EUnetHTA 21 Public Consultation
D4.7.1/D4.7.2 – Framework for high risk MD

Name organisation & abbreviation	Country
European Union of General Practitioners/Family Physicians UEMO	Belgium
BIOTRONIK SE & Co. KG	Germany
RedETS, Spanish HTA Agencies Network	Spain
Bundesarbeitsgemeinschaft Selbsthilfe von Menschen mit Behinderung und chronischer Erkrankung und ihren Angehörigen e.V. (BAG SELBSTHILFE)	Germany
Edwards Lifesciences	Europe
Lumanity	Lumanity is a global company with several European entities, including in Ireland and the Netherlands.
Medtronic	Switzerland
MTE (MedTech Europe)	
Norwegian Institute of Public Health (NIPH)	Norway
AIM – International Association of Mutual Benefit Societies	Belgium
Astellas Pharma Europe Ltd	UK

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
RedETS	General		We really appreciate the work done to elaborate this document. It helps to progress in establishing processes. Comment: For future HTA R implementation, it would be particularly important to have a better definition of the TISP process and how the technologies are going to be selected and how the identification process starts. In this sense, the coordination group should have a relevant role in this process according the HTA Regulation.	Thank you for your comment. Details on the TIPS process (including the use of EUDAMED) are addressed in D4.7.3 & 4 (D7.4.3 EUDAMED data reporting template & D7.4.4 Guidance for EUDAMED based TIPS process) which has been on public consultation in June 2022. Nevertheless, your comment might be taken into account as a further recommendation at the end of EUnetHTA 21 (when guidance D7.4.4 will be reviewed). Indeed, the coordination group and the relevant subgroup will discuss the TISP process further when drafting the relevant Implementing Act.

Please add extra rows as needed.

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			In any case, there are some open issues such as the use of EUDAMED database as a source for identification of MD/IVD to be evaluated that advice another review of this document in the near future	
Edwards Lifesciences	General		We would request to have another round of review of this draft framework, once all the methodological draft guidelines are available. It is extremely misleading to provide comments on this draft framework when we have poor visibility on the overall process and inputs. Knowing that key methodological guidelines that are factored in this draft framework are either open for consultation in parallel to this framework (i.e. D4.2 Scoping process and D4.3.2 Guideline on direct /indirect comparison) or are not yet open for consultation (i.e. D4.7.3/4 Guidance for EUDAMED/TISP, D4.3.1Comparators and comparison; D4.4 Endpoints; D4.6 Validity of Clinical studies; D5.1 JCA/CA submission dossier template; D7.1 Guidance for interaction between HTD and HTAb for JCA /JSC).	Thank you for your comment. We understand your concern. However, all deliverables couldn't be developed at the same time during the EUnetHTA 21 service contract due to obvious organisational constraints. While within EUnetHTA 21 no further public consultations are foreseen, they may take place when the final implementing act or guidance documents are created by the subgroup and/or coordination group of the HTA Regulation.
Silke Walleser Autiero Medtronic	General		What are the consequences of having a device assessed by the EUNETHA21 consortium prior to the HTA R being in place? Will it be considered a "draft" assessment based on non-approved methods (and therefore not widely shared?)	Thank you for your comment. Based on EUnetHTA Joint Action 3 methods, it will be an opportunity for health technology developers to engage with EUnetHTA with close support during the assessment production. It is the last opportunity before a submission by the HTD becomes mandatory under the HTAR. EUnetHTA 21 consortium members and associated HTA bodies that will all be subject to the rules of the HTAR will also have the opportunity to use the produced JCA reports for their national appraisals and prepare for the HTAR. However, it will not replace a national appraisal.

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MTE			**JCA will take place earlier (for most EU member states) in the lifecycle (1)** What does justify this approach? How is earlier defined? It will be important to take into consideration the framework defined in the regulation and to provide a rational to divert from it : HTAR recital 37 *"The establishment of a timeframe for the joint clinical assessments for medical devices and in vitro diagnostic medical devices should take into account the highly decentralised market access pathway for those devices and the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after the medical device or the in vitro diagnostic medical device has been placed on the market, and in order to allow for their selection for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place after their placing on the market"* In line with HTAR recital 37, there needs to be flexibility in the timing of a JCA, such that it allows for JCA to be fit for purpose and inform local decision-making, i.e. the JCA meets the appropriate needs of MS HTAbs. HTAR recital 37 does not state that the JCA will take place earlier in the MD lifecycle than	Thank you for your comment. The EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. In order to avoid the confusion related to the use of the word "earlier" here, we changed the sentence to "These JCAs will take place **after CE marking** and will be based on dossiers submitted by health technology developers (HTDs)."

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			at present, or immediately after CE marking. In fact, doing a JCA too early in the lifecycle could be detrimental and create risk for duplication and inefficiencies. Some further consideration on how to address this in exceptional cases is provided in following comment.	
MTE			JCA process would benefit from **regular exchanges with regulators, specifically between expert panels and HTAb.** We call to clearly define the nature of these exchanges. Clarity is needed with regards to the legal remit of the expert panel. Hereby are expert panels not a regulator and if any interaction with regulator are be set-up it should be an interaction with the with the NB. The need and value of any such interactions will also need to be clarified as their is no foreseeable direct benefit during the conduct of the JCA and our of scope of the NB. On the contrary for the JSC process experts panel do have a foreseen role of scientific advice described in the MDR/ IVDR and here as such can be an valuable actors in case a parallel JSC is planned. Hereby again within a clear given remit of responsibility.	Thank you for your comment. It has been taken into account. Additionally, more details on the cooperation between the actors of the MDR/IVDR regulatory process and EUnetHTA 21 might be addressed by the deliverable D7.4.2 which is currently under development and aims at preparing for the Implementing act referred to in Article 15 (1b) of the HTAR: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;"
MTE			**Review of no interference with MDR/IVDR**: To ensure the JCA report has a scientific consistency and does not interfere (eg. Does not duplicate, conflicting statement and/or create ambiguity on safety and clinical benefit), it will be important in the	Thank you for your comment. It is already planned that the EC will review the final JCA report for a procedural review (see §4.5.2 Review of the JAC report). A factual accuracy check by the HTD is also foreseen in the same section of the deliverable. Its purpose is to highlight any errors or inaccuracies with the factual content of the document that are related to the technology under

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			review/finalization procure that a provision of review is foreseen supervised by the EC or and to be pointed out during the factual review done be the HTD	assessment. Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are considered outside the scope of a factual accuracy check.
Astellas Pharma Europe Ltd		245-248	EUnetHTA should consider that some digital therapeutics may be class III or IIb Digital Medical Devices/Digital Therapeutics. In this case, the JCA should take into account the 'Guidance on Clinical Evaluation (MDR)/Performance Evaluation (IVDR) of Medical Device Software. March 2020'. In particular the JCA should include the important role of post-marketing evidence generation in the assessment of digital therapeutics.	Thank you for your comment. In this guidance https://ec.europa.eu/docsroom/documents/40323, the approach to assess "medical device software (MDSW)" conformity is not different from the one to assess "classic" MDs. Clinical evidence is necessary at the CE assessment stage and the plan for post marketing evidence generation (= the PMCF Post Market Clinical Follow-up) is part of the elements which are assessed by the notified body. Therefore, there is no need for adjustment in the deliverable. Nevertheless, it might be a recommendation at the end of EUnetHTA 21 when this deliverable will be reviewed to specify that clinical data obtained with the MD under assessment are expected in order to conduct a JCA of this MD, whatever the type of the MD (= including MDSW).
RedETS	13-14	313-319	Comment: It will be of high interest to engage a specific column in the figures for HTA R instead to be join with EUnetHTA 21 JCA Process	Thank you for your comment. We want to clarify that we aim at piloting the JCA process according to the HTAR during EUnetHTA 21, which explains the joined EUnetHTA 21/HTAR column in the figures. This column might be changed to a column for HTAR only when this deliverable will be reviewed at the end of EUnetHTA 21.
Edwards Lifesciences	7	128-131 /Section 1.1 GENERAL PRINCIPLES	This draft framework indicates that the JCA under the HTA regulation will cover single-technology and they will take place earlier in the MD lifecycle than at present. This approach is misleading as it is not clear at which stage of the MD lifecycle it is referring to, knowing that the regulation	Thank you for your comment. It has been taken into account. The wording was changed to "These JCAs will take place ~~(for most EU member states)~~ after CE marking ~~earlier in the MD lifecycle than at present~~ and will be based on dossiers submitted by health technology developers (HTDs).

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			refers to technologies with CE mark. We believe that JCA should be linked to a **timely decision on reimbursement, funding, use and/or uptake and should not delay the access for patient to innovative therapies.** We recommend to reword as following (additional text in bold): "After January 2025, Regulation (EU) 2021/2282 on HTA will drive towards JCA for single-technology high-risk MDs and class D IVDs. These JCAs will take place (for most EU member states) **after CE mark is granted avoiding delaying access for patients** ~~earlier in the MD lifecycle than at present~~ and will be based on dossiers submitted by health technology developers (HTDs)."	
Edwards Lifesciences	7	142-147/Section 1.2 PURPOSE AND SCOPE	According to the HTA regulation, Article 9 (1(a)), the JCA report "shall be limited to a description of the scientific analysis of the relative effects of the health technology **as assessed on the health outcomes against the chosen parameters which are based on the assessment scope** as set out pursuant to Article 8(6);" The draft framework seems to be in contradiction with the regulation given it excludes this comparative assessment of multiple technologies stating that this is not within the scope for JCA in the HTA R.	Thank you for your comment. It has been taken into account, though not considering the proposed rewording. The deliverable already states that collaborative assessments (CAs) are not in the scope of this deliverable. In order to clarify that comparative assessments will be possible under HTAR the following sentence was added "However, CAs will be possible under HTAR and could be the opportunity to conduct comparative assessment of multiple technologies later in their life cycle." at the end of the paragraph on line 147.

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			We believe JCA should be adaptive and flexible in incorporating disease and intervention specific considerations for high risk implantable medical devices. We recommend to reword as following (additional text in bold): "The present guidance document aims to define the framework for JCAs of high-risk MDs and IVDs with a view to foster national uptake of the JCA reports early in the life cycle of a single technology (i.e., immediately after CE marking, within the scope of the HTA R). The general rules laid down in the HTA R serve as specifications for this framework. The framework ~~does not~~ **covers** comparative assessment of multiple technologies for indication groups ~~later in their life cycle~~ (~~this is not within the scope for JCA in~~ **per** the HTA R) or collaborative assessments (CAs)."	
RedETS	7	145 - 147	Comment regarding the future implementation of HTA R: It should be discussed what is happen with multiple technologies for same indication after CE marking. It could be possible that appear at the same time (or in a short period) in the market similar MD/IVD of different manufacturers. Then, they would be analysed them one by one? We have to take in account the effort it takes the production of a JCA or CA. The MD/IVD market is in constant evolution.	Thank you for your comment. It has been taken into account. The deliverable already states that collaborative assessments (CAs) are not in the scope of this deliverable. In order to clarify that comparative assessments will be possible under HTAR the following sentence was added "However, CAs will be possible under HTAR and could be the opportunity to conduct comparative assessment of multiple technologies later in their life cycle." at the end of the paragraph on line 147.

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Silke Walleser Autiero Medtronic	7	129-131	We note that the regulation does not specify that JCAs need to take place early in the lifecycle of a medical device. We indeed question the relevance and added value of systematically undertaking a JCA early in the lifecycle, linked to regulatory approval. Given specificities of medical devices, and the fact that JCA shall be limited to novel high-risk medical devices, this timing does not seem appropriate for most of these devices that will not yet have been used in most jurisdictions. Medical device effectiveness can often only be fully assessed after their use has become routine in clinical practice. Medical device specific features such as the learning curve and the setting of care affect their clinical effectiveness and are important considerations. Therefore, the availability of the right evidence is a key determinant of the right timing for a HTA, considering that at launch, medical devices by their nature might not be able to have the HTA relevant clinical evidence available. In addition, most importantly, the value of the JCA should be in facilitating reimbursement and funding decisions in member states, by facilitating national HTA processes and decisions. The timing for the JCA should therefore be linked to the needs of member states to have answers to their policy questions regarding innovative medical devices.	Thank you for your comment. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. In order to avoid the confusion related to the use of the word "earlier" here, we changed the sentence to "These JCAs will take place **after CE marking** and will be based on dossiers submitted by health technology developers (HTDs)."

