table.
6c	confidential information – confidentiality agreement with HTD	Confidentiality agreement between the participating HTD and EUnetHTA 21 is not necessary, since all HTAb participants sign a confidentiality agreement (ECA form), are made aware of the consequence and agree to comply therewith. Moreover representatives of all participating HTAb are bound to national confidentiality agreements with their employer (in addition to the EUnetHTA 21 confidentiality agreement [ECA form]). An additional confidentiality agreement with the HTD would not provide any additional legal commitment or consequences. A clarification was added to the text.
6d	JSC info in JCA	EUnetHTA 21 agrees, that JSC information is confidential in its entirety until the respective product is authorized and assessed. However, at the time of publication of the JCA report, EUnetHTA 21 considers that information from JSCs containing general, generic EUnetHTA 21 methodological recommendations is of public interest. These recommendations may apply to the specific situations of the study design but are applicable to other products as well and may not be included in general methodological guidelines, which is why they are mentioned in a specific JCA. The specific questions of the JSC or confidential information of the HTD will not be published. In addition, the general

		information, that a recommendation made during a JSC could not implemented in the study design, is not considered to be commercially confidential.
7	Submission of new evidence	As explained in item 2b, no specifications can be given on timelines. The topic of submission of new evidence during a JCA is brought forward as a future consideration.
8	Interaction for class of MD	This comment is answered directly in the comment form below
9	Interaction with EMA	The current deliverables only describe the interaction between HTD and HTA bodies (HTAb,) and therefore the interaction between EMA and HTAb is out of scope. The interaction process between EMA and HTAb is an activity under the EMA-EUnetHTA 21 work plan.
10	Consultation on manual for HTD	No JCA procedure manual for HTD will be developed in EUnetHTA 21, however the development of such manual is recommended for the future.
11	Discontinuation - resubmission	HTD can stop a JSC, since a JSC is a decision of the HTD. However, as capacities are low, accepted requests for consultation should only be withdrawn in exceptional cases and with good justification. *The current text of the D7.1 is clear that no submitted information will be published in case of a discontinued JSC or JCA. Therefore, no change is made to the text.*
11a	Publication of PICO of discontinued assessment	For transparency reasons, it is important to publish the consolidated PICO(s) even for a discontinued JCA. However, no commercially in-confidence data will be released with this and this will be fact-checked with the submitting HTD. EMA also publishes a statement on the withdrawal of a compound, and explains the intervention.
12	submission dossier	
12a	publication of submission dossier - redaction of confidential info	To ensure transparency of the data assessed in the JCA, it is important the core submission dossier is publicly available. This was also done in EUnetHTA JA3 (for medicinal products) and was considered important for re-use of the JCA on a national level.
12b	incomplete submission dossier	Thank you – we note the text of Article 9 (3)(a) to (d) and given that the text clearly contains elements which are beyond the scope a purely administrative check it will be important that both the assessment team and the secretariat have a role in ensuring that the dossier meets the requirements laid down in the HTAR. It will be important for HTDs to provide all necessary documents to allow the assessment to continue in a timely manner. The matter of incompleteness is likely to be determined by the assessment team in conjunction with the secretariat. However, as the roles and tasks of the secretariat is under the responsibility of the EU Commission, it is outside the scope of this deliverable.

		No definition or examples for a 'sound justification' can be provided, as this depends on the technology under assessment and therefore is a matter of the assessment team who are reviewing the information and have context on the rationale provided
13	Security of data storage	Several security and Logging/Audit measures are taken, to ensure safe data storage on SharePoint. For example, sharing of sites outside of existing accounts is disabled and is restricted to only Azure AD registered members. Further, Permission Matrix reports are automatically generated by means of ShareGate on a regular basis for security control and auditing. Also, for all users that have access to the SharePoint, two-factor authentication is enabled.
14	JCA	
14a	Re-use of JCA	Thank you for your comment. We agree a pilot JCA would be a useful exercise for both the HTAb and the HTD to investigate necessary changes in their procedures for the re-use of a JCA in a national setting.
14b	Scoping process & initiation of JCA	The scoping process is laid out under a separate deliverable (4.2 Scoping Guidelines). The responses to public consultation comments on deliverable 4.2 are also published. The specifics in relation to submission under the HTAR will be for decision under the HTAR CG. With regard to medical devices, please also see D4.7.3/4 Guidance for EUDAMED-based TISP process.
15	Applicability after EUnetHTA 21	These comments are addressed in the comment form below.
16	Alignment with EMA guidelines for handling commercial confidential information	Different documents are submitted for the HTA process and the approval process, so that not every aspect is relevant for the HTA process. If similar information is submitted to EMA and HTA bodies, equal treatment with regard to confidentiality is sought. In addition, it must be taken into account that the JCA is only published after approval, so that at this point in time corresponding information is already publicly available within the scope of the approval. Where applicable, additions have been made to the guideline considering the following documents. • Regulation (EC) No 1049/2001 • EMA's Policy 0040 or • EMA's Policy 0043 or • EMA's Policy 0070

EUnetHTA 21 Public Consultation & Responses
of the documents part of D7.1 on interaction between HTA bodies and Health Technology Developer

Name organisation	Country
European Federation of Pharmaceutical Industries and Associations	Belgium
F. Hoffmann-La Roche Ltd (Roche)	Switzerland (head quarters)
European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	Belgium
Medtech Europe (MTE)	Belgium
Intuitive	United states
Verband Forschender Arzneimittelhersteller (vfa) e.V	Germany
IGES Institut GmbH and HealthEcon AG (IGES LifeScience)	Germany
Ecker + Ecker GmbH (E+E)	Germany
Medtronic	Switzerland
Takeda Pharmaceuticals International AG (Takeda)	Belgium, Switzerland, pan-European operations
European Union of General practitioners/ Family Physicians. UEMO	Belgium

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			General comments		
Mihai Rotaru - EFPIA	General		While we acknowledge that EUnetHTA 21 Service Contract does not follow the same legal framework as the HTAR (as it does not apply yet), to avoid confusion, clear and separate statements should be made in all instances about what is going to be the process under EUnetHTA21 and what is EUnetHTA21's recommendation for future JCAs and JSCs 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 future JCAs and JSCs under HTAR should be developed. More information and recommendations are provided and more clarity is given for the process under EUnetHTA21 compared to the process under HTAR. Therefore we suggest being consulted on the interaction between HTD and HTA once the rules under HTAR will be settled.		Thank you for your comment. Decision on the process for under the HTAR will be the responsibility of the HTAR Coordination Group.
	General		This document is very much focused on one-way communication meaning that there are no opportunities for the HTD to ask questions in the process. The suggestion is to offer two-way communication between HTD and HTA for meaningful interactions. We believe that there is a missing communication opportunity in the process in terms of Joint Scientific Consultations so the suggestion is to add opportunities for follow-up advice (e.g. having the opportunity to ask further questions once the design has been modified or the standard of care has developed following the 1st JSC) as well as PLEG consultations. Two-way interaction between HTD and EU HTA (assessors/co-assessors) are mediated by a project manager who should remain the same, to the possible extent, throughout a given JCA/JSC procedure		2d (direct interaction with assessor and co-assessor)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
D7.1.1 - practical guideline on the interaction between HTD and HTAb					
Mihai Rotaru - EFPIA	General		EFPIA would like to clearly reference and re-iterate some of the main points brought for consideration in the EFPIA response to the scoping process consultation, notably: • The need for Health Technology Developer (HTD) involvement in the scoping and PICO development process – EFPIA believes that the involvement of the HTD in the process will make the PICO development process more fair and efficient and allow the HTD to commence preparation of the dossier earlier. • Breadth of the Scope for EU JCA - EFPIA recommends that the JCA adopt an explicitly European perspective and focus on that which is common to Member State health systems rather than aiming to meet all the needs of each. The HTAR allows for what material differences that do exist between MS to be accommodated in subsequent local, complementary clinical analyses. • Sufficient time for HTD to produce a high-quality dossier - EUnetHTA JA3 experiences show cases that HTDs should have sufficient time to prepare for a submission. Importantly, the time required to produce the submission will be sensitive to the complexity of analyses that flow from the agreed set of PICOs – the greater the complexity and scope, the more time will be required. • More opportunity to interact with the assessor/co-assessor (via the Secretariat) – the ability to formally interact with the assessor/co-assessor (via the Secretariat) only helps to expedite the process and understanding of data requirements and availability. Dialogue must be built into the process - Regular direct dialogue between the HTD and those developing the scope and later the submission is essential as without dialogue this risks that a Scope is imposed without an understanding of the evidence available or the feasibility of conducting certain analyses which could in turn		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			result in a mismatch between what the HTD is able to submit and a failure of the JCA process to deliver evidence fit for decision wasting the time and resource of everyone involved.		
Mihai Rotaru - EFPIA	General		The guidance should establish processes which are aligned with the principle of good administration, and which ensure the highest level of quality (recital 12, HTAR). We believe that a meaningful interaction between HTD and HTAb is one essential prerequisite for achieving the highest level of quality in JSC and JCA. A meaningful interaction should be provided following the principle of good administration. Therefore, the HTD should have the possibility to effectively make known its perspectives on the correctness and relevance of the facts and circumstances which are subject matter of the processes: •The HTD should get the possibility to effectively comment on the PICO scope, including a meeting. •The HTD should get the possibility to effectively comment on the answers and classifications of HTAb to the HTD's factual check. •The HTD should get the possibility to effectively comment on the opinions expressed by the HTAb about the HTDs designation of commercial in confidence information. •HTD should get the possibility to effectively comment on the recommendations for Joint Scientific Consultations The possibility of response should include a subsequent exchange on unresolved issues. For commercially in confidence information the process should include a conflict resolution mechanism.		2 (good administration)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	General		Time windows provided in the guidance document are not tailored to take into account the varying challenges of different questions – some questions may require additional specific discussions between the assessor and the HTD to allow for more flexibility according to the extent of data analyses. Opportunities for dialogue should not be limited based on a one size fits all approach but rather a commitment on all sides to allow additional discussion of more complex issues to resolve the approach in a way that all parties can live with. In addition, the guideline should foresee/establish a specific process for managing last minute changes and allow for a procedure to cover all eventualities. For example, a restriction in the final indication may be dealt with as a sub-PICO (and may have already been covered in the original scope) but other changes require a specific process and appropriate timelines to be dealt with.		2b (good administration - time window)
Mihai Rotaru - EFPIA	General		EFPIA welcomes the EUnetHTA21 JSC procedural guidance as manual of reference for companies applying to a JSC. Although the manual provides a comprehensive description of the process EFPIA recommends it to be updated in order to make the key reference points and timelines more explicit. According to the EunetHTA21 guidelines the process starts after the acceptance of the Health Technology by EUnetHTA21 whereas the EMA/EUnetHTA21 JSC procedural guidance refers to the entire procedure lasting approximately 3.5 months starting from the receipt of the draft briefing book. Also, a D0 time point is mentioned without being defined.		3 (JSC)
Mihai Rotaru - EFPIA	General		EFPIA takes note of the Secretariat as primary point of contact for the HTD and as the body responsible for all external communication. EFPIA would recommend the Secretariat should be common to all JSCs/JCAs and therefore best placed to ensure a consistent, predictable and fair process in accordance with the rules. The Secretariat should recognize the need for all stakeholders to have an equal voice and facilitate the fair and efficient communications between them. In addition to agreed		4 (Secretariat)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			communication timepoints there must be the capacity for ad hoc questions and dialogues to resolve both technical and process-related questions. EFPIA assumes that the role of Secretariat under EUnetHTA21 will be taken over by the European Commission in the future system (as foreseen in the HTA R) therefore all references to 'Secretariat' in this consultation response should be understood both for EUnetHTA21 and the future system.		
Mihai Rotaru - EFPIA	General		EFPIA believes that the guidance document would benefit from a further split out HTAb into different relevant functions: Assessor/ Co-assessor, Secretariat, CSCQ, project manager etc. and assign roles & responsibilities; include clear definitions for each of the functions/ roles.		5 (editorial/linguistic)
Mihai Rotaru - EFPIA	General		EFPIA would like to reiterate that Article 6c(5) provides manufacturers with the limited right to "[signal] any purely technical or factual inaccuracies…" but they "shall not provide any comments on the results of the draft assessment." The absence of any right to comment on the results of the draft assessment arguably falls short of the right to good administration which includes the right to be heard before any individual measure with adverse effect be taken. A violation of the right to be heard will lead to the illegality of the decision taken if there is a possibility that in the absence of the violation the content of the decision would have been different. The fact that the assessment report is not binding does not detract from this because the report is intended to be taken into account by Member States and will affect the manufacturers' legal position at that level. The fact that manufacturers cannot comment directly at the level of the Coordination Group but must wait for the continuation of the procedure at national level unnecessarily risks divergent outcomes and is a material additional burden on manufacturers.		2a (good administration - fact check)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			We note that CMD(h) and CHMP procedures allow for an opportunity for the applicant to be heard before scientific conclusions are adopted and, by analogy, it would be entirely appropriate to allow manufacturers to comment on the draft assessment in Article 6c(5). The 5 calendar day delay for comment should be extended (see above comments) to provide for a reasonable delay to be determined by the Commission in the implementing act as there are serious doubts as to whether the envisaged 5 days are sufficient for the meaningful exercise of any right to comment and this may well infringe the right to good administration in violation of Article 41 of the Charter of Fundamental Rights. As such, the mechanism for fact-checking should be expanded as outlined below: The process to include an opportunity (right to reply) for HTD to 'comment' on the final report shared with the Coordination Group (i.e. HTD receives the final Assessors report at the same time as the Coordination Group, with opportunity to comment). The process to include for the documents (comments) submitted by HTD on the draft assessors report to be included with (submitted alongside) the final Assessor report that is submitted to the CG (this being done at the same time that the report is shared with the CG). Also, the Assessors should complete a report on their response to the consultation process (comments received from HTD, and others), and include this with the submission of the Assessors final report to the CG.		
Mihai Rotaru - EFPIA	General		EMA guidance for handling commercial confidential information should be replicated for the future EU JCA system - In case of differing opinions on commercially confidential, a solution mechanism must be deployed before publication (interaction for clarification).		6 – confidential information
Mihai Rotaru - EFPIA	General		Specifically in the case of JSCs, by submitting a request for a Parallel EMA/EUnetHTA 21 JSC, the HTD should be bound by		3 (JSC)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			the confidentiality framework already established with EMA and therefore will agree to the exchange of information between EMA and participating EUnetHTA 21 HTAbs. The Parallel EMA/EUnetHTA 21 JSC process is confidential. EMA and associated regulatory experts are bound by the EMA code of conduct, and confidentiality agreements, and operate under the **EMA policy on access to documents (Policy/0043).** EUnetHTA 21 prioritises confidentiality and each HTAb participant and associated expert, e.g. healthcare professionals and patient representatives, is required to submit a signed EUnetHTA 21 Confidentiality Agreement. Therefore, commercially confidential information provided to the EMA and EUnetHTA 21 within the context of a Parallel EMA/EUnetHTA 21 JSC is not shared with any party before authorisation outside of the respective EMA and HTA networks in the absence of a signed confidentiality undertaking or the consent of the sponsor.		
Matias Olsen, EUCOPE	General		We are concerned that this draft practical guidance will not lead to efficient communication between HTD and HTA bodies. Especially OMPs and ATMPs would require a more interactive process to appropriately capture the complexity of the disease and the technology, and to ultimately achieve a robust assessment. If all communication is limited to a 'question/response' type of written interaction, there is an increased risk of misunderstandings (e.g. due to the correct questions not being posed), and final assessment results would be negatively impacted. Efficient points of interactions need to be established for the HTD to communicate relevant information to the Assessors throughout the process (e.g. to provide information relevant to the scoping process, in accordance with the Regulation on health technology assessment (EU) 2021/2282 Article 8 (6) or to proactively inform the Coordination Group of new clinical data that becomes available during the assessment process, in accordance with Article 11 (2).		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Matias Olsen, EUCOPE	General		If new information becomes available during the assessment process (for example new data cut-off or output from analyses based on a PICO, there should be an option to include this evidence in the assessment.		7 (submission of new evidence)
Matias Olsen, EUCOPE	General		As we have noted in our comments on deliverable D4.2 "Scoping Guideline", the proposed guidance on the scoping process so far does not provide sufficient detail on the methodology for consolidating the requested PICO schemes by Member States, despite reference made to relevant existing guidance such as the 2015 EUnetHTA guideline on "Criteria for the choice of the most appropriate comparator(s)". With the general lack of interaction and opportunities for the HTD to provide input in the scoping process and raise concerns with proposed comparators in this practical guideline, there is an even greater need to develop an updated clear guidance for choosing appropriate comparators, based on the abovementioned guidance, that should be developed with input from relevant stakeholders similar to the other EUnetHTA 21 deliverables. Clear guidance on the choice of appropriate comparators is needed to provide predictability and transparency to the procedure, especially given the large heterogeneity in standards of care between Member States, which also includes use of off-label products.		1 (related to PICO)
MTE	General		MedTech Europe likes to re-iterate the importance of a well designed two way (collaborative) communication / interaction with practical guidelines of the modalities of such an interaction to results in obtain the highest quality and usability of the reports in future national decision making. We therefore want to reiterate the importance notably : - for Health Technology Developer (HTD) involvement in the scoping and consolidated PICO development process, - for a direct interaction / communication with the assessors and co-assessors' organizations with appropriate measures of transparency and frameworks put in place We therefore would appreciate in the finalization of the interaction guidelines with HTD of medical technologies, to take the		1 (related to PICO) 2 (good administration)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			specificities of medical technologies, the use is in national health care pathways and the legal provision of the HTA-R into consideration and define in cooperation the area's whereby a direct interaction would be beneficial. We would recommend to develop an overview of models of interaction available in other European regulations and directives to benefit from best practices and legal frameworks.		
MTE	General		With the intend to apply the guidances in JCA test cases, we would welcome further clarity on the proposals made for a future interaction within the HTA-R and complementary guidances specific for JCA/JSC specific to EUNETHTA21. We suggest to also align fully the guidance to the future legal basis provided within the HTA-R whereby the full legal text is provided in section 1.3, ensuring completeness. Eg. Consider HTA input on PICO (art 8(6) / The scoping process shall also take into account information provided by the health technology developer,		5 (editorial / linguistic) --> focus on future, not on EUnetHTA 21 1 (related to PICO)
MTE	General		For the content of the guidances itself, we would like to request that further clarity is added on specific roles of the actors involved, timing and we look forward to an opportunity to be consulted on the "JCA Manual for HTD" and other documents further developed.		Thank you, we will consider providing further details. Consultations on future documents will also be considered, when applicable and relevant.
MTE	General		As the information on confidentiality is scattered over multiple deliverables it is challenging to comments and make suggestions. Specific further comments on handling confidential and commercial in-confidence data is provide on consultation 7.1.2 and 7.1.3. and we propose to compile all confidentiality related information. The fact that no confidentiality agreement, nor any other agreement between HTD and EUNETHTA21 will be foreseen is of a major concern in a rules of cooperation. We welcome further clarification on the rationale and necessary provision to protect commercial in confidence (CiC) data, intellectual properties and infringement of other EU Legislation and how CiC with eg recital 41 will effectively be protected. We look forward to elaborate a comprehensive confidentiality framework and agreement and mechanism to redact reports. Beyond the concern of data protection rights the potential		6 (confidential information (related to D7.1.3)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			publication risks to heavily affect intellect properties There must be an appropriate procedure put in place to protect the publication of information that could unreasonable prejudice the business interest and limit the accessibility to innovation (first) in Europe. This especially in a context of limited additional protection mechanism in the field of medical technologies.		
MTE MEMBER	general		The document would signal a more collaborative mindset towards stakeholders if less prescriptive language ('has to make sure', 'has to submit', 'must be', etc) was used and just the intended process and actions ('submits', 'provides', etc) be described rather than duties stipulated.		5 (editorial/ linguistic) *Thank you for the suggestion. Since we are following the framework laid down in the HTA Regulation, we will not change the language used*
MTE MEMBER	General		The document only focuses on interaction between the HTD and HTAb in case of a single technology assessment. However, within medtech/medical device evaluations might focus on class. Therefore, the documents need to consider how interaction with several HTDs will function.		8 (Interaction for class of MD) Please see D4.7.1/2 Framework for the assessment of high-risk medical devices and in-vitro-diagnostics. After January 2025, Regulation (EU) 2021/2282 on HTA will drive towards JCA for selected single technology high-risk MDs and class D IVDs. The framework does not cover comparative assessment of multiple technologies for indication groups later in their life cycle (this is not within the scope for JCA in the HTAR) or collaborative assessments (CAs). We also consider this out of scope of this guidance.
Intuitive	General		Intuitive would suggest that the simultaneous discussion and comparison between the processes associated with EUnetHTA and the HTAR confuses the overall intent of the guidance. If the purpose is to provide recommendations for HTAR, we		5 (editorial/linguistic)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			recommend a focus on HTAR with minimal reference to EUnetHTA, unless to note that the rationale for making a specific recommendation is to align it with existing EUnetHTA practices (or those of other national bodies or best practices in the field). Any differences can then be highlighted at a later stage. Furthermore, if the intention of the guidance is to strictly provide recommendations that are non-binding and subject to change, we recommend this should be stated clearly.		
Sebastian Werner vfa	General		The administrative processes described in this guidance, mainly lack a meaningful interaction between health technology developer (HTD) and the assessors of the health technology assessment bodies (HTAb). The processes are organised as a one-way information transfer from the HTAb to the HTD about important provisions that can influence the outcome of Joint clinical assessments (JCA) and Joint Scientific Consultations (JSC). The HTD is not given the possibility to effectively make known their views on the correctness and relevance of the facts and circumstances which are subject matter of these processes. Examples are: - PICO information meeting (for EUnetHTA21): information about the PICO (scope) is given to the HTD without the possibility to effectively make known their views on the definition of the scope - Factual check: Assessors and co-assessors answers and classifications to the HTD's factual check are published without the possibility of the HTD to effectively make known their views on these subjects - Confidentiality designation: In case of differing opinions of the HTAb, commercially in confidence information designated by the HTD are published with the JCA report without the possibility of the HTD to effectively make known their views on the opinions expressed by the HTAb. - JSC: recommendation of HTAb is given to the HTD without the possibility to effectively make known their views on the recommendation		2 (good administration) 1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			The guidance should establish processes which are aligned with the principle of good administration, and which ensure the highest level of quality (recital 12, HTAR). The vfa believes that a meaningful interaction between HTD and HTAb is one essential prerequisite for achieving the highest level of quality in JSC and JCA. A meaningful interaction should be provided following the principle of good administration. Therefore, the HTD should have the possibility to effectively make known their views on the correctness and relevance of the facts and circumstances which are subject matter of the processes: • The HTD should get the possibility to effectively comment on the PICO scope, including a meeting. • The HTD should get the possibility to effectively comment on the answers and classifications of HTAb to the HTD's factual check. • The HTD should get the possibility to effectively comment on the opinions expressed by the HTAb about the HTDs designation of commercial in confidence information. • HTD should get the possibility to effectively comment on the recommendations for Joint Scientific Consultations The possibility to respond should include a subsequent exchange on unresolved issues. For commercially in confidence information the process should include a conflict resolution mechanism.		
Sebastian Werner vfa	General		A "PICO information meeting" is set up under EUnetHTA21. The guidance does not set up a separate PICO meeting for JCA under der HTAR. However, in both instances the guidance does not give the HTD the possibility to respond and effectively make known their views on the PICO-scope. But it is necessary to give the HTD this possibility to effectively comment and interact on the PICO scope suggested by the HTAb. This would not only follow the principle of good administrative practice (HTAR, recital 12) but would also increase the quality of the joint clinical assessment. The vfa strongly recommends establishing a PICO "scoping"		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			meeting with the HTD for JCA under the HTAR. The vfa believes that only with sufficient involvement of the HTD the JCA can aim to achieve the highest level of quality (HTAR, recital 12). The past practice in EUnetHTA assessments and current practice in Germany stand witness of the big advantages such meetings exert of the quality of the work. Further, the implementation of a scoping meeting would be consistent with the HTAR, as scoping meetings with the HTD are permitted. Indeed, the regulation establishes a similar involvement of HTD, patients and clinical experts in the scoping process [Article 8(6)]. Thus, it is hardly comprehensible how a JCA CSCQ Scoping-Meeting is set up for patients and clinical experts but not the HTD (cf. Draft Practical Guideline Scoping Process). The implementation of a PICO "scoping" meeting with the HTD is necessary following the principle of good administrative practice, ensuring quality of the joint work, and given the same opportunities to HTD, patients, clinical experts and other relevant experts to effectively comment on the PICO scope as foreseen in the HTAR.		
Sebastian Werner vfa	General		Joint clinical assessments and joint scientific consultations require the sharing of confidential information between HTD and HTAb. The protection of commercial in confidence data must be warranted. Therefore, confidentiality agreements between HTD and HTAb are always necessary. Information provided to the HTAb should only be disclosed to a third party after a confidentiality agreement has been concluded. Any person involved in the preparation of HTA documents or having access to the information should sign a confidentiality agreement (staff of the HTAbs, regulatory authorities, involved clinical experts, patients or other experts). However, the guidance foresees no such confidentiality agreement between the participating HTD and EUnetHTA 21, neither for a JSC process, nor for a JCA. The authors make it clear that "no confidentiality agreement would be needed" (cf. D7.1.2 Factual accuracy check). However, there are no objective reasons apparent why confidentiality agreements should not be necessary for EUnetHTA21 JCA or JSC pilots, but for the regular		6 (confidential information)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			JSC and JCA. Confidentiality agreements between HTD and HTAb are always necessary, incl. EUnetHTA21.		
Sebastian Werner vfa	General		Durations for processes that involve a response of the HTD should be clearly defined or revised to ensure sufficient time for completion of high-quality responses by the HTD. Deadlines should be communicated in "working days" or active days" where possible. For the formal interaction of HTAb with HTD during the JCA for clarification requests, the deadline for responses should be increased to 7 working days for medicinal products. For the factual accuracy response of the HTD the completed comments should be send within 7 working or active days. The grace period for amending the dossier after CHMP label changes should be increased to 30 calendar days.		2b (time window)
Dr. Thomas Ecker, Ecker + Ecker GmbH	general	-	Ecker + Ecker GmbH, a healthcare consultancy based in Germany with strong expertise in the early benefit assessment, welcomes the establishment of a European Health Technology Assessment (HTA) fostering closer cooperation between member states on health technology assessment by introducing a permanent framework for this joint work. The legal requirements for a European HTA have been determined as a legislative act by the end of 2021 with the EU regulation 2021/2282. From 2025, before placing innovative medicinal products on the market, oncology products and ATMP are subject to a European joint clinical assessment. In the next step, Orphan Medicinal Products (OMPs) will follow, beginning in 2028 and from 2030 all medicinal products will have to go through the European assessment. While the regulation does not come into force until 2025, the process of implementation is already ongoing to ensure effective application from January 2025 onwards. At present, the development of a methodology for joint HTA work is facilitated by	-	Thank you