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			However, timing of the JCA should not be automatically linked to timing of regulatory approval. For medical devices, regulatory approval grants access in many key markets in Europe and the need for HTA often emerges later in the products (evidence) lifecycle; in these markets early JCA risks being obsolete quickly if national agencies see the need for assessing the technology a bit later when more evidence has emerged by then. In other markets, the need for a HTA to inform reimbursement decisions can be but doesn't have to be at the same time as CE mark. But again, decisions for a HTA are generally not triggered by the availability of the CE mark, but by HTD submissions (eg in France), or hospitals (eg in Germany – NUB process) We recommend to review the following article: *R.TARRICONE ET AL. Lifecycle evidence requirements for high-risk implantable medical devices: a European perspective. 2020. EXPERT REVIEW OF MEDICAL DEVICES*	

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Silke Walleser Autiero Medtronic	7	145-147	Early JCAs need to consider regular updates as otherwise they will quickly be outdated and of no relevance by the time certain countries decide to undertake a local HTA assessment. In the case of Spain for example, national HTA agencies often assess technologies that have been in the market for a considerable amount of time.	Thank you for your comment. Your comment is not considered, since it falls out of the scope of this deliverable. Nevertheless, it may be taken into account as a future recommendation. Additionally, you could refer to Article 14 of HTAR on updates of joint clinical assessments precising when updates of JCAs shall be carried out by the Coordination Group. This article also states that national updates of assessments on health technologies that have been subject to JCA may be carried by Members States (Art. 14 (4)).
BIOTRONIK SE & Co. KG	7	129-130	Suggest deleting *'These JCAs ~~will take place (for most EU member states) earlier in the MD lifecycle than at present and~~ will be based on …'* as this is not necessarily true and pre-empts the result of the consultation process and guidance for EUnetHTA21.	Thank you for your comment. Your rewording is not considered as proposed. Nevertheless, the wording was changed to "These JCAs will take place ~~(for most EU member states)~~ after CE marking ~~earlier in the MD lifecycle than at present~~ and will be based on dossiers submitted by health technology developers (HTDs).
BIOTRONIK SE & Co. KG	7	143-144	Suggest removing *'early in the life cycle of a single technology (i.e., immediately after CE marking, within the scope of the HTA R).'*. The HTA R does not stipulate a need for early assessments, in fact it does not mention any such thing. It intends for technologies to be assessed at an <u>appropriate</u> time (Recital 37 in the HTA R). Therefore, the statement above should be removed.	Thank you for your comment. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. Your change is not considered as proposed. However, in order to reflect the two proposed processes, we changed the part in brackets to "(*i.e., immediately* ***or soon*** *after CE marking, within the scope of the HTAR)".*

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RedETS	7	107-108	Consider deleting: (HTA) work ~~supporting the continuation of EU cooperation on HTA~~ with the aim of supporting…	Thank you for your comment. Your rewording is however not considered as we used the original wording of the call for tenders "CHAFEA/LUX/2020/OP/0013-Chafea/2020/Health/04".
RedETS	7	143-144	These sentences point out that JCA production will take place immediately after CE marking. Nevertheless, in the section 4, two processes are reported, in parallel with regulatory process or after CE marking is obtained. Please consider rewording the following phrase: "The present guidance document aims to define the framework for JCAs of high-risk MDs and IVDs with a view to foster national uptake of the JCA reports early in the life cycle of a single technology (i.e., immediately after CE marking *or in parallel with regulatory process*, within the scope of HTA R"	Thank you for your comment. It has been taken into account, though your rewording is not considered as proposed. We changed the part in brackets to "(*i.e., immediately* ***or soon*** *after CE marking, within the scope of the HTAR)".*
Silke Walleser Autiero Medtronic	7	1.2 141-147	We welcome the Regulation's intent to facilitate processes that foster uptake of JCA at member state level with the view to ensure the added value of a JCA in facilitating access to innovative technology with established added benefits to patients. A particular added value and ambition of a European JCA, in addition to national processes in place, could be in accelerating reimbursement, funding and uptake of innovative medical devices with clear value add. However, as indicated above, we question the value of JCA automatically linked to the	Thank you for your comment. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. In order to reflect the two proposed processes, we changed the part in brackets in line 144 to "(*i.e., immediately* ***or***

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			CE-marking process. We request that it be further clarified and defined how these JCAs will be taken up by member states and exactly what their purpose is. We also believe the timing of assessment should be better defined so that is relevant for this purpose, and consideration should be given to defining the timing individually for each medical device, in consultation with HTD and broader stakeholders.	***soon*** *after CE marking, within the scope of the HTAR)".* Interaction with HTDs is foreseen in the context of JCAs (see deliverable D7.1 Guidance for the interaction between HTD and HTA (for JCA and JSC). However, a consultation with HTD to define the timing of a JCA is not foreseen at this stage.
Astellas Pharma Europe Ltd	7	142-144 also related to Figure 4-1 and 4-2:	Text: "…technology (i.e., immediately after CE marketing, within .....": the guideline should clarify how this activity relates to the CHMP/CAT assessment timelines. See also information from the EMA website that the notified bodies can start a consultation procedure. Recently EMA has released two timetable governing initial consultations for notified bodies (namely for CDx and for CDx associated with advanced therapy medicinal products (ATMPs). (timetables can be found via link: https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/submission-dates/procedural-timetables#companion-diagnostic-consultation-section) For this procedure the notified body is expected to provide an "intention to submit	Thank you for your comment. Your comment is not considered as the deliverable already mentions future adaptions for IVDs: see p.12 l.306-307 "For IVDs, adaptations to the process might be necessary to comply with the IVD regulatory process, which is currently being implemented." We confirm that both figures only relate to high-risk MDs (class IIb and III), and not IVDs. Nevertheless, your comment might be further considered at the end of EUnetHTA 21 when this deliverable will be reviewed.

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			letter" at least 3 months before the planned date of submission. The CAT/CHMP assessment will follow a 60-day timetable and the opinion is expected within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days if needed. Therefore, it would be of important to also clarify how this procedure will relate (timewise) to the process depicted in Figure 4-1 and 4-2, including the time until a clinical evaluation assessment report (CEAR) can be submitted to the expert panel (assuming that the below mentioned consultation will take place prior to CEAR creation).	
BIOTRONIK SE & Co. KG	7	122	Suggest removing '*tertiary'* as it does not necessarily apply to all member states, and thus, does not contribute to clarity of the document.	Thank you for your comment. It has been taken into account.
BIOTRONIK SE & Co. KG	7	123	Suggest removing '*via selective contracts'* as it does not necessarily apply to all member states, and thus, does not contribute to clarity of the document.	Thank you for your comment. It has been taken into account. As it is an example, it means implicitly that it doesn't necessarily apply to all member states. We added "for instance" at the beginning of the text in brackets.
MTE	7	127	• Given the consideration of linking both the CE and Early JCA and a reference to the use of data, and bodies as part of the CECP (Clinical Evaluation Consultation Procedure)	Thank you for your comment. However, considering that an MD doesn't enter the scope of the HTAR if a scientific opinion is not issued for this MD, the proposed text has not been added.

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			or PECP (Performance Evaluation Consultation Procedure described in the MDR/IVDR A more detailed description is needed to have a clear understanding of the MDR/IVDR process and reports generated as part of the MDR/IVDR. (SEE ITALIC describe the process based upon the MDR/IVDR). This also as previous experience during the presidency report that the process was not always correctly referred to, we consider it important to be explicit and have a common understanding. Therefore we propose to complement the current text: • "The MDR/IVDR set the basis for a more centralized approach for MD risk classes IIb and IVD risk class D, *by the introduction of a process whereby per regulation 2017/745 Annex IX 5.1.* • *(a) For class III implantable devices, and for class IIb active devices intended to administer and/or remove a medicinal product as referred to in Section 6.4. of Annex VIII (Rule 12),* ***the notified body shall, having verified the quality of clinical data*** *based upon the clinical evaluation report of the manufacturer referred to in Article 61(12), prepare a* ***clinical evaluation assessment report.*** *This report sets* ***out the NB conclusions*** *concerning the clinical evidence provided by the manufacturer, in*	

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			particular concerning the (A)benefit-risk determination, (B)the consistency of that evidence with the intended purpose, (C) including the medical indication or indications and (D) the PMCF plan referred to in Article 10(3) and Part B of Annex XIV. *The **notified body shall transmit** its **clinical evaluation assessment report**, along with the manufacturer's clinical evaluation documentation, referred to in points (c) and (d) of Section 6.1 of Annex II, **to the Commission**.* • *The Commission shall immediately transmit those documents to a screening expert panel and based upon specific criteria* and *send it to the specialized **relevant expert panel** referred to in Article 106. . the above mentioned criteria are (A)* the novelty of the device or of the related clinical procedure involved, and the possible major clinical or health impact thereof. (B) significantly adverse change in the benefit-risk profile in respect of components or source material or in respect of the impact on health in the case of failure of the device (C) significantly increased rate of serious incidents reported. • *The screening expert panel and the specialized expert panel might decide that they do not intend to deliver an opinion within 21 days*	

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			• *The **expert panel reviews of NB Clinical Evaluation Assessment Report on benefit/risk, quality of evidence for given indication** and **provide an opinion*** • *If the expert panel does not deliver an opinion within 60 days, the NB may proceed to the issue of a certificate* • *The **NB might based upon the opinion, decide to** restrict the intended purpose (eg restrict to certain patients groups or medical indication, limit duration of validity of certificate, recommend specific PMCF studies, …) until further clinical evidence becomes available. The NB will then (conditionally) grant or not a CE mark* • *The notified body may be requested to present its conclusions to the expert panel concerned.* *MTE is open to share a graphical representation.*	
BIOTRONIK SE & Co. KG	7	128	Suggest adding *'… will drive towards JCA for **selected** single-technology high-risk MDs and class D IVDs.'* to add clarity.	Thank you for your comment. It has been taken into account.
MTE	7	128	**Early JCA: Single Technology only.** We recommended to seek legal advice if the proposed solution does not infringes competition laws. Particularly if only 1st in class will go through the JCA process of STA. Fundamental to note, that unlike Pharma, the MedTech industry does not benefit of similar patent nor data protection as pharma does. Hence competitive product	Thank you for your comment. Your comment is not considered, since it falls out of the scope of this deliverable. Nevertheless, it may be taken into account as a future recommendation. Additionally, you could refer to Article 14 of HTAR on updates of joint clinical assessments precising when updates of JCAs shall be carried out by the Coordination Group. This article also states that national updates of assessments on health technologies that have been subject to JCA may be

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			with similar "intended purpose" are expected to be available shortly after the introduction of the first in class. Also, the next generation of 1st technology will become available shortly (eg after 12-18 months). This will results in continued, evolving and a strengthened evidence portfolio and outcomes and possibly also further reducing probability of side effects. This evolving evidence base will need to be accounted for in the joint clinical assessments scientific reports. The assessment reporting a snapshot impacted by multiple confounding factors.	carried by Members States (Art. 14 (4)).
MTE	7	128	**JCA at a later point in the lifecycle:** We recommend that if a JCA reassessment or if JCA is done at a later time in lifecycle, all relevant clinical evidence, effectiveness data is taken into consideration as well as the confounding factors. The latter can be done so through: - Including all input from HTD offering this innovation; - Leveraging the latest Summary of Clinical Evidence reports, which are prepared in the context of the MDR/IVDR. For the JCA Scientific report we propose also to have an analysis, whereby the evidence is linked to the brand specific technology. - Involving the HTD in the process to obtain insights on the confounding factors. Given the availability of competitive and next generation technologies, as a result, the Scoping and consolidated PICO might also evolve over time and need to be redefined as	Thank you for your comment. Your comment is not considered, since reassessments fall out of the scope of this deliverable. Nevertheless, it may be taken into account as a future recommendation. Additionally, you could refer to Article 14 of HTAR on updates of joint clinical assessments precising when updates of JCAs shall be carried out by the Coordination Group. This article also states that national updates of assessments on health technologies that have been subject to JCA may be carried by Members States (Art. 14 (4)).

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			part of the reassessment process. This should also be accounted for and best reported through the involvement of the HTD in those processes.	
MTE	7	129	**JCA will take place earlier (for most EU member states) in the lifecycle**: (2) What does justify this approach? How is earlier defined ? Possible rewording: If European wide member states seek to have an JCA (for use by most EU member states) earlier in the lifecycle in order to ***accelerate the accessibility to innovation, this will be produced*** based on dossier of current available evidence submitted by the HTD. This early JCA will be conducted to accelerate timely accessibility of innovation whereby provision are made to not interfere or ultimately delay market access. Rationale: (Our view is that an appropriate time should be established based upon the need for innovation and with a clear purpose expressed by the member states. to accelerate the accessibility and inform investment/reimbursement decisions,). Hereby it will be needed to accept the available clinical evidence in the lifecycle. Such an "Early" JCA, should not interfere or delay market access (preamble 38) and recognize that additional effectiveness evidence will become available over time. (preamble 37)	Thank you for your comment. However, the suggested rewording has not been considered. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. Additionally, more details on the cooperation between the actors of the MDR/IVDR regulatory process and EUnetHTA 21 might be addressed by the deliverable D7.4.2 which is currently under development and aims at preparing for the Implementing act referred to in Article 15 (1b) of the HTA R: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;" This cooperation also aims at preventing duplication of work for members states and HTDs.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			Also there might be scenarios whereby the JCA capacity or expertise is insufficient when seeking to perform early JCA. Here also provision are needed not delay the use of national access schemes, and secure a timely decision on adoption and reimbursement. In order to achieve a successful implementation, we propose that further discussion and consideration will take place to define and apply concepts under discussion as: 1. Use of Adaptive evidence generation and assessment for high risk medical devices ; 2. Apply concept of (adapted) minimal sufficient evidence set. These adapted to the nature of technology, nature of disease, outcome, lifecycle, … 3. Define processes to have timely and predictable identification on the technology to go through an JCA and especially "Early JCA". Hereby also to put processes in place for timely consolidated PICO discussions to enable preparatory work on comparative data of current practices with use of indirect and other types of comparisons. 4. Define processes to leverage the unique expertise and application of the innovation into clinical practice and involve the HTD within the processes of Scoping, Consolidated PICO' and confounding factors. Define mechanism to ensure the early JCA does not duplication and interfere with the	

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			MDR/IVDR and in no means risks to delay market access.	
RedETS	7	130	Please consider to add the following phrase: ……although the assessor and the co-assessor may also have to use databases and other sources of clinical information (art 11.2, regulation HTA)	Thank you for your comment. We agree on the fact that the HTAR provides that the assessor and co-assessor may also have recourse to databases and other sources of clinical information, where it is deemed necessary in Article 11 (2). Nevertheless, the suggested text has not been added in this general sentence highlighting the major changes for joint assessments introduced by the HTAR compared to JA3. Nevertheless, your comment might be further considered at the end of EUneHTA 21 when this deliverable will be reviewed.
MTE	7	133	"**foresee further adaptations of the JCA production Guidance**" We confirm that it will be of value to foresee further adaptations towards the end of the service agreement on the guidelines to comply with the HTA R for MD. Hereby we call to define an updated workplan as part of the service agreement and already foresee continued planned interactions with HTD over the time of the service agreement and to foresee appropriate time for a public consultation. Hereby also to foresee the time and opportunity to **review of the full general guidance document** when a full guidance document with all pieces related to JCA are completed. At this moment this draft deliverable and others draft deliverables are done in isolation, and inconsistencies are noted. Specific for the JCA we call that the JCA will be integrated and streamlined with the phase	Thank you for your comment. We understand your concern to review this guidance with all its related documents. However, all deliverables couldn't be developed at the same time during the EUnetHTA 21 service contract due to obvious organisational constraints. While within EUnetHTA 21 no further public consultations are foreseen, they may take place when the final implementing act or guidance documents are created by the subgroup and/or coordination group of the HTA Regulation. Nevertheless, your comment might be further considered at the end of EUnetHTA 21 when this guidance will be reviewed in the light of the other related documents developed during EunetHTA 21. Possible inconsistencies would be streamlined then.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			preceeding the JCA and the concrete purpose and planned use of the JCA report are described in this guidance document.	
BIOTRONIK SE & Co. KG	7	134	Please insert explanation for why the disclaimer '*as much as possible for IVDs.*' is introduced here.	Thank you for your comment. The wording has been changed to, as this disclaimer was valid for a previous draft version of the deliverable and not anymore for this one: *This general guidance defines the framework for the assessment of high-risk MDs during the EUnetHTA 21 service contract and proposes foreseen further adaptations to comply with the HTAR for MDs and ~~as much as possible for~~ IVDs.*
RedETS	7	134	In this phrase states: "This guidance aims to specify which elements could also be applicable for IVD assessment" However, any specific element for IVD assessment is provided. Therefore, at least now the procedure is common to both types of devices. Please, consider rewording this phrase: Therefore, the elements included in this guidance are also applicable for IVD assessment.	Thank you for your comment. This sentence has been deleted.
BIOTRONIK SE & Co. KG	7	136	The cross-reference '*The framework includes adapted processes for assessment of relevant technologies once they have been identified (see D4.7.4 Guidance for EUDAMED based TISP process).*' is confusing as guidance 4.7.4 is not yet available. Please note that as per the MDR, HTA entities are not foreseen to have access to non-public information in EUDAMED.	Thank you for your comment. We understand your concern to review this guidance when other related documents were not yet available, including guidance D4.7.4. However, all deliverables couldn't be developed at the same time during the EUnetHTA 21 service contract due to obvious organisational constraints. Note that the public consultation for deliverable D4.7.4 is now over and took place in June 2022, i.e. a month after public consultation on D4.7.2.
MTE	7	142	While the **purpose** to foster national uptake of JCA reports early in the lifecycle might be part of it, we call for a **more ambitious "purpose"** with clear, proportionate,	Thank you for sharing this comment.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			predictable and consistent in evidence acceptance to result in **fit-for-purpose scientific JCA report** As such and early JCA might become part of accelerated **pathways** with **accelerated access innovation** throughout Europe **and specialized financing of innovation**. This will justifying the significant EU investments and will ensure that **European patients benefit timely of selected disruptive and transformative medical technology innovation. These innovation which are** now increasingly **make available first in other jurisdictions, where multiple initiative seek to bring innovation first to their patients.**	
RedETS	7	145	Please clarify if "comparative assessment of multiple technologies later in their life cycle" is out of scope of the JCA and CA only during the EUnetHTA21 Consortium or it will be a proposal for the future HTA network.	Thank you for your comment. It was already stated in the deliverable that "comparative assessment of multiple technologies later in their life cycle" is out of the scope of JCA in the HTAR and therefore during EUnetHTA 21. However, collaborative assessments (CA) will be possible under HTAR and could be the opportunity to conduct "comparative assessment of multiple technologies later in their life cycle". We added this precision in the deliverable.
MTE	7	145	**Comparative - Head-to-Head Technology Comparison:** While comparative head to head assessment of technologies might indeed not be a priority focus and alignment with the regulation should be double checked. The regulation states that JCA report "shall be limited to a description of the scientific analysis of the **relative effects** of	Thank you for your comment. We agree that head-to-head technology comparison is out of the scope of this deliverable. However, collaborative assessments (CA) will be possible under HTAR and could be the opportunity to conduct "comparative assessment of multiple technologies later in their life cycle". We added this precision in the deliverable.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			the health technology as assessed on the health outcomes **against the chosen parameters** which are based on the assessment scope as set out pursuant to Article 8(6);" In a scenario where multiple technologies with similar intended purposes are available, these should not be excluded but be part of a joint clinical assessment with a generic and brand specific analysis...	
BIOTRONIK SE & Co. KG	7	152	Suggest removing *'after CE marking'* as it is confusing and leaves room for multiple interpretations.	Thank you for your comment. It was implemented. We deleted "after CE-marking" and added "CE marked" according to the following wording: *This document provides general guidance for JCA of single-technology CE marked high-risk MDs ~~after CE marking~~, (…).*
Silke Walleser Autiero Medtronic	7	152	It is noted that JCA will apply to "single-technology high risk medical devices". If a single technology gets accessed early in its lifecycle, what are the implications for other technologies of the same class/therapy that will be launched later? Can it be clarified how updates of JCAs will be considered and what will trigger an update? In particular with early JCA it is likely that updates will be needed frequently given technology developments/competitors entering the market as well as evidence updates. It will be important that the investments in clinical evidence by a manufacturer are appropriately rewarded, and therefore different technologies of the same class should be looked at differentially from an evidence point of view.	Thank you for your comment. Your comment is not considered, since reassessments fall out of the scope of this deliverable. Nevertheless, it may be taken into account for a future recommendation. Additionally, you could refer to Article 14 of HTAR on updates of joint clinical assessments precising when updates of JCAs shall be carried out by the Coordination Group.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Edwards Lifesciences	8	155-157/ Section 1.2 PURPOSE AND SCOPE	The notified bodies in charge of granting the CE mark certification, represent a key stakeholder to be included in this alignment process together with the expert panel and the national regulatory competent authorities. It is critical to include the notified bodies too as key stakeholders.	Thank you for your comment. In order to include the notified bodies, we now refer to "actors in the MDR/IVDR regulatory process" instead of "regulators". More details on the cooperation between the actors of the MDR/IVDR regulatory process and EUnetHTA 21 might be addressed by the deliverable D7.4.2 which is currently under development and aims at preparing for the Implementing act referred to in Article 15 (1b) of the HTA R: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;"
BIOTRONIK SE & Co. KG	8	155-159	*'The guidance shall be discussed with regulatory bodies in the context of the interaction with MDR/IVDR regulators (see D7.4.2, currently under development). However, it has not yet been possible to start discussions with regulators, so there could be a delay in creating a final version of this guidance. It is part of the scope and objective of this guidance document to identify the remaining open questions. Not all of these can be clarified at this stage for the HTA R.'.* The two processes / actors must not influence each other, as this is outside the mandate of either body or procedure. Information submitted in confidence to	Thank you for your comment. We agree on the fact that the HTA process should not interfere with the CE marking process (see recital 38 of HTAR). However, cooperation between the actors of the MDR/IVDR regulatory process and HTA bodies conducting JCAs is foreseen, as stated in Article 15 (1b) of the HTA R: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;". We changed "interaction" to "cooperation" in the deliverable, as it is stated in the HTAR. Regarding the second issue of your comment, it has not

Please add extra rows as needed.

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			Notified Bodies as part of the market authorization process must not be shared with any other party without consent of the HTD. Please insert statement that this confidentiality will be maintained.	been taken into account, as the HTAR provides for the exchange of information, including the sharing of confidential information, with expert panels and the Medical Device Coordination Group on the joint work (JCA, JSC) (see Article 28 (i) of the HTAR). However, at this stage, we foresee that we'll mainly use information from the SSCP or the CEAR.
MTE	8	155	Conform pre-amble art.38, **interaction of regulatory bodies** will need to be done witin a remit that the new EU Regulation on HTA **do not interfere with the CE marking or delay the market access** and will have no impact on decisions taken in accordance the MDR/IVDR regulations. **In the context of the JCA**, given different research questions are addressed there will be little if any value to implement a direct interaction. Also there are no provisions in the MDR/IVDR to do so. Most valuable will be to leverage reports generated by the MDR/IVDR, as the frequently updated Summary of Safety and Clinical Performance (SSCP (MDR), SSP(IVD), and evaluation reports by the NB REAR, and opinion by the expert panels. Confidential data submitted as part of the Clinical Dossier in the process of the MDR/IVDR should be out of scope or mechamism for continued confidentialy to be put in place (current not foreseen). Herefore again the SSCP nad SSP are more appropriate).	Thank you for your comment. We agree on the fact that the HTA process should not interfere with the CE marking process (see recital 38 of HTAR). However, cooperation between the actors of the MDR/IVDR regulatory process and HTA bodies conducting JCAs is foreseen, as stated in Article 15 (1b) of the HTA R: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;". More details on the cooperation between the actors of the MDR/IVDR regulatory process and EUnetHTA 21 might be addressed by the deliverable D7.4.2 which is currently under development and aims at preparing for the Implementing act referred to in Article 15 (1b) of the HTA R. We changed "interaction" to "cooperation" in the deliverable, as it is stated in the HTAR. Regarding the second issue of your comment, it has not been taken into account, as the HTAR provides for the exchange of information, including the sharing of confidential information, with expert panels and the Medical Device Coordination Group on the joint work (JCA, JSC) (see Article 28 (i) of the HTAR). However, at this stage, we

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			To ensure the JCA report has a scientific consistency and does not interfere (eg. Does not duplicate, conflicting statement and/or create ambiguity on safety and clinical benefit), it will be important that appropriate processes are put in place under EC supervision to avoid any duplication or interferences caused by the JCA Scientific Report. Hereby an evolvement of the HTD in the process of review ahead of submission to other stakeholders will be critical and not only in a 2nd round of review. This to point ouT timely factual issues	foresee that we'll mainly use information from the SSCP or the CEAR. Regarding the third issue of your comment, it is already planned that the EC will review the final JCA report for a procedural review (see §4.5.2 Review of the JAC report). A factual accuracy check by the HTD is also foreseen in the same section of the deliverable. Its purpose is to highlight any errors or inaccuracies with the factual content of the document that are related to the technology under assessment. Any comments affecting the interpretation of data (data presentation, description and conclusions of the report) are considered outside the scope of a factual accuracy check.
Edwards Lifesciences	9	174-175/ Section 2.2 REGULATORS	The notified bodies in charge of granting the CE mark certification, represent a key stakeholder to be included in this alignment process together with the expert panel and the national regulatory competent authorities. It is critical to include the notified bodies too as key stakeholders. We recommend to reword as following (additional text in bold): "The JCA process would benefit from regular exchanges with regulators, specifically exchanges between expert panels, **notified bodies** and HTAbs regarding the MDs submitted to the expert panels by notified bodies".	Thank you for your comment. It has been taken into account.
Edwards Lifesciences	9	196-198/ Section 2.3.1 Patients, Health Care Professionals and Other External	The exclusion of part of experts, especially clinical experts, who have been working with the technology developers, would be limiting the level of expertise required for the assessment of technologies. Especially in	Thank you for your comment. However, the proposed rewording has not been considered. EUnetHTA 21 will recruit experts on an ad-hoc basis based on their knowledge in a particular field. A declaration of