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			the European Network for Health Technology Assessment (EUnetHTA) 21 consortium. Numerous guidelines are currently under development regulating specific aspects of the HTA process. As an important outcome, a consolidated document on the timelines and requirements for EU-HTA would be highly desirable. On July 20, the EUnetHTA 21 draft deliverable "D7.1.1 – Practical Guideline for interaction between Health Technology Developer and HTA bodies" was published and is now available for public consultation. Within the European HTA, the vivid exchange between HTA bodies (HTAb) and Health Technology Developers (HTD) is crucial and therefore, this draft deliverable (as of April 2022 in version 0.1), represents an important guideline that provides the opportunity to establish a framework for the interaction between HTA bodies, the respective assessors and HTD.		
Dr. Thomas Ecker, Ecker + Ecker GmbH	general	-	While the draft guideline "D7.1.1 – Practical Guideline for interaction between Health Technology Developer and HTA bodies" aims to establish an initial framework for the interaction between HTD and HTA bodies, we are deeply concerned that this draft guideline will not enable efficient communication between HTD and HTA bodies within the EU HTA procedure. While from our point of view exchange between HTD and HTA bodies represents a crucial part of the EU HTA process in order to ensure the best possible quality for the submitted dossiers, this guideline limits the communication between the HTD, HTA bodies and respective assessors to a minimum. However, from our perspective, it is therefore essential to allow for dialogues and appropriate interactions between HTD and HTA bodies to take place in the EU HTA procedure. In summary, our main concern with regard to deliverable "D7.1.1 – Practical Guideline for interaction between Health Technology	-	2 (good administration) and 1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Developer and HTA bodies" is, that only minor, insufficient involvement of HTD within the EU HTA procedure is planned. – The proposed insufficient exchange between HTD and European HTA bodies is a major point of concern. Exchange between HTD and EU HTA bodies within the procedure is crucial. Therefore, exchange between HTD and assessors should be established within the assessment, including early stages such as the scoping process as well as the Joint Clinical Assessment (JCA) itself. Possible ways of interaction might comprise for example a letter of intent submitted by HTD, participation of HTD in the scoping meeting, and a publicly available comment by HTD on final JCA		
Tanja Podkonjak, Takeda	General		To ensure an efficient, informed, and fair system, we believe that both the JCA and JSC procedures should have meaningful inclusion of all key stakeholders, including the health technology developer (HTD). To ensure the highest level of quality (recital 12, HTAR), the procedures for JCA/JSC should be aligned with the principle of good administration which includes representation and meaningful interaction of key stakeholders. Under the current document, there is little, if any, involvement of the HTD which is not aligned to most current national HTA procedures that include interactions at key appraisal milestone such as scoping, a clarifying question, oral hearing or meeting, and final report review. Following the principles of good administration and best practices in current national HTA procedures, the HTD should have the possibility to comment on accuracy, interpretation and relevance of the data and context of the topic under evaluation. In specific, we request the HTD be involved in the following stages:		2 (good administration)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			• JCA: The scoping stage by participating in a PICO / scoping meeting • JCA: The HTD should have the opportunity of dialogue with the assessor/co-assessor with the Secretariat in a clarifying call to address any outstanding questions or data requirements. This would result in a more efficient process. • JCA: The HTD should get the possibility to effectively comment on the answers and classifications of HTAb to the HTD's factual check. • JCA: The HTD should get the possibility to effectively comment on the opinions expressed by the HTAb about the HTDs designation of commercial in confidence information. Furthermore, a conflict resolution mechanism needs to be established in case of unresolved issues, such as disagreement in the classification of confidential material. • JSC: HTD should get the possibility to effectively comment on the recommendations for Joint Scientific Consultations We note that although an oral hearing or HTACG meeting is not specifically requested in the current Regulation, the introduction of such a meeting, with participation from the HTD, patient and clinical experts, would improve the efficiency of a JCA and result in a more representative final report. HTA oral hearings with participation of key stakeholders are established practice in many leading international HTA agencies. These meetings improve the quality of the HTA process and result in a robust final report, but as all stakeholders are present, do not compromise on integrity. Takeda requests the introduction of an oral hearing or clarifying meeting be considered for the JCA.		
Tanja Podkonjak, Takeda	General		In line with our feedback on the Scoping consultation, Takeda requests the re-introduction of a scoping meeting into the future JCA process. This critical step is currently a part of the EUnetHTA-21 JCA procedure and the former Joint Action 3		1 (related to PICO (D4.2))

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			process and is also a part of many current national HTA procedures via a meeting or correspondence. An interactive PICO meeting, with all key stakeholder present, would be beneficial to the quality, efficiency, and representativeness of the JCA process. This would ensure that the HTD can provide a comprehensive and complete dossier based on available data which is aligned to the expectations of the JCA assessors. It would further provide the opportunity to: • Verify the choice of comparators to ensure that the assessment covers a truly pan-European perspective. • Discuss possible ways of comparison (ITC), as for some comparators this will introduce significant uncertainty. Having discussed/agreed upon relevant methods for comparison in advance, may be an advantage when engaging national HTAb's. Regular direct dialogue between the HTD and those developing the scope and later the submission is essential as without dialogue this risks data misinterpretation about the new technology, the anticipated population and awareness of evidence available or the feasibility of conducting certain analyses. Without regular dialogue, the result could be inefficient use of resources due to misinterpretation or a mismatch between what the HTD is able to submit and the expectation of and a failure of the JCA process to deliver evidence fit for decision wasting the time and resource of everyone involved.		
Daniel Widmer UEMO	general		We applause to see the confirmation of assessor and co-assessor independance		Thank you
MTE MEMBER		133-140	Strongly believe that the possibility of having clarification points of contacts via e-mails, conf. calls, face to face meetings should be added, given the impact of the final deliverables and the overall impact on European patients access whereby highest standards and best practices should be applied		2 (good administration) *It is specified in the document clarification questions can be asked upon request of the assessor and co-assessor (via the*

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
					Secretariat)
MTE MEMBER		143-145	It is stated, that the HTD should have no interaction for JSCs or JCAs with national HTAbs unless it is publicly available information. We see this problematic from a member state point of view as early interaction is needed with the local HTAb to plan for local Consultations or to get information form the local HTAb if and what type of additional analyses would be needed for national purposes.To have a seamless HTA process across EU and member state level respective interactions are warranted to accelerate patient access as this is the purpose of EU-HTA.These lines should be modified to allow the HTD and the national HTAbs for this kind of interaction.		2c (good administration – interaction national level during JCA/JSC)
Silke Walleser Autiero Medtronic	307-314		All interactions will be conducted through the secretariat and in writing. Such a formal approach may lead to misunderstanding and might lead to delays, which is incompatible with the short timelines of the process.		2 (good administration)
Tanja Podkonjak, Takeda	7-8	146-152	This paragraph discusses not duplicating scientific consultations and questions between EU JSC and national advice for individual member states. This seems too limiting as it is possible that HTDs will want to pose similar questions to an individual MS and during the JSC if the anticipated final funding recommendations may differ. Furthermore, there may be merit in asking the same question if the feedback from the individual MS would have implications on any economic or cost-effectiveness analyses, which are only considered within the national domain. Takeda recommends this paragraph be re-written to incorporate flexibility in seeking national vs EU advice as the context and ultimate use of the information received from the advice may different (comparators asked for economic considerations vs clinical).		2c (good administration – interaction national level during JCA/JSC)
Matias Olsen, EUCOPE	7-8	146-151	It is appreciated that interaction with national HTA bodies for the purpose of receiving complementary scientific consultation is mentioned, especially since the interaction with the Assessors is limited and not all developers are guaranteed to receive Joint Scientific Consultation. In general, the communication channel to the national HTA bodies should be maintained as open and wide as possible.		2c (good administration – interaction national level during JCA/JSC)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Roche	6-7	121, Table 1-1	*"Art 8 (6): Consider HTA input on PICO* *Art 11 (2): Interaction with HTD in case clarifying questions during JCA* *Art 11 (5): HTD to flag which sections are confidential"* Roche is aligned with those regulation statements and would suggest to translate them clearly in this guidance in terms of bilateral interactions between HTD and HTA **under the HTAR**.		2 (good administration)
Mihai Rotaru - EFPIA	5	75 - 89	EFPIA agrees with the principle of transparency, openness and fair engagement with stakeholders and specifically agree that all information relevant to the assessments should be made available to the assessor/co-assessor, the members of the Coordination Group, and the relevant experts involved in the assessment. However, the HTA R specifically allows for HTDs to indicate commercially confidential information and allows for the protection of that information. While we recognise the public interest in the production of JCA reports, we strongly object to EUnetHTA21 making the determination that the public interest trumps the right of HTDs to protect commercially confidential information. A final determination as to the primacy of the rights of any constituency involved in the JCA over another constituency can only be made by the European Court of Justice.		6 (confidential information (related to D7.1.3))
Mihai Rotaru - EFPIA	6	102 - 107	EFPIA believes that not using the EUnetHTA21 experience (deliverable development as well as JCA/JSC production) as a means to properly inform and test in practice the rules governing the future system foreseen by the HTA Regulation is a missed opportunity. Furthermore, establishing a different precedent for interaction between the HTD and HTA bodies goes against the objective of increased predictability, one of the main objectives of the HTA Regulation		The ambition of EUnetHTA 21 is to design the guidelines as applicable as possible for the future HTAR. Due to different legal backgrounds, capacities and structures, not all steps are equally transferable.
Mihai Rotaru - EFPIA	6	136 - 138	The guideline should however specify that any interpretation as to what constituted commercially confidential information should be based on existing legal practice, as defined by ECJ jurisprudence.		6 (confidential information (related to D7.1.3))
Matias Olsen, EUCOPE	6	104-105	Discussions between the HTD and the HTA bodies are considered to be a vital part of the process to ensure the best possible quality for the submitted dossiers. Reducing the communication between		2 (Good administration)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			the HTD and HTA bodies may lead to unresolved misunderstandings and subsequently to a reduced quality of the assessments. It is therefore crucial to allow for dialogues and appropriate interactions between the HTD and the HTA bodies to take place in the EU HTA procedure. Remove: "~~This means that activities (JCA and JSC) carried out within EUnetHTA 21 may have a more interactive 104 process with the HTD than the JCA and JSC carried out under the HTAR.~~"		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	6	114/115	**Comment:** DRAFT GUIDANCE: *"…may take place than what is foreseen in the HTAR, due to the fact that the HTAR is not into force yet."* The HTAR is in force since 11 January 2022 but "shall apply from 12 January 2025", cited from Art. 36 No. 2 of Regulation (EU) 2021/2282 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021R2282 **Suggestion**: "…may take place than what is foreseen in the HTAR, due to the fact that the HTAR will be applied from 12 January 2025".	X	5 (editorial/ linguistic) Thank you, text will be clarified
Roche	6	107	Chapter 6 refers to the Considerations for the HTAR, therefore we believe it was meant Chapter 6 instead of Chapter 3. "*Chapter **6** will explain this in more detail."*	X	5 (editorial/ linguistic) Thank you, text will be clarified
Mihai Rotaru - EFPIA	7	154 - 166	EFPIA would like to point out that respect for Personal Data also extends to Individual Patient Data (IPD). Moreover, A JCA process which is designed properly and transparently (including the HTD in the process) does not require IPD, it also seems to breach the fundamental principle of proportionality as it places considerable additional burden on both the HTD and the assessor and co-assessor without any obvious gain. It also seems in breach of the well understood principle of data minimization (as		6a (confidential information – IPD and GDPR)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			foreseen by GDPR).		
Mihai Rotaru - EFPIA	7	146 - 152	The JSC is of greatest value when it is actionable and HTA agencies can align on a consolidated recommendation which allow the HTD to leverage the recommendation to adapt the Clinical Development Plan before the start of the pivotal trials as well as explore alternative approaches to generate relevant evidence beyond RCTs. Advice should not be a list of individual country requirements but should make every effort to align as far as possible on a joint view that facilitates the conduct of a future JCA.		3 (JSC) Many thanks for your comment however the issue raised is not within scope of this deliverable and is covered under the deliverables related to JSC.
Mihai Rotaru - EFPIA	7	127 - 132	To ensure consistency across deliverables, and specific link with D7.1.1 EFPIA recommends that it should be the role of the Secretariat to channel the communication between HTD and HTAs (the Project Manager role can be described as being part of the Secretariat).		4 (Secretariat) *The Project Management role will indeed be described as part of the secretariat in all three sub-deliverables.*
Silke Walleser Autiero Medtronic	7	129 -132	This appears to be a top-down process that doesn't recognize the unique technology knowledge that HTD can provide neither its relevance for the JCA process. it is likely to lead to isunderstandings and poor quality of JCA. As such it will not allow for a fair JCA process for the HTD. Also, how are timely feedback and processes guaranteed if feedback/interactions with HTD need to always be handled through the Secretariat? The example of France demonstrates that interaction between assessors and HTD works and is meaningful: The HTD has a direct contact with the individuals in charge of the HTA for a specific medical device MD but none with the commission members who are voting on the dossier. The process leads to a high quality of interaction and assessment whilst not impacting the independence of those who are voting on the dossier. A direct interaction seems particularly relevant in the PICO process, and an opportunity might be to invite a HTD representative to the scoping meeting. Given the PICO is such a critical		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			component of the JCA it seems counterproductive to a high quality JCA process to exclude HTDs with critical knowledge on the technology and therapy area.		
Roche	7	143-145	It is stated, that the HTD should have no interaction for JSCs or JCAs with national HTAbs unless it is publicly available information. We see this problematic from a member state point of view as early interaction is needed with the local HTAb to plan for local additional JSCs or to get information form the local HTAb if and what type of additional analyses would be needed for national purposes.To have a seamless HTA process across EU and member state level respective interactions are warranted to accelerate patient access as this is the purpose of EU-HTA.These lines should be modified to allow the HTD and the national HTAbs for this kind of interaction.		2c (good administration – interaction national level during JCA/JSC)
Sebastian Werner vfa	7	143-145	*"The HTD is not allowed to communicate directly with Assessors and/or Co-Assessors of JCA or JSC, nor interact with other HTAb about the ongoing JCA or JSC on a European level unless it is publicly available information."* There should be a formal possibility to interact with the assessor/co-assessors, especially in JSC. Direct interactions are possible with EMA in the scientific advice. It would be appropriate to provide similar interaction in JSC. Please clarify this section to allow for this possibility or further justify why this option is excluded.		2c (good administration – interaction national level during JCA/JSC)
Silke Walleser Autiero Medtronic	7	143-145	Can you please confirm and specify this statement. Does it mean HTDs will also not be able to discuss our therapies directly at a local level if a JCA is being performed? Hence HTDs will be forbidden to have direct interaction with HTAb? If this is the case, then it is a major issue for HTDs and those HTAb if there are ongoing local HTA processes and there is a risk that local reimbursement decisions and hence patient access would be		2c (good administration – interaction national level during JCA/JSC)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			delayed.		
Tanja Podkonjak, Takeda	7	130-132	Current text: "HTAb Assessor and Co-Assessor should have no direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat." Proposed text: "HTAb Assessor and Co-Assessor may only interact with the HTD in the presence or copy of the Secretariat." ~~no direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat."~~ Rationale: Forbidding direct interaction between HTDs & HTAb assessors/co-assessors may lead to misinterpretation, misunderstanding and most concerningly potentially incorrect conclusions being drawn which is a risk to patients for the proper and most appropriate use of technologies. Furthermore, by utilising the Secretariat as a 'gatekeeper' for all communication and correspondence between the HTD and HTAb is adding an additional layer which will result in a slower, less reactive, and ultimately less productive process. Takeda encourages the JCA procedures be developed based on the learnings of national HTA agencies and best practices – local processes that have introduced additional layers have resulted in slower processes and misunderstandings meanwhile ones that have enabled interactions, under the proper controls, have improved efficiency. To ensure transparency and an unbiased process, Takeda proposes that the Secretariat facilitate any HTD-HTAb interaction as a standard part of the process so that there is a shared understanding of any data or dialogue that took part in the JCA.		2c (good administration – interaction national level during JCA/JSC)
Tanja Podkonjak,	7	143 - 145	Current text: The HTD is not allowed to communicate directly with Assessors		2c (good administration – interaction national level during JCA/JSC)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Takeda			and/or Co-Assessors of JCA or JSC, nor interact with other HTAb about the ongoing JCA or JSC on a European level unless it is publicly available information. Proposed text: The HTD should only communicate directly with Assessors and/or Co-Assessors of JCA or JCA when facilitated by the Secretariat, with the Secretariat present. Interaction with other HTAb about ongoing JCA or JCA at a European level should not take place unless it is in regards to publically available information. Rationale: Forbidding direct interaction between HTDs & HTAb assessors/co-assessors may lead to misinterpretation, misunderstanding and most concerningly potentially incorrect conclusions being drawn which is a risk to patients for the proper and most appropriate use of technologies.		
Mihai Rotaru - EFPIA	7	139 - 140	EFPIA would like to request that additional clarity be added to this guidance document with respect to the division of responsibilities between the HTD and the EMA when it comes to providing information to the assessor/co-assessor regarding changes to the regulatory timeline. It is our understanding that the separate guidance document, dealing with the interaction/exchange of information with the EMA, would cover exactly this process.		9 (interaction with EMA)
Mihai Rotaru - EFPIA	7	146 - 147	The decision to apply for a national consultation is and should remain a decision of the HTD. The paragraph related to national consultations in the guideline is ambiguous as it can be read as the national consultations are mandatory for products undergoing a JSC.		3a (JSC – national consultations) Clarification added.
Matias Olsen, EUCOPE	7	130-131	While we understand the reasons for limiting the interactions between HTD and the Assessors, and we agree that any interaction should be done in a structured way, we don't agree that no direct communication between HTD and the Assessors is the right approach, as this could give way to misunderstandings and reduce the quality of the assessment.		2d (good administration - Direct interaction with assessor and co-assessor)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Regular interaction with the HTD is a common feature of HTA at Member State level (see for example European Commission, Directorate-General for Health and Food Safety, Chamova, J., Mapping of HTA national organisations, programmes and processes in EU and Norway, Publications Office, 2018, https://data.europa.eu/doi/10.2875/5065), and as pointed out in other comments, was also standard procedure during EUnetHTA JA3. To ensure a successful EU HTA procedure, especially for rare or complex diseases without clear treatment standards throughout the EU at the very least one pre-scheduled interaction meeting must be included in the EU HTA procedure. Replace: "HTAb Assessor and Co-Assessor should have no direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat.". With: "HTAb Assessor and Co-Assessor should have **limited** ~~no~~ direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat. **A PICO meeting will be offered to all HTD to discuss the preparation of the dossier and clarify any potential issues, as part of the JCA/CA process, after the Secretariat informs the HTD of the draft consolidated PICO(s). See 4.2.1** ".		
Sebastian Werner vfa	7	139-140	*"In EUnetHTA 21, the HTD is requested to provide timely information and status updates on the regulatory process, challenges and potential deviations in the regulatory timetable"* The HTAR does not mention that the HTD must proactively communicate challenges within the regulatory process to EU HTA. As this can be classified as commercial in confidence information the sentence should be changed to: *"In EUnetHTA*		6 (confidential information – update on regulatory status)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			21, the HTD is requested to provide timely information and status updates on the regulatory process and potential deviations in the regulatory timetable."		
Sebastian Werner vfa	7	146-147	*For JSC, national consultations must be requested directly from the Member State (MS).* It should be clarified that national consultations must be requested by the HTD in the relevant member state. *"For JSC, national consultations must be requested by HTD in relevant Member State (MS)."*	x	3a (JSC – national consultation)
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	7	143/144	**Comment:** DRAFT GUIDANCE: „*The HTD is not allowed to communicate directly with Assessors and/or Co-Assessors of JCA or JSC, nor interact with other HTAb about the ongoing JCA or JSC on a European level unless it is publicly available information.*" Direct exchange and communication reduces inefficiency and raises accuracy of conversation compared to communication via a third party. As such there is no reason why HTD and Assessor/Co-Assessor should not directly communicate in case of upcoming questions or e.g. missing documents - especially considering the short timelines imposed by the HTAR. Also there may be communication needs with national HTAbs which consider or disclose what was already asked by the HTD at european level or questions to national HTAbs that consider potential outcomes of the JSC / JCA.. To ensure the transparency of communication under HTAR it could be implemented and documented within the IT platform foreseen by Art. 30 HTAR. **Suggestion:** „Any direct communication of the HTD with Assessors and/or Co-Assessors of JCA or JSC must include both Assessor and Co-Assessor and should be endorsed. Assessor and Co-Assessor must also be informed by the HTD on any interaction with other		2d (good administration – direct interaction with assessor and co-assessor)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			HTAb about the ongoing JCA or JSC on a European level. Direct communication under HTAR could be enabled by electronic means using the IT platform foreseen by Art. 30 HTAR."		
Roche	7	Footnote 1	Typo to be corrected, as follows: *"This document is under* ***~~develoSecretariatent~~ development."*** Furthermore, as this document is under development and hence it was not made available for public consultation, for transparency towards external stakeholders, we ask to state when this manual will be publicly available for consultation.	X	5 (editorial/linguistic)
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	7	Footnote 1	**Comment:** DRAFT GUIDANCE: Typo *"…This document is under develo<u>Secretariat</u>ent.*" Probably meant: "development".	x	5 (editorial/linguistic
Dr. Thomas Ecker, Ecker + Ecker GmbH	7	Footnote 1	**Comment:** Change „*develoSecretariatent*" to "*development*".	x	5 (editorial/linguistic
MTE MEMBER	7	130	While we understand that maintaining independence for the assessment is important, there will be instances when the HTD and Assessor/Co-assessor need to communicate directly. This should be reflected within this document		2d (good administration – direct interaction with assessor and co-assessor)
Mihai Rotaru - EFPIA	7	134	EFPIA formally requests that a consultation process be foreseen for the development of the 'JCA manual for HTD'. Clarity should also be provided as to who will develop this manual, who will be responsible for its updates and what will be its role during the HTA Regulation.		10 (consultation on manual for HTD)
Sebastian Werner vfa	7	134	*"For JCA, the HTD is requested to follow the JCA manual for HTD."* The JCA manual for HTD should have been accessible before the consultation of this guidance to allow meaningful feedback.		10 (consultation on manual for HTD) .

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Dr. Thomas Ecker, Ecker + Ecker GmbH	7	130–131, 143–145	**Statement in guideline:** "*HTAb Assessor and Co-Assessor should have no direct interaction with the HTD. Should the HTD reach out to them directly with questions on the EUnetHTA 21 JCA or JSC, the Assessor and Co-Assessor should direct them to the Secretariat.*" *"The HTD is not allowed to communicate directly with Assessors and/or Co-Assessors of JCA or JSC, nor interact with other HTAb about the ongoing JCA or JSC on a European level unless it is publicly available information."* **Comment:** While we agree that interactions between the assessors and HTD should be organised in a structed framework, we would like to highlight the importance of direct communication between the assessors and HTD in order to ensure the best possible quality of the assessment. As already successfully established during EUnetHTA Joint Action 3, regular interactions between HTD and the assessors should be continued. Moreover, these interactions do represent a common feature of HTA at national level (such as consultations on study design and on the appropriate comparator, written statements and oral hearings in the German benefit assessment process) providing the opportunity for a valuable exchange between assessors and HTD. To ensure a successful EU HTA procedure, the possibility for exchange between assessors and HTD should be established as regular part in the overall process.	-	2d (good administration – direct interaction with assessor and co-assessor)
Roche	7	134 and 141	We suggest softening the language related to the JCA manual and JSC procedural guidance, which are not guidelines (see below proposal). Our understanding is that these documents are meant to guide HTDs and provide an	X	5 (editorial/linguistic)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			overview of the JCA and JSC end-to-end processes, including mention of versions of guidelines to be followed and timelines. Proposal: Line 134: ***"For EUnetHTA21 JCAs, a JCA manual will be shared with the HTD with end-to-end procedural guidance (e.g. references to relevant guidelines, timelines, etc.)."*** Line 141: ***"For EUnetHTA21 JSC, the JSC procedural guidance published on EUnetHTA 21 and EMA websites will be shared with the HTD."***		
Mihai Rotaru - EFPIA	7	143 – 145	There should be a formal possibility to interact with the assessor/co-assessor, via the Secretariat, to clarify any questions that come up during the process, to proactively submit new information/data etc.		2d (good administration – direct interaction with assessor and co-assessor)
Silke Walleser Autiero Medtronic	8	157-158/3.1	Study results should not be made public before any formal publication and this should be guaranteed in the process. If there is no guarantee that this will be the case, then it may lead to no submission of such data. Additionally, such data could be commercially sensitive and therefore should not be made publicly available.		6 (confidential information)
Matias Olsen, EUCOPE	8	168-176	The Regulation on health technology assessment (EU) 2021/2282 Article 10 (6) and (7) sets out the obligations of the HTD and establishes the conditions for a discontinued assessment, however there is still a need to clarify, what the consequences of an "incomplete" dossier and "discontinued" procedure are (i.e. regarding assessment of some of the PICO(s) and opportunities for re-submission). Under the same conditions, when an assessment is discontinued, documentation submitted by the HTD (including the dossier and any requested information) shall not be published on the IT platform unless the procedure is concluded and the joint clinical assessment is published, as specified in Regulation (EU) 2021/2282 Article 30 (d). A discontinuation and/or re-submission of a dossier must be		11 (discontinuation – resubmission) *The current text is clear that no submitted information will be published in case of a discontinued JSC or JCA. Therefore, no change is made to the text.*