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		Experts	highly specialized medical technologies or extremely specific disease areas. It would be a pity to have the assessment conducted by people who have poor understanding of the disease area, the unmet medical need and the technology itself. For the sake of transparency, we believe the names of the external experts consulted should be published. We recommend to reword as following (additional text in bold): "Individuals involved on behalf of HTDs for the specific JCA in these lines of expertise **could be qualified** ~~do not qualify~~ as external experts."	Interest (DoI) is required, is assessed by a dedicated committee, and the person must be without conflict of interest. Under exceptional circumstances (e.g., lack of available experts without COI for a rare/ultra- rare disease), EUnetHTA 21 may still seek the expert opinion of an individual with an existing COI if this expert has unique skills and no other expert (with at least the same level of competency and without COI) can be identified, despite having contacted multiple experts. More information on how EUnetHTA21 manages conflicts of interest can be found in our Guidance Document. The issue of naming experts is not easy to resolve due to legal issues in some Member States. An expert who had a strategic role in the development of the product i.e. that has advised the company on the clinical trial protocol will not be considered as independent. Any participation in a clinical trial using the product under development will not be an exclusionary criterion. Please refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
Silke Walleser Autiero Medtronic	9	196-198	We encourage the consortium to consider the value HTD alone or in their collaboration with clinical experts bring to the JCA process, in particular in relation to technologies that might not have been launched yet in Europe (eg as per scenario 1). It is highly likely that the key experts available on specific	Thank you for your comment. EUnetHTA 21 will recruit experts on an ad-hoc basis based on their knowledge in a particular field. A declaration of Interest (DoI) is required, is assessed by a dedicated committee, and the person must be without conflict of interest. Under exceptional circumstances (e.g., lack of available

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			technology have worked with the HTD on the general development of the technology as well as its associated clinical evidence programme. Not considering the experts proposed by HTDs risks involvement of experts with no direct expertise on the technology, with a risk to miss critical points on the use of the technology and its place in the patient pathway, with subsequently a potentially flawed JCA.	experts without COI for a rare/ultra- rare disease), EUnetHTA 21 may still seek the expert opinion of an individual with an existing COI if this expert has unique skills and no other expert (with at least the same level of competency and without COI) can be identified, despite having contacted multiple experts. More information on how EUnetHTA21 manages conflicts of interest can be found in our Guidance Document. An expert who had a strategic role in the development of the product i.e. that has advised the company on the clinical trial protocol will not be considered as independent. Any participation in a clinical trial using the product under development will not be an exclusionary criterion. Please refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
Silke Walleser Autiero Medtronic	9	199-201	We welcome the involvement of patients and HCPs in the JCA. We recommend that more detail be elaborated to define how these individuals will be recruited and selected, to ensure expertise and perspective pertinent to the evaluated technology and disease area is available.	Thank you for your comment. A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*)

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Marit Austeng and Alexandra Poulsson, Norwegian Institute of Public Health	9	167-169	".... HTA R as part of the JCA subgroup and are invited to certain EUnetHTA 21 activities." - The statement is ambiguous. Please clarify which "certain activities" the HTAbs will be invited to be involved in.	Thank you for your comment. These activities were already listed in table A-1 in Appendix 1. The reference to this Appendix has been clarified in the text. "During EUnetHTA 21, they are invited to the activities which are described in Appendix 1, in the line "Associated HTA bodies" of Table A 1."
Silke Walleser Autiero	9	191-192	We note that the Regulation (article 9) does not specifiy timelines for dossier submission for medical devices, and request that the 45 days be reconsidered given the large scope of information that is required (see comment below).	Thank you for your comment. We added the two general following sentences at the end of section "Purpose and scope": "The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."
Marit Austeng and Alexandra Poulsson, Norwegian Institute of Public Health	9	200-201	Other external experts can be involved as needed. - The statement is ambiguous. Which other experts, under what circumstances and how will it be decided whether to call in other experts or not? Please clarify.	Thank you for your comment. As listed in section 2.4, "An individual who is not technical staff of an HTAb involved in the production of joint work, e.g. including but not limited to the following: health care professionals (HCP), academics, epidemiologists, patients, patient representatives, consumers, citizens etc. Individuals involved on behalf of HTDs for the specific JCA in these lines of expertise do not qualify as external experts. Patients and HCPs will be involved to contribute to the key steps of the JCA process to ensure their expertise is considered throughout the assessment procedure."
Silke Walleser Autiero Medtronic	9	Section 2.1	The interaction with relevant HTA bodies/institutions will be crucial in countries with a fragmented landscape for HTA and access decisions (eg Italy, Spain), and with	Thank you for your comment. It has not been taken into account as it is beyond the scope of the guidance.

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			important actors/stakeholders not just at national but also at regional and hospital level. Can it be clarified how the uptake of the JCA be ensured?	
Silke Walleser Autiero Medtronic	9	2.3.	Can it please be clarified what the content should be of the letter by HTD? Is it "specifying the intended indication of the medical device" as intended for the JCA, or should the indication/intended use for the regulatory approval be shared, as outlined in the draft guidance document for scoping (D 4.2.). As outlined in the comments for the scoping document, the indication for CE mark might be different from intended indication for HTA. We also request that the role of the HTD be expanded so that its expertise can be recognised and leveraged throughout the JCA process, from scoping to evaluation. Best practice HTA processes (eg NICE, MSAC) all have HTD as relevant stakeholders included in the process of scoping and evidence evaluation.	Our guidance now says: "The HTD shall then send a letter of information specifying the intended use of the MD/IVD." - instead of "intended indication". Please note that the D.4.2. scoping process is also currently being revised. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and specific information might be further clarified as deemed appropriate. Please also refer to the D7.1. Guidance for the interaction between HTD and HTA (for JCA and JSC) in which the different steps where HTD is involved, are outlined. References to both deliverables (D4.2. and D7.1) were added to our guidance.
BIOTRONIK SE & Co. KG	9	174	The term '*regulators'* is considered fuzzy and should be defined better in the document.	Thank you for your comment. We changed the word "regulators" to "actors of the MDR/IVDR regulatory process".
MTE	9	177	Exact wording from regulation needed ... pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation (see also pag.11 line 249-250 of the draft deliverable.	Thank you for your comment. As the exact wording of the HTAR is already used twice in the deliverable, before and after this section (on page 7 and on page 11), we do not consider to modify this slightly simplified wording here. It allows for a shorter sentence which aims is to introduce which actors from the regulatory process have an impact on the JCA process and by which means (expert panels and scientific opinion/view).
MTE	9	182	**The involvement of the HTD**, especially	Thank you for the comment. The D7.1. Guidance for the

Please add extra rows as needed.

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			for the targeted novel medical implantable technologies, drug delivery and population based test, where the involvement of the HTD is critical given the expert knowledge on the innovation and the use in clinical practices. This would otherwise result in a non-use and a gap of information available. The knowledge and expertise within the health tech developers following clinical investigation, should therefore be also part of the scoping discussion, the consolidated PICO discussion to appreciate also the confounding factors having a broader information on the specificity of current organizational structure and clinical practice for the care delivery, confounding factors for the analysis. This to ensure fit-for-purpose and fit-for-future analysis. This will contributing to the quality and applicability of the JCA scientific reports, whereby a scientific analysis is performed and no value judgement part of the reports In more detail the specific knowledge build out will consist of a good understanding of the specificities of the health technology and the clinical pathways of the health systems, the expertise and the pre-condition for successful implantations, use of the technology as well as the HC system specific co-founding factors, the evolving learning curves etc. . All these key consideration to perform a quality JCA which should be of value to inform an adoption or coverage decision, and be linked to a timely decision on reimbursement, funding, use and/or	interaction between HTD and HTA (for JCA and JSC) outlines the different steps where HTD is involved. It will be available for public consultation in August 2022.

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			uptake at the national level.	
MTE	9	190	**Letter of information.** It is unclear if it is part of the HTAR process. In the process the NB *prepare a **clinical evaluation** assessment report which sets out its conclusions concerning the clinical evidence provided by the manufacturer, in particular concerning the benefit-risk determination, the consistency of that evidence with the intended purpose, **including the medical indication or indications**. Following review by the expert panel the NB might draw updated conclusion but these are available. Therefore the medical indication is well defined within the MDR/IVDR.* *Nevertheless as the targeted indication for seeking reimbursement might be more specific, the **concept of a letter of information is of interest**, allowing to indicate ahead of the scoping the specific indication(s) – subpopulation for which additional evidence might have been created and to define the Intervention of the consolidated* *PICO for the JCA to be performed on*	Thank you for your comment. The letter of information is not mentioned in the HTAR as such. It is a EunetHTA 21 recommendation based on the last sentence of Article 8 (6) "The scoping process shall also take into account information provided by health technology developer (...."). Please note that this guidance now says: "The HTD shall then send a letter of information specifying the intended use of the MD/IVD." - instead of "intended indication". Please note that the D.4.2. scoping process is also currently being revised. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and specific information might be further clarified as deemed appropriate. Please also refer to the D7.1. Guidance for the interaction between HTD and HTA (for JCA and JSC) in which the different steps where HTD is involved, are outlined. References to both deliverables (D4.2. and D7.1) were added to our guidance.
RedETS	9	193	We guess section 2.3.1 should be 2.4. It does not make sense to have other agents under the 'developer'.	Thanks for pointing out this typo.

Please add extra rows as needed.

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MTE	9	193	**The Involvement of Patients, HCP, Other external experts**. This section is very vague. Should there not be a minimum of HCP, patients etc for each JCA to guarantee the quality of the outcome? Thererfore giventhe involvement of patient, HCP and expert is critical and we look forward to further details and granularity on how, when, they will be involved. Also for the targeted implantable technologies, it will be important to consider the implanter, the disease specific expert and the supportive HCP to seek input from. We also call that this is not limited to the assessment phase but also when eg identifying the outcomes parameters in the PICO – Scoping discussions. Hereby it will be imporant that mechamism are found to engage those that have experience with the novel technology and manage the COI. Mechanism should also be foreseen whereby HTD can provide overview list of those that have experience the technology and have specific technical expertise on used scientific methodologies (trial design, analysis, ... Hereby also taking on board the confounding factors.	Thank you for your comment. A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) An expert who had a strategic role in the development of the product i.e. that has advised the company on the clinical trial protocol will not be considered as independent. Any participation in a clinical trial using the product under development will not be an exclusionary criterion. Please refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
BIOTRONIK SE & Co. KG	9	199	Please specify • whether it is planned to involve individual patients or patient organisations, individual HCPs or associations, • how the consultations will be supported, e.g. is it envisaged to provide education	Thank you for your comment. A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient*

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			on HTA / JCA methods & process to these external parties to enable their input. It is assumed that you will not only work with English-speaking patient groups, or HCP associations. Please specify • how language barriers will be bridged, • how many countries will be involved at a minimum, • how translations will be quality-checked. Clarify how confidentiality of information would be maintained. Please also specify whether patient advocacy groups would be involved in all stages or any of the stages of the JCA process, as an involvement in scoping seems less appropriate. Specify the suggested approach for when the HTD is the sole source of knowledge, which is likely to be the case for e.g innovative technologies, software, algorithms, and similar.	*representative, healthcare professional and other experts*) For information about Confidentiality (and conflict of interest please refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613. As noted in the HTA Regulation it is required to include patients and HCP. The number involved will depend on the success of recruitment, we do not plan to limit the number of participants. (e.g. 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."; Article 11.4, "The subgroup shall ensure that patients, clinical experts and other relevant experts are involved in the assessment process by being given the opportunity to provide input on the draft reports.").
MTE	9	199	***Patients and HCPs will be involved*** *in contributing to the key steps of the JCA process to ensure that their expertise is considered throughout the assessment procedure. Other external experts can be involved as needed.* Suggest: HTD should also be involved in each key step of the JCA process and should be able to nominate clinical experts. In addition to patients and HCPs, patient groups should	Thank you for your comment. Guidelines and templates for the involvement of patients and HCPs (both as experts [individually] and as stakeholders [associations]) are currently being developed in EUnetHTA 21. The guidelines cover most, if not all, of the topics you have raised. These documents should respond to your comments and will be available for public consultation in August 2022. There is also a guidance on the implication of HTD under development D7.1: *Guidance for the interaction between HTD and HTA (for JCA and JSC)*

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			also be included as stakeholders within the process to provide the collective patient perspective.	To identify independent external experts, the implication of HTD in their recruitment does not seem relevant.
BIOTRONIK SE & Co. KG	9	200	Please specify what *'other external experts'* would be and how they may be recruited. Specify how these will be supported, e.g. is it envisaged to provide education on HTA / JCA methods & process to these external experts to enable their commenting? Is it envisaged that these experts come from non-English-speaking countries? If yes, specify how language barriers will be bridged. Specify how many countries will be involved at a minimum. Specify how translations will be quality-checked. Clarify how confidentiality of information will be maintained.	Thank you for your comment. A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) Please also refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* for additional information regarding confidentiality. The document is available here: https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
Edwards Lifesciences	10	211-212 /Section 3.1 CONFIDENTIALITY	"The JCA report and submission dossier will be confidential until publication of the final JCA report." This sentence is misleading. Does this imply that the submission dossier will be published as well, once the final JCA report is published?	As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d).
Edwards Lifesciences	10	235-236/ Section 3.3 STATUS OF OUTPUTS	"The final assessment scope, including the validated final PICO, is to be shared with the HTD (D.4.2.1. Scoping process)." For the sake of transparency and to have an inclusive approach of the key stakeholders, we believe the HTDs should be involved across the entire process including the PICO	Please refer to the D7.1. Guidance for the interaction between HTD and HTA (for JCA and JSC) in which the different steps where HTD is involved, are outlined and the D4.2. scoping process guidance.