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			possible without publication of originally submitted documents. This is particularly relevant in case the expected indication or SmPC have materially changed (i.e. label changes) and the PICO(s) deviate considerably from the granted marketing authorisation. In any case, the HTD must be given the option to redact commercial confidential information (e.g. critical clinical study data). The consolidated PICO(s) can be published. Replace: "As soon as the HTD has submitted their draft briefing book (for JSC) or the submission dossier (for JCA), the process cannot be terminated by the HTD. This means the documents submitted by the HTD cannot be withdrawn and the JCA/CA or JSC process will continue also with publication of documents as required for the JCA/CA or JSC procedure. However, the HTD should inform EUnetHTA21 about any changes in the deveoSecretariant plans that might have impact on the ongoing JSC or JCA. In the event the HTD withdraws the product from the regulatory marketing authorisation process, if the HTD goes bankrupt or in case there is a negative outcome of the regulatory process, the JCA will be discontinued. In such event, there is no final JCA report and thus the submission dossier will not be published, however the consolidated PICO will be published." With: "~~As soon as the HTD has submitted their draft briefing book (for JSC) or the submission dossier (for JCA), the process cannot be terminated by the HTD. This means the documents submitted by the HTD cannot be withdrawn and the JCA/CA or JSC process will continue also with publication of documents as required for the JCA/CA or JSC procedure. However, the HTD should inform EUnetHTA21 about any changes in the deveoSecretariant plans that might have impact on the ongoing JSC or JCA. In the event the HTD withdraws the product from the regulatory marketing~~		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			~~authorisation process, if the HTD goes bankrupt or in case there is a negative outcome of the regulatory process, the JCA will be discontinued.~~ **In order to avoid a discontinued assessment, there should be continued communication with designated points of interaction between the HTD and the assessor/co-assessor, the Coordination Group and the European Commission in order to share relevant information and inform about any changes in the development plans. If at any point following the submission of the draft briefing book (for JSC) or the submission dossier (for JCA), the procedure is discontinued**, there is no final JCA report and thus the submission dossier **and other requested information** will not be published, ~~however~~ **and only** the consolidated PICO**(s)** will be published."		
Mihai Rotaru - EFPIA	8	184 - 188	The last sentence of Article 6(6) which provides that the sub-group's scoping process "*shall also take into account input received from patients, clinical and other relevant experts*" should be extended to include "*the health technology provider(s)*". Article 6c(5) provides HTD with the limited right to "*[signal] any purely technical or factual inaccuracies…*" but they "*shall not provide any comments on the results of the draft assessment.*" The absence of any right to comment on the results of the draft assessment arguably falls short of the right to good administration which includes the right to be heard before any individual measure with adverse effect be taken. A violation of the right to be heard will lead to the illegality of the decision taken if there is a possibility that in the absence of the violation the content of the decision would have been different. The fact that the assessment report is not binding does not detract from this because the report is intended to be taken into account by Member States and will affect the HTDs' legal position at that level. The fact that HTDs cannot comment directly at the level of the Coordination Group but must wait for the continuation of the procedure at national level unnecessarily risks divergent outcomes and is a material additional burden on HTDs.		Many thanks for your comment but we consider the issues raised to not be in scope of this deliverable. The text of the regulation is not adjustable at this stage and the issues which relate to the ownership of the deliverables is also out of scope of this deliverable.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			The fact that EUnetHTA21 is a consortium under contract by the European Commission, who will be the owner of the deliverables, does not create any understanding that the respect of due process rights by HTDs should be watered down in any way.		
Silke Walleser Autiero Medtronic	8	184-188	It would be helpful to understand the rationale for why the HTD will not be able to suggest modifications to the consolidated PICO? The HTD will have considerable knowledge to share that would enhance the quality of decisions regarding the PICO (and ideally, as mentioned previously on the scoping process guidance, HTD input would be provided during the PICO process and not only after its consolidation). Given the PICO is such a critical component of the JCA it seems counterproductive to a high quality JCA process to exclude HTDs with critical knowledge on the technology and therapy area.		1 (related to PICO)
Silke Walleser Autiero Medtronic	8	184-188	Can it please be explained why minutes cannot be shared? – As a stakeholder in the process, we request that the HTD should receive the minutes of the meeting.		1 (related to PICO)
Mihai Rotaru - EFPIA	8	163 - 166	The guideline should clearly describe how this process/sequence of steps is foreseen to take place under the HTA Regulation specifically what is the role of the 'JCA manual for HTD'.		10 (consultation on manual for HTD)
Matias Olsen, EUCOPE	8	176-179	Including generic aggregate information could be misleading without also knowing the context and reasons for a "deviation". In order to avoid misunderstandings, this should be avoided whenever it could lead to misinterpretation of the report. Replace: "For a JSC, Only aggregated generic information on JSC can be content of an JCA report, e.g. whether the HTD deviated from the common recommendation of the JSC. No information on product specific questions or national specifications nor the complete content of an advice can be published." With:		3 (JSC) Thank you for your comment. The sentence was modified. However, EUnetHTA 21 is of the opinion that provided information should always be used to increase knowledge and put into context.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			"For a JSC, **no information on product specific questions or national specifications nor the complete content of an advice can be published in the JCA report.** Aggregated generic information on JSC ~~can be content of an JCA report,~~ e.g. whether the HTD deviated from the common recommendation of the JSC, **can only be content of a JCA report if it adds knowledge and will not be misleading without the specific context of the JSC**. ~~No information on product specific questions or national specifications nor the complete content of an advice can be published~~."		
Matias Olsen, EUCOPE	8	184-187	It would, in the interest of developing a robust submission dossier that can support a successful EU HTA procedure, be appropriate if the PICO meeting allows for an open discussion instead of being a one-sided relay of information. Especially for rare diseases and large heterogeneity regarding standards of care between Member States, including use of off-label products, there should be a discussion meeting with the HTD prior to the definition of the final PICO(s). Since the PICO scheme is essential for the assessment, it is also considered to be highly important that the HTD is supplied with written proof of the meeting contents (minutes) to avoid misunderstandings and for later reference. This is especially important if multiple PICOs need to be addressed at once. Recital 12 of Regulation (EU) 2021/2282 states that "Joint work should be produced following the principle of good administrative practice, and it should aim to achieve the highest level of quality, transparency and independence". As we have also stressed in our comments on EUnetHTA 21 deliverable D4.2 "Scoping Guideline", the role of the HTD in the scoping phase needs to be clarified and addressed in the guidance documents. Article 8 (6) of Regulation (EU) 2021/2282, which describes the initiation of the scoping process, states that "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.".		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Article 4 (4) of Regulation (EU) 2021/2282 specifies that the methodology and procedural guidance shall take into account, where appropriate, methodology developed by EUnetHTA Joint Actions. In EUnetHTA JA 3 the PICO was developed with input from the HTD, in the form of a letter of intent, as well as an in-person scoping meeting with the Assessors, before final PICO(s) for the assessment was defined. The guidance document should elaborate on the interactions with the HTD as part of the scoping process and propose a procedure and format for conducting the scoping meeting, and there must be an option for HTD to have a scoping meeting with the Assessors. It is critical that the HTD be invited to a scoping meeting to discuss the draft PICO(s) with the Assessors under the EU HTA procedure and the minutes of the meeting should be recorded. Replace: "If, for JCA in EUnetHTA21, a PICO information meeting is held, such a meeting only serves the purpose to inform the HTD about the consolidated PICO(s), and there is no provision to alter the PICO(s) at this point and no final decision will be taken during the PICO information meeting. No minutes will be published or shared with the HTD after the meeting, nor will the meeting be recorded." With: "~~If, for JCA in EUnetHTA21, a PICO information meeting is held, such a meeting only~~ **An in-person (or alternatively a virtual) PICO meeting will be arranged with the HTD. The meeting** serves the purpose to ~~inform~~ **discuss the draft consolidated PICO(s) with** the HTD ~~about the consolidated PICO(s), and there is no provision to alter the PICO(s) at this point and~~**, however** no final decision will be taken during the PICO ~~information~~ meeting. ~~No~~ **The** minutes will be **taken by the appointed Assessors and** ~~published or~~ shared with the HTD after the meeting **for comments**,		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			to avoid misunderstandings and in accordance with good administrative practice. ~~nor will the~~ **The** meeting **will not** be recorded."		
Sebastian Werner vfa	8	173-176	*"In the event the HTD withdraws the product from the regulatory marketing authorisation process, if the HTD goes bankrupt or in case there is a negative outcome of the regulatory process, the JCA will be discontinued. In such event, there is no final JCA report and thus the submission dossier will not be published, however, the consolidated PICO will be published."* It is unclear for what purpose the consolidated PICO for discontinued JCA should be published. The consolidated PICO of a discontinued JCA should not be published because this may disclose commercial confidential information of the HTD.		11a (confidential information – publication of PICO of discontinued assessment)
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	8	168-171	**Comment:** DRAFT GUIDANCE: "*As soon as the HTD has submitted their draft briefing book (for JSC) or the submission dossier (for JCA), the process cannot be terminated by the HTD. This means the documents submitted by the HTD cannot be withdrawn and the JCA/CA or JSC process will continue also with publication of documents as required for the JCA/CA or JSC procedure.*" Why should an HTD not be able to withdraw his application? There may be a vanished need for a JSC or a decision not to market a product for good reasons. The Guidance foresees and accepts the need for discontinuation for other reaseons, therefore this case as well the HTD must be able to opt out. In any case an opt-out during the JSC of EUnetHTA21 is extremely improbable as HTD will only apply for JSC in this phase for very carefully selected products. **Suggestion**: "*If the HTD withdraws his application for JSC or JCA after he has submitted the draft briefing book (for JSC) or the submission dossier (for JCA), the process is terminated. The documents submitted by the HTD cannot be withdrawn but will not be published like it is foreseen in a regular JCA/CA or JSC*		11 (discontinuation re-submission)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			procedure."		
Roche	8	184-186	As mentioned in a previous consultation, we find this questionable and consider it a violation of the right of the HTD to be heard according to Art. 41 EU-Charta.		1 (related to PICO)
Sebastian Werner vfa	8	184-186	*"If, for JCA in EUnetHTA 21, a PICO information meeting is held, such a meeting only serves the purpose to inform the HTD about the consolidated PICO(s), and there is no provision to alter the PICO(s) at this point and no final decisions will be taken during the PICO information meeting."* A "PICO information meeting" is set up under EUnetHTA21. The guidance does not set up a separate PICO meeting for JCA under der HTAR. However, in both instances the guidance does not give the HTD the possibility to respond and effectively make known their views on the PICO-scope. But it is necessary to give the HTD this possibility to effectively comment and interact on the PICO scope suggested by the HTAb. This would not only follow principle of good administration (Art. 41 EU-Charter) but would also increase the quality of the joint clinical assessment. The vfa strongly recommends establishing a PICO "scoping" meeting with the HTD for JCA under the HTAR. The vfa believes that only with sufficient involvement of the HTD the JCA can aim to achieve the highest level of quality (HTAR, recital 12). The past practice in EUnetHTA assessments and current practice in Germany stand witness of the big advantages such meetings exert of the quality of the work. Further, the implementation of a scoping meeting would be consistent with the HTAR, as scoping meetings with the HTD are permitted. Indeed, the regulation establishes a similar involvement of HTD, patients and clinical experts in the scoping process [Article 8(6)]: *"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."*		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Hence, it is hardly comprehensible how a JCA CSCQ Scoping Meetings is set up for patients and clinical experts but not the HTD (cf. Draft Practical Guideline Scoping Process). The implementation of a PICO "scoping" meeting with the HTD is necessary following the principle of good administrative practice, ensuring quality of the joint work, and given the same opportunities to HTD, patients, clinical experts, and other relevant experts to comment on the PICO scope as foreseen in the HTAR.		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	8	164-166	**Comment:** DRAFT GUIDANCE: *"The manual will be shared with the HTD after they submitted their Letter of Intent and once they have been accepted for a JCA in EUnetHTA 21*." The HTAR in its entirety is built on transparency and consistency. Therefore this is an intransparent and therefore incomprehensible regulation. Like the methods papers of national HTAbs the manual must be publicly available at the HTAb website for information and preparation purposes, especially considering the very short timelines conceded by HTAR/EUnetHTA 21.. **Suggestion**: "*The manual will be publicly available in its current version as well as in consultation versions for updates."*		10 (consultation on manual for HTD) 5 (editorial/linguistic)
Tanja Podkonjak, Takeda	8	163-165	Current text: The manual will be shared with the HTD after they submitted their Letter of Intent and once they have been accepted for a JCA in EUnetHTA 21. Receiving the manual only once a Letter of Intent is submission is very late and will result in unnecessary pressure on the HTD to complete the documents according to the manual and may result in more errors if done in a rush. We strongly advise the manual be published and publically available on the future HTACG website for all manufacturers to review and familiarise themselves with the processes and		10 (consultation on manual for HTD) 5 (editorial/linguistic)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			procedures of the JCA. Understanding the requirements and formats as early as possible will enable a more systematic data colleciton and synethesis process, and better quality submissions with less errors. Once the Horizon Scanning Process, envisioned under the HTA Regulation, is finalised we would also encourage HTD of technologies which have a subimission coming up in the next 12 months automatically receive a notification with a link to the manual.		
Mihai Rotaru - EFPIA	8	155-156	As the EU-HTA assessment will require that the HTD share commercially confidential data for JSC and JCA, confidentiality must be guaranteed, and a confidentiality agreement is necessary. The statement here is also in direct contradiction to D7.1.3 where, on page 5 in line 93-95 it is stated that: "*Any person involved in the preparation of HTA documents or having access to the information must sign a EUnetHTA21 confidentiality agreement (ECA).*" The guidance foresees no such confidentiality agreement between the participating HTD and EUnetHTA 21, neither for a JSC process, nor for a JCA. The authors make it clear that "no confidentiality agreement would be needed" (cf. D7.1.2 Factual accuracy check). However, there are no objective reasons apparent why confidentiality agreements should not be necessary for EUnetHTA21 JCA or JSC pilots, but for the regular JSC and JCA. Confidentiality agreements between HTD and HTAb are always necessary, incl. EUnetHTA21.		6c (confidential information – confidentiality agreement with HTD)
Roche	8	155-156	*"There will be no confidentiality agreement between the participating HTD and EUnetHTA 21, neither for a JSC process, nor for a JCA."* We ask for an explanation of why it doesn't need it and how the Commercially Confidential Information ("CCI") will be effectively protected (see Recital 41). In the absence of a clear confidentiality framework, higher data requirements in		6c (confidential information – confidentiality agreement with HTD)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			the EUnetHTA21 publication documents than in the past for JCA pilots create an unforeseeable risk for companies and patients. HTD should be involved in protecting their Commercial Confidential Information ("CCI") and in developing the confidentiality framework needed. We understand that EUnetHTA21 is contracting with third parties a CDA (so called ECA). A clarification would be useful at this point, otherwise one can get the impression that this is not the case. We as HTD are also concerned that our data will be shared randomly with third parties because they are "somehow" involved in the preparation of the JSC/JCA. The persons with whom it can be shared should be more precisely defined (assessor, co-assessor, one expert, etc.).		
Roche	8	167-168	The EMA/EUnetHTA21 JSC procedural guidance provides a comprehensive description of the JSC process under EUnetHTA21. For the future guidance under the HTAR, it would need to be updated in order to make the key reference points and timelines more explicit. Indeed, in this present guidance, the process starts after the acceptance of the Health Technology by EUnetHTA21 whereas page 10 of the EMA/EUnetHTA21 JSC procedural guidance refers to the entire procedure lasting approximately 3.5 months starting from the receipt of the draft briefing book. Also, in the EMA/EUnetHTA21 JCS procedural guidance, a D0 time point is mentioned without being defined.		3b (JSC – update to procedural guidance) Thank you, the comment will be taken into consideration for the next revision. D0 is the start of the procedure with the submission of the final briefing book.
Roche	8	172-173	Typo to be corrected, as follows: *"However, the HTD should inform EUnetHTA 21 about any changes in the* ***~~develo~~Secretariatent~~~~development.*** *plans that might have an impact on the ongoing JSC or JCA.*	X	5 (editorial/linguistic)
Roche	8	169-170	For JCAs and JSCs conducted under EUnetHTA 21, for which HTAR does not yet apply, HTD must be allowed to withdraw them at any time and justification can be provided on a voluntary basis; in these cases, no documents must be published related to the withdrawn procedures. For future JSC under HTAR, as it is a voluntary procedure,		11 (discontinuation- resubmission)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			HTD must be allowed to withdraw at any time, with justification on a voluntary basis and no documents must be published. Requests for advices submitted in Germany to the G-BA e.g. can be withdrawn at any time and no documents or PICOs will be published.		
Matias Olsen, EUCOPE	8	155-156	Confidentiality, especially for Joint Scientific Consultation, where ongoing clinical trials are to be discussed is essential, and the way that confidentiality is maintained needs to be communicated in a transparent and clear manner before the start of any such process. It also needs to be guaranteed that all commercially sensitive in-confidence information is maintained confidential, i.e. the submission dossier cannot be published in full (especially relating to unpublished scientific and/or commercial in confidence information) The HTD needs to have opportunity to mark certain information as commercial in confidence (see also EMA EPAR publication process where HTD checks confidentiality before publication).		6 (confidential information (related to D7.1.3))
Sebastian Werner vfa	8	177-178	*"For a JSC, only aggregated generic information on JSC can be content of an JCA report, e.g. whether the HTD deviated from the common recommendation of the JSC."* In accordance with the HTAR, only anonymized, aggregated, non-confidential summary information on joint scientific consultations is allowed to be published on the IT platform (Article 30 para. 3 (k)). Further, the dossier of the HTD should comprise the explanation from the HTD on any deviation from the recommended evidence if a health technology has been subject to a joint scientific consultation (Annex 1 (e)). The guidance is unclear about why "*aggregated generic information on JSC can be content of an JCA report".* Information about JSC can be only published as anonymized, aggregated, non-confidential summary information on the IT platform but not as part of the JCA. The JCA contains individual, non-aggregated information about the JSC as part of the dossier or the JCA report. Aggregated generic information on JSC should be excluded from the JCA report.		6d (confidential information – JSC info in JCA) Thank you – we have made minor modifications to the text to improve clarity.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Due to their confidential and non-binding nature, the JSC must remain confidential. Hence only information about the existence of a JSC for the health technology should be disclosed. The explicit JSC recommendations must not be published. Further, information of the HTD to explain deviations from the recommendation might be commercially sensitive, in a competitive drug development environment. This might include methodological aspects of the study design and analyses in the developmental plan that are considered trade secrets by the EMA definition (cf. line 150, D7.1.3 – guidance on handling commercially in-confidence data). Thus, the HTD should have the general possibility to mark section 1.3 of the submission dossier as "commercial confidential" (cf. Submission Dossier Guidance).		
Silke Walleser Autiero Medtronic	8	189-190	In the HTAR, it is not mentioned that the final submission dossier should be published therefore we do not believe it to be consistent or appropriate here. As mentioned in a previous consultation, publication of the submission dossier is problematic for HTDs in particular for early innovative devices, as it could provide a lot of sensitive information to competition.		12 (publication of submission dossier)
Tanja Podkonjak, Takeda	8	155-156	Current text: There will be no confidentiality agreement between the participating HTD and EUnetHTA 21, neither for a JSC process, nor for a JCA. As the contents of the JSC are fully confidential (briefing book, trial protocols, development plans, and advice book), it is unclear why EUnetHTA-21 does not forsee a confidentiality agreement being required? This is commercially sensitive data, which is not publically available, and if dislosed could have significant commerical and anti-competitive consequences. Takeda requests this sentence be removed or re-written to include a confidentiality agreement for any parties involved in a JSC. Furthermore, the intended label of a medicine undergoing regulatory review is confidential and is also a significant commerical risk if it is dislosed to the public prior to the final marketing authorisation being received. In this circumstance, any		6c (confidential information – confidentiality agreement with HTD)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			assessors, external experts (patient, clinical or technical) or stakeholders should also be required to sign a confidentality agreement.		
Tanja Podkonjak, Takeda	8	168-169	Current text: "As soon as the HTD has submitted their draft briefing book (for JSC) or the submission dossier (for JCA), the process cannot be terminated by the HTD." It is unclear the rationale of why the procedure for a JCA/JSC cannot be paused or stopped once they have begun. Development plans, particularly in early stages where a JSC would take place, are dynamic to respond to the evolving treatment discovery of competitors and information from the clinical programs. It is common for changes in timelines and development plans to occur in this stage – not allowing a pause or a termination in the event of a change would result in a redundant process that would use public resources without any useful yield or impact on patient access. Likewise, the JCA procedure should have a mechanism built in to be able to deal with any material change in the regulatory review process resulting in a label change, pause, delay or withdrawal of the regulatory submission. We suggest a "pause" option or mechanism be developed for JSC and JCAs which can be used for major reasons such as key new data/information becoming available that would have an impact of the research question or PICOS. This is for optimal use of resources from all parties and to avoid having to undergo another, separate JCA/JSC or, worse, having a resulting report that is outdated and potentially misleading despite new, better data being available to guide patient care.		11 (discontinuation – resubmission)
Tanja Podkonjak, Takeda	8	177-178	Current text: "Only aggregated generic information on JSC can be content of an JCA report, e.g., whether the HTD deviated from the common recommendation of the JSC" Any recommendations from JSC and the action resulting from		6d (confidential information – JSC info in JCA)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			them should remain redacted this is commercially confidential data. The advice, proposals and ultimate decisions on the technology data will disclose development plan and strategies of patented protected medicines and potentially the HTD overall research and development strategy which should not be disclosed to the public. Furthermore, it is likely that multiple recommendations will result from JSC, and it is not clear how this can be presented in an "aggregated generic" way in the context of whether the HTD did or did not follow individual recommendations. We request this sentence be removed or reworded.		
Tanja Podkonjak, Takeda	8	186-187	Current text on the PICO meeting: No minutes will be published or shared with the HTD after the meeting, nor will the meeting be recorded. Takeda would like to re-iterate the importance of having an inclusive process to ensure a representative and efficient assessment. Therefore, we strongly recommend the PICO meeting include key stakeholders which include patient and clinical experts and the HTD. If this is not possible, at a minimum the minutes of the PICO meeting must be shared with the HTD. This transparency will enable more efficiency in preparing the dossier and allow the HTD to understand the likely needs of individual MS for any complimentary data. The latter is critical to preparation of analyses, more complete dossiers, and ultimately faster time to access for patients. It is not clear to Takeda what the rationale is from EUnetHTA-21 to not disclose the minutes of the PICO meeting to the stakeholders in process. Please amend this section or provide justification for this lack of transparency.		1 (related to PICO)
Norbert Gerbsch for IGES Institut	8	184/187	**Comment:** DRAFT GUIDANCE: "*If, for JCA in EUnetHTA 21, a PICO information meeting is held, such a meeting only serves the*		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
GmbH and HealthEcon AG			*purpose to inform the HTD about the consolidated PICO(s), and there is no provision to alter the PICO(s) at this point and no final decisions will be taken during the PICO information meeting. No minutes will be published or shared with the HTD after the meeting, nor will the meeting be recorded*." Are the PICOs disclosed to the HTD not final then? As "there is no provision to alter the PICO(S) at this point" (line 185) this seems to be a final decision. If no minutes are taken and shared, does the HTD note down the PICOs himself? How can the HTD adress and document a potential disagreement with the PICOs if there are no minutes? The draft guidance states that the consolidated PICOs are published anyway. Given the transparent approach of EUnetHTA21 and HTAR this intransparency on the PICO meeting is rather irritating. Furthernore, the HTD should be given the opportunity to discuss any questions that may arise during the PICO information meeting. When minutes are provided, the HTD should have the chance to clarify any potential misunderstandings. **Suggestion**: The PICO information meeting is held as an open discussion that allows for clarifying questions from the HTD. Minutes of the PICO meeting will be shared with the HTD within 10 days after the meeting for review and comments."		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	8	148/149	**Comment:** DRAFT GUIDANCE: "*Duplicated full scientific consultations at the national level (similar questions for the JSC and the national advice) are not foreseen according to the HTAR provisions.*" This is fine if there is sufficient capacity on european level to provide JSC. This will most likely not occur, as is demonstrated by a comparison between the number of early consultations provided by the G-BA in Germany (292 in 2021 acc. to the G-BA business report 2021) and the 25 JSCs per year estimated by the european commission demonstrating a gap in the magnitude of a factor of larger than ten! Such the capacity for JSC must be		3a (JSC – national consultations)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			dramatically increased on EU level or the HTD must be allowed to submit parallel requests for scientific consultations. Otherwise an alternative for JSC requests - that cannot be fulfilled on european level - must be implemented. E.g. bi- or trinational consultations on national level that are equally accepted on european level. It is acknowledged that EUnetHTA21 cannot make any commitments in guidance documents. But as the lack of capacity for JSC is obvious and common sense in the HTA community, EUnetHTA21 may be in the position to describe the need to improve the situation. **Suggestion**:: "*Duplicated full scientific consultations at the national level (similar questions for the JSC and the national advice) are not foreseen according to the HTAR provisions.* ***If requests for JSC per year cannot be satisfied by HTAb on european level, alternatives need to be implemented and acknowledged as equivalent to JSCs on european level such as bi- or multinational JSCs agreed with national HTAbs.*****"**		
MTE MEMBER	8	155	There should be a confidentiality agreement in place whenever information is being exchanged		6c (confidential information – confidentiality agreement with HTD)
MTE MEMBER	8	158	It is vital that HTD are able to mark confidential information as academic-in-confidence or commercial-in-confidence, which is then redacted within any published material		6 (confidential information)
Mihai Rotaru - EFPIA	8	162	In the 'process' flow chart, last step 'after', the assessor/co-assessor should also provide a justification as to how they have determined a certain comment from the HTD relates to a factual check or not.		2a (fact check)
Roche	8	163	*"For JCA, the HTD should follow the JCA Manual for HTD. This manual is binding…* The JCA Manual for HTD is not mentioned anywhere in the HTAR and our understanding is that the manual per se is not binding but the guidelines, templates, tools are. Therefore, we suggest rephrasing as follows: "*This manual* ***~~is binding and~~*** *describes which (version of the) tools, templates, guidelines etc.* ***are binding*** *to* ***~~be used~~***		10 (consultation on manual for HTD)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			~~during~~ *the JCA."* Furthermore, this manual is currently under development by the EUnetHTA secretariat and hence it was not made available for public consultation. For transparency towards external stakeholders, EUnetHTA21 JCA secretariat should state when this manual will be publicly available for consultation.		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	8	172	**Comment:** DRAFT GUIDANCE: Typo "…about any changes in the develoSecretariatent plans.."	x	5 (editorial/linguistic)
Dr. Thomas Ecker, Ecker + Ecker GmbH	8	172	**Comment:** Change „*develoSecretariatent*" to "*development*".	x	5 (editorial/linguistic
Roche	8	176	It is described in case there is no final JCA report and no submission dossier published, a consolidated PICO will be published. As this might affect confidential commercial information the HTD should be consulted before publication.		11a (discontinuations – publication of PICO of discontinued assessment)
Tanja Podkonjak, Takeda	8	176	Current text: In such event, there is no final JCA report and thus the submission dossier will not be published, however, the consolidated PICO will be published. Proposed text: In such event, there is no final JCA report and thus the submission dossier will not be published.~~, however, the consolidated PICO will be published.~~ Rationale: If the dossier is withdrawn, there should be no publication of any material, including the consolidated PICO. The PICO will have information on the population and therefore the anticipated technology indication which is commercially sensitive information		11a (discontinuations – publication of PICO of discontinued assessment)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			– even if the regulatory submission is withdrawn, this information remains sensitive and should not be publicly disclosed		
Roche	8	177	‘’*For a JSC, only aggregated generic information on JSC can be content of an JCA report*” As aggregated generic information on JSC is not specific enough as description, we suggest that, as stated in the Regulation, the HTD flags which elements are confidential.		6d (confidential information - JSC info in JCA)
Roche	8	178	We think this information is not necessary for the joint clinical assessment. The outcome of the joint scientific consultation is not legally binding and the HTD has therefore the liberty to deviate. Not the rationale for the deviation is eventually of relevance but the outcome which should be considered in a non-biased manner.		6d (confidential information - JSC info in JCA)
Roche	8	180	For EUnetHTA21 it is said that all documents submitted by the HTD will be stored internally on SharePoint. No further information on data security is given. Adequate technical and organisational measures must be put in place by the platform owner to prevent, detect and address any potential security incidents, including personal data breaches.		13 (security of data storage)
MTE MEMBER	8	180	For EUnetHTA21 it is said that all documents submitted by the HTD will be stored internally on SharePoint. We would welcome how adequate technical and organisational measures will be put in place by the platform owner to prevent, detect and address any potential security incidents, including personal data breaches and limit access to those in need not all CEB members		13 (security of data storage)
MTE MEMBER	8	184	What is the purpose of a meeting on PICO if in the end the PICO(s) will not further reflect reality by adjusting initial PICO following discussion with HTD. This weakens the process to address the complexity of PICO consolidation and as such the potential impact of the deliverable		1 (related to PICO) --> scoping meeting
MTE MEMBER	8	189	‘*Both in EUnetHTA 21 as in the HTAR, the final submission dossier (for JCA) will be published together with the final JCA report.*’ Suggest to please add confirmation that information labelled as commercial-in-confidence by the HTD will be redacted from the original submission dossier.		12a (publication of submission dossier - redaction of confidential info)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	8	168 – 169	There are legitimate reasons for which an HTD may choose to withdraw its request for JSC (e.g. change in strategy, no longer intended for EU market etc.). The HTA Regulation is silent as to whether or not a JSC request can be withdrawn and what are the consequences of such a withdrawal. As such, it should be possible for the HTD to withdraw from the JSC process at any time, and the confidentiality of the documentation should be maintained at all times in this case. The voluntary nature of the JSC cannot create the same legal effects on the process/outputs as the mandatory nature of the participation in the JCA.		11 (discontinuation)
Dr. Thomas Ecker, Ecker + Ecker GmbH	8	184–187	**Statement in guideline:** "*If, for JCA in EUnetHTA 21, a PICO information meeting is held, such a meeting only serves the purpose to inform the HTD about the consolidated PICO(s), and there is no provision to alter the PICO(s) at this point and no final decisions will be taken during the PICO information meeting. No minutes will be published or shared with the HTD after the meeting, nor will the meeting be recorded.*" **Comment:** A PICO meeting, as established within EUnetHTA Joint Action 3, should be incorporated into JCA. Importantly, these meetings should enable the opportunity to exchange information and discuss unclear aspects with regard to the suggested PICO(s). Additionally, since the consolidated PICO scheme is essential for the HTA, minutes of these meetings should be recorded and shared with the HTD.	-	1 (related to PICO)
Mihai Rotaru - EFPIA	9	206-212	*Transparent information, public awareness of the process and sharing data on methodology and on clinical data is in the public interest. Therefore, these data will be generally considered as non-confidential.*		6 (confidential information (related to D7.1.3)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			This statement violates the right of pharmaceutical companies for protection of their trade secrets that are legally protected by Directive EU 2016/943. Development plans of companies, that are shared with the HTAb in the context of JSC often contain methodological aspects of the study design and analyses. These are commercially confidential information as acknowledged by the EMA definition (cf. line 150 of the Guidance). Sharing methodological aspects of developmental plans in the name of public interests is not admissible. EUnetHTA21 must make clear that methodological aspects cannot be generally designated as non-confidential in the context of JSC. It is important to clarify that methodological aspects cannot be generally considered as non-confidential, as in the context of JSC these must be classified as commercially confidential information.		
Sebastian Werner vfa	9	193-195	*"Both in EUnetHTA 21 as in the HTAR, comments provided by the HTD during a factual accuracy check of the final draft JCA report will be made publicly available, together with the Assessor and Co-Assessor answers to the comments, once the final JCA report is published."* The process of the factual check of the HTD lacks a meaningful interaction between health technology developer (HTD) and the assessors of the health technology assessment bodies (HTAb). Answers of the assessors and co-assessors to the HTD's factual check are published with the joint clinical assessment (JCA) report without the possibility of the HTD to effectively make known their views on the answers and classifications of the factual check (factual vs. not). However, it should be possible for the HTD to effectively make known their views on answers and classifications that are subject matter of this process. The vfa believes that only with sufficient involvement of the HTD the JCA can aim to achieve the highest level of quality (HTAR, recital 12). The vfa recommends establishing a process by which the HTD can effectively respond to the answers and classifications of the factual check of the assessors of the HTAb with a subsequent exchange on unresolved issues.		2a (good administration – fact check)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	9	191 - 192	EFPIA believes that the re-use of the JCA report at national level under EUnetHTA21 should be more than just strongly encouraged. The efforts of both parties (HTDs and HTAs) in undertaking a pilot under the EUnetHTA21 framework will be simply wasted if no effort is made at national level to also develop a more granular understanding of how the future JCA outputs (submission dossier & JCA report) can be integrated in the national processes. The JCA pilot should provide the opportunity for Member States to track what are the barriers for their re-use in the national setting.		14 (re-use of JCA)
Roche	9	Figure 4.1 Process for JSCs	In this process description the possibility for the HTD after having received the final recommendations for JSC to object e.g. in case something is missing or not appropriately worded or not reflecting specific circumstances. This would be necessary to add in order to ensure procedurally fair processes and in particular the right to be heard for the HTD.		2e (good administration – hearing after JSC or JCA)
Mihai Rotaru - EFPIA	9	180	EFPIA would like to point out that 5 calendar days are not enough to provide for a properly documented/referenced response to the factual check process. The maximal duration for the factual accuracy check of the HTD to is 5 "calendar days". This duration is reduced by possible weekend days or bank holidays. The duration should be determined according to "working or active days". We recommend increasing the duration to 7 working days. Moreover, the guideline fails to justify how the CSCQ has reached the recommendation that this procedural step should take only 5 working days.		2b (good administration – time window)
MTE MEMBER	9	194	HTD comments made during the factual accuracy check should have the option to mark confidential information as academic-in-confidence or commercial-in-confidence, which is then redacted within any published material		2 (good administration – fact check)
Mihai Rotaru	9	208	If the guideline will impose a deadline for the HTD to respond to		2 (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
- EFPIA			the factual check, then the same deadline should be mirrored for the assessor/co-assessor to provide written answers to the questions received.		
Mihai Rotaru - EFPIA	10	255-261	*"The HTD shall signal any information it considers to be confidential and justify its commercially sensitive nature when they submit the submission dossier and during the factual accuracy check of the JCA report. The HTD must submit a written objection to the publication prior to the deadline of the factual accuracy check. The comments will be discussed within EUnetHTA 21 (CSCQ, assessor and co-assessor). In case of a differing opinion to the HTD's opinion, the HTD will be informed prior to publication."* Commercially in confidence data designated by the HTD might be published without given the HTD the possibility to respond to the divergent opinions expressed by the HTAb regarding their classification. Without this possibility, the guidance is not aligned with the principle of fair trial (Art. 47 EU-Charter). In case of the publication of confidential information, the damage to the HTD is irretrievable. The HTD must be provided with the possibility to effectively make known their views on the opinions of the HTAb assessors regarding commercial in confidence. A process must be established by which the HTD can effectively respond to the opinions of the HTAb which should include a conflict resolution mechanism for cases where different opinions between the HTD and the assessors of the HTAb persist. To avoid these issues the process should also include a conflict resolution mechanism for final declaration of commercial in confidence information to ensure that no confidential information is published.		6 (confidential information (related to D7.1.3))
Sebastian Werner vfa	10	206-212	*"Under the HTAR, it is envisaged that the Coordination Group shall publish the dates of request periods and state the planned number of JSCs for each of those request periods on the IT platform referred to in Article 30. At the end of each request period, where the number of eligible requests exceeds the number of planned JSCs, the Coordination Group shall select the*		3c (JSC – capacity)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			health technologies that are to be subject to JSCs, ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3)).” Scientific consultations are paramount for ensuring that the evidence provided by HTD meets the needs of regulators and HTAb. An early and intensive exchange of regulators, HTAb and HTD in Joint Scientific Consultations parallel with the scientific EMA advice can facilitate drug development and improve patient access. For these opportunities to be realized, sufficient capacity must be provided to ensure that all technology developers seeking guidance will have access to it. Currently, however, HTD requests for JSCs may be rejected based on certain criteria if the capacity provided by the Coordination Group is insufficient (HTAR Art. 17 para. 3). Restricting the access of HTD to joint scientific consultations due to capacity limitations is not compatible with European primary law, under Art. 41 (principle of good administration) and Art. 20/21 (principle of equality before the law/non-discrimination) of the EU Charter. Joint scientific consultations constitute an integral part of the right to be heard (Art 41 para. 2 EU-Charter). These procedural guarantees apply to everyone, which is why a link to existing capacities and further distinctions regarding the importance or other individual characteristics of the applicant are inadmissible. Granting this right only to a select group while denying it to others is contrary to the law. It is therefore crucial that sufficient capacity is created to prevent HTD request rejections. Until then, the number of joint clinical assessments (JCA) must be adjusted to the number or capacity for JSCs. Legal action against the rejection of HTD requests for JSCs are possible at the national level and are considered promising for the pharmaceutical companies (Clifford Chance, 2022) The vfa strongly recommends that sufficient capacity be made available to ensure access for all technology developers seeking		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			advice in joint scientific consultations. ▪ Clifford Chance (01.04.2022): Memorandum "No discrimination on requests for Joint Scientific Consultations under Regulation (EU) 2021/2282" ▪ Reese, U. (2022) Zum Anspruch auf gemeinsame wissenschaftliche Beratungen gemäß der Verordnung (EU) 2021/2282, PharmR 2022, 434		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	10	208-211	**Comment:** DRAFT GUIDANCE: "*At the end of each request period, where the number of eligible requests exceeds the number of planned JSCs, the Coordination Group shall select the health technologies that are to be subject to JSCs, ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3))*." Denying a JSC due to missing capacities is contradictory to the whole EUnetHTA 21 process of aligning consultation and HTA procedures on european level. Also see comments on line 148/149 **Suggestion**: *„In each request period, when it becomes forseeable that the number of eligible requests exceeds the number of planned JSCs, the Coordination Group shall select the health technologies that are to be subject to JSCs, ensuring the equal treatment of requests concerning all health technologies. The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3)). For requests that cannot be satisfied on european level, bi- or multinational JSCs agreed with national HTAbs are acknowledged as equivalent to JSCs on european level."*		3c (JSC – capacity)
Tanja Podkonjak,	10	216 - 218	Current text: "At the end of each request period, the CSCQ select eligible	X	3c (JSC – capacity)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Takeda			applications which will be subject to JSC. The criteria for selecting eligible requests are publicly available 3 and are based on the criteria outlined in the HTAR and supplemented with additional prioritisation criteria for EUnetHTA 2." Rationale: The first sentence may have a typo: "At the end of each request period, the CSCQ **will** select eligible applications which will be subject to JSC." Furthermore, the second sentence references supplemental prioritisation for EUnetHTA-21. We request these additional criteria be specified and clearly stated in this document for completion and transparency.		
Roche	10	208-209	Under the HTAR, the Coordination group should be open to receive JSC requests at any time and so create the appropriate number of slots to allow for ALL needed JSC AND follow-up advices AND PLEG consultations. There should be a commitment from the European Commission and the HTAb from the member states to provide adequate resources for JSC under the HTAR. Besides that a procedure should be in place to allow capability building for HTAb currently not running JCS.		3c (JSC – capacity)
Roche	10	211-212	We consider the criteria set out by Art. 17 (3) as not compatible with the procedural principle of non-discrimenation under Art. 41 EU-Charter.		3c (JSC – capacity)
Mihai Rotaru - EFPIA	10	200	Figure 4-1 would be more informative with timelines.		3c (JSC)
Tanja Podkonjak, Takeda	10	211	"The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3))." For clarify and ease of use, Takeda recommends that the criteria for JSC selection be re-specified in this guidance. Furthermore, we request EUnetHTA specify whether the crietira are cumulative.		3c (JSC)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Roche	10	219	The additional criteria from EUnetHTA21 should be integrated in this guidance document.		3c (JSC)
Mihai Rotaru - EFPIA	10	206 – 212	The guideline implies that there will always be a mismatch between the demand for JSC and the capacity available for the Coordination Group. While EFPIA deplores the situation currently unfolding today under EUnetHTA21, we would like to stress that recourse to the selection criteria mentioned in the HTA R should be the exceptional situation rather than the rule. There should be a clear political willingness to properly resource the future system and a strategy should be put in place for building capability within the network for a pool of experienced JSC assessors and co-assessors given that many HTA agencies may not have been able to participate in scientific advice in the past.		3c (JSC – capacity)
Dr. Thomas Ecker, Ecker + Ecker GmbH	10	206–212	**Statement in guideline:** *"Under the HTAR, it is envisaged that the Coordination Group shall publish the dates of request periods and state the planned number of JSCs for each of those request periods on the IT platform referred to in Article 30. At the end of each request period, where the number of eligible requests exceeds the number of planned JSCs, the Coordination Group shall select the health technologies that are to be subject to JSCs, ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices are outlined in the HTAR (Art. 17 (3))."* **Comment:** While we appreciate the possibility of JSC, both the limited number of JSC as well as the restriction of JSC to "eligible" requests are considered as problematic from our point of view. It must be	-	3c (JSC – capacity)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			ensured that a sufficient number of JSCs are available for HTD in order to enable the best possible quality of submitted dossiers. Moreover, as currently stated, requests will only be possible during specific request periods. However, from our point of view, requests for JSC should always be possible, regardless of the certain request periods.		
Sebastian Werner vfa	11	246-252	*"The HTD sends the F2F meeting minutes to the JSC secretariat. The meeting minutes will only serve as a tool of record and will not be commented on by EUnetHTA 21, nor will they be included in the final recommendations" [...] After the F2F meeting the HTD can expect the final written recommendations according to the timelines in the procedure for JSC"* Minutes are a very important tool to create a common understanding about contents and possible conclusions of the F2F meeting on JSC. However, minutes that are not endorsed by HTAb have very limited value for the HTD and the process in general. Further, the HTD has no possibility to respond to the subsequently delivered written recommendation of the HTAb. In Germany, a proven procedure takes interests of HTA and HTAb into account and ensuring a high quality of the outcome documents and the process in general: 1. F2F meeting is conducted with minutes that are endorsed by HTAb 2. The HTAb sends a written prefinal recommendation to the HTD. 3. The HTD has ten working days to submit an answer to HTAb to clarify statements. 4. The HTAb clarifies the statements or initiates an additional short exchange on unclarified points 5. The HTAb delivers the final recommendation to the HTD.		3d (JSC – minutes)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			The vfa recommends establishing a JSC process with a possibility for the HTD to respond and effectively make known their views on the HTAb recommendations. The vfa recommends developing a process like the German example which is well-proven. A similar process should be installed for the scoping meeting ensuring the sufficient interaction between HTD and HTAb on the PICO scope.		
Matias Olsen, EUCOPE	11	226-231	In this section, the basic structure of the Briefing Book should be presented in detail, indicating what content is considered most relevant and the best way to present it in order to minimize the clarifications requested on the briefing book and the F2F deck after review.		3 (JSC)
Silke Walleser Autiero Medtronic	11	226-231	Regarding the briefing book:a template would be really helpful for this.		3 (JSC)
Mihai Rotaru - EFPIA	11	247-249	*The HTD sends the F2F meeting minutes to the JSC secretariat. The meeting minutes will only serve as a tool of record and will not be commented on by EUnetHTA 21, nor will they be included in the final recommendations.* Minutes are a very important tool to create a common understanding about contents and possible conclusions of the F2F meeting on JSC. However, minutes that are not endorsed by HTAb have very limited value for the HTD and the process in general. Further, the HTD has no possibility to respond to the subsequently delivered written recommendation of the HTAb. It is important to establish a JSC process with a possibility for the HTD to respond and effectively make known their views on the HTAb recommendations.		3d (JSC – minutes)
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	11	247-249	**Comment:** DRAFT GUIDANCE: "*The HTD sends the F2F meeting minutes to the JSC secretariat. The meeting minutes will only serve as a tool of record and will not be commented on by EUnetHTA 21, nor will they be included in the final recommendations.*"		3d (JSC – minutes)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Under those circumstances there is no value in taking minutes. **Suggestion**: **"***The HTD sends the F2F meeting minutes to the JSC secretariat. The meeting minutes will* ***be commented by EUnetHTA 21 and will be finally aligned between HTD and EUnetHTA21 to document the discussion****."*		
Silke Walleser Autiero Medtronic	11	242-244	EMA is not applicable for medical devices; could this please be corrected in the text.		5 (editorial/linguistic)
Matias Olsen, EUCOPE	11	244-245	The meeting minutes should be supplied by the HTA bodies instead of the HTD to avoid misunderstandings and for future reference. It is important that both parties have agreed on the meeting discussion. Replace: "The HTD has to take meeting minutes" With: "The ~~HTD has to~~ **HTA bodies will** take meeting minutes **and share this with the HTD for review and comment**."		3d (JSC – minutes)
Tanja Podkonjak, Takeda	11	225	Selection of products for JSC: For technologies which were not selected for a JSC, would it be possible to have an alternate option to receive early advice or a "plan B"? One possibility would be eligibility for a future slot or a streamlined procedure which only has written recommendations and not a full meeting. We are concerned about the impact on the development plans and the competitiveness of technologies which did not have the opportunity to receive advice vs their counterparts that did undergo JSC. We encourage exploration of options to enable all technologies to undergo JSC, should they request it. The current selection process for a JSC as described is static and		3c (JSC - capacity)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			is at odds with the highly dynamic nature of drug development. To be of most use and have the best influence on the development of future technologies, the future JSC process must be flexible and take into account the dynamic nature of drug development and their changing timelines. To improve the current proposed we recommend the following: •Options of pausing the procedure in case of material changes •Alternatives to receive streamlined advice in less depth, with shorter timelines •Adequate JSC advice slots so all technologies have the opportunity to receive advice. Takeda encourages dialogue with all stakeholders, including industry on mechanisms to fund this expanded program.		
Tanja Podkonjak, Takeda	11	Line 227 Line 240 Line 247 Line 268	Throughout section 4.1, timelines for procedures are mentioned however the not specified directly but instead the guideline refers to other documents. We recommend the guideline fully re-specify any deadlines mentioned, either in text or as an appendix. This would improve clarity of the guidance document and make it easier for the end use to understand and implement the procedure.		2b (good administration – time window) 3c JSC procedure
MTE Member	11	232	Timelines are missing on all processes – should possible stop the clock be foresee for to manage unforeseen complications.		2b (good administration – time window) 3c JSC procedure
Sebastian Werner vfa	11	235	Approximately 30 days after submission of the final Briefing book the JSC secretariat will share the EUnetHTA 21 List of issues and the template for Applicant's Written Response, with the HTD. The imprecision of the process is not desirable. HTD need reliability for their planning process.		2b (good administration – time window) 3c JSC procedure
Tanja Podkonjak, Takeda	11	238	Current text: "The HTD has to provide all introduced changes in a table format and to provide answers to "Issues to be addressed in writing only" **ato** the JSC secretariat."	x	5 (editorial/linguistic)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Typo		
Tanja Podkonjak, Takeda	11	240	Current text: "The HTD has to submit the slides that will be presented during the F2F meeting. ." Typo – two periods	x	5 (editorial/linguistic
Tanja Podkonjak, Takeda	11	244	Section 4.1.3. suggest that HTDs will take and prepare minutes of JSC meetings however, these will have no bearing on the final recommendation. If the minutes are complete and appropriately express the discussion in a fair, accurate and balanced way, it is unclear why these are not included in the final recommendation. We recommend this section be modified to include the JSC meeting minutes in the JSC report as an appendix and be considered in the final JSC advice.		3d (JSC – minutes)
Mihai Rotaru - EFPIA	11	246	The process should also allow for a follow-up meeting to deal with circumstances where new findings from the clinical development program require reconsideration of the advice received in the first meeting.		2d (good administration – hearing after **JSC** or JCA) 3c JSC procedure
MTE MEMBER	11	251	'*After the F2F meeting the HTD can expect the final written recommendations according to the timelines in the procedure for JSC.'* Please specify the actual timeline, to avoid reference within what is intended to be the reference document.		2b (good administration – time window) 3c JSC procedure
	11	224–225	**Statement in guideline:** "*Where a request for JSC was refused, the HTD will be informed thereof and the reasons explained."* **Comment:** Within the guideline, it should be specified what happens if a medicinal product is not selected for a JSC. Are these medicinal products supposed to undergo numerous consultations on national level instead?	-	3 (JSC - capacity)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	11	239 – 245	The meeting format should allow an efficient and constructive discussion of all the key scientific questions. The meeting co-chairs should ensure all the meeting objectives are achieved and encourage balanced involvement from all the participants.		3c JSC procedure
Sebastian Werner vfa	12	266-272	*"During EUnetHTA 21, the HTD is expected to submit a signed Letter of Intent, in which they indicate their intent to participate in a JCA. [...]* *A Letter of Intent is not foreseen under the HTA Regulation."* It should be specified how the Scoping Process starts with JCA under the HTAR as there is no letter of intent foreseen. In 4.2 (Scoping Process) the submission of a request for assessment is mentioned. This interaction is missing in 7.1.		14b (scoping process and initiation of JCA)
Matias Olsen, EUCOPE	12	257-259	The scoping meeting is considered to be a vital part of the scoping process and it is crucial that this is also implemented under the new EU HTA procedure. Replace: "Initiation of a JCA/CA scoping phase – HTD may attend PICO information meeting (EUnetHTA 21 only)" With: "Initiation of a JCA/CA scoping phase – HTD ~~may~~ **is invited to** attend **in-person (or virtual)** PICO ~~information~~ meeting ~~(EUnetHTA 21 only)"~~		1 (related to PICO) --> scoping meeting
Roche	12	258-260, Figure 4-2	Typo to be corrected, as follows, on the second bullet point: *"Project Manager to in~~n~~form HTD about consolidated PICO."*	X	5 (editorial)
Roche	12	258-260, Figure 4-2	This is the first time the term "project manager" is introduced in the document, as such a role is not specified in the HTAR. The affiliation and role of the project manager should be clarified. We suggest adding this clarification under section "2 Actors and their scope", "2.2 HTA bodies". Furthermore, we would recommend that the project manager		4 (Secretariat)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			remains the same, to the possible extent, throughout a given JCA/JSC procedure.		
Roche	12	Figure 4-2	The HTD should amend the dossier if it is considered incomplete by the HTAb. We miss a definition of incompleteness in this guidance. A dossier should not be seen as incomplete e.g. if data do not exist, if data can not be accessed by the HTD or can not be obtained with a reasonable effort by the HTD from other stakeholders.		12b (incomplete submission dossier).
Roche	12	Figure 4-2	The HTD should amend the dossier if label changes require this. Label changes could influence the content of the dossier heavily. An amendment might not be able to reflect the total changes nor might be such a short period to be sufficient to do all the work. Close interaction between HTAb and EMA having JSC for all products subject to the HTAR is required to avoid these situations.		Thank you for your comment – we agree that interaction is needed between EMA and HTAbs and is the matter of a separate deliverable under EUnetHTA21.
Intuitive	12	4.2.1	Intuitive believes the material here only describes the pathway where HTDs voluntarily submit for a JCA by affirmatively submitting a letter of intent. However, we understand that the HTAR also makes provision for medical device technologies to be selected for assessment without affirmative steps from the HTD. If that is accurate under D4.7.3 or D4.7.4, then consider making a clear summary here, for example: "There are two pathways for initiating JCAs. Typically, once a technology is selected as eligible for assessment, an HTD can affirmatively signal their interest in proceeding with an assessment using a letter of intent. In other cases, technologies may be selected for assessment as further described under (procedure D4.7.3 or D4.7.4) without any action on the part of the HTD if [clearly explain circumstances under which an HTD would be asked to respond to a JCA without any affirmative action on their part]. If there is no potential for a JCA to be initiated without the affirmative action or consent of the HTD, then state clearly: "The ONLY way to initiate a JCA is for a HTD to submit a letter of intent."		The HTAR includes scope for voluntary work, this is not covered under any of EUnetHTA 21's deliverables
Mihai Rotaru - EFPIA	12	258	Figure 4-2 would be more informative with timelines		14 (JCA) --> inclusion of timelines