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			definition and the scoping meetings, as well as the review of the first draft JCA.	
Edwards Lifesciences	10	240-241/ Section 3.4 OTHER	For the sake of transparency, we believe the name of the individuals and that of the organizations they represent of the assessors and co-assessors should be published.	For the JCAs produced under EUnetHTA 21 consortium agreement, only the names of the participating HTAb/institutions will be publicly available. In the future, according to the HTAR (Article 30: IT platform in the HTA regulation), the publicly accessible webpage will contain an up-to-date list of the members of the subgroups and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work.
BIOTRONIK SE & Co. KG	10	207-208	'For associated HTAb members, an additional confidentiality agreement may be required and any information collected from regulatory bodies may be redacted.'. EUnetHTA21 and later HTA R must continue the current principle of confidentiality of information submitted in confidence to Notified Bodies. Therefore, we suggest the word 'may' be replaced by 'is to be' or 'must', or another word indicating a necessity rather than possibility.	Thank you for your comment. It has not been taken into account, as the HTAR provides for the exchange of information, including the sharing of confidential information, with expert panels and the Medical Device Coordination Group on the joint work (JCA, JSC) (see Article 28 (i) of the HTAR). At this stage, we foresee that we'll mainly use information from the SSCP or the CEAR.
BIOTRONIK SE & Co. KG	10	211-212	*'The JCA report and submission dossier will be confidential until publication of the final JCA report.'.* This seem to indicate the release of information submitted as academic-in-confidence, or commercial-in-confidence. Any confidential information submitted to either Notified Bodies, EUnetHTA21, or under HTA R must be redacted, as to neither jeopardize publication of at that point embargoed data, nor disclose intellectual property, nor commercially sensitive data of	The HTD has the opportunity of a factual accuracy check of the draft JCA where any errors or inaccuracies with the factual content of the document that are related to the technology under assessment can be highlighted. Furthermore, the HTD shall highlight any information it considers confidential due to its commercially sensitive nature by following the D7.1. guidance commercially confidential information. The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			the HTD. Rules for keeping information confidential established with national HTA bodies should be adopted. Please change the wording of the guidance to maintain confidentiality where necessary also for the published JCA report.	in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production. As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d).
BIOTRONIK SE & Co. KG	10	214-215	*'A confidentiality agreement between the HTD and EUnetHTA 21 is not necessary since an assessment with a single HTD is involved.'* If confidential information is being provided by the HTD, it must be kept confidential by EUnetHTA21. So, a confidentiality agreement seems to be warranted. Suggest deleting in full or changing the sentence adequately.	No confidentiality agreement between EUnetHTA and HTD is foreseen. The information on what is kept confidential and what cannot be kept confidential because of public interest and assessment requirements is outlined in the D7.1. guidance for handling commercially confidential data. HTD are therefore aware of any information that might be released in the JCA procedure.
BIOTRONIK SE & Co. KG	10	220-221	*'The JCA report and submission dossier will be confidential until publication of the final JCA report.'.* This seem to indicate the release of information submitted as academic-in-confidence, or commercial-in-confidence. Any confidential information submitted to either Notified Bodies, EUnetHTA21, or under HTA R must be redacted, as to neither jeopardize publication of at that point	As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d). Detailed information can be found in the D7.1. guidance for handling commercially confidential data.

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			embargoed data, nor disclose intellectual property, nor commercially sensitive data of the HTD. The above also does not seem to be in line with Art 5(6) of the HTA R stating *'The representatives appointed to the Coordination Group and its subgroups as well as patients, clinical experts and other relevant experts involved in the work of any subgroup shall, even after their duties have ceased, be subject to a requirement of professional secrecy.',* which indicates an intent to keep information confidential. This should be reflected in the entire guidance, and rules for keeping information confidential be based on what has been established in the past with the national HTA bodies. Please add provisions to facilitate this.	The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production. Further information might also be covered in D7.4.2. about the cooperation with the actors of the MDR/IVDR regulatory process. And, further clarification might be part of an implementing act (Art 15).
RedETS	10	220-221	This sentence is repeated (see line 211-212), please delete it here: ~~The JAC report and submission dossier will be…~~	It is not a repetition. The first sentence is in the paragraph referring to EUnetHTA 21 and the second in the paragraph related to HTA R.
Linda Murphy, Lumanity	10	Lines 235-236	The 'scope' output should go first ahead of publication of the report and reassessment.	Thanks, changed.
Silke Walleser Autiero Medtronic	10	3.1	Full publication of the HTD dossier submitted will be difficult for us as HTD as it might reveal details of our strategy to competitors. As HTD, we need to ensure confidentiality of the data submitted in our dossier when needed (also stated in line 559 page 20). In addition, information in the dossier might be considered scientific in-confidence if not fully	As mentioned on page 20, publication of the HTD submission dossier follows the requirements established in D.5.1 (Submission dossier template) and D7.1 (Guidance for the interaction between HTD and HTA (for JCA and JSC)), which are currently under development. As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will

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			published. We note that the regulation does not mention this requirement so we would like this to be reconsidered.	be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d). Reference to the D7.1. guidance for handling commercially confidential data was added.
MTE	10	203	**Confidentiality.** Given the framework in the field of medical technology of IP - Patent protection, data protection and requirements of the scientific community the confidentiality paragraphs under 3.1 and the statement that it will only be confidential till final JCA report will **need to be revisited.** For any data/information submitted under confidentiality and any confidentiality agreement within other regulations there is a need for a **continuity in confidentiality** till the data/information is in the public domain. This is especially sensitive given the advanced nature of the technologies under consideration, the implementations within other regulations and the standards applied to obtain valid scientific publications.	As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d). Detailed information can be found in the D7.1. guidance for handling commercially confidential data. Further information might also be covered in D7.4.2. about the cooperation with the actors of the MDR/IVDR regulatory process. The HTAR provides for the exchange of information, including the sharing of confidential information, with expert panels and the Medical Device Coordination Group on the joint work (JCA, JSC) (see Article 28 (i) of the HTAR). However, at this stage, we foresee that we'll mainly use information from the SSCP or the CEAR. And, further clarification might be part of an implementing act (Art 15).

Please add extra rows as needed.

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MTE	10	206	For associated HTAb members, an additional confidentiality agreement may be required and any information collected from regulatory bodies may be redacted. Suggest: We would expect that any information required from regulatory bodies would be requested from the HTD, especially as the HTAR states that these two processes are separate. However, not only Regulatory information should be redacted, but also AIC and CIC information deemed to be sensitive by the HTD as well. Any confidential information should remain redacted in published documents	Thank you for your comment. It has not been taken into account, as the HTAR provides for the exchange of information, including the sharing of confidential information, with expert panels and the Medical Device Coordination Group on the joint work (JCA, JSC) (see Article 28 (i) of the HTAR). At this stage, we foresee that we'll mainly use information from the SSCP or the CEAR. Thank you for your comment. Your re-wording was not implemented. Detailed information can be found in the D7.1. guidance for handling commercially confidential data. The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production.
MTE	10	214	Given the above and certainly also in the context of the EUNETHTA21 - not being a	Thank you for your comment. This will be further discussed.

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			legal entity the **provision are needed to put contractual agreements in place** to foster the accessibility and completeness of a dossier to be submitted and to engage in any type of cooperation/piloting. Current good practice should be applied and an EU wide legal guidance developed.	
RedETS	10	220	We guess the acronym "tMD" is wrong. Please correct the mistake.	Thanks for pointing it out. Changed.
RedETS	10	220	Consider rewording: "the tMD, followed by Commission requesting about evidence dossier submission. The JCA report…"	This paragraph has been changed.
Alexandra Poulsson, Norwegian Institute of Public Health	10	220	Typo – tMD – please correct to MD.	Thanks for pointing it out. Changed.
MTE	10	222	**Conflict of interest.** As described above the involvement of experience Patients, HCP, Other external experts as well as a degree of involvement of HTD is critical for obtaining the appropriate experience. A balance approach to come from a declaration of interest to an evaluation of the conflict of interest will be needed, ie. Having good mechanism to handle the conflict of interest. This to ensure and appropriate knowledgeable and experienced persons are part of the assessment.	The analysis of the Declaration of Interest is of high importance. Guidance on the handling of DOI can be found on the EUnetHTA Website: https://d2yaq9q3r816qq.cloudfront.net/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
MTE	10	235	*The final assessment scope, including the validated final PICO, is to be shared with the HTD (D.4.2.1. 235 Scoping process).* Suggest:	Further information is provided in the D4.2. scoping process and D7.1. Guidance for the interaction between HTD and HTA (for JCA and JSC)

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			The PICO and scoping document should both be developed via a consultation process, as per processes that exist at member state level, so the HTD and other stakeholders have the opportunity to input into these documents	
MTE	10	237	**Transparency:** As transparency is key for success, the names of assessor and co-assessor should be make available. This is done also in Pharma assessment and other regulatory assessment. Authors of the report should also be listed.	For the JCAs produced under EUnetHTA 21 consortium agreement, only the names of the participating HTAb/institutions will be publicly available. In the future, according to the HTAR (Article 30: IT platform in the HTA regulation), the publicly accessible webpage will contain an up-to-date list of the members of the subgroups and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work.
BIOTRONIK SE & Co. KG	10	240	*'The names of individual assessors/participants are not mentioned;…'.* 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'.	For the JCAs produced under EUnetHTA 21 consortium agreement, only the names of the participating HTAb/institutions will be publicly available. In the future, according to the HTAR (Article 30: IT platform in the HTA regulation), the publicly accessible webpage will contain an up-to-date list of the members of the subgroups and their appointed representatives, together with their qualifications and areas of expertise and their declarations of conflict of interest after the finalisation of the joint work.
BIOTRONIK SE & Co. KG	11	292-294	*'This option could be considered too early in the device lifecycle according to provisions in the HTA R (Recital 38) that a JCA should only be conducted once an MD has obtained a CE marking but it should also ensure there is no delay to access in some countries, as also indicated in the HTA R (Recital 38).'* Undue preference seems to be given here to 'no delay' over what would be sensible and	Thank you for your comment. There is not yet any definitive scenario, we aimed to outline possible scenarios that can be amended and further clarified at a later stage. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be

Please add extra rows as needed.