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MTE Member	12	258	HTD should be involved in the development and attend PICO meeting under the HTAR (as with EUnetHTA) As per previous comments, HTD should be actively involved in all steps of the HTAR development, including the scope, PICO, addressing any questions of the Assessor/Co-assessor, fact check and appeal process.		1 (related to PICO)
Tanja Podkonjak, Takeda	12	270	Current text: In the Letter of Intent, the HTD is requested to state the contact person for the JCA process, the **claimed** indication and the anticipated regulatory pathway. Proposed text: In the Letter of Intent, the HTD is requested to state the contact person for the JCA process, the **anticipated** indication and the anticipated regulatory pathway. At the stage of the JCA Letter of Intent and even the JCA dossier submission, the HTD has not yet been granted an MA therefore it would be inappropriate to use the word 'claimed'. Instead, we recommend using 'anticipated' indication.		1 (related to PICO)
Mihai Rotaru - EFPIA	12	272	As mentioned in the EFPIA response to the scoping consultation, EFPIA believes that the JCA process would benefit from having a concrete 'starting point/step' foreseen in the process. As such EFPIA is proposing that the HTD submits a letter of notification to the Coordination Group, following acceptance of the EMA dossier, outlining the characteristics of the technology as well as the intended PICO(s) for the assessment. Similar to the EUnetHTA JA3pilots, the HTD should propose a base-case European PICO, based on the expected regulatory approval, taking into consideration the likely patient population covered and comparators used in most MS. Secondary PICOs may be incorporated based on HTD knowledge of likely but common requirements of MS and how new technology will be positioned within health systems.		1 (related to PICO) & 14b (JCA – scoping process and initation) Thank you for your suggestion and as highlighted such documentation will be decided under the HTAR CG.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MTE MEMBER	12	272	*'A Letter of Intent is not foreseen under the HTA Regulation.'* While no such letter is described in the Regulation, it does not rule out self-nomination to JCA. It therefore is kindly suggested to delete this sentence.		This sentence was deleted from the deliverable
Dr. Thomas Ecker, Ecker + Ecker GmbH	12	272	**Statement in guideline:** *"A Letter of Intent is not foreseen under the HTA Regulation."* **Comment:** In EUnetHTA Joint Action 3, the HTD was given the opportunity to outline a draft PICO scheme in the letter of intent. This input from the HTD as well as the direct exchange between assessors and HTD within the subsequent scoping meeting represented a crucial part of finalizing the PICO scheme. Therefore, a letter of intent should be implemented in the HTA regulation.	-	Thank you for your recommendation however this will be a matter to be decided under the HTA R CG.
MTE MEMBER	12	275	*'…requests a completed submission dossier as per the PICO(s) by a specified deadline.'* We are seeking clarification about the actual timelines foreseen here, please. The text as is does not hint at what such timeline might be.		2b (good administration – time window)
Roche	12	287	It is described that the secretariat performs a procedural completeness check. But no further information is given about this kind of planned check. Please give more details about it.		12b (submission dossier – incomplete dossier)
MTE MEMBER	12	289	*'…(i.e. submit data or prove there is no data available for all identified PICO(s)),… '* Please provide explanation for how to prove a negative. What would constitute evidence of absence ?		12b (submission dossier – incomplete dossier)
Matias Olsen, EUCOPE	13	324-333	A HTD should be able to provide a formal commentary on the final JCA that enters the public domain alongside the JCA factual accuracy check. Completion only of a factual accuracy check does		2e (good administration – hearing after JSC or JCA)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			not allow any commentary and it would be transparent and appropriate to have this response as part of the JCA rather than through other means such a press releases or media commentary. Of particular concern is that with no interaction between the HTD and the HTA bodies in the JCA beyond responding to gaps identified by the Assessors, the ability for a HTD to inform, comment, challenge or recommend optimisation of approaches in the JCA is absent and in such a case a final HTD commentary is especially needed. This would also allow HTA bodies to identify the official HTD commentary and use this in the local assessment of the product and application of the JCA report.		
Matias Olsen, EUCOPE	13	307-312, 315-318	The HTD should be able to communicate with the Assessors, through the Coordination Group or the European Commission, when needed. Regulation (EU) 2021/2282 Article 11 (2) specifies that the HTD shall proactively inform the Coordination Group when new clinical data becomes available during the assessment process. The interactions between the HTD and the Assessors should be continuous and bi-directional throughout the assessment. The reasons for which the HTD can contact the Assessors should be indicated.		2d (good administration – direct interaction with assessor and co-assessor) & 7 (submission of new evidence)
Sebastian Werner vfa	13	308-315	*"[..] in case the Assessor and Co-Assessor consider that further specifications or clarifications [..] are necessary to carry out the assessment. […] . Depending on the type of request, a deadline (with a maximum of 5 calendar days for medicinal products [..] will be communicated."* The deadline for the HTD for sending further clarifications (5 calendar day) is not sufficient. 5 calendar days might include weekends or bank holidays. The maximal duration should use "working or active days". In Germany, maximally 5 working days are given for HTD responses. However, practical experience largely shows this duration to be insufficient with negative effects on quality of the submissions depending on the type of request. The vfa recommends a deadline with a maximum of 7 working days for medicinal products depending on the type of request		2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			should be used and communicated.		
Roche	13	308-314	Art 11 (2) does not refer to a permanent availability of the HTD "at any time". First of all, the deadlines should be based on business days. Secondly, up to 5 calendar days for medicinal products can be too short and may be 2 days more are helpful.		2b (good administration – time window)
Mihai Rotaru - EFPIA	13	278 - 283	EFPIA re-iterates the comments made to lines 184 – 188.		1 (related to PICO)
Mihai Rotaru - EFPIA	13	301 - 306	The guidance document should be much more precise as to how these proposed clock-stops may interact (overlap, be sequential etc.) with the regulatory clock stops. 10 days to amend the dossier (after CHMP label change) should be lengthened to ensure sufficient time for data update in dossiers. We see that submission is not feasible in this timeframe. Even in the case that one European PICO or a manageable set of PICO can be agreed upon, the timely preparation of a complete amendment would be a major challenge. Further, the grace period for amending the dossier is obviously shortened by 1 week of the PICO update and possible weekends or bank holidays. Therefore, the duration of the grace period should be increased (e.g. 30 days). Furthermore, the technical completeness check for such amendments to the dossier should be handled more flexibly and allow for more interactions between the HTD and HTAb.		2b (good administration – time window)
	13	301-306	For consistency and fairness for all parties, all the timelines should be expressed in business days and be precise (10 calendar days for grace period vs approximately 1 week for assessor and co-assessor to update the PICO). Furthermore, our interpretation is that if the grace period is a maximum of 10 calendar days, and the assessors and co-assessors will have approximately 1 week (7 calendar days) to update the PICO, this means that effectively HTD is only given 3 calendar days to amend the dossier as per the redefined PICO. It remains unclear what the rules for grace period will be under the HTAR. In any case, instead of a fixed grace period, it should be		2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			proportionate to the extent of changes to the PICO and consequently impact on the submission dossier.		
Matias Olsen, EUCOPE	13	278-283	The scoping meeting is a vital part of the scoping process, and it is crucial that this is also implemented as part of the EU HTA procedure. The consolidated PICO(s) should be discussed in a meeting between the Assessors and HTD. This will allow the HTA bodies to provide the rationale for the scope and give the HTD an opportunity to better understand the PICO(s). The HTD should be able to share their insight, specific considerations or identified execution issues as part of a PICO scoping and on a final draft recommendation for consolidated PICO(s), prior to their finalisation. Not allowing a discussion of the PICO(s) will inevitably result in methodological, practical and execution issues that will create issues in the dossier completion, evaluation, and would result in a JCA that is flawed and not practical for adoption by Member States. While a scoping meeting is not described in the regulation, neither are many of the other detailed procedural and methodological steps of health technology assessment. We therefore disagree with the interpretation that a scoping meeting is not "envisioned" by the Regulation. The Regulation on health technology assessment (EU) 2021/2282 stipulates that the detailed procedural and methodological guidance and rules for interactions shall be developed through implementing acts, and that the same will be based on the experiences to date under the EUnetHTA Joint Actions. Recital 47 of Regulation (EU) 2021/2282 states that "In order to ensure a uniform and Member State-driven approach to the joint work provided for in this Regulation, the Coordination Group should develop its detailed procedural steps and the timeframe for joint clinical assessments, updates of joint clinical assessments and joint scientific consultations. Where appropriate, and taking into account the results of the work undertaken in the EUnetHTA Joint Actions, the Coordination Group should develop distinct rules for medicinal products, medical devices and *in vitro* diagnostic		1 (related to PICO)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			devices.". Further, Article 15 (1) (c) of Regulation (EU) 2021/2282 states that the European Commission shall adopt, by means of implementing acts, detailed procedural rules for "interaction, including timing thereof, with and between the Coordination Group, its subgroups and the health technology developers, patients, clinical experts and other relevant experts during joint clinical assessments and updates.". Scoping meetings, as a well-established procedural step of interaction in HTA (e.g. EunetHTA JA3), cannot be considered to not be foreseen by the Regulation, since there are specific provisions that foresee implementation of procedural interactions in tertiary legislation to be adopted by the European Commission. As we have noted in other comments, a scoping meeting with the HTD is critical to a robust assessment and the guidance document should elaborate on the interactions with the HTD as part of the scoping process and propose a procedure and format for conducting the scoping meeting, based on the work carried out under EUnetHTA JA3. Replace: "PICO information meeting (only EUnetHTA 21) In the HTAR there is no meeting envisioned between the HTD and HTAb during or after the scoping process. In EUnetHTA 21, the HTD is invited to join a PICO information meeting, in which the assessor and co-assessor present the consolidated PICO(s). The purpose of this meeting is to provide the HTD with information on the consolidated PICO(s), and is not a meeting to discuss submission requirements. There is no provision to amend the EUnetHTA21 consolidated PICO(s) at this point." With: "PICO ~~information~~ meeting ~~(only EUnetHTA 21)~~		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			~~In the HTAR there is no meeting envisioned between the HTD and HTAb during or after the scoping process. In EUnetHTA 21, the~~ **The** HTD is invited to join a PICO ~~information~~ meeting, ~~in which the assessor and co-assessor present~~ **where** the consolidated PICO(s) **are discussed**. **The PICO meeting should be interactive. The PICO(s) should be sent to the HTD prior to the meeting for review. The HTD should be able to prepare a written list of issues and share it with the Assessor and Co-Assessor.** The purpose of this meeting is to provide the HTD with information on the consolidated PICO(s), and ~~is not a meeting~~ to discuss submission requirements **such as relevant comparators and other evidence needed to respond to the PICO(s)**. **Major points of divergence, if any, should be clarified during the meeting. The list of issues should be published.** ~~There is no provision to amend the EUnetHTA21 consolidated PICO(s) at this point."~~		
Sebastian Werner vfa	13	301-306	*"For medicinal products only: Although EUnetHTA 21 does not have clock-stops, a grace period to amend the Submission Dossier is allowed if CHMP opinion differs from what was anticipated and only to those sections impacted by the CHMP opinion. The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat, but can take a maximum of 10 calendar days (starting once CHMP opinion is available). During the grace period the Assessor and Co-Assessor will update the PICO, which will be published approximately 1 week after CHMP opinion."* A grace period to amend the Submission Dossier, if the CHMP opinion differs from the anticipated therapeutic indication ("Label-change") gives the HTD the possibility to submit data and analyses that conform to the new label and to an updated PICO-scope. A grace period is therefore very useful, and necessary, as changes in label can have a strong impact on the clinical assessment. In Germany, in approx. 8%-12% of the procedures relevant changes in the label occur that lead to a substantial change in data requirements. The vfa welcomes the proposal to deal with this important concern. However, the suggested grace period of a maximum of 10 calendar days is not sufficient for the		2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			preparation. The preparation of an amendment to the dossier with many PICO questions as a complete submission is not feasible in this timeframe. Even in the case that one European PICO or a manageable set of PICO can be agreed upon, the timely preparation of a complete amendment would be a major challenge. Further, the grace period for amending the dossier is obviously shortened by 1 week of the PICO update and possible weekends or bank holidays. Therefore, the duration of the grace period must be increased. Furthermore, the technical completeness check for such amendments to the dossier should be handled more flexibly. The vfa recommends increasing the duration of the grace period to 30 calendar days and establishing a flexible technical completeness check that allows for more interactions between HTD and HTAb. The vfa further recommends adapted publication plans for submission dossiers and amendments. As the submission dossier might be completely irrelevant to the JCA, it should not be published.		
Matias Olsen, EUCOPE	13	301-305	Depending on the nature of the label change, new analyses may be required. In this case, 10 calendar days will not be sufficient to reanalyse the data and provide a written report. If required, the HTD and JCA Secretariat need to work together to establish a reasonable time to make the necessary changes, however the grace period should be at least 45 calendar days. Furthermore, this paragraph specifically refers to EUnetHTA21. It needs to be specified how clock-stops and/or grace periods are foreseen to be handled under the EU HTA Procedure. Replace: "The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat, but can take a maximum of 10 calendar days (starting once CHMP opinion is available)." With:		2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			"The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat, ~~but can take a maximum~~ **and cannot be less than** of ~~10~~ **45** calendar days (starting once CHMP opinion is available)."		
Sebastian Werner vfa	13	286-290	*The HTD has to submit a dossier according to the scope of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)), otherwise the dossier has to be declared incomplete.* For dossier completeness, the guidance requires the HTD to submit a dossier according to the scope of the JCA where the HTD should submit data or prove that there is no data available for all identified PICO. The part lacks specifications regarding the adequacy of available data that could inform the assessment. In accordance with the HTAR the dossier must be (a) complete regarding the available studies and data that could inform the assessment and (b) the data has been analysed using appropriate methods to answer all research questions of the assessment (Art. 9, para. 3). Hence the HTD should not be obliged to submit data that are uninformative for the assessment and that *cannot* be appropriately analysed. Consequently, the HTD should only submit available informative data or show that there is no informative data available for all identified PICO using appropriate methods. With the current requirements of the guidance, HTD might be forced to submit, e.g., indirect comparisons that cannot inform the assessment due to inadequate available data that cannot be appropriately analysed. This case must be prevented. In such cases the HTD should not be obliged to submit any data, but rather have the possibility to state that there is no data available that could inform the assessment using appropriate methods. The vfa recommends changing the sentence in "*The HTD should submit <u>available informative data</u> or show that there is <u>no informative data available</u> for all identified PICO <u>using appropriate methods</u>*." Further, criteria for technical and procedural		12b (submission dossier – incomplete submission) Thank you for your observations and comments. We consider the issues raised in the first two paragraphs to be outside of the scope of this deliverable and adequately addressed under the Scoping Guidelines (Deliverable 4.2 and under Methodological Guidelines (4.3, 4.4 and 4.5). We also consider the points raised to be a matter for the assessment teams who are reviewing the information and have context on the rationale provided.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			completeness should be clarified and published, incl. the processes in case a dossier might be incomplete. In addition, the HTD should have the possibility to included further PICO which the HTD considers to be informative for the assessment.		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	13	301-305	**Comment:** DRAFT GUIDANCE: **"***For medicinal products only: Although EUnetHTA 21 does not have clock-stops, a grace period to amend the Submission Dossier is allowed if CHMP opinion differs from what was anticipated and only to those sections impacted by the CHMP opinion. The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat, but can take a maximum of 10 calendar days (starting once CHMP opinion is available).*"** Label changes may lead to re-analyses of all clinical data due to the potential new patient population according to the label. 10 days are not considered sufficient to address these potentially fundamental changes, since all analyses for the new population(s) have to be conducted and quality checked to ensure a high standard of the JCA. We are well aware of the time constraints imposed by HTAR but given the fundamental impact of such changes at least 30 calendar seem more appropriate, at any case every prolongation of the timeframe making it longer than 10 days will help.		2b (good administration – time window)
Mihai Rotaru - EFPIA	13	315 - 318	Paragraph contains a contradiction contraction. It is not possible for the HTD to inform the Coordination Group prior to the beginning of the assessment of clinical data that becomes available during the assessment. The HTD can only inform of the data being available when it becomes available. Potential rewording: Both under the HTAR and EUnetHTA 21, according to art. 11(2), where new clinical data ~~becomes~~ **is expected to become** available during the assessment process, the HTD concerned shall proactively inform the ~~Coordination Group~~ **Secretariat** about		Thank you but this wording is taken directly from the text of the HTAR and therefore proposed changes are not possible.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			this prior to the start of the JCA indicating anticipated timelines. ~~when it will become available.~~		
Matias Olsen, EUCOPE	13	297-300	The JCA Secretariat must confirm that the HTD has received the deadline communication as this is a critical point. It can have irreparable consequences if for some reason the HTD does not receive this communication. It also needs to be clarified, what the consequences of an "incomplete" dossier and "discontinued" procedure are (i.e. regarding assessment of some of the PICO(s) and opportunities for re-submission.".		2b (good administration – time window)
Sebastian Werner vfa	13	315-318	*Both under the HTAR and EUnetHTA 21, according to art. 11(2), where new clinical data becomes available during the assessment process, the HTD concerned shall proactively inform the Coordination Group about this prior to the start of the JCA indicating anticipated timelines when it will become available.* The section contains a contradiction. The HTD cannot inform "proactively" before the JCA when new clinical data becomes available during the assessment process. The section should be clarified regarding how and when the HTD must inform EUnetHTA or the CG.		Thank you but this wording is taken directly from the text of the HTAR and therefore proposed changes are not possible.
Mihai Rotaru - EFPIA	13	292 - 294	EFPIA calls into question the approach that any interaction between HTD and HTAs (via the Secretariat) is to be avoided, therefore there is a need for a technical completeness check by the assessor/co-assessor before the dossier is accepted. There may be legitimate circumstances where the assessor/co-assessor would benefit from having a dialogue with the HTD to understand the context and rationale for the submission of certain evidence, in scope of the assessment. Not allowing this possibility risks undermining the timing of the JCA assessment as well as un-necessary confusion as to the contents of the submission dossier, and, in the worst case scenario an unfounded decision to discontinue an assessments (with all the legal implications under the HTA R).		We consider there to be adequate scope within the submission dossier to present any rationale that may be relevant. We don't anticipate that an "unfounded" decision will be arrived at in relation to the discontinuation of a JCA dossier given the consequences that you outline.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	13	312 - 314	EFPIA believes that the time windows provided in the guidance document are not tailored to take into account the challenges of the specific question – some questions may require additional specific discussions between the assessor and the HTD to allow for more flexibility according to the extent of data analyses. The deadline for the HTD for sending further clarifications (5 calendar day) is not sufficient. 5 calendar days might include weekends or bank holidays. The maximal duration should use "working or active days". Moreover, there is no justification provided as to why there would be a difference in the response times needed for medicinal products vs medical devices), implying that they have been selected arbitrarily or at the very least without testing for feasibility.		2b (good administration – time window)
Roche	13	292-294	Based on experiences from JA3 some relevant "missing documents" may be overlooked during the completeness check and are only noticed during the actual thorough assessment of the evidence provided in the JCA dossier. In these cases, further interaction with HTD (via the Secretariat) should be allowed as these documents may be available on HTD side or may have been overlooked/could not be found by the assessors in the submission package. The HTD can then provide the missing document and/or guide the assessor/co-assessor to the right section of the dossier. Therefore, and for consistency with what is stated under "Formal interaction with HTD during the JCA", we suggest rephrasing to: "*The objective of the technical check of completeness is to ensure completeness of the dossier to avoid interaction (via Secretariat) between the HTD and the Assessor and Co-Assessor during the actual assessment.* ***Nonetheless, further interaction with the HTD should be possible - see "Formal interaction with HTD during the JCA".***		2d (good administration – direct interaction with assessor and co-assessor) Thank you. It will be important for HTDs to provide all necessary documents to allow the assessment to continue in a timely manner and we do not forsee the arrangement that existed in JA3 being repeated here given the legal ramifications and the tight timelines.
Silke	13	278-280	We would like to understand why a PICO information meeting is		1 (related to D4.2)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Walleser Autiero Medtronic			not planned for the JCA process under EU HTA regulation? The HTDs will have considerable knowledge to share that would enhance the quality of decisions regarding the PICO and such an information meeting would be one way to allow this.		
Tanja Podkonjak, Takeda	13	303-305	Current text: The need for and duration of a grace period has to be approved between the Assessor and Co-Assessor and the Secretariat, but can take a maximum of 10 calendar days (starting once CHMP opinion is available). During the grace period the Assessor and Co-Assessor will update the PICO, which will be published approximately 1 week after CHMP opinion. The grace period proposed under this guidance, 10 calendar days, in the event of a differing CHMP opinion to the aniticpated is not sufficient. If the CHMP final indication is materially different than the anticipated and therefore the submission JCA dossier, this will require significant re-analysis and potentially new evidence synthesis activities. Furthermore, under the proposed grace period, the HTD would only receive the final re-worked PICO 5 days after the CHMP opinion is published leaving only 5 additional days for the HTD to be able to re-analyse, update, present and submit the extensive JCA dossier. This is not feasible and depending on the scale of the change, may lead to incomplete dossiers, inaccuracies and ultimatley lower quality JCA submissions and report which will adversly national HTA procedures and ultimatley patient access. At a minimum, any quoted deadlines and timelines should consider working days only and not calendar days. It is not appropriate to count weekends or public holidays (which are outside of many European employees contract terms) as effective days for the HTD to be able to execute on additional data requests or modify submissions. Takeda requests that all future deadlines for JSC and JCA consider working days only. Takeda suggests a 'clock stop' mechanism, similiar to what is currently done within the EMA and many national HTA agencies be introduced in the event of a label change. The appraisal may		2b (good administration - time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			be suspended or paused and the lenght of time to update the submission should be flexible and discussed between the HTD, assessors and Secretariat. As the scale of the change will differ between appraisals, there needs to be flexibility via a 'clock stop' mechanism on the best way to address the change, resulting in a high quality subission and report. Try to negotiate 7 calendar days (= 1 week) to be consistent with the 2 weeks granted to MDs this can be a problem if the request is received on Friday		
Roche	13	282-283	As per the learnings from EUnetHTA JA3, the PICO information meeting (formerly called scoping meeting) should allow for discussion about the submission requirements and details on appropriate methodologies to be used in the context of the concerning health technology and disease area (e.g. comparison methods, information retrieval PICOS, etc.) to optimise the dossier submission and hence the assessment. We suggest rephrasing to: *"The purpose of this meeting is to* ***~~provide the HTD with information on~~ discuss*** *the consolidated PICO(s)* ***with the HTD, as well as appropriate methodologies and data presentation to be used in the submission dossier."***		1 (related to D4.2)
Roche	13	291-292	*"The time for providing the amended dossier responding to the LoMI depends on the JCA procedure (i.e. medicinal products or medical devices)."* Please specify how much time the HTD will be given to respond to the LoMI in both cases (medicinal products and medical devices).		2b (good administration – time window)
Matias Olsen, EUCOPE	13	288-289	Definitively proving the non-existence of data may be challenging. Clear guidelines should be produced on what effort is considered sufficient to "demonstrate" the lack of data (e.g. search with X criteria on PubMed). Replace:		12b (submission dossier – incompleteness) The sentence has been clarified

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			"The HTD has to submit a dossier according to the scope of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)), otherwise the dossier has to be declared incomplete" With: ~~*"The HTD has to submit a dossier according to the scope of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)),*~~ ***In case the HTD does not submit data for a PICO, the HTD has to explain the reasons for failing to do so (e.g. demonstrate the lack of published data),*** *otherwise the dossier has to be declared incomplete. "*		
Matias Olsen, EUCOPE	13	305-306	Does this mean that the grace period is 10 calendar days, but the HTD will first be informed of the new PICO after 7 of these 10 days have already passed? This would mean that instead of 10 days, the HTD only has 3 calendar days (which may as well cover a weekend) left to amend the dossier according to the label change. Depending on the amount of changes required, this time is not sufficient and there needs to be an open and pragmatic discussion between the HTD and the JCA Secretariat to agree on a reasonable timeframe. Furthermore, the grace period should rather start after the updated PICO scheme has been communicated to the HTD.		2b (good administration - time window)
Matias Olsen, EUCOPE	13	312-313	5 days in order to present missing information is insufficient and not enough for all foreseeable cases, especially where additional data analyses or gathering of additional evidence is required (e.g. evidence requested for a comparator that was not used in registration studies and/or subpopulations of patients). If there is no option for an extension, 14 calendar days should be granted for medicinal products as is suggested for MDs/IVDs. See also our comments on the "grace period"/clock-stops and the need for continuous and bi-directional communication throughout the procedure. Add:		2b (good administration - time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			"Depending on the type of request, a**n initial** deadline (with a maximum of 5 calendar days for medicinal products and 14 calendar days for MDs/IVDs) to provide the requested information will be communicated. **The deadline can be extended upon request of the HTD, depending on the type and complexity of the requested information.**"		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	13	288-289	**Comment:** DRAFT GUIDANCE: **"***The HTD has to submit a dossier according to the scope of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)), otherwise the dossier has to be declared incomplete*." It should be clarified as to how the proof of the non-existence of data is to be provided. **Suggestion:** *".. i.e. submit data or state that potentially relevant 3rd party data is not available / cannot be accessed.."*		12b (submission dossier – incompleteness) The sentence has been clarified
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	13	305/306	**Comment:** DRAFT GUIDANCE: "*During the grace period the Assessor and Co-Assessor will update the PICO, which will be published approximately 1 week after CHMP opinion*." This would reduce the grace period to only 5 days. **Suggestion**: **"***In case of a grace period the Assessor and Co-Assessor will update the PICO, which will be published approximately 1 week after CHMP opinion. The grace period for the HTD starts after the updated PICO was published."*		2b (good administration - time window)
Roche	13	272 in conjunction with 278-281	There will be neither a Letter of Intent in HTAR, nor a meeting where the HTD has the opportunity to comment on the PICO. We consider this a violation of our right to be heard according to Art. 41 EU-Charta. Of note, as PICO(s) provides the basis and sets the framework for the JCA, the HTD must have the opportunity to		1 (related to D4.2)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			comment. Based on the learnings from 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. In the draft for consultation D4.2 "Scoping process", there is an interaction described as "request for assessment". Please add the request for assessment here.		
Roche	13	279	*"In the HTAR there is no meeting envisioned between the HTD and HTAb during or after the scoping process."* Indeed the HTAR does not specifically mention how HTD will interact with HTAb during the scoping process, but it does state in Article 8 (6), that the scoping process shall also take into account information provided by the health technology developer. Therefore, we suggest deleting this sentence and adding to Chapter 6 a recommendation to implement scoping meetings based on experiences from EUnetHTA JA3.		1 (related to D4.2)
MTE MEMBER	13	279	We strongly believe that there should be interaction between the HTD and HTAb during both the scoping and PICO development so that both can be amended if necessary to inform the most accurate deliverables		1 (related to D4.2)
Tanja Podkonjak, Takeda	13	279	Current text: In the HTAR there is no meeting envisioned between the HTD and HTAb during or after the scoping process. As stated above, Takeda strong recommend a scoping meeting which includes all key stakehoders, as well as the HTD, be included in the JCA process. We believe that the involvement of the HTD in the process will make the PICO development process more fair, representative and efficient and allow the HTD to commence preparation of the dossier earlier. A scoping meeting was of great value in the JA3 former procedures and also is highly effective in reducing misunderstandings and improving efficiencies in national HTA systems. We are requesting it be re-introduced in the JCA		1 (related to D4.2)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			process.		
Mihai Rotaru - EFPIA	13	286	EFPIA disputes the interpretation that the HTA R foresees a technical completeness check to be carried out by the assessors/co-assessors. Article 10 of the HTA R only foresees that the Commission will confirm that the dossier "meets the requirements laid down in Article 9(2), (3) and (4)" without making any judgement as to whether this check is to be interpreted narrowly on procedural grounds or broadly on technical grounds. For dossier completeness, the guidance requires the HTD to submit a dossier according to the scope of the JCA where the HTD should submit data or prove that there is no data available for all identified PICO. The requirement lacks specifications regarding the adequacy of available data that could inform the assessment. In accordance with the HTAR the dossier must be (a) complete regarding the available studies and data that could inform the assessment and (b) the data has been analysed using appropriate methods to answer all research questions of the assessment (Art. 9, para. 3). Hence the HTD should not be obliged to submit data that could not inform the assessment and that cannot be appropriately analysed. Consequently, the HTD should only submit available adequate data or show that there is no adequate data available for all identified PICO using appropriate methods.		12b (submission dossier – incompleteness)
MTE MEMBER	13	293	Rather than try and avoid contact between the HTD and Assessor/Co-assessor during the assessment, all efforts should be made to clear discrepancies before this stage via active interaction, as already stated		2d (good administration - direct interaction with assessor)
Roche	13	296	Please provide a definition or examples for a "sound justification".		12b (submission dossier – incompleteness)
Roche	13	307	The interactions described are related to only one way of communication meaning if Assessors/Co-Assessors have questions to ask to HTD and there could be cases also where the HTD has questions to ask to Assessors/Co-Assessors. The suggestion is to allow communication as needed from both sides.		2d (good administration - direct interaction with assessor)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Intuitive	13	307	Intuitive would note that continued interaction between the HTD and HTAb during the assessment is beneficial for both parties. We believe that a high level of engagement can help with any additional information or clarifications that are needed.		2d (good administration - direct interaction with assessor)
MTE MEMBER	13	308	*'As per Art. 11(2), interaction with the HTD should be possible at any time during preparation of the JCA in case the Assessor and Co-Assessor consider that further specifications or clarifications or additional … are necessary …'* While Art 11(2) of the HTA R does use the term '*at any time',* it is meant to indicate that whenever a question occurs it should be followed up with. It does not refer to the availability of the HTD. It is kindly suggested to replace *'at any time'* by *'within reasonable timeframe'*.		Thank you but this wording is taken directly from the text of the HTAR and therefore proposed changes are not possible.
MTE MEMBER	13	308	It should also stand that the HTD can interact with the Assessor/Co-assessor during the development of the JCA to discuss further specifications or clarifications or additional information, data, analyses or other evidence are necessary in order to carry out the assessment		2d (good administration - direct interaction with assessor)
MTE MEMBER	13	312	*'Depending on the type of request, a deadline (with a maximum of 5 calendar days for medicinal products and 14 calendar days for MDs/IVDs) to provide the requested information will be communicated.'* Such short timelines do not seem acceptable. Referring to calendar days means weekends and public holidays are included. That seems unduly burdensome to HTDs, given that some changes may need cross-functional alignment. Please re-consider your proposition. Consider that EU law defines Saturday as a workday - but many employees tasked with replying to your outreach do not usually work on weekends.		2b (good administration - time window)
Tanja Podkonjak, Takeda	13	312	Current text: Depending on the type of request, a deadline (with a maximum of 5 calendar days for medicinal products and 14 calendar days for MDs/IVDs) to provide the requested information will be communicated. The current proposed timeline for 5 calendar days for HTDs to provide responses to additional information is not sufficient, particularly for complicated requests that require significant re-analyses. It is also unclear why medicinal products have a		2b (good administration - time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			fraction of the time allocated to respond for MDs/IVDs. As stated above, it is not appropriate to count weekends or public holidays (which are outside of many European employees contract terms) as effective days for the HTD to be able to execute on additional data requests or modify submissions. At a minimum, any quoted deadlines and timelines should consider working days only and not calendar days. Furthermore, for fairness and consistency, Takeda requests that the same duration of time, maximum of 14 working days, be granted to both medicinal products and devices. We strive to provide the best quality data and submission packages to the EU JCA asessors and it is integral that sufficient time be granted to enable HTDs to preapre and present any requested data.		
Mihai Rotaru - EFPIA	13	315	EFPIA would like to question the interpretation by EUnetHTA21 of Art. 11(2), which foresees that the assessors/co-assessors are the ones to contact the HTD (via the European Commission) if any additional information or specifications are needed for finalize the JCA report. EFPIA requests that this paragraph be further clarified to allow for the HTD to contact the assessor/co-assessor, via the Secretariat, (not the Coordination Group) at any time during the assessment phase if new information, data becomes available pertinent to the assessment. The assessor/co-assessor are the most relevant persons to provide this information to, and this information may be shared by the Secretariat with the Coordination Group, under the same conditions as sharing the submission dossier at the start of the process.		2d (good administration - direct interaction with assessor)
Roche	13	315	It is requested that the HTD informs the Coordination Group about upcoming new data. Further information about the process how to handle these data should be given, e.g. let's assume the data will become available shortly before or after CHMP opinion. A new process needs to be defined.		7 (submission of new evidence)
Dr. Thomas	13	288–290	**Statement in guideline:**	-	12b (submission dossier –incompleteness)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Ecker, Ecker + Ecker GmbH			*"The HTD has to submit a dossier according to the scope of the JCA (i.e. submit data or prove there is no data available for all identified PICO(s)), otherwise the dossier has to be declared incomplete"* **Comment:** It should be clearly outlined, which rules apply in order to demonstrate the lack of data. Moreover, it should be clarified, what the consequences of an "incomplete" dossier are.		
Dr. Thomas Ecker, Ecker + Ecker GmbH	13	291–294	**Statement in guideline:** *"The time for providing the amended dossier responding to the LoMI [List of Missing Items] depends on the JCA procedure (i.e. medicinal products or medical devices). The objective of the technical check of completeness is to ensure completeness of the dossier to avoid interaction (via Secretariat) between the HTD and the Assessor and Co-Assessor during the actual assessment."* **Comment:** Please specify the duration of the time for providing the amended dossier responding to the LoMI. How should extensive additional requests be handled? Is an extension of the deadline possible or planned in such cases?	-	2b (good administration – time window)
Dr. Thomas Ecker, Ecker + Ecker GmbH	13	301–306	**Statement in guideline:** *"For medicinal products only: Although EUnetHTA 21 does not have clock-stops, a grace period to amend the Submission Dossier is allowed if CHMP opinion differs from what was anticipated and only to those sections impacted by the CHMP opinion. The need for and duration of a grace period has to be approved between the*	-	2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Assessor and Co-Assessor and the Secretariat, but can take a maximum of 10 calendar days (starting once CHMP opinion is available). During the grace period the Assessor and Co-Assessor will update the PICO, which will be published approximately 1 week after CHMP opinion." **Comment:** If we understand the above correctly, this means that the HTD only has 3 calendar days to adjust the dossier accordingly: As stated in the cited paragraph, the grace period corresponds to 10 calendar days, but the updated PICO will be communicated to HTD after 7 days ("approximately 1 week") of the grace period have already passed resulting in only 3 calendar days left to adapt the dossier to the updated label? Importantly, depending on the extent of required modifications (such as additional data analyses or re-analyses of data), the suggested period of 3 calendar days is not sufficient. Even if the requested analyses are already available, 3 calendar days are not sufficient to modify the dossier accordingly. Therefore, the grace period should rather start *after* the updated PICO scheme has been communicated to the HTD. Moreover, so far, this paragraph only refers to EUnetHTA 21. However, it should be specified how grace periods are handled within the EU-HTA procedure. Overall, the suggested process is not feasible and in the worst case, might lead to incomplete or discontinued dossiers. This in turn could undermine the whole EU-HTA process and lead to clinical assessment on a national level exclusively. At present, it is unclear, how exactly it will be handled if the corresponding adjustments are not finalized within the grace		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			period. Notably, the consequences of such delays or discontinuations on national level are not further specificized: Would this potentially result in a later market access?		
Dr. Thomas Ecker, Ecker + Ecker GmbH	13	308–314	**Statement in guideline:** *"As per Art. 11(2), interaction with the HTD should be possible at any time during preparation of the JCA in case the Assessor and Co-Assessor consider that further specifications or clarifications or additional information, data, analyses or other evidence are necessary in order to carry out the assessment. [..] Depending on the type of request, a deadline (with a maximum of 5 calendar days for medicinal products and 14 calendar days for MDs/IVDs) to provide the requested information will be communicated."* **Comment:** A deadline of 5 calendar days to provide additional data, analyses or other information requested by the assessor and/or Co-Assessor is not feasible. In case the request is sent on a Friday, only 2 working days are left for the HTD to address the request. Moreover, in certain cases, it should be possible to extend the deadline upon request of the HTD.	-	2b (good administration – time window)
Silke Walleser Autiero Medtronic	14	324-329	It appears that no contradictory phase will exist. The process will therefore not permit a fair JCA for the HTD.		2a (good administration - fact check)
Roche	14	322-323	*"There will be no direct contact between the HTD and the Assessor and/or Co-Assessor during the JCA,* ***outside of the PICO information meeting****"* We understand, that the PICO information meeting (to inform the HTD about the consolidated PICOs and not to discuss		2d (good administration - direct interaction with assessor)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			submission requirements) will only happen under EUnetHTA21. For the HTAR no meeting with the HTD is foreseen. As aligned with Table 1.1 page 6 stating "Art 8 (6): Consider HTD input on PICO", the JCA interaction process should consider an interactive scoping meeting with the HTD to clarify and discuss the PICO. Furthermore additional exchange opportunities during the JCA process between HTD and HTA should be possible to clarify questions in a timely manner to allow for a high quality JCA within the given timeframe.		
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	14	338/339	**Comment:** DRAFT GUIDANCE: "In case potential errors are identified in a EUnetHTA 21 JCA report after its publication, EUnetHTA can start the error reporting procedure." **Suggestion**: In case potential errors are identified in a EUnetHTA 21 JCA report after its publication, EUnetHTA **WILL** start the error reporting procedure.		5 (editorial/linguistic)
	14	Section 4.2.3, line 326–327	**Statement in guideline:** "*The HTD shall signal any purely technical or factual inaccuracies in accordance with the timeframes established pursuant to Article 15."* **Comment:** In addition to the *factual accuracy check, the* HTD should have the opportunity to provide a statement on the final JCA that will be published together with the factual accuracy check.	-	2d (good administration - direct interaction with assessor)
MTE	14	322	Please consider adding *'In EUnetHTA21'* at the beginning of the		5 (editorial/linguistic)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MEMBER			sentence, to distinguish the different situations.		
Roche	14	327	"*The HTD shall signal any purely technical or factual inaccuracies*" Suggest to remove "*purely technical or factual*" as any inaccuracies should be signalled.		2a (good administration - fact check)
MTE MEMBER	14	327	HTD should also be checking the JCA for redacted confidential marking, HTD should be checking ALL materials that will be published		2a (good administration - fact check)
MTE MEMBER	14	327	"*The HTD shall signal any purely technical or factual inaccuracies*" Suggest to remove "*purely technical or factual*" as any inaccuracies should be signalled.		2a (good administration - fact check)
MTE MEMBER	14	328	*'For more information on the factual accuracy check, please see the document D7.1 Procedure and Framework for the Factual Accuracy Check'.* Maybe this gets tidied up when finalising the documents, but different documents refer to the same topic: Please consider consolidating the topics into one single reference document, to ease its use.		2a (good administration - fact check)
MTE MEMBER	14	369	It is kindly suggested to add another topic *'Define a procedure for reporting errors (in content or process)'* here, to signal the need for further clarification.		2f (good administration - error reporting procedure)
Roche	15	357-368	We suggest adding the following points: **"- Consider the implementation of a scoping meeting, to discuss the PICO and submission requirements (e.g. appropriate methodologies and information retrieval PICOS).**		1 (related to D4.2)
Mihai Rotaru - EFPIA	15	363 - 366	EFPIA would like to propose that the Letter of Notification, to be sent by the HTD to the Coordination Group, be used as a tool to provide the information listed in this guidance document.		1 (related to D4.2)
Roche	15	350-352	As contact points during the EUNetHTA21 phase a national JSC (Germany) and a national JCA (The Netherlands) secretariat is mentioned. The respective information for the HTAR should be displayed in addition.		4 (Secretariat)
Roche	15	359-360	The understanding is that an additional JSC and JCA HTD		10 (consultation on procedure manual)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			manual will be produced. Please open a consultation for this manual.		
Silke Walleser Autiero Medtronic	15	367-368	Given the fact that JCA may happen very early, it seems to be mandator that new evidence can be submitted during an ongoing JCA.		7 (submission of new evidence)
Roche	15	356	Suggest rephrasing to **"Further considerations for JCAs/JSCs to be carrled under the HTAR".**	x	5 (editorial)
MTE MEMBER	15	356	A confidentiality agreement should form part of the procedure and templates – this should be signed by identified parties before any exchange of information takes place		6c (confidential information – confidentiality agreement with HTD)
Dr. Thomas Ecker, Ecker + Ecker GmbH	15	367–368	**Statement in guideline:** *"Discuss if new evidence can be accepted during an ongoing JCA and if so, define a process for submission of this new evidence during an ongoing JCA."* **Comment:** Submission and assessment of new evidence during an ongoing JCA is highly problematic due to the tight submission and assessment schedule already in place. However, the assessment should always be based on the newest scientific results to ensure the best possible quality of the assessment process. Therefore, a process to submit additional data during an ongoing JCA should be developed for cases where either the HTD or Assessor and Co-Assessor deem it necessary.	-	7 (submission of new evidence)
	12, 13	258–259 (Figure 4.2), 279–280	**Statement in guideline:** *"Initiation of a JCA/CA scoping phase – HTD may attend PICO information meeting (EUnetHTA 21 only)"* *"In the HTAR there is no [PICO information] meeting envisioned between the HTD and HTAb during or after the scoping process."*	-	1 (related to D4.2)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Comment: While in EUnetHTA Joint Action 3, a direct exchange between assessors and HTD within the PICO information meeting represented a crucial part of finalizing the PICO scheme, no such meeting is foreseen in the current draft guideline. However, from our view, a PICO information meeting enabling the active participation of HTD should be implemented within the EU HTA procedure. The HTD should have the opportunity to clarify open questions regarding the PICO scheme and discuss further outstanding issues.		
Dr. Thomas Ecker, Ecker + Ecker GmbH	12–13	273–277	**Statement in guideline:** ***"Submission of PICO(s) & Request Submission Dossier*** *Both under the HTAR and EUnetHTA 21, as per Art 10 (1) of the HTAR, the Secretariat informs the HTD about the consolidated PICO(s) for the JCA and requests a completed submission dossier as per the PICO(s) by a specified deadline. The HTD has to submit their JCA dossier, after the consolidated PICO(s) has been submitted to the HTD."* **Comment:** In this draft guideline, no specific timelines are mentioned. At which timepoint is the HTD informed about the consolidated PICO(s)? When exactly has the dossier to be submitted? Due to the fact, that data analyses can be very time-consuming depending on the scope of these analyses, consolidated PICO(s) should be communicated as early as possible within the procedure. Therefore, we suggest that the scoping process starts	-	2b (good administration – time window)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			as soon as the marketing authorisation application (MAA) has been confirmed.		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
D7.1.2 – guidance on the process for a factual accuracy check					
Mihai Rotaru - EFPIA	General		EFPIA would like to reiterate that Article 6c(5) provides manufacturers with the limited right to "[signal] any purely technical or factual inaccuracies…" but they "shall not provide any comments on the results of the draft assessment." The absence of any right to comment on the results of the draft assessment arguably falls short of the right to good administration which includes the right to be heard before any individual measure with adverse effect be taken. A violation of the right to be heard will lead to the illegality of the decision taken if there is a possibility that in the absence of the violation the content of the decision would have been different. The fact that the assessment report is not binding does not detract from this because the report is intended to be taken into account by Member States and will affect the manufacturers' legal position at that level. The fact that manufacturers cannot comment directly at the level of the Coordination Group but must wait for the continuation of the procedure at national level unnecessarily risks divergent outcomes and is a material additional burden on manufacturers. We note that CMD(h) and CHMP procedures allow for an opportunity for the applicant to be heard before scientific conclusions are adopted and, by analogy, it would be entirely appropriate to allow manufacturers to comment on the draft assessment in Article 6c(5). The 5 calendar day delay for comment should be extended (see above comments) to provide for a reasonable delay to be determined by the Commission in the implementing act as there are serious doubts as to whether the envisaged 5 days are sufficient for the meaningful exercise of any right to comment and this may well infringe the right to good administration in violation of Article 41 of the Charter of Fundamental		2. Good administration – interpretation of Art 11 (5). and 2a 2b Time window