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			create value in the sense of additional insight for the Member States: This proposed option is considered inappropriately early as the datasets available at the time of CE mark for these types of technologies (class IIb and III medical devices and class D IVD) are unlikely to allow for relative assessments of efficacy and safety. Thus, assessments that early are futile and a poor use of EU taxpayer money. Further, the term 'access' is ambiguous. Access to a technology is available with the provision of the CE mark. Granting of access is not within the mandate of JCA; as a result, this should not be suggested, neither directly nor through inference. If uptake is meant here – which would fall under the responsibility of the Member States to facilitate – it is influenced by local health policy goals, clinical and societal needs, available budget and many other influencing factors outside of health technology assessment. In fact, a JCA too early, as is proposed here, would most likely contain repeated statements of 'no or insufficient evidence', creating confusion for national decision makers and hinder uptake of innovative technologies. Please remove the option presented in Figure 1 and all related wording from the guidance.	responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate. Here we mean "market access", was changed in our document.
Silke Walleser Autiero Medtronic	11	292-294	We welcome the consideration that JCA should not lead to a delay in access. It might be worthwhile to highlight that for high-risk medical devices, CE mark grants market access in Europe, which means hospitals and healthcare institutions are allowed to	Here we mean "market access", was changed in our document.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			purchase devices. National HTA inform access decisions to various degrees, and the value of a JCA could be in informing national processes with the view to accelerate access to highly innovative medical technology with clear value add. We recommend more consideration should be given on how this could be achieved with the JCAs and the HTAR framework.	
Linda Murphy, Lumanity	11	Section 4	This section does not mention the clause that: *it may be possible to assess class IIb and III MDs that have not gone through this procedure (i.e. scientific opinion that they are relevant etc.) if these are the only MDs for which EUnetHTA 21 received HTD submission dossiers*	This will be covered in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process.
Edwards Lifesciences	11	287-291/Section 4 PROCESS	"In Figure 1, the JCA process is conducted in parallel to the MD regulatory process to ensure timely availability of the JCA report for subsequent national appraisal. In this option, MD selection and the scoping process start before the end of the conformity evaluation procedure, but the JCA itself would start only after CE marking." The process EUnetHTA21 proposed in Figure 1 suggests that: - technologies identification will start even before the HTD submits for the CE mark - the MD selection and scoping starts even before the conformity assessment report is issued by the notified bodies While we appreciate that "the annual work	Thank you for your comment. This will be covered in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process. Post-JCA timeframe and any appeal procedure is considered on national level. No appraisal will be done on EU level.

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			programme shall set out the joint work to be carried out in the calendar year following its adoption" (per the HTA regulation Article 6), it is unclear to us and concerning how the process in Figure 1 will be initiated as early as before the submission for the CE mark certificate by the HTDs, leaving room for many uncertainties and potential delays in the access pathway and risk of duplication at the national level. For the sake of transparency and to have an inclusive approach of the key stakeholders, we believe **the HTDs should be involved across the entire process and participate during:** - **the pre-JCA (PICO definition and the scoping meetings, align on the evidence requirements and on the timelines** required for the submission of the dossier for JCA), - **the JCA** (i.e. dossier submission and review of the first draft JCA, and not only for fact checking of the final JCA report), - **the post-JCA timeframe (the use and uptake of the** JCA to inform **timely decision on reimbursement, funding and use of the technologies)** Separately, we regret the absence of any appeal opportunity for the HTDs in the proposed framework, to provide additional information or for further dialogue with the	

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			HTA coordination group. This emphasizes even more the need to include the HTD across the entire JCA process, as described above. Edwards Lifesciences believes that any proposed assessment scenario should consider the following points to be successful: - Ensure the **predictability** of the process and its outcomes for the innovative technology developers - Ensure JCA accelerates the access for the patients and is linked and secures **reimbursement/coverage decisions** - We would like to encourage innovative approaches in conducting assessment and generating the evidence and **move to a lifecycle approach** in the evidence generation and the assessment methods - The **adaptability of the assessment** could consider the following 3 dimensions: o **nature of the technology** (i.e. implantable MD, CDx, MDx, digital technologies….) o **nature of the disease** (i.e. CVD, diabetes, oncology…) o **evidence needs** : identify the minimum sufficient dataset (not necessarily limited only to the regulatory evidence requirement) in line with the product lifecycle through early interaction with	

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			both regulatory (expert panel and notified bodies) and HTA bodies (i.e. in early trial design; in continuous RWE/RWD collection) The above should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO criteria.	
MTE	11	243	Overall the **process of JCA** should not be limited to the timeline for the assessment but to include as well the preassessment phase and post-assessment (use of the scientific reports). Hereby as a guiding principle, being aware of whether the innovation responds to the specific needs of member states and to the EU selection criteria to undergo a JCA. Enabling to have information related to consolidate PICO, evidence acceptance, ahead of the HTD timeline on the development of the evidence generation plan will be a key factor of success.	This will be covered in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process.
MTE	11	261	A graphical representation can be provided to clarify the expert panel role, process and timelines for the MDR.	This is neither in the scope of our deliverable nor in the HTA R scope
RedETS	11	269	Comment: Regarding the medical devices selection, please take into account all of what the HTA Regulation states about it. The Regulation states that devices are subject to be selected pursuant paragraph 4 of article 7, which states the six criteria: a) unmet medical needs and so on. We think this should be incorporated in this	Thak you for your comment. This will be covered in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process.

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			document. Please consider adding the following paragraph: According the HTA R, the Coordination Group will recommend the MD and IVMSD for JCA. The six criteria for selecting pursuant paragraph 4 of article 7 are: a) unmet medical needs and so on…	
MTE	11	287	*In Figure 1, the JCA process is conducted in parallel to the MD regulatory process to ensure timely availability of the JCA report for subsequent national appraisal.* Suggest: In line with HTAR recital 37, there needs to be flexibility in the timing of a JCA, such that it allows for JCA to be fit for purpose and inform local decision-making, i.e. the JCA meets the appropriate needs of MS HTAbs. HTAR does not state that the JCA will take place immediately after CE marking. In fact, doing a JCA too early in the lifecycle could be detrimental and create inefficiencies – which in effect would potentially create duplication of effort. For high-risk MD, there is no urgency for earlier assessment unlike the pharm sector, because in the majority of EU countries, upon CE Mark, the product can gain market access via DRG and other forms of funding. If an early access scheme were to be in place for high-risk MD, it would need to be directly linked with reimbursement.	Thank you for your comment. There is not yet any definitive scenario, we aimed to outline possible scenarios that can be amended and further clarified at a later stage. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. Moreover, Recital 37, though not explicitly quoted, was taken into account during the drafting of this deliverable. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			Clarification is needed on the intended purpose of seeking an early JCA?	
MTE	11	290	Immediate : What does this mean, there should be an codefined reasonable time foreseen	The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.
MTE	11	294	**No delay in access.** As within the access pathways of medical technologies, the CE marking ensures the access to the market in Europe for high risk medical technologies. Therefore innovation, within the current open access models for medical technologies can then be purchased, procured by hospitals and healthcare institutions. The point in time of the JCA to directly or indirectly inform decision making will only become relevant if it has the purpose to inform drivers for accessibility In any case a JCA might not interfere with market access and a mechanism to monitor will be important. (pag 12 – line 304) However to **stimulate the accessibility and use of disruptive and transformative medical technology innovation across Europe**, we propose to futher explore the concepts and adaptive evidence and assessment to be applied if of early JCA in the lifecycle is of interest.	Thank you for sharing this comment. We agree on the fact that the HTA process should not interfere with the CE marking process (see recital 38 of HTAR). Line 294: changed it to "market access". Line 305: changed to "patient access".
Silke Walleser Autiero	12	295-303	CE mark grants access in most member states, so the concern for this delay does not hold true everywhere. For countries where	Thanks, changed to "market access".

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Medtronic			HTA is critical for access, company/hospital submissions are required to trigger HTA, and these generally take into account the availability of the right evidence for HTA (see comment above).	
Marit Austeng and Alexandra Poulsson, Norwegian Institute of Public Health	12	295-303	The issue with duplication would be avoided if the JCA Secretariat online platform would allow MS HTA Bodies to register national HTAs with ID and HTD information, and if completed have the report available or if underway open for collaboration between the national HTA and JCA?	Thank you for sharing this comment. However, it would be unlikely that such a system would always be up-to-date.
BIOTRONIK SE & Co. KG	12	296-297 (and Figure 1)	*'In this scenario, some MDs may have already been assessed at national level.'* While this is theoretically possible it is unlikely to occur in practice and often enough to support the option presented in Figure 1. Please delete the sentence.	Thank you for your comment. However, it was not implemented. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.
BIOTRONIK SE & Co. KG	12	301-303 (and Figure 1)	*'There is also a risk of parallel submissions at the national and European levels to avoid delaying access in some countries and this could result in duplication of work for both the HTD and HTAbs.'.* While this is theoretically possible, it is	Thank you for your comment. There is not yet any definitive scenario, we aimed to outline possible scenarios that can be amended and further clarified at a later stage. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			unlikely that a manufacturer submits twice, given the effort any submission requires, and not enough reason to support the option presented in Figure 1. Again, the term 'access' is ambiguous here. See comment above. Please delete the sentence.	MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate. We clarified that we mean "market access" here.
BIOTRONIK SE & Co. KG	12	304-305	*'Monitoring is required in the future to determine if final JCA reports are delivered in time without delaying access to patients.'* The term 'access' is ambiguous. Access is conferred through CE marking and granting of access is not within the mandate of JCA; as a result, this should not be suggested, neither directly nor through inference. If uptake is meant – local funding decisions, healthcare service capacity, local capability, pricing etc at the Member State level are much more relevant to facilitate uptake and dissemination. Please clarify what is meant here.	Thanks, we reworded it to "patient access".
Edwards Lifesciences	12	295-303/Section 4 PROCESS	We believes that Figure 2 is in complete contradiction with the core spirit of the HTA Regulation and which is: 1- avoid duplication of the assessment of technologies, 2- accelerate the access for the patients of innovative technologies 3- ensure equal access of innovative therapies for all patients across	Thank you for your comment. There is not yet any definitive scenario, we aimed to outline possible scenarios that can be amended and further clarified at a later stage. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA).

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			Europe. The alternative JCA process presented by figure 2 is unacceptable for us. Edwards Lifesciences believes that any proposed assessment scenario should consider the following points to be successful: - Ensure the **predictability** of the process and its outcomes for the innovative technology developers - Ensure JCA accelerates the access for the patients and is linked and secures **reimbursement/coverage decisions** - We would like to encourage innovative approaches in conducting assessment and generating the evidence and **move to a lifecycle approach** in the evidence generation and the assessment methods - The **adaptability of the assessment** could consider the following 3 dimensions: o **nature of the technology** (i.e. implantable MD, CDx, MDx, digital technologies….) o **nature of the disease** (i.e. CVD, diabetes, oncology…) o **evidence needs** : identify the minimum sufficient dataset (not necessarily limited only to the regulatory evidence requirement) in line with the product lifecycle through early interaction with	However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate

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			both regulatory (expert panel and notified bodies) and HTA bodies (i.e. in early trial design; in continuous RWE/RWD collection) - The above should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO criteria.	
RedETS	12	295	Comment: Regarding the options on timing of joint assessment it should be noted that, according to the HTA R, joint work should be separate and distinct from the regulatory assessments conducted pursuant to Regulations (EU) 2017/745 and (EU) 2017/746 and should have no impact on decisions taken in accordance with those Regulations	We agree with the comment.
MTE	12	298	As for **scenario B,** this scenario need to also be further clarified and the possible benefits and be guided by principles to avoid duplication and inconsistency.	Unclear, what exactly needs to be clarified. Some pros and cons for the scenarios were listed.
MTE	12	304	**Monitoring** is required in the future to determine if JCA reports are without interfering with the market access and in time to respond to member states needs ensuring the accessibility and use of innovation of value.	Thank you for sharing this comment. We agree on the fact that the HTA process should not interfere with the CE marking process (see recital 38 of HTAR). However, cooperation between the actors of the MDR/IVDR regulatory process and HTA bodies conducting JCAs is foreseen, as stated in Article 15 (1b) of the HTA R: "The Commission shall adopt, by means of implementing acts, detailed procedural rules for: (b) cooperation, in particular by exchange of information, with the notified bodies and expert panels on the

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
				preparation and update of joint clinical assessments of medical devices and in vitro diagnostic medical devices;".
BIOTRONIK SE & Co. KG	13	Figure 4-1	Remove figure and related text for all the reasons mentioned above.	Thank you for your comment. However, it was not implemented. There is not yet any definitive scenario, we aimed to outline possible scenarios that can be amended and further clarified at a later stage. EUnetHTA 21 was tasked to elaborate different scenarios and requested that these scenarios should reflect MS needs without delaying market access of MDs in EU countries. The current two suggested JCA processes described in the deliverable take into account different MS needs (incl. timely availability of a JCA). However, the HTA Coordination Group will be responsible for the establishment of the final JCA process. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate
MTE	14	Figure 2	*Figure 2: JCA process for MD conducted after CE marking* Suggest: In line with HTAR recital 37, there needs to be flexibility in the timing of a JCA, such that it allows for JCA to be fit for purpose and inform local decision-making, i.e. the JCA meets the appropriate needs of MS HTAbs. Ideally, the timing of the JCA should begin after CE marking – being conditional on an adequate level of evidence AND need at the MS level.	The assessment process in both figures/scenarios start after CE-marking. Only the topic selection/scoping phase might start beforehand in one scenario. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.

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			Each step in the JCA process should allow adequate time to develop quality submissions and assessment reports, both of which should undergo a consultation process with the HTD. Upon receipt of a request from MS HTA Coordinating group to undergo a JCA, a period of multiple months is needed to develop a dossier. In addition, the scoping phase can only happen AFTER the technology has been selected by the Coordination Group and by means of the implementing act. This step – concept is not included in the diagram.	
Silke Walleser Autiero Medtronic	15	356-362	We welcome the particular attention given to COI. Indeed, a participating individual from HTAb can be free of COI with the HTD at stake, but not with one of its competitors. It also needs to be ensured that the relevant expertise is available amongst HTAb, experts (and HTDs)to ensure high quality JCAs, which in our view would require a clear process for managing existing conflicts of interests amongst all individuals involved in the JCA.	When we evaluate the COI, we consider the indication, thus covering the technology under assessment and its competitors. You can find the guidance on how CoI are assessed on the EUnetHTA website: https://d2yaq9q3r816qq.cloudfront.net/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613
Silke Walleser Autiero Medtronic	15	336-340	We request that the interactions with regulatory bodies be clarified and clearly defined. The specific purposes of regulatory approval and HTA/JCA should be considered and that should be reflected in the remit and roles of each interlocutor in the JCA process.	This is out of the scope of this deliverable, it will be described in the deliverable D7.4.2, currently under development.
Silke Walleser	15	333-334	It is not clear to us what is meant by "acquisition activities need to be pursued by	We mean the following as described in D4.7.4. Guidance for EUDAMED-based TISP process:

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Autiero Medtronic			the JCA production Hands-on Group". Could this be clarified and the wording refined?	"….the acquisition process, which is a proactive approach developed by EUnetHTA, to identify topics for JCA by contacting HTDs and promoting their voluntary submission for a JCA."
MTE	15	325	We propose further reflection is given on this section as well as to the associated **timelines.** Hereby also to consider the proposed selection criteria of the regulation. Of critical important will be which countries will commit – plan to use the **"early JCA"** and others who would plan to have consider it at a later stage (given a planned HTA at a later stage). This also enabling to take forward an **adaptive approach** on a consolidated PICO and be purpose-driven (use of JCA). Overall,with an aim to have a timely information of comparative evidence expectations and increased predictability if the technology will be selected.	Please refer to the D4.7.4. Guidance for EUDAMED-based TISP process and are listed there.
Linda Murphy, Lumanity	15	Line 330	The 'other sources of information' should be listed.	These "other sources of information" are part of the deliverable D4.7.4. Guidance for EUDAMED-based TISP process and are listed there.
Alexandra Poulsson, Norwegian Institute of Public Health	15	342	Typo - Identification OF the – should be corrected to Identification of the.	Thank you, corrected.
MTE	15	345	MTE commented on the current limitations of the procedural guideline. We look forward to seeing these addressed.	The guidance will be reviewed as we are approaching the end of EUnetHTA21 and further modifications will be proposed as appropriate.
Linda Murphy,	15	Line 353	'Relevant expertise and remit' – you should also add 'time'. I would assume many	We will add "capacity" to the sentence.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Lumanity			HTAbs, particularly the smaller HTAbs will be restricted by their time and capacity.	
MTE	15	357	In line with the **view on the COI,** (on page 10, line 222) special provisions (currently lacking) are needed to ensure sufficient knowledge and expertise to ensure qualitative joint clinical assessment both covering the technological innovation and the methodological approaches. In case of external expert being involved here again applies this consideration.	The relevant expertise required for the Assessor and co-Assessor team is detailed in the guidance on Assessor and co-Assessor. This guidance can be found here: http://www.eunethta.eu/d5-3/ A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*)
Edwards Lifesciences	16	377-385/ Section 4.2.2 Identification of relevant HCPS and/or patient association(s) and/or other experts	As mentioned in the HTA regulation, "external experts with relevant in-depth specialised expertise should provide input on JCA reports." We believe, JCA should involve **early, dynamic and active scientific dialogue between all relevant stakeholders**, including HTA bodies, regulators, manufacturers, patients, clinicians and healthcare professionals involved through the care pathway, **being all of them experts on the matter.** The exclusion of part of experts, as suggested by the EUnetHTA21 framework, especially clinical experts who have been working with the technology developers, would be limiting the level of expertise required for the assessment of technologies.	A dedicated Guidance document on the Involvement of HCP and Patients (both as experts [individually] and as stakeholders [associations]) is under development. This document should respond to your comments and will be available for public consultation in August 2022. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) The implication of these groups will be done, as noted in the HTAR 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."; Article 11.4, "The subgroup shall ensure that patients, clinical experts and other relevant experts are involved in the assessment process by being given the opportunity to provide input on the draft reports." Within EUnetHTA 21 guidelines are being developed for interaction with HTD, D7.1 *Guidance for the interaction between HTD and HTA (for JCA and JSC)*

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Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			Especially in highly specialized medical technologies or extremely specific disease areas. It would be a pity to have the assessment conducted by people who have poor understanding of the disease area, the unmet medical need and the technology itself.	An expert who had a strategic role in the development of the product i.e. that has advised the company on the clinical trial protocol will not be considered as independent. Any participation in a clinical trial using the product under development will not be an exclusionary criterion. Please refer to our published *"Procedure Guidance for handling Declaration of Interest (DOI) and EUnetHTA 21 Confidentiality Agreement (ECA) forms"* https://www.eunethta.eu/wp-content/uploads/2022/03/D7.5-Procedure-Guidance-for-DOI-and-ECA_final-deliverable-v1.0.pdf?x69613.
Linda Murphy, Lumanity	7 and 9	Lines 177-181	The 'scope' of the document could be clearer at the outset. For example, it states that the scope of JCA are Class IIb and III MDS/IVDs for which the relevant expert panels have provided a scientific opinion/their view in the framework of the clinical evaluation consultation procedure are eligible for a JCA. However, section 2.2 states that *"However, in the context of the EUnetHTA 21 service contract it may be possible to assess class IIb and III MDs that have not gone through this procedure if these are the only MDs for which EUnetHTA 21 received HTD submission dossiers."* Should this be added to the 'Purpose and scope section' and also noted in Figure 4-1 and 4-2. Also, the scope should note that to progress with JCA requires a letter of intent from the HTD.	Further clarifications on the scope of JCAs will be given in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process. Other information is provided later in the text where appropriate.
BIOTRONIK SE & Co. KG	16	366-369	*'In EUnetHTA 21, identification and recruitment of patient representatives, HCPs and other experts (e.g., information*	There is a separate group developing guidelines and templates for the involvement of patients and HCPs (both as experts [individually] and as stakeholders [associations]).

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			specialists, statisticians and other experts if needed, such as epidemiologists and methodologists) are carried out centrally by the EUnetHTA 21 Secretariat in consultation with the assessor and co-assessor…. ' It should be specified, how a potential language barrier will be addressed. See comments above with regards to educational and translational needs before patient groups / HCP associations / experts can contribute in a meaningful way.	The guidelines cover most, if not all, of the topics you have raised. These documents should respond to your comments and will be available for public consultation in August 2022.
Astellas Pharma Europe Ltd	16	411-412	Text: "…to hand in a submission dossier, which is not the case in EUnetHTA 21". -> This text is not clear. Is reference being made to "EUnetHTA21 document D7.1?" If so, please add this reference (or the applicable one) after this sentence. If no submission dossier is required to be submitted please include how the background information should be provided.	The words "which is not the case in EUnetHTA 21" which brought confusion in the sentence were deleted.
Linda Murphy, Lumanity	16	Section 4.2.2	Do you have criteria in place to determine whether EU patient or clinical expertise is enough – local expertise may be required in some instances.	We have a guideline in development that will explain how and when to involve these experts, however it does not address criteria. The guidance plans to include both EU and national experts. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) This document will be available for public consultation in August 2022. The expertise needed will depend on the dossier being examined and the questions the Assessor and Co-Assessor would like them to answer. For these reasons, defining strict criteria could be difficult.
AIM – International Association	16	4.2.2 Identification of relevant HCPs	European organisations covering bodies responsible for pricing and reimbursement, or affiliated with bodies responsible for	These groups are identified in the HTAR, but we have not yet determined how to involve them and work on this subject is not planned in EUnetHTA 21.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
of Mutual Benefit Societies		and/or patient associations and/or other experts	pricing and reimbursement, should also be part of the relevant stakeholders to consult.	
Dr Daniel Widmer UEMO	16	378-79	The notion of "clinical experts in the therapeutic area concerned" seems to us a little restrictive. For example an insulin pump concerns not only the diabetologist but also the GP who sees his/her patient more frequently and has the task to integrate the device in the daily life, with other co-morbidities, to suggest adaptations and to explain or make therapeutic education. It is also true for the nurse working in primary care. I suggest to formulate differently: " clinical experts in the therapeutic area concerned including HCP in charge to integrate the device in daily life or to make therapeutic education."	Please note that this is a direct citation from the HTAR.
MTE	16	364	We confirm the importance of **identifying relevant** HCP/ patient association and other experts. As indicated (line 377 -385) external experts will need to have in depth specialized expertise and should be selected for their subject matter expertise as indicated in the HTAR .This should not be limited to the application with external experts but also to HCP, Patients . We call for clear criteria and a mechanism to take industry information on relevant persons into consideration. Overall, it will be important to have consideration of national as well as European representatives and develop sufficiently granular guidelines and tools used to capture these insights.	We have a guideline in development that will explain how and when to involve these experts, however it does not address criteria. The guidance plans to include both EU and national experts. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) This document will be available for public consultation in August 2022. The expertise needed will depend on the dossier being examined and the questions the Assessor and Co-Assessor would like them to answer. For these reasons, defining strict criteria could be difficult.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
MTE	16	368	As it is planned to be done centrally in EUNETHTA21 we look for guidelines on the process to **capture national specificities and consideration.**	We have a guideline in development that will explain how and when to involve these experts, however it does not address criteria. The guidance plans to include both EU and national experts. (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) This document will be available for public consultation in August 2022. The expertise needed will depend on the dossier being examined and the questions the Assessor and Co-Assessor would like them to answer. For these reasons, defining strict criteria could be difficult.
Dr Martin Danner BAG SELBSTHILFE	16	369	The word "/or" should be deteted: "The national perspective on the PICO's is very important. Therefore it has to be mandatory to involve the national patient organizations in the process.	It is planned to include national perspective in PICO. More details will be developed in the guidance on the involvement of HCP/Patients (D7.2/7.3 *Guidance and template for the interaction with patient representative, healthcare professional and other experts*) This document will be available for public consultation in August 2022.
Linda Murphy, Lumanity	16	Line 376	'possible compensation for their involvement' – can you expand on this?	We removed this information, since the European Commission will decide on how to handle this under the HTAR.
RedETS	16	409	Please consider rewording the paragraph as follows: According to HTA R, the Coordination Group will recommend the MD and IVMSD for JCA. The EC will adopt…	Thanks, reworded.
MTE	16	413	**Selective indication in letter information**: The medical indication is already part CE. A specific request if specific indication are to be considered is welcomed. This provide an opportunity for a selective indication(s)for	In the guidance we specify that the HTD shall send a letter of information specifying the intended use of the MD/IVD, we are aware that the indication provided in the CE marking could be quite broad. Further information can be found in the D4.2. scoping process and D7.1. Practical guideline for interaction

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			which a request for comparative evidence will be made available and in line for which investment/ reimbursement is planned. These to serve as an input to address national needs in terms of policy questions to be addressed and for assessor/co-assessor to make informed decisions to define a consolidated (adaptive) PICO. Overall, we call also for the involvement as HTD in the consolidated PICO and Scoping discussions to ensure well informed decisions are taken in line with the intended purpose.	between HTD and HTA bodies. The latter deliverable will be available for public consultation in August 2022.
Edwards Lifesciences	17	417-426/ Section 4.3.1 PICO definition	For the sake of transparency and to have an inclusive approach of the key stakeholders, we believe **the HTDs should be involved across the entire process and participate during the pre-JCA timeframe: PICO definition and the scoping meetings, align on the evidence requirements and on the timelines** required for the submission of the dossier for JCA. The suggested timelines of 45 calendar days is not realistic and depending on the PICO definitions, or additional evidence requirements, more timelines would be required for the HTD to provide sufficient agreeable evidence set. The above should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO	Further information on the interaction with HTDs can be found in the D7.1. Practical guideline for interaction between HTD and HTA bodies. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.