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Rights. As such, the mechanism for fact-checking should be expanded as outlined below: The process to include an opportunity (right to reply) for HTD to 'comment' on the final report shared with the Coordination Group (i.e. HTD receives the final Assessors report at the same time as the Coordination Group, with opportunity to comment). The process to include for the documents (comments) submitted by HTD on the draft assessors report to be included with (submitted alongside) the final Assessor report that is submitted to the CG (this being done at the same time that the report is shared with the CG). Also, the Assessors should complete a report on their response to the consultation process (comments received from HTD, and others), and include this with the submission of the Assessors final report to the CG.		
Roche	General		There are many references to EUnetHTA21 tools and processes in this document and it's not clear how this will be managed after EUnetHTA21 (EUnetHTA21 website, EUnetHTA21 Sharepoint etc…)		15 Applicability after EUnetHTA21 On page 6 under 1.2. Purpose and Scope we state the following: "The document might need to be revised at a later date to ensure full compatibility with the HTAR and relevant implementing acts." Some of the mentioned issues are out of scope of the current guidance, since these need to be decided by the European Commission in due course.
Matias Olsen, EUCOPE	general		As noted in our comments on EUnetHTA21 Deliverable D7.1 "Practical Guideline for interaction between Health Technology Developer and HTA bodies", it would be appropriate to establish a procedure whereby the HTD is able to provide a formal commentary on the final JCA that enters the public domain alongside the JCA factual accuracy check. The proposed draft guidance minimises the opportunities for interactions		2e (good administration – hearing after JSC or JCA)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			and opportunities for discussion and clarification of results, which is to the detriment of the overall quality of the procedure.		
MTE MEMBER	General		Given its numerous unclarities in the actual wording resutting in multiple ways of interpretation, , the document leaves doubt about the degree of commitment to keeping commercial information confidential.		6 Confidential information (how to keep commercial info confidential)
MEMBER MTE	General		There is repeated use of the term 'CE marking' throughout this document. Please note: Device do not receive CE mark, but the HTD a Certificate that allows him to put the CE mark on his products.		Thanks, we use this terminology throughout the deliverables in EUnetHTA and believe it is understandable
Sebastian Werner vfa	General		The process of the factual check of the HTD lacks a meaningful interaction between health technology developer (HTD) and the assessors of the health technology assessment bodies (HTAb). Answers of the assessors and co-assessors to the HTD's factual check are published with the joint clinical assessment (JCA) report without the possibility of the HTD to effectively make known their views on the answers and classifications of the factual check. However, it should be possible for the HTD to effectively make known their views on the correctness and relevance of the facts and circumstances which are subject matter of this process. The vfa recommends establishing a process by which the HTD can effectively respond to the answers and classifications of the factual check of the assessors of the HTAb with a subsequent exchange on unresolved issues.		2a (good administration – fact check)
Daniel Widmer UEMO	general		Contact with project manager as guarantee of independance		Thanks, this was added as a clarification.
Roche	9-10	213-240	An issue resolution mechanism should be in place, involving the HTD, in case there are conflicting views/comments on the final draft report, to be resolved prior to the publication of the final JCA report.		2. good administration.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Roche	9-10	218-223	We suggest removing this bullet point, based on our comment made to page 6, lines 108-110.	X	This bullet point will be kept, please see answer below.
Roche	6	108-110	HTD should be allowed to signal any inaccuracy during the accuracy check including comments affecting the interpretation of the data. This is particularly critical in case the final submission dossier template does not include sections for discussion and conclusion, where HTD can provide interpretation of the data and describe limitations and strengths of the evidence. Otherwise, we consider this a violation of our right to be heard according to Art. 41 EU-Charta.		2a fact check, 2a1 extent of fact check 2e good administration
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	6	106/107	**Comment:** DRAFT GUIDANCE: "*The purpose of a factual accuracy check is to highlight any errors or inaccuracies with the factual content of the document that are related to the technology under assessment.*" *"The health technology developer shall signal any purely technical or factual inaccuracies..."* This would deprive the HTD of requesting to correct methodological flaws. **Suggestion**: "The purpose of a factual accuracy check is to highlight any errors or inaccuracies with the factual content of the document that are related to the technology under assessment **as well as with the methods applied in the JCA**." "The health technology developer shall signal any purely technical**, methodological** or factual inaccuracies..."		2a1 extend scope of fact check
MEMBER MTE	6	102	Factual accuracy checks should be made on ALL documents that will be made publicly available		2a1 extend scope of fact check
Intuitive	6	106	Intuitive would reiterate that continued interactions		Thank you.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			between HTD and HTAb can be instrumental in providing necessary information and avoiding confusion and inaccuracies.		
MEMBER MTE	6	109	If data has not been interpreted correctly, then this would count as a factual inaccuracy and would need to be corrected		2a1 extend scope of fact check.
MEMBER MTE	6	111	What about unpublished data that is considered Academic-in-confidence (AIC)?		6 (confidential information (related to D7.1.3))
Mihai Rotaru - EFPIA	7	127 - 132	To ensure consistency across deliverables, and specific link with D7.1.1 EFPIA recommends that it should be the role of the Secretariat to channel the communication between HTD and HTAs (the Project Manager role can be described as being part of the Secretariat).		4 Secretariat
Roche	7	129-132	We suggest adding clarification about the affiliation of the project manager as this role is not specified in the HTAR. Will the project manager be from the same HTAb as of the assessor or co-assessor? Or from the EC secretariat (for future JCAs) or EUnetHTA21 secretariat (for pilot JCAS)? Furthermore, we would recommend that the project manager remains the same, to the possible extent, throughout a given JCA/JSC procedure.		4 Secretariat 15 Applicability after EUnetHTA21 On page 6 under 1.2. Purpose and Scope we state the following: "The document might need to be revised at a later date to ensure full compatibility with the HTAR and relevant implementing acts." The issue about the details of appointment/role of the Secretariat under HTAR are out of scope of the current guidance, since these need to be decided by the European Commission in due course.
Silke Walleser Autiero Medtronic	7	137-140	We request this point to be reconsidered. What if there is a misinterpretation of data in the JCA draft that could possibly change the assessment? It is not acceptable that these comments "may not be considered nor answered (line 219)". It seems in appropriate that such comments would be published but not addressed (line 179).		2a1 extend scope of fact check.
Matias Olsen, EUCOPE	7	136-137, 268-269	The checklist must be expanded to include all draft JCA report sections, or alternatively an "any other comments" line should be added.		2a1 extend scope of fact check.
Roche	7	137-138	In line with our comments to lines 108-110, we suggest adding that comments on interpretation of data will be		2a1 extend scope of fact check. 2e

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			accepted. Furthermore, An issue resolution mechanism should be in place, involving the HTD, in case there are conflicting views/comments on the final draft report., to be resolved prior to the publication of the final JCA report.		
Roche	7	151-152	We ask for an explanation of why confidentiality agreement between an HTD participating in a EUnetHTA 21 JCA and EUnetHTA 21 is not needed and how the Commercially Confidential Information ("CCI") will be effectively protected (see Recital 41). In the absence of a clear confidentiality framework, higher data requirements in the EUnetHTA21 publication documents than in the past for JCA pilots create an unforeseeable risk for companies and patients. HTD should be involved in protecting their Commercial Confidential Information ("CCI") and in developing the confidentiality framework needed.		6c confidential information – confidentiality agreement with HTD
Matias Olsen, EUCOPE	7	125-126	The names of the individual Assessors/Co-Assessors should be made available to the HTD at the beginning of the process and an arbitration process should be implemented if for any reason the HTD has an objection.		No individual names of assessor/co-assessor will be disclosed. Please also see D5.3.1 Procedural guidelines for appointing assessors and co-assessors
Sebastian Werner vfa	7	151-152	*"No confidentiality agreement between an HTD participating in a EUnetHTA 21 JCA and EUnetHTA 21 is needed."* As the EUnetHTA21 pilots will require that the HTD share commercially in confidence data for JSC and JCA confidentiality must be guaranteed, and a confidentiality agreement is necessary. The statement here is also in direct contradiction to D7.1.3 where, on page 5 in line 93-95 it is stated that: "*Any person involved in the preparation of HTA documents or having access to the information must sign a EUnetHTA21 confidentiality agreement (ECA).*" It is not comprehensible for why such confidentiality agreements should not be necessary for EUnetHTA21 JCA or JSC Pilots. Confidentiality agreements between		6c confidential information – confidentiality agreement with HTD

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			HTD and HTAb are always necessary, incl. EUnetHTA21.		
Tanja Podkonjak, Takeda	7	123-124	Current text: Assessor/co-assessor are not in direct contact with HTD, any communication with the HTD runs via the project manager. This document references a 'project manager' however the document D7.1.1 – Practical guideline on the interaction between HTD and HTAb referenced the JCA Secretariat. It is unclear who the actors are in the process, so Takeda suggests an appendix with a list of definitions be included and consistency between all documents on the terminology used to refer to all actors.		4 Secretariat
Silke Walleser Autiero Medtronic	7	119	The role of the project manager seems very limited therefore may lead to misinterpretations and delays. Opportunities for direct contact between HTDs and the assessor and co/assessor would lead to a timelier and more accurate process and hence higher quality JCAs.		4 Secretariat 2.d. Direct interaction with assessor and co-assessor
Matias Olsen, EUCOPE	7	124	As noted in our comments on EUnetHTA21 Deliverable D7.1 "Practical Guideline for interaction between Health Technology Developer and HTA bodies", there should be communication between the Assessors and the HTD that is structured and defined in the process (e.g. in the format of the scoping meeting).		1 (related to D4.2 (PCIO)) & 2 (good administration)
MEMBER MTE	7	124	The HTD and Assessor/Co-assessor should be able to have direct interaction to achieve the best possible outcomes when responding to factual inaccuracies		2.d. Direct interaction with assessor and co-assessor
MEMBER MTE	7	125	*'.. any communication with the HTD runs via the project manager.'* Please confirm that the project manager is part of the Secretariat (?). This is unclear as is.		4 Secretariat
MEMBER MTE	7	125	*'The names of individual assessors/co-assessors are not mentioned; only the names of the organisations acting as the assessor and co-assessor are included.'*		No individual names of assessor/co-assessor will be disclosed. Please also see D5.3.1 Procedural guidelines for appointing assessors

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			This is in stark contrast to the usual practice in national HTA processes, where both the names of the evaluators and involved experts are disclosed to enable transparency of the process and prevent a notion of bias. For JCA, the names of the contributors should be disclosed, to increase transparency and maintain current practice. Please replace 'are not' by 'will be'.		and co-assessors
MEMBER MTE	7	133	Interpretation of data is not accepted: While it is understandable that a factual check is not equal to a critical review, it should be underlined that (especially with also the increased complexity) the should be a way to discuss points that deserve clarification or (contextual) nuances		2a1 extend scope of fact check.
MEMBER MTE	7	151	We strongly disagree with this statement. A confidentiality agreement must be in place before any exchange of information takes place		6c confidential information – confidentiality agreement with HTD
Tanja Podkonjak, Takeda	7	151	Current text: No confidentiality agreement between an HTD participating in a EUnetHTA 21 JCA and EUnetHTA 21 is needed. This statement may not apply to all situations as commerical in confidence data may be present in JCA dossiers. Given the the high data protection standards in the patented medicines and devices industry, and the number of actors involved in handling the JCA data (assessors, project maanger, Secretariat, experts network) there is a need to protect confidential information that has not yet been publically disclosed. Should there be confidential data, a confidentality agreement needs to be available and signed by all parties. EMA guidance for handling commercial confidential information should be replicated for the future EU JCA system - In case of differing opinions on commercially		6c confidential information – confidentiality agreement with HTD

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			confidential, a solution mechanism must be deployed before publication (interaction for clarification).		
Matias Olsen, EUCOPE	8	157-161	Commercial in confidence information must be redacted following D7.1.3 guidance.		We added a reference to the 1.2. Purpose and Scope, where this is outlined. Furthermore a reference to the D7.1.3 guidance was added in this paragraph as well.
Silke Walleser Autiero Medtronic	8	159-161	Some HTD comments (eg regarding technical characteristics of the medical device under evaluation) might be commercially sensitive and confidential, and should therefore not be published		Reference to D7.1.3. was added
MEMBER MTE	8	157	All documents that will be published must go through the factual accuracy check, along with the redacting of confidential information		2a1 extend scope of fact check
MEMBER MTE	8	159	*'No confidentiality agreement between an HTD participating in a EUnetHTA 21 JCA and EUnetHTA 21 is needed.'* This statement is in contradiction to line 93 ff. in D7.1.3 on confidentiality *('Any person involved ….')*. Please ensure internal alignment. A lack of an NDA is not acceptable as it would legally waive any and all right to confidentiality in the future in the light of existing EU law. Therein the owner of commercially confidential data must ensure appropriate measures to retain confidentiality of such information and those related to such information including those by which information may be reverse engineered, by setting up e.g. NDAs.		The line was clarified in D7.1.3. guidance.
MEMBER MTE	8	159	*'This means that the comments forms ….'* Please add confirmation that any commercial-in-confidence information will be redacted before publication.		Reference to D7.1.3. was made
Mihai Rotaru - EFPIA	8	162	In the 'process' flow chart, last step 'after', the assessor/co-assessor should also provide a justification as to how they have determined a certain comment from the HTD relates to a factual check or not.		2a (good administration – fact check)
MEMBER	8	162	Is there a requirement for the HTD to keep the		6c confidential information – confidentiality agreement

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MTE			contents of the JCA draft report confidential until it is published, i.e. when they are checking it for factual accuracy?		with HTD
MEMBER MTE	8	163 – 'During'	*'HTD to send back completed comment form and completed checklist within 5 calendar days.'* Such short timelines do not seem acceptable. Referring to calendar days means weekends and public holidays are included. That seems unduly burdensome to HTDs, given that some changes may need cross-functional alignment. Please re-consider your proposal. Consider that EU law defines Saturday as a work day - but many employees tasked with replying to your outreach do not usually work on weekends.		2a fact check 2b time window
MEMBER MTE	8	163	Please add mentioning that CIC info will be edited out, and who is responsible to do so.		A reference to guidance D7.1.3 was added
Sebastian Werner vfa	8	162; 180ff	*"The HTD to send back completed comment form and completed comment check list within 5 calendar days"* The maximal duration for the factual accuracy check of the HTD to is 5 "calendar days". This duration is reduced by possible weekend days or bank holidays. The duration should be determined according to "working or active days". The vfa recommends increasing the duration to 7 working days.		2a fact check 2b time window
Tanja Podkonjak, Takeda	8	162, 191	The proposed 5 calendar days to complete the factual acuracy check (FAC) is not sufficient and inappropriate. At a minimum, any quoted deadlines and timelines should consider working days only and not calendar days. It is not appropriate to count weekends or public holidays (which are outside of many European employees contract terms) as effective days for the HTD to be able to a factual accuracy check. Takeda requests that all future deadlines for JSC and JCA		2a fact check 2b time window

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			consider working days only. Given that the HTA Regulation envisioned the factual accuracy step and build in time dedicated to it, it is unclear why the guidleine only allows for 5 calendar days. Tthe guideline fails to justify how the CSCQ has reached the recommendation that this procedural step should take only 5 working days. We recommend increasing the duration of the factual accuracy check to 7 working days. Furthermore, the same deadline as given to the HTD to conduct a FAC should be mirrored for the assessor/co-assessor to provide written answers to the questions received.		
Mihai Rotaru - EFPIA	9	218 - 223	EFPIA objects to the simplistic procedural step foreseen in the guideline to allow the assessor/co-assessor to not respond to a comment provided by the HTD. Such an approach significantly increases the risk of confusion and the legal uncertainty of the final JCA report in the context of its use at national level.		2a fact check
Matias Olsen, EUCOPE	9	218-223	As noted in other comments, a predictable, fair, and transparent process should be established for the factual accuracy check and an independent body should define if a comment is a factual accuracy check or not. It should be specifically defined and listed which comments are related to the veracity of the facts and which comments will be considered unrelated, in order to ensure the predictability of the procedure. While the HTD shall not provide any comments on the result of the draft assessment, HTD shall signal any purely technical or factual inaccuracies (see Regulation (EU) 2021/2282 Article 11 (5)) and must therefore be allowed to comment on the assessment performed by the Assessors, as far as it relates to their interpretation		2a (good administration – fact check)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			of the data and the disease. If technical or factual inaccuracies are discovered, this could realistically have varying degrees of impact on the results of the draft report and it is therefore not accurate to state that comments cannot affect the interpretation of results. Remove: "~~Make clear that comments outside the scope of a factual accuracy check will not be considered nor answered. However, these comments will be published as well together with a standard sentence.~~". Replace: "Assessor and co-assessor are responsible for defining whether a comment is factual accuracy check related or not (based on the definition of the purpose and scope of a factual accuracy check). In case of doubt, the CSCQ JCA (or JCA subgroup in the case HTAR) can be involved. The assessor and co-assessor inform the project manager accordingly, who will forward any questions to the CSCQ JCA (or JCA subgroup in the HTAR). Comments that are outside the scope of a factual accuracy check, i.e. any comments affecting the interpretation of data (data presentation, description and summary of the report), are neither considered nor answered by the assessor/co-assessor. In the 'assessor/co-assessor reply' column, the author states: 'The manufacturer was asked to check for factual accuracy of the document. This comment is not related to a factual inaccuracy and is, therefore, outside the scope of a factual accuracy check". With: "~~Assessor and co-assessor are responsible~~ **An**		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			independent body (e.g. the JCA subgroup) are responsible for defining whether a comment is factual accuracy check related or not (based on the definition of the purpose and scope of a factual accuracy check). In case of doubt, the ~~CSCQ JCA (or JCA subgroup in the case HTAR) can be involved. The assessor and co-assessor~~ **the independent body (e.g. the JCA subgroup)** ~~inform the project manager accordingly, who~~ will forward any questions **in case of doubt** to the ~~CSCQ JCA (or JCA subgroup in the HTAR)~~ **the European Commission.** Comments that are **found to be** outside the scope of a factual accuracy check, i.e. any comments ~~affecting the interpretation of data (data presentation, description and summary of the report)~~ **on the results of the draft assessment**, are neither **to be** considered nor answered by the assessor/co-assessor. In the 'assessor/co-assessor reply' column, the author states: 'The manufacturer was asked to check for factual accuracy of the document. This comment is not related to a factual inaccuracy and is, therefore, outside the scope of a factual accuracy check".		
Mihai Rotaru - EFPIA	9	213 - 217	Assessor/co-assessor must also provide a justification for how they have arrived to the conclusion that any given comment provided by the HTD is a factual accuracy check or not.		2a (good administration – fact check)
Tanja Podkonjak, Takeda	9	213 - 217	Takeda strongly suggests that the Assessor/co-assessor must also provide a justification for how they have arrived to the conclusion that any given comment provided by the HTD is a factual accuracy check or not.		2a (good administration – fact check)
Matias Olsen, EUCOPE	9	188-191,	Considering the length of the JCA, 5 calendar days is considered a very short time to check all the data included in the JCA, especially if additional clarifying questions are also included. For smaller companies with limited resources the proposed timeframe is especially prohibitive, while larger companies would need additional time for internal alignment. This period should		2a fact check 2b time window

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			be extended to 10 working days. Replace: "…and to provide its input in the corresponding comment form and to share it via a secure platform prior to the set deadline (5 calendar days).". With: "…and to provide its input in the corresponding comment form and to share it via a secure platform prior to the set deadline (**10** ~~calendar~~ **working** days).".		
Mihai Rotaru - EFPIA	9	231 - 233	All exchanges between the assessor/co-assessor regarding comments provided during the factual check and the responses from the HTD should also be included in the final JCA report, along side the original comment.		As mentioned on page 10: In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process, otherwise their comment is disregarded. Clarification provided is noted down in the "comments" column in the comments form.
Roche	9	177-179	We suggest removing this bullet point, based on our comment made to page 6, lines 108-110.	X	Please see answer above. Therefore, there is no need to remove this bullet point.
Roche	9	181-182	The factual accuracy check is a more thorough and time-consuming step compared e.g. with the completeness check of the submission dossier; therefore, for fairness, the HTD must be given at least 10 calendar days (or ideally 10 business days), i.e. at least the same time that the assessor/co-assessor will have to perform the initial completeness check of the submission dossier.		2a fact check 2b time window
Roche	9	190-191	Suggest to reword as follows: prior *"... **~~prior to~~ by** the set deadline..".*	X	Thank you.
Roche	9	198-199	Does this mean that if the HTD does not submit anything, that this will be counted as "no comments" or does the HTD need to actively confirm that they have		2a fact check

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			no comments?		
Roche	9	202-203	We find it concerning that no extension option is granted for special circumstances based on the decision of the HTD.		2b time window
Mihai Rotaru - EFPIA	9	180	EFPIA would like to point out that 5 calendar days are not enough to provide for a properly documented/referenced response to the factual check process. The maximal duration for the factual accuracy check of the HTD to is 5 "calendar days". This duration is reduced by possible weekend days or bank holidays. The duration should be determined according to "working or active days". We recommend increasing the duration to 7 working days. Moreover, the guideline fails to justify how the CSCQ has reached the recommendation that this procedural step should take only 5 working days.		2a fact check 2b time window
MEMBER MTE	9	186	Noting that draft JCA report will be marked "confidential" yet no confidentiality agreement will be in place.		6c confidential information
MEMBER MTE	9	191	5 days not acceptable should be at least double.		2a fact check 2b time window
Silke Walleser Autiero Medtronic	9	191	We request that this be clarified and reconsidered. Would 5 calendar days span a weekend? This could lead to a situation when the response would need to be completed in 3 days and that is just not feasible. We propose a longer timeframe such as 10 calendar days (such as eg HAS timing).		2a fact check 2b time window
Matias Olsen, EUCOPE	9	202	While the publication of the JCA report should not be delayed, this leaves too little flexibility for the Assessors to update the report, in the case the factual accuracy check unveils technical or factual errors that must be		2a fact check 2b time window

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			corrected. Remove: ~~"No deadline extension for the factual accuracy check can be granted, the process will proceed as foreseen in the project plan and the publication of the JCA report will not be delayed.".~~		
Mihai Rotaru - EFPIA	9	208	If the guideline will impose a deadline for the HTD to respond to the factual check, then the same deadline should be mirrored for the assessor/co-assessor to provide written answers to the questions received.		2a fact check
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	9	215	**Comment:** DRAFT GUIDANCE: *In case of doubt, the CSCQ JCA (or JCA subgroup in the HTAR) can be involved.* Why is the HTD disregarded? **Suggestion**: In case of doubt, the CSCQ JCA (or JCA subgroup in the HTAR) **and the HTD** can be involved.		2a (good administration – fact check)
MEMBER MTE	9	219	If data has not been interpreted correctly, then this would count as a factual inaccuracy and would need to be corrected		2a1 extent scope of fact check
Matias Olsen, EUCOPE	10	226-230	If no clarification was received, the comment should not be disregarded, but acknowledged in the report for publishing stating that it was not understood, and no further clarification was received after x days of request. Remove: "In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process~~, otherwise their comment is disregarded.~~ Clarification provided is noted down in the 'comments' column in the comments form.".		Thanks, a respective sentence was added.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Sebastian Werner vfa	10	226-230	"*In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process, otherwise their comment is disregarded. Clarification provided is noted down in the "comments" column in the comments form."* The deadline is not specified. The deadline should provide sufficient time (5 working days) to respond and should allow flexibility depending on the extend of the request for clarification.		2b time window
Norbert Gerbsch for IGES Institut GmbH and HealthEcon AG	10	226-229	**Comment:** DRAFT GUIDANCE: **„***In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process, otherwise their comment is disregarded.*" This leaves the HTD in a situation without the chance for a reasonable planning and with potentially insufficient time to respond to the request in case this request reaches the HTD shortly before the deadline. **Suggestion** DRAFT GUIDANCE: In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the **HTD at latest 5 working days before the deadline indicated by the project manager expires**. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process, otherwise their comment is disregarded.		2b time window
Sebastian	10	210-212	*"After the factual accuracy check period, while revising*		2a (good administration – fact check)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Werner vfa		213-215 218-220 226-227 231-236	*the draft report, the assessor and co-assessor provide written answers to all factual accuracy check related comments received from HTD directly in the comments form (i.e. in the column "assessor/co-assessor reply")."* *"Assessor and co-assessor are responsible for defining whether a comment is factual accuracy check related or not (based on the definition of the purpose and scope of a factual accuracy check)."* *"Comments that are outside the scope of a factual accuracy check, i.e. any comments affecting the interpretation of data (data presentation, description and summary of the report), are neither considered nor answered by the assessor/co-assessor."* *"In case assessor/co-assessor need clarification regarding a comment, the project manager sends a request to the HTD."* *"All comments received, and answers provided are shared with the entire CSCQ (JCA subgroup in HTAR), CEB (coordination group in HTAR), DG Sante and HaDEA prior to final endorsement of the JCA report.* *"All comments from factual accuracy check and respective answers are published on the EUnetHTA website together with the final JCA report."* Answers of the assessors and co-assessors to the HTD's factual check are published together with JCA report without the possibility of the HTD to effectively make known their views on these answers or on classifications of the factual accuracy check. However, the HTD should be provided with the possibility to effectively make known their views on the answers and classifications of the factual check. The vfa recommends establishing a process by which the HTD can respond to the assessor's answers with a subsequent exchange on unresolved issues.		
MEMBER MTE	10	227	*'In case assessor/co-assessor need clarification regarding a comment, the project manager sends a*		2b time window

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			request to the HTD. The HTD is requested to answer the comment until the deadline indicated by the project manager at the start of the process, otherwise their comment is disregarded.' By referring to the *'deadline indicated .. at the start of the process'*, it reads like even though the HTD does respond in time, the original timeline continues to clock down and the evaluators can decide to disregard any input, even if submitted in time. This seems to be giving the assessors undue leverage to dismiss comments by letting the deadline lapse. There should be a commitment to raising any questions before a certain time period, to assure that these two timelines do not conflict. Please clarify and consider rewording.		
MEMBER MTE	10	230	There needs to be a process whereby HTD can trigger an appeal if there is disagreement on a substantive issue		2a (good administration – fact check) 2e good administration
Roche	10	232	We think comments received and answers provided need not to be shared with the European Health and Digital Executive Agency. This is not foreseen in the HTAR. Please delete.		The comments form will be published. Please refer to Art 30 (IT platform), 3i: ".....the JCA reports considered procedurally compliant in accordance with Art 12, together with all comments received during their preparation."
Mihai Rotaru - EFPIA	10	231-233	All exchanges between the assessor/co-assessor regarding comments provided during the factual check and the responses from the HTD should also be included in the final JCA report, along side the original comment.		Same comment, see above
MEMBER MTE	10	238	*'In case there are objections regarding the published document, the process defined in the "Erratum Procedure" needs to be followed. Further information can be found on the EUnetHTA website (see question "What should I do if I see a potential error in a EUnetHTA report?").* It is kindly suggested to add a proposal for how to report errors under HTA R, or signal the need for further clarification.		15 Applicability after EUnetHTA21 So far, the HTAR does not specify this further, so this is up to the European Commission. We added a sentence to clarify this.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Roche	10	244	As contact point during the EUNetHTA21 phase a national secretariat (The Netherlands) secretariat is mentioned. The respective information for the HTAR should be shown additionally.		15 Applicability after EUnetHTA21 The HTAR mentions that the European Commission shall act as the secretariat of the coordination group. However, further details still need to be defined by the EC. Therefore, we consider that this is out of scope of the current guidance.
MEMBER MTE	10	244	Suggested to add *'Under EUnetHTA21,'* at the beginning of this sentence, to distinguish the different situations.		Thank you.
Mihai Rotaru - EFPIA	12	256 - 269	The HTD must be allowed to extend this check-list to be able to account for any eventuality depending on the specificities/complexities of the respective assessment.		2a1 extend scope of fact check
Tanja Podkonjak, Takeda	12	256 - 269	The draft factual accuracy checklist provided in Appendix (Section 7) should be positioned as a sample only. The current checklist is not exhaustive and is missing key elements like correct referencing, omission of important evidence etc. The HTD must be allowed to extend this checklist to be able to account for any eventuality depending on the specificities/complexities of the respective assessment.		2a1 extend scope of fact check
MEMBER MTE	12	256	The HTD should be allowed to extend the checklist to address and eventuality due to specificites/ complexities		2a1 extend scope of fact check
MEMBER MTE	12	264	Will the manufacturer of the comparator technology also have the opportunity to undertake a factual accuracy check? Likewise, the HTD should also be able to comment on factual inaccuracies that pertain to the comparator technology. This is important for single technology evaluations but absolutely imperative to class evaluations where several HTDs are involved.		We only have singly technology assessments under HTAR for JCA. Furthermore, the comparator might be an intervention and therefore the question might not be applicable for MDs. Also we cannot require HTDs to comment on comparator technologies. The comparator technology HTD will not do a factual accuracy check.
Matias Olsen,	7, 8	145-147, 162 - 163	As the Assessors are tasked with conducting the assessment, an independent body should define if a		2a (good administration – fact check)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
EUCOPE			comment is a factual accuracy check or not. This role could be carried out by the JCA subgroup, and in case of doubt the European Commission, acting as Secretariat in accordance with Regulation (EU) 2021/2282 Article 28 (d) could be involved. Remove: "The CSCQ JCA ~~(or JCA subgroup in the HTAR)~~ can be involved by the assessor/co-assessor in case it is unclear if the comments received are factual accuracy check related or not.".		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
D7.1.3 – guidance on handling commercially in-confidence data					
Mihai Rotaru - EFPIA	General		EMA guidance for handling commercial confidential information should be replicated for the future EU JCA system - In case of differing opinions on commercially confidential, a solution mechanism must be deployed before publication (interaction for clarification).		16 *Alignment with EMA guidelines for handling commercial confidential information*
Mihai Rotaru - EFPIA	General		Specifically in the case of JSCs, by submitting a request for a Parallel EMA/EUnetHTA 21 JSC, the HTD should be bound by the confidentiality framework already established with EMA and therefore will agree to the exchange of information between EMA and participating EUnetHTA 21 HTAbs. The Parallel EMA/EUnetHTA 21 JSC process is confidential. EMA and associated regulatory experts are bound by the EMA code of conduct, and confidentiality agreements, and operate under the **EMA policy on access to documents (Policy/0043).** EUnetHTA 21 prioritises confidentiality and each HTAb participant and associated expert, e.g. healthcare professionals and patient representatives, is required to submit a signed EUnetHTA 21 Confidentiality Agreement. Therefore, commercially confidential information provided to the EMA and EUnetHTA 21 within the context of a Parallel EMA/EUnetHTA 21 JSC is not shared with any party before authorisation outside of the respective EMA and HTA networks in the absence of a signed confidentiality undertaking or the consent of the sponsor.		*16 Alignment with EMA guidelines for handling commercial confidential information* *6c confidential information- confidentiality agreement with HTD*
Roche	General		Roche agrees with EUnetHTA21 that all documents related to JSCs shall be generally treated as confidential in their entirety, but Roche disagrees that information from the recommendations that relate to methodological aspects of study design may be included in the final JCA report, if required. This information does not contribute to the clinical assessment and must be treated as confidential.		6d confidential information of JSC in JCA
MTE	General		While we welcome the principle of transparency, openness		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			and fair engagement, there is a high degree of unclarity related to the confidentiality in general and the handling of the commercial in confidence data. This leads to significant concerns of possible competition distortion within the medical technology sector and infringement of EU laws. A more in dept discussion and consideration is welcomed. The document also leaves significant doubt about the commitment to keeping selected information confidential and lacks a description of who exactly will be responsible for this key task. Therefore EU Legislative consideration and regulation are to be considered to ensure compliance and avoid any interterence with other EU regulation. Whenever the opportunity exist information whereby commercial in confidence data – proprietary data concerns have already been addressed, such data should become a primary source avoiding potential confidentiality breaches.		
MTE Member	General		Uncertainty – Unpredictability for HTD about confidentiality handling it will eventually result in a much smaller incentive to undergo HTA/JCA and engage actively with the HTAbs and provide early access to information and data. This will potentially lead to a poorly functioning regulation with fewer and lower quality JCAs and infringe current good national practices		6 confidential information Thank you for your comment. The guideline was updated to provide more details and more predictability for HTDs.
MTE MEMBER	Appendix	Submission dossier/JCA report	We consider that the HTD should have the right to redact confidential information prior to publication. This to implement art.11 (5)		2e good administration Interaction HTA-HTD 6 confidential information
Sebastian Werner vfa	General		Although EUnetHTA 21 expresses its commitment to fair engagement with all stakeholders and balancing public and companies' commercial interests, it is surprising that at the same time the authors express their clear focus on the public interest in having access to the widest possible range of information on which reports, and decisions are based. The vfa is concerned that this might pose a risk for the rights for protection of commercially in confidence data of companies or the rights of patients regarding the protection of their data privacy. EUnetHTA21 should follow a well-balanced approach considering public interests to the same		Thank you for your comment. The guideline was updated to provide more details and more predictability for HTDs.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			extent as commercial interests of companies and interests of patients.		
Sebastian Werner vfa	General		Joint clinical assessment and joint scientific consultations require sharing of confidential information between HTD and HTAb. The protection of commercial in confidence data must be warranted. Therefore, confidentiality agreements between HTD and HTAb are always necessary. Information provided to the HTAb should only be disclosed to a third party after a confidentiality agreement has been concluded. Any person involved in the preparation of HTA documents or having access to the information should sign a confidentiality agreement (staff of the HTAbs, regulatory authorities, involved clinical experts, patients or other experts). However, the guidance specifies no such confidentiality agreement between the participating HTD and EUnetHTA21, neither for a JSC process, nor for a JCA. However, there are no objective reasons apparent why confidentiality agreements should not be necessary for EUnetHTA21 JCA or JSC pilots, but for the regular JSC and JCA. Confidentiality agreements between HTD and HTAb are always necessary, incl. EUnetHTA21.		6c (confidential information – confidentiality agreement with HTD)
Sebastian Werner vfa	General		The process for handling commercially in confidence data lacks a meaningful interaction between health technology developer (HTD) and the assessors of the health technology assessment bodies (HTAb). Commercially in confidence data designated by the HTD might be published without given the HTD the possibility to respond to opinions expressed by the HTAb regarding their classification. However, the HTD must be provided with the possibility to effectively make known their views on the correctness and relevance of the facts and circumstances which are subject matter of this administrative process. If this possibility is not granted, there is a risk that trade secrets will be published that are legally protected by Directive EU 2016/943. In case of the publication of trade secrets, the damage to the HTD is irretrievable. Additionally, it is mandatory, in the spirit of fair		6 confidential information 2e good administration Interaction HTA-HTD

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			procedure under Art. 47 EU-Charter, to establish a process by which the HTD can effectively respond to the opinions of the assessors with a subsequent exchange on unresolved issues, to prevent its trade secrets from being published. The process must include a conflict resolution mechanism for cases where different opinions between the HTD and the assessors of the HTAb persist.		
Sebastian Werner vfa	General		Only aggregated data shall be presented in submission dossiers and JCA reports. Nevertheless, the guidance asks for new requirements regarding the submission of patient individual data and patient individual characteristics for the possible purpose of the scientific evaluations. The data should be provided by the HTD in the underlying documentation of the submission dossiers, which is not going to be published. The HTAR does not contain any requirement regarding the transfer or the use of individual patient data. Further, the purpose of patient individual data for the scientific evaluations remains completely elusive. The guidance does not give any detail on why these data are indeed necessary. The German Ministry of Health concluded in 2019 that pseudonymized individual patient data of clinical studies are generally not necessary for ensuring that the clinical assessment process is designed appropriately and functionally. By reason of the principle of proportionality and the principle of data minimization according to Art. 5 para. 1 lit. c of the General Data Protection Regulation (GDPR), patient individual data are therefore not required for dossier submissions in Germany. At most, a case-by-case justifiable requests (of anonymized data) to the HTD are admissible in Germany, should this be necessary for the health technology assessment in specific cases. The processing of pseudonymized individual patient data of the clinical studies by EUnetHTA and under the HTAR is not GDPR complaint and would require a separate legal basis.		6 confidential information 6a individual patient data

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			In addition, HTD cannot transfer individual patient data to EUnetHTA and the Coordination Group without a separate legal basis, as breaches of the GDPR by companies carry significant penalties (3-4% of global turnover).		
Tanja Podkonjak, Takeda	General		A mechanism for handling disagreements in what classifies as confidential data must be established. EMA guidance for handling commercial confidential information should be replicated for the future EU JCA system - In case of differing opinions on commercially confidential, a solution mechanism must be deployed before publication (interaction for clarification).		6 Confidental information
Daniel Widmer UEMO	general		Balancing public interest against the commercial interest of individuals and companies is very important for UEMO		Thank you for your comment
Matias Olsen, EUCOPE	6-7	146-151	Add: "• **Any kind of data on-file of any research developed by a HTD e.g., data cuts of research clinical trials, etc., as disclosing not mature data could jeopardise the results of a clinical trial, but can provide useful information for HTA** • **Manufacturing or logistics processes**"		Thank you for your comment. The guideline was updated to provide more details and more predictability for HTDs with regard to confidential information.
Mihai Rotaru - EFPIA	5	75 - 89	EFPIA agrees with the principle of transparency, openness and fair engagement with stakeholders and specifically agree that all information relevant to the assessments should be made available to the assessor/co-assessor, the members of the Coordination Group, and the relevant experts involved in the assessment. However, the HTA R specifically allows for HTDs to indicate commercially confidential information and allows for the protection of that information. While we recognise the public interest in the production of JCA reports, we strongly object to EUnetHTA21 making the determination that the public interest trumps the right of HTDs to protect commercially confidential information. A final determination as to the		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			primacy of the rights of any constituency involved in the JCA over another constituency can only be made by the European Court of Justice.		
Matias Olsen, EUCOPE	5	102-108	The ICMJE recommendation is non-governmental and not legally binding and the fact that ICMJE would not consider information published in HTA "duplicate publications" does not render the question of confidential handling of such information irrelevant to the EU HTA procedure. Once information is publicly available (e.g. in a JCA report), it influences the potential granting of patents and may influence activities of others, be it researchers or other companies. Besides a competitive disadvantage, this may also lead to a disadvantage for academic researchers involved, as data/ideas may be copied by other researchers who then may end up being first to publish similar findings. The publication of confidential data of the HTD with commercial interest cannot be bound to such a recommendation which may be subject to change. The HTD must be given the opportunity to signal any information it considers to be confidential, in accordance with Regulation (EU) 2021/2282 Article 11 (5) and there needs to be a guidance on academic in confidence data / guidance on handling of clinical data.		6 confidential information
Sebastian Werner vfa	5	93-96	*"It relates primarily to information published in HTA documents. Any person involved in the preparation of HTA documents or having access to the information must sign a EUnetHTA 21 confidentiality agreement (ECA)1. This applies to staff of the HTAbs, regulatory authorities, involved clinical experts, patients or other experts."* A confidentiality agreement is important and should be in place. However, the statement contradicts directly statements made in 7.1.1 and 7.1.3., where no such confidentiality agreement between the participating HTD and EUnetHTA21, is specified. Thus, 7.1.1 and 7.1.3. should be		6c confidentiality agreement

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			amended accordingly to reflect, that a confidentiality agreement will be in place.		
Roche	5	93-95	We as HTD are concerned that our data will be shared randomly with third parties because they are "somehow" involved in the preparation. The persons with whom it can be shared should be more precisely defined or limited in number. The data still belongs (partly) to the HTD and therefore he should be able to control and keep track with whom the data is shared. The HTD is being completely taken out of control, especially with which third parties the data is shared. Therefore, for HTAR, the procedure proposed in Rectal 41 (HTD includes CDA with third parties) should be considered.		6 confidential information
Matias Olsen, EUCOPE	5	79-80	This sentence should be removed. While transparency of the process itself is essential, a good balance of public interest and commercial interest of the companies is necessary. As stated in Recital 29 of Regulation (EU) 2021/2282 "Transparency and public awareness of the process is essential. Where there is confidential data for commercial reasons, the reasons for confidentiality need to be clearly set out and justified and the confidential data well delimitated and protected". Remove: "~~However, the focus must be on the public interest in having access to the information on which reports and decisions are based~~".		Thank you for your comment. The sentence was modified.
MTE MEMBER	5	93	*'Any person involved in the preparation of HTA documents or having access to the information must sign a EUnetHTA 21 confidentiality agreement (ECA)1. This applies to staff of the HTAbs , regulatory authorities, involved clinical experts, patients or other experts.'* Please ensure this is reflected throughout all other procedural guidance documents as there are currently direct		*6c (confidential information – confidentiality agreement with HTD)*

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			contradictions in D7.1.1 (on interaction) and D7.1.2 (on factual accuracy check).		
Tanja Podkonjak, Takeda	5	101	Takeda notes the statement from the International Committee of Medical Journal Editors (ICMJE) regarding the treatment of academic in confidence data used and published in the context of an HTA appraisal. However, we seek further clarity and guidance from medcial assocciations and medical congresses as well. Data is general under strict embargo until presentation. We request EUnetHTA seek a similar commitment from medical associations and congresses in regardgs to acaedmic in confidenc data.		6 confidential information
MTE MEMBER	5	107	Given that trials for medical technologies are often lead, have as data owners by academic institution land academic in confidence data, analysis might have and impact on competitions, HTD propose to foresee the necessary provision unless this will be covered by the definition of CIC. Clarification is needed		6 confidential information
Sebastian Werner vfa	6	140-145	*"Within the framework of the service contract, EUnetHTA 21 will adopt the definition of Commercial confidential information of the EMA (according to HMA/EMA Guidance document on the identification of commercially confidential information)"* The vfa recommends using the EMA policy 0070 to define commercial confidential information. *"CCI shall mean any information contained in the clinical reports submitted to EMA by the applicant/MAH which is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH."*		Details were added. 16 *Alignment with EMA guidelines for handling commercial confidential information*
Matias Olsen, EUCOPE	6	142-145	We suggest using the more general definition available on EMA webpage: "Commercial confidential information: Information whose publication might prejudice the commercial interests of individuals or companies to an unreasonable degree.".		16 *Alignment with EMA guidelines for handling commercial confidential information*

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Mihai Rotaru - EFPIA	6	136 - 138	The guideline should however specify that any interpretation as to what constituted commercially confidential information should be based on existing legal practice, as defined by ECJ jurisprudence.		16 *Alignment with EMA guidelines for handling commercial confidential information*
MTE MEMBER	6	142ff	*'Commercial confidential information' shall mean any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. (EMA/484118/2010)).'* Note that the EMA has a further definition for this, which in the spirit of this pan-EU procedure, should be adopted in addition: Commercially confidential information = Information whose publication might prejudice the commercial interests of individuals or companies to an unreasonable degree. The Agency cannot disclose commercially confidential information unless there is an overriding public interest in disclosure. (Ref: https://www.ema.europa.eu/en/glossary/commercially-confidential-information) In addition, the EU antitrust law provide a definition as to what constitute business secrets - e.g. technical and/or financial information relating to an undertaking's know-how, methods of assessing costs, production secrets and processes, supply sources, quantities produced and sold, market shares, customer and distributor lists, marketing plans, cost and price structure and sales strategy. We urge the proposers to be highly diligent in their judgement and handling of submitted information. This also extends to clinical information - it cannot be a priori excluded from informed judgement, as this draft guidance seem to indicate repeatedly.		16 *Alignment with EMA guidelines for handling commercial confidential information*
Roche	6	146	The list is too short and gives the impression that it is conclusive. There is already an established system with examples of what is recognised as CCI (Regulation (EC) No 1049/2001 and EMA's Policy 0040 or Policy 0070). Particularly in the case of innovative products, it cannot be said with certainty that further information could be added		16 *Alignment with EMA guidelines for handling commercial confidential information*

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			that could be classified as CCI. Since the HTD has to issue a justification anyway, the list should remain flexible and expandable in the future.Therefore it should be clarified that this is not an exhaustive list.		
Tanja Podkonjak, Takeda	6	Line 147	The current list of eligible aspects will be considered as commercially confidential information is not exhaustive and needs to be expanded to include the following: - Development plans o an asset (medical product or device) - Sales forecasts, population projections (treated patients) - Market share and coverage - Volume projections - Trade secrets around recruitment, development plans, methodology and site management As this list is incomplete, we recommend the HTD claim and list the confidential information in their submission. In the case of disputes, a mechanism must be established.		16 *Alignment with EMA guidelines for handling commercial confidential information* 6 confidential information
Silke Walleser Autiero Medtronic	7	139-145/ 2.1	We agree with the definition given by EMA. However, it should be recognised that medical devices/technologies enjoy far less intellectual property protection than medicinal products. This should be acknowledged by the HTAb and ensure that MTDs requests for confidentiality are fully respected. Indeed, it appears that the final decision on commercial confidentiality sits with the HTAb and not the HTD and this is not acceptable.		16 *Alignment with EMA guidelines for handling commercial confidential information*
Mihai Rotaru - EFPIA	7	154 - 166	EFPIA would like to point out that respect for Personal Data also extends to Individual Patient Data (IPD). Moreover, A JCA process which is designed properly and transparently (including the HTD in the process) does not require IPD, it also seems to breach the fundamental principle of proportionality as it places considerable additional burden on both the HTD and the assessor and co-assessor without any obvious gain. It also seems in breach of the well understood principle of data minimization (as foreseen by GDPR).		6a confidential information – IPD

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Sebastian Werner vfa	7	146-151	*"The following aspects will be considered as commercially confidential information: trade secrets (including e.g. formulas, programs, process or information contained or embodied in a product, unpublished aspects of trade marks, patents, etc); structures, chemical analytics; development plans of a company; pricing details"* Pricing details are associated with contracting information. Please add "*and contracting details"* to pricing details.		amended
Roche	7	163-166	If the assessor and co-assessor are conducting their own scientific evaluations and require access to individual patient characteristics and individual patient results, they are processing personal data and GDPR is applicable. So far there is no adequate proof of concept presented to do this in a compliant way based on the following reasons: ● There is no legal basis that justifies processing personal data for the European HTA assessment on EUnetHTA or HTAR level. ● In that case the assessor and co-assessor are controllers of the data and thus obligated to inform the patients and responsible for possible data subject rights requests in accordance with GDPR. ● Furthermore, technical and organisational measures must be taken to protect the data and audit rights to control compliance. If EUnetHTA or HTAR cannot provide an adequate proof of concept, only anonymous data shall be used for the purpose of scientific evaluation. In addition, for reasons of data minimization according to Art. 5 I lit. c of GDPR and the principle of proportionality, individual patient characteristics and individual patient results as well as the conduct of scientific evaluations by the assessor / co-assessor are generally not necessary for		6a confidential information- IPD

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			ensuring that the evaluation process is designed appropriately and functionally. The assessor / co-assessor can also request additional evaluations from the HTD. As a minimum the HTD should be involved in all other evaluations (after all, it is its data).		

Sebastian Werner vfa	7	163-166	*"However, the assessor and co-assessor may require access to individual patient characteristics and individual patient results for the purpose of their scientific evaluations. Therefore, this information should be available in the underlying documentation. EUnetHTA 21 citations will be GDPR compliant."* The guidance sets new requirements regarding the submission of patient individual data and patient individual characteristics for the possible purpose of the scientific evaluations. However, the HTAR does not contain any requirement regarding the transfer or the use of individual patient data. Further, the purpose of patient individual data for the scientific evaluations remains completely elusive without any detail on why these data are indeed necessary. The same issue already had to be clarified in Germany in 2019. The German Ministry of Health concluded that pseudonymized individual patient data of clinical study reports are generally not necessary for ensuring that the clinical assessment process is designed appropriately and functionally. By reason of the principle of proportionality and the principle of data minimization according to Art. 5 para. 1 lit. c of the General Data Protection Regulation (GDPR), patient individual data are therefore not to be submitted as a regularly mandatory component for dossier submissions in Germany. At most, a case-by-case justifiable requests (of anonymized data, because of no sufficient legal basis for pseudonymised data) to the HTD are admissible in Germany, should this be necessary for the health technology assessment in specific cases (BMG, 2019). The processing of pseudonymized individual patient data of the clinical studies by EUnetHTA and under the HTAR is not GDPR complaint and would require a separate legal basis. In addition, HTD cannot transfer individual patient data to EUnetHTA and the Coordination Group without a separate legal basis, as breaches of the GDPR by companies carry significant penalties (3-4% of global turnover). • Decision of the German Ministry of Health on the resolution of the Joint Federal Committee pursuant to Section 91 Social Code Book V, 1. resolution of March 16, 2018, on an		6a confidential information- IPD

			amendment to the Rules of Procedure (Amendment of Annex I and II to Chapter 5.) https://www.g-ba.de/downloads/40-268-5737/2018_03_16_2019-02-21_VerfO_Aenderung-Anlage-II_Kapitel-5_konsolidiert_BMG.pdf		

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
Matias Olsen, EUCOPE	7	163-165	The Assessors cannot disclose confidential information when citing the HTD submission if that information is provided as commercial confidential information. Due to data protection reasons, individual patient data should not be published nor shared, even with the Assessor or Co-Assessor. It is furthermore unclear how this information would be used in the assessment and how patient individual data may be used to inform the overall assessment of a new drug.		6 confidential information 6a confidential information- IPD
Silke Walleser Autiero Medtronic	7	163-165	It has to be taken into consideration, that in some cases HTD do not have access to individual patient data, eg in case of third party projects (even if they are co-sponsored by the HTD)for which only a publication is available. The HTD would therefore not be able to submit these data.		6a confidential information- IPD
Roche	7	152-153	Just because sharing data on methodology and on clinical data is in the public interest, it cannot automatically be inferred that this information is not confidential. This is a wrong conclusion. The public interest reaches the limit where CCI of the HTD begins. Instead, a process should be developed to protect CCI in a meaningful way where the confidentiality can be clearly set out. We recommend a procedure whereby certain parts, such as the underlying documentation, are not published instead of blacking out confidential information. This would otherwise involve a disproportionate effort. .		6 confidential information
Silke Walleser Autiero Medtronic	7	152-153	Although we recognise the statement from ICMJE, could this please be reconsidered. This may limit the will of clinicians/investigators to share unpublished clinical data (academic in-confidence data) for the HTAR before the submission of a manuscript in a medical journal.		6 confidential information
MTE MEMBER	7	152	*Transparent information and sharing data on methodology and on clinical data is the public interest. Therefore these data will be generally considered as non-confidential.* Further clarification and definition of public interest is needed as the clinical data and methodology might well be not the public domain		16 *Alignment with EMA guidelines for handling commercial confidential information* Details were added

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MTE MEMBER	7	152	Sharing information on methodology/clinical data, if unpublished, may compromise a HTD's position (like share price, etc.) therefore this information should be considered as confidential		amended
MTE MEMBER	7	163	*'However, the assessor and co-assessor may require access to individual patient characteristics and individual patient results for the purpose of their scientific evaluations. Therefore, this information should be available in the underlying documentation. EUnetHTA 21 citations will be GDPR compliant.'* The HTD would in this case remain the data controller and EUnetHTA 21 would become the data processor as per GDPR. As data breaches on the site of the processor have to be reasonably anticipated, a crisis plan has to be established in the case of wrongful access, loss or destruction of personal data. This process should in particular outline: timelines from breach on processor side to notification of controller (HTD), duty of notification of affected individuals i.e. data subjects, and cost liability for all resulting crisis proceedings. Please clarify that such crisis plan will be put in place.		6a confidential information- IPD
MTE MEMBER	7	163	As (Assessors/Co-assessors) may require access to individualised patient characteristics/ results), confidentiality agreements need to be in place before any information is shared for a JCA		6 confidential information
Matias Olsen, EUCOPE	7,9	152-153, 206-212	While we agree that all such information should ultimately be made publicly available, we want to stress that a premature publication of clinical data may undermine the economic interest or competitive position of the owner of the information (i.e. this may have a negative impact on the competitive position of the data owner, especially given that scientific merit is measured in number of publications in high-profile academic journals). There may also be cases where the HTD is not the owner of the information, such as when the HTD is the licensee or may have supported a clinical trial/registry without being the (sole) sponsor. In such cases, it is very likely that information can only be shared with authorities if confidentiality can be guaranteed by the information owner.		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Therefore, unpublished clinical data in any case needs to be considered with caution, and there needs to be the possibility to redact this type of information if justified (in particular relating to CSRs or outcome of registry studies, except for already public information in EPAR/Clinicaltrials.gov/clinicaltrialsregister.eu). Methodology and clinical results included in the submission dossier could be considered to be non-confidential. All information exceeding the dossier (e.g. underlying documentation such as CSR, protocol, SAPs, etc.) should be considered confidential. Add: "Transparent information and sharing data on methodology and on clinical data is in the public interest. Therefore, these data will be generally considered as non-confidential **unless it is provided in the procedure as commercial confidential information**." At the end of this section, it should be mentioned as it is done in '2.2 Personal data' that as a general rule, commercial confidential information will not be released and will be redacted before a document is made available. Add: "**As a general rule, commercial confidential information will not be released and will be redacted before a document is made available.**".		
Sebastian Werner vfa	8	171-174	*"All documents related to JSCs shall be generally treated as confidential in their entirety. In particular, this is mandatory prior to marketing authorisation. However, the documents will be shared with those involved in the specific JSC within EUnetHTA 21 and with the experts (e.g. HCP, patients) involved, as appropriate. All participants with access to the*		6 confidential information 6d confidential information : JSC in JCA

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			documents have signed an ECA." Due to the very high commercially sensitivity of Joint scientific consultations the number of experts (e.g. HCP, patients) to be involved should be kept to a necessary minimum. Further, it should be clarified whether these processes are likewise planned under the HTAR.		
Sebastian Werner vfa	8	180-183	*"The Final recommendations from the JSC must be submitted in the underlying documentation of the subsequent JCA submission dossier by the HTD and will therefore be shared with the JCA assessor and co-assessor. Information from the recommendations that relate to methodological aspects of study design may be included in the final JCA report, if required."* Joint scientific consultations included in the submission dossier must remain confidential as they contain commercially sensitive information about the developmental plan of the health technology. Developmental plans are considered commercially confidential information (cf. Line 150). Methodological aspects of the study design and analyses can be part of these develpmental plans. Methodological information in the development plan must be therefore treated as commercially confidential information. These methodological aspects might reveal the global strategy decisions of the HTD. Methodological information in the context of JSC must therefore be treated as confidential. Therefore, iinformation from the recommendations that relate to methodological aspects of study design must not be included in the final JCA report. The HTD must have the possibility to mark section 1.3 of the submission dossier as "commercial confidential" (cf. Submission Dossier Guidance) to prevent that this methodological information becomes publicly available.		6d confidential information : JSC in JCA
MTE MEMBER	8	174	Will signing a ECA also be the case outside of EUnetHTA21?		15 applicability after EUnetHTA 21

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			Please provide clarification for proposal for a future HTA-R methodology vs specific application in EUNETHTA21 JCA/JSC planned		On page 6 under 1.2. Purpose and Scope we state the following: "The document might need to be revised at a later date to ensure full compatibility with the HTAR and relevant implementing acts." We consider this comment out of scope of the current guidance, it needs to be decided by the European Commission in due course.
Sebastian Werner vfa	9	206-212	*Transparent information, public awareness of the process and sharing data on methodology and on clinical data is in the public interest. Therefore, these data will be generally considered as non-confidential.* This statement violates the right of pharmaceutical companies for protection of their trade secrets that are legally protected by Directive EU 2016/943. Development plans of companies, that are shared with the HTAb in the context of JSC often contain methodological aspects of the study design and analyses. These are commercially confidential information as acknowledged by the EMA definition (cf. line 150 of the Guidance). Sharing methodological aspects of developmental plans in the name of public interests is not admissible. EUnetHTA21 must make clear that methodological aspects cannot be generally designated as non-confidential in the context of JSC. It is important to clarify that methodological aspects cannot be generally considered as non-confidential, as in the context of JSC these must be classified as commercially confidential information.		6 confidential information
Roche	9	217-219 in conjunction with 259-260	EUnetHTA gives itself the unjustified authority to decide whether something is classified as CCI or not. The regulation contains no legal basis for this. In addition there is no indication of the legal remedy if the HTD does not agree to the rejection of a redaction. In addition we miss any time-frame in which EUnetHTA should assess what can be redacted from the submission dossier and what not and		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			inform the HTD about it to give the HTD some opportunity to react.The right to seek effective remedies can not be excluded.		
Roche	9	217-219	The last sentence is a bit confusing. Did you mean *"If EUnetHTA **disagrees** ~~concludes~~ that the information needs to be redacted, it will state in its report that the HTD has objected to the publication of relevant data for commercial reasons."?*	X	
Matias Olsen, EUCOPE	9	210-212	Add: "Transparent information, public awareness of the process and sharing data on methodology and on clinical data is in the public interest. Therefore, these data will be generally considered as non-confidential **unless it is provided in the procedure as commercial confidential information."**		6 confidential information
Matias Olsen, EUCOPE	9	213-215	This must exclude information present in the submission dossier that is identified by the HTD as commercial confidential information.		6 confidential information
Matias Olsen, EUCOPE	9	233-234	Any commercial confidential information must be redacted before any document enter the public domain.		2e good administration – hearing after JSC or JCA
MTE MEMBER	9	206	*'To support the production and transparency of the JCA, the assessor and co-assessor can cite and transcribe any information on methods and clinical results from the entire submission dossier, including information from the Clinical Study Reports (including study protocols and statistical analysis plans), safety data or statistical analysis plan.'* The term 'any' is confusing as confidential information must be withhold. There might elements of information, even in regards to clinical data, that cannot be disclosed publicly. Please add clarification that both citation and transcription do not result in disclosing confidential information.		6 confidential information
MTE MEMBER	9	211	We consider that the HTD should have the final say in what information is considered confidential and in the case of the Assessor/Co-assessor citing these (potential) information, it should be considered on a case-by-case basis.		2e good administration – hearing after JSC or JCA
MTE	9	213	*'Information from the entire Submission Dossier (including*		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
MEMBER			*underlying documentation) may be cited and transcribed for the JCA report and thus enter the public domain.'* The term 'entire' is confusing as confidential information must be withhold from entiring public domain. Please add clarification that confidential information will not be made available publicly and who is responsible for this.		
MTE MEMBER	9	213	We consider that the HTD has the right to mark confidential information within the submission dossier and this will remain redacted upon publication.		2e good administration – hearing after JSC or JCA
MTE MEMBER	9	216	*'Where there is confidential data for commercial reasons, the reasons for confidentiality need to be clearly set out and justified. If EUnetHTA 21 concludes that the information needs to be redacted, it will state in its report that the HTD has objected to the publication of relevant data for commercial reasons.'* It is not acceptable that EUnetHTA21 can override HTD judgement without further consultation. For this to work, re-assurance is needed that the process is safe. Please reconsider your proposal to also be conform the legal basis within the HTA-R.		2e good administration – hearing after JSC or JCA
Roche	9	217	*"(...) it will state in its report that the HTD has objected to the publication of relevant data for commercial reasons."* We criticise this wording. This is an unnecessary negative portrayal of the HTD. It portrays the HTD as blocking something when it is only exercising its right to protect its CCI. We recommend something more neutral like: "The report contains commercial confidential information and is therefore partially redacted".	X	6 confidential information
MTE MEMBER	9	217	*The HTD has objected to the publication of relevant data for commercial reasons.* A more neutral statement would be welcomed eg. a general clause indicating that commercial confidential data is redacted.	x	5 (editorial)
Mihai Rotaru – EFPIA	9	218-223	EFPIA objects to the simplistic procedural step foreseen in the guideline to allow the assessor/co-assessor to not		2e good administration – hearing after JSC or JCA

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			respond to a comment provided by the HTD. Such an approach significantly increases the risk of confusion and the legal uncertainty of the final JCA report in the context of its use at national level.		
Mihai Rotaru - EFPIA	9	213-217	Assessor/co-assessor must also provide a justification for how they have arrived to the conclusion that any given comment provided by the HTD is a factual accuracy check or not.		6 confidential information
Matias Olsen, EUCOPE	9	232	This should include contractual agreements and pricing details.		amended
MTE MEMBER	9	233	*'The underlying documentation included in the Submission Dossier will not be published as such, however, they may be cited or transcribed in the JCA report.'* Citation and transcription are fine but confidential information ultimately must be redacted out from the final JCA report. Please introduce wording to such extent and declare who is responsible to do so. Alternatively, as this is a repeat of lines 214-215, it could be removed.		6 confidential information
Matias Olsen, EUCOPE	10	236 - 253	This paragraph states that clinical trial study reports will be released externally after marketing authorisation is granted. This is in direct contradiction to page 9 line 213-214 ("The Submission Dossier, excluding the underlying documentation, will be published (without redaction) on the EUnetHTA 21 website") and the table in the appendix on page 11 which both say that attachments to the submission dossier/underlying documentation are not to be published. Any commercial confidential information should be redacted before any document enters the public domain.		6 confidential information
	10	255-261	*"The HTD shall signal any information it considers to be confidential and justify its commercially sensitive nature when they submit the submission dossier and during the factual accuracy check of the JCA report. The HTD must submit a written objection to the publication prior to the*		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			deadline of the factual accuracy check. The comments will be discussed within EUnetHTA 21 (CSCQ, assessor and co-assessor). In case of a differing opinion to the HTD's opinion, the HTD will be informed prior to publication." Commercially in confidence data designated by the HTD might be published without given the HTD the possibility to respond to the divergent opinions expressed by the HTAb regarding their classification. Without this possibility, the guidance is not aligned with the principle of fair trial (Art. 47 EU-Charter). In case of the publication of confidential information, the damage to the HTD is irretrievable. The HTD must be provided with the possibility to effectively make known their views on the opinions of the HTAb assessors regarding commercial in confidence. A process must be established by which the HTD can effectively respond to the opinions of the HTAb which should include a conflict resolution mechanism for cases where different opinions between the HTD and the assessors of the HTAb persist. To avoid these issues the process should also include a conflict resolution mechanism for final declaration of commercial in confidence information to ensure that no confidential information is published.		
Matias Olsen, EUCOPE	10	255-261	Any commercial confidential information should be redacted before any document enter the public domain Further, there should be an appeal mechanism in place to deal with situations where HTA bodies and HTD opinions diverge. Publication of un-redacted information should not happen while independent review is ongoing. Add: The HTD must submit written objections to the publication prior to the deadline of the factual accuracy check. The		2e good administration – hearing after JSC or JCA

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			comments will be discussed within EUnetHTA 21 (CSCQ, assessor and co-assessor). In case of a differing opinion to the HTD's opinion, the HTD will be informed prior to publication **and allowed to remove any information provided. In this case CSCQ, assessor and co-assessor will not consider the data in their assessment**."		
Sebastian Werner vfa	10	255-259	*"The HTD shall signal any information it considers to be confidential and justify its commercially sensitive nature when they submit the submission dossier and during the factual accuracy check of the JCA report. The HTD must submit a written objection to the publication prior to the deadline of the factual accuracy check. The comments will be discussed within EUnetHTA 21 (CSCQ, assessor and co-assessor). In case of a differing opinion to the HTD's opinion, the HTD will be informed prior to publication."* Commercially in confidence data designated by the HTD might be published without given the HTD the possibility to respond to the divergent opinions expressed by the HTAb regarding their classification. Without this possibility, the guidance is not aligned with the principle of fair trail (Art. 47 EU-Charter). In case of the publication of confidential information, the damage to the HTD is irretrievable. The HTD must be provided with the possibility to effectively make known their views on the opinions of the HTAb assessors regarding commercial in confidence. The vfa recommends establishing a process by which the HTD can effectively respond to the opinions of the HTAb including a conflict resolution mechanism for cases where different opinions between the HTD and the assessors of the HTAb persist.		2e good administration – hearing after JSC or JCA 6 confidential information
Roche	10	250-251	EMA/Regulatory national competent authorities (NCAs) remit should not overlap or be confused with EU HTAb remit. GxP inspections do not fall into the remit of EU HTA, according to the EU HTAR; these are a component of the EMA assessment of a marketing authorisation application. As soon as CHMP adopts a positive opinion, which will	X	5 (editorial)

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			trigger the continuation of a JCA procedure, it means that there are no outstanding compliance/non-compliance issues to be addressed. Furthermore, if there were any major concerns these were resolved during the regulatory assessment and will be reflected in the EPAR. Hence any information related to inspections is deemed out of scope and irrelevant for JCAs and the sentence transcribed below should be deleted: *"Information on Inspections (Information on the outcome of inspections (e.g. compliance/non-compliance/outstanding issues to be addressed)."*		
Sebastian Werner vfa	10	260-261	*"Data on methodology or clinical trial results (including safety data) that are considered relevant to the evaluation are generally not considered commercially confidential."* This statement violates the right of pharmaceutical companies for protection of their trade secrets that are legally protected by Directive EU 2016/943. Development plans of companies, that are shared with the HTAb in the context of JSC often contain methodological aspects of the study design and analyses. These are commercially confidential information as acknowledged by the EMA definition (cf. line 150 of the Guidance). Sharing methodological aspects of developmental plans in the name of public interests is not admissible. EUnetHTA21 must make clear that methodological aspects cannot be generally designated as non-confidential in the context of JSC.		6 confidential information
MTE MEMBER	10	236	We consider that the HTD should have the authority to determine what information is deemed confidential and therefore redacted before publication. These criteria should be set out in the confidentiality agreement		2e good administration – hearing after JSC or JCA
MTE MEMBER	10	257	*'The HTD must submit a written objection to the publication prior to the deadline of the factual accuracy check .'* How can one provide written objection before knowing what is in the draft document ? How will be ensured that the two timelines do not conflict ? Please clarify what exactly is meant here and consider		6 confidential information

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			rewording.		
MTE MEMBER	10	260	We consider that the HTD should have the final decision on what data (i.e. methodology/clinical trial results) is considered confidential and therefore will be redacted before publication		6 confidential information
Tanja Podkonjak, Takeda	10	255, 257	"The HTD shall signal any information it considers to be confidential and justify its commercially sensitive" Further clarity is required on what type of justification is expected and aligned with the definition of confidentiality		6 confidential information
Tanja Podkonjak, Takeda	11	Appendix	Based on Section 4 there does seem to be an opportunity for the HTD to signal information it considers to the confidential with justification. In such an instance, should EUnetHTA agree – will this then be redacted? If so, this should be noted in the table in the Appendix.		2e good administration – hearing after JSC or JCA
Mihai Rotaru - EFPIA	11	271 - 273	EFPIA would like to specifically dispute that, in the Appendix table, none of the steps foresees the possibility to redact information. This goes against the HTA R Art 11 (5) Assessment process for joint clinical assessments: "The health technology developer shall also signal any information it considers to be confidential and justify its commercially sensitive nature."		2e good administration – hearing after JSC or JCA 6 confidential information The HTD shall signal information during the factual accuracy check. Conflict resolution mechanism was added.
Matias Olsen, EUCOPE	11	271-273	All rows in the "Free to cite?" column should say "Yes, excluding confidential information" All rows in the "Redaction possible?" Column should say "Yes"		2e good administration – hearing after JSC or JCA
MTE MEMBER	11	272	The table indicates no option for redaction of the submission dossier and its attachments, JCA report and summary. This contradicts other parts of the document. It also signals a non-commitment to keeping confidential information out of the public domain which is highly disturbing. Please clarify.		2e good administration – hearing after JSC or JCA
Sebastian Werner vfa	11	272	According to the table, redactions of data/information is not possible in the submission dossier and the JCA report and summary. This is not comprehensible as commercially in confidence information designated by the HTD must be		2e good administration – hearing after JSC or JCA

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?	HOG answer
			protected and must not be published. If redaction is not possible for submission dossiers, the HTD cannot included any commercially in confidence information. If redaction of the JCA is not possible, the assessors and co-assessors cannot prepare a report which might include commercially confidential information. A redaction should be possible.		