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			criteria.	
Edwards Lifesciences	17	435-436/ Section 4.3.2 Request for a submission dossier from the HTD	This should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO criteria.	Early dialogues/joint scientific consultations (JSC) are performed in EUnetHTA21 (medicinal products) and under HTAR (both medicinal products and medical devices). Further information on the interaction with HTDs can be found in the D7.1. Practical guideline for interaction between HTD and HTA bodies.
Edwards Lifesciences	17	443-452/ Section 4.4.1 Check for completeness of the HTD submission dossier	Edwards Lifesciences believes that any proposed assessment scenario should consider the following points to be successful: - Ensure the **predictability** of the process and its outcomes for the innovative technology developers - Ensure JCA accelerates the access for the patients and is linked and secures **reimbursement/coverage decisions** - We would like to encourage innovative approaches in conducting assessment and generating the evidence and **move to a lifecycle approach** in the evidence generation and the assessment methods - The **adaptability of the assessment** could consider the following 3 dimensions: o **nature of the technology** (i.e. implantable MD, CDx, MDx, digital technologies….) o **nature of the disease** (i.e. CVD, diabetes, oncology…) o **evidence needs** : identify the minimum sufficient dataset (not necessarily limited only to the	Thanks, noted.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			regulatory evidence requirement) in line with the product lifecycle through early interaction with both regulatory (expert panel and notified bodies) and HTA bodies (i.e. in early trial design; in continuous RWE/RWD collection) - The above should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO criteria.	
BIOTRONIK SE & Co. KG	17	432-434	*'The request should mention the agreed PICO(s) and the timeframe for this submission, which is 45 calendar days after the HTD has received the consolidated PICO (note that this timeframe is proposed as an alignment with the JCA process for medicinal products).'.* Forty-five calendar days represent about 32 working days, provided no public holidays in the timeframe. This is unduly short given how convoluted the PICOs might turn out and the resulting necessity to generate evidence which to that point is non-existent. It is not considered feasible for HTDs to re-analyse data sets for multiple subgroups, comparators and outcomes, undertake multiple meta-analyses and indirect comparisons, access advanced statistical experience, and ensure internal review and quality control in such a short timeframe. Further, there is no requirement in the HTA R	The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.

Please add extra rows as needed.

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			and in reality, to align with the process for pharmaceuticals, who usually do not need to cater to multiple populations and comparators. No fixed timelines should be stipulated by this guidance but agreed on between either the EC secretariat or the Coordination Group for MedTech, and the manufacturer, depending on the complexity of the required analyses. The timelines of existing HTA processes can serve as baseline, as they are based on years of experience. Please change wording accordingly.	
Silke Walleser Autiero Medtronic	17	432-434	It is stated that the 45 days timeframe for HTD submission is proposed as an alignment with the JCA process for medicinal products. It is not adapted to medical devices. Alignment with process for medicinal product is not a relevant justification in itself.	The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.
Silke Walleser Autiero Medtronic	17	454-456	We look forward to review the submission dossier template	The submission dossier template will go under public consultation too. Please provide your comments in that public consultation. Before the end of EUnetHTA21, this guidance will be streamlined with the final deliverable on the submission dossier template.
Linda Murphy, Lumanity	17	Lines 419-420	'Conduct of a PICO survey among HTAb members of the EUnetHTA 21 consortium and associated HTAbs in which they express their national needs'. What happens if one HTAb doesn't reply to the survey, does everything get delayed? Is there a plan in place for this?	Then this HTAb's view is not reflected in the PICO. Further information on the PICO survey can be found in the D4.2. scoping process guidance.
Silke Walleser Autiero Medtronic	17	4.3.1	For developing the scope/PICO and its validation, a scoping meeting can bring added value and facilitate clarification of PICO that are generally complex, and are	Thank you for your comment. Further information can be found in the D4.2. scoping process and D7.1. Practical guideline for interaction between HTD and HTA bodies which outlines the different

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			expected to be even more so for the JCA considering they take into account all member states' views on PICO questions. It should be considered that HTD are important stakeholders and experts that can provide crucial information as to the intended use of the technology, its mechanism of action and application and place in clinical practice, and clinical evidence, all critical factors for the right definition of the PICO. We therefore request that the HTD be considered a relevant stakeholder in the PICOs development process.	points of interaction during the HTA production process. In EUnetHTA21 a PICO information meeting is foreseen, where the HTD participates.
MTE	17	414	We call for a more in-depth analysis whereby the planned use and timing are indicated. These will be used to inform an adaptive approach as well as deadlines for JCA.	More in-depth information will be provided in other deliverables such as D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process, D4.2. Scoping process. The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate.
MTE	17	414	Selection technology in HTAR: Overall the process whereby the EC, by implementing acts minimally every 2 years, defines the technologies to be assessed will need to be further aligned with timelines on evidence generation and comparative data analysis. (Possibly supported with adaptive and minimal sufficient data sets and Topic	This will be covered in the Topic Identification, Selection and Prioritisation (TISP) process, which is explained in further detail in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			Identification, prioritization, early in the lifecycle)	
Linda Murphy, Lumanity	17	Line 423	What criteria are in pace for consolidating PICOs?	At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and further recommendations/adaptations might be added, if needed, including making sure to be aligned with the scoping guideline. The Scoping guideline is a separate deliverable, also undergoing public consultation. Please provide your comment under that public consultation.
Linda Murphy, Lumanity	17	Line 424	What criteria are in pace for validating PICOs?	At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and further recommendations/adaptations might be added, if needed, including making sure to be aligned with the scoping guideline. The Scoping guideline is a separate deliverable, also undergoing public consultation. Please provide your comment under that public consultation.
MTE	17	427	Timelines dossier submission: Within the HTAR, the submission of dossier framework is more generic. The EC informs the HTD on the assessments' scope and requests the dossier. We question the rationale of the given timeline and welcome a clarification on this was informed. It is also unclear why this does not seem to be informed by established and wellfunctioning processes established in practice. Processes that consider needed analysis and internal quality review processes of the HTD. In light of seeking to accelerate and have early JCA, we call to apply the adaptive approach. This approach suggests having an involvement of the HTD in defining an	"The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			appropriate timeline to have the specific comparative analysis performed and to make the dossier available.	
Edwards Lifesciences	18	465-467/ Section 4.4.2 Request to the HTD to complete the dossier where relevant	Edwards Lifesciences believes that any proposed assessment scenario should consider the following points to be successful: - Ensure the **predictability** of the process and its outcomes for the innovative technology developers - Ensure JCA accelerates the access for the patients and is linked and secures **reimbursement/coverage decisions** - We would like to encourage innovative approaches in conducting assessment and generating the evidence and **move to a lifecycle approach** in the evidence generation and the assessment methods - The **adaptability of the assessment** could consider the following 3 dimensions: o **nature of the technology** (i.e. implantable MD, CDx, MDx, digital technologies….) o **nature of the disease** (i.e. CVD, diabetes, oncology…) o **evidence needs** : identify the minimum sufficient dataset (not necessarily limited only to the regulatory evidence requirement) in line with the product lifecycle through early interaction with both regulatory (expert panel and notified bodies) and HTA	Thanks, noted.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			bodies (i.e. in early trial design; in continuous RWE/RWD collection) - The above should be facilitated through **early dialogue together with the technology developers** to define the evidence needs, the timelines and the PICO criteria.	
BIOTRONIK SE & Co. KG	18	460-461	'*and draft a second request to the HTD.'.* Please clarify how this would affect timelines. This may require updating Figure 4-2.	The time frame is specified later in the document. "The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."
Linda Murphy, Lumanity	18	Line 460-461	Is there a time limit on the second request to HTD? Actually, included on line 469, may be worth adding to line 461 so this is clear.	Thanks, the time limit was added here as well.
Silke Walleser Autiero Medtronic	18	469-470	7-14 days to clarify open issue may be short in some instances. (Experience from local HTA processes, eg HAS, shows that this can take longer to answer adequately)	"The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."
Alexandra Poulsson, Norwegian Institute of Public Health	18	469-470	Several places in this guidance the term calendar days is used, this substantially reduces the time available for tasks to be completed, please clarify why working days has not been used. Specifically, here it would only allow maximum 10 working days for the HTD to resubmit missing documentation for the dossier, this is a very short period of time, especially seeing as this is a new Regulation	We understood that the EC also uses the term calendar days. Working days would vary in the different countries. "The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			and the process is not well established, and there may be a bit of trial and error from both sides before the process runs smoothly.	
AIM – International Association of Mutual Benefit Societies	18	4.5.1 Drafting of the JCA report	The description of the content of the JCA report could be fleshed out, on the model of the content of the PICO requests in the scoping guideline.	Thank you for your comment. It was not implemented. However, your comment might be taken into account as a further recommendation at the end of EUnetHTA 21 when the present guidance will be reviewed based on the experiences made.
MTE	18	469	**Completion of dossier**: A foreseen period of 7 – 14 days is unrealistic, especially if additional data, analysis is requested.	The following clarification was added to the guidance: "The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."
MTE	18	477	Overall,within the JCA production we would welcome an understanding about how in the guidance of JCA production proposals, the reported factors that limited the use of collaborative assessment in EUNETHTA JA3 will be addressed. Hereby was the timing of availability a primary factor for 90%. Other elements were: Language (32%), relevance (23%), Time-duration of assessment (18%), evidence & methodology (14%), transferability (9%), Accountability 4%.	Thank you for your comment. The outcomes, experiences and recommendations from JA3 are taken into account in the production of deliverables in EUnetHTA21. Some elements might be (partly) solved by the development of certain deliverables (including this one and D4.7.4 Guidance for EUDAMED-based TISP process.), and/or by the implementation of the HTAR.
RedETS	18	496	Please consider engaging: of scientific analysis (HTA R Article 9 (1) a b): - of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters which are based on the assessment scope of the degree of	Thanks, we added the reference accordingly.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			certainty of the relative effects, taking into account the strengths and limitations of the available evidence	
Edwards Lifesciences	19	520-521/ Section 4.5.2 Review of the JCA report	For the sake of transparency and to have an inclusive approach of the key stakeholders, we believe **the HTDs should be involved across the entire process and participate during:** - **the pre-JCA (PICO definition and the scoping meetings, align on the evidence requirements and on the timelines** required for the submission of the dossier for JCA), - **the JCA** (i.e. dossier submission and review of the first draft JCA, and not only for fact checking of the final JCA report), **the post-JCA timeframe (the use and uptake of the** JCA to inform **timely decision on reimbursement, funding and use of the technologies)**	Please refer to the D7.1. Practical guidance for interaction between the health technology developer and HTA bodies.
Silke Walleser Autiero Medtronic	19	529-542 532-533	It is not acceptable that the HTD cannot comment on the result of the draft assessment itself, and only on technical/factual inaccuracies. As per other standard best practice HTA processes, HTD should be considered relevant experts for input on draft report, with the view to produce a relevant, high quality and timely JCA report.	Please refer to the D7.1. Practical guidance for interaction between the health technology developer and HTA bodies and the D7.1. Procedure and Framework for the Factual Accuracy Check.
BIOTRONIK SE & Co. KG	19	510-512	*'According to the CSCQ procedure, a minimum of one and a maximum of two JCA CSCQ members (depending on the number of volunteers) are assigned to act as dedicated reviewer(s).'*	As stated in the guidance, the aim is to have 2 dedicated reviewers, but this depends on the availability of the CSCQ JCA members.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			We would consider it warranted to aim for two reviewers. Please insert accordingly.	
BIOTRONIK SE & Co. KG	19	516-517	Please remove 'In addition, further HTAbs from the EUnetHTA might be invited to participate in the review in parallel to the JCA CSCQ review.'. Such approach is not acceptable moving forward beyond EUnetHTA21, due to a lack of transparency and process. How are they selected, how is their input documented, etc? For any guidance beyond EUnetHTA21, this provision should be removed.	This comment seems to refer on the period after EUnetHTA 21, when only HTAb which are members of the Coordination Group will be allowed to participate to JCAs. In EUnetHTA21, their involvement will be made transparent in the JCA report, and they also need to sign a declaration of interest and confidentiality agreement forms.
BIOTRONIK SE & Co. KG	19	533-534	It remains unclear from section 5.4.2 who is responsible for editing out academic in confidence (AIC) / commercial in confidence (CIC) information. This should be clarified and added to the guidance.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data. The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
MTE	19	508/520	Input to draft assessment: The mechanism of identification and transparency in the involvement of HCP / Patients is not clear. We would welcome a further degree of granularity. Also, considerations on how to address the template in terms of language challenges and capturing cultural differences will be equally important.(eg. in Canada this is done through phone interviews. Is this mechanism foreseeable?	There is a separate group developing guidelines and templates for the involvement of patients and HCPs (both as experts [|individually] and as stakeholders [associations]) during EUnetHTA 21. The guidelines cover most, if not all, of the topics you have raised. These documents should respond to your comments and will be available for public consultation in August 2022.
BIOTRONIK SE & Co. KG	19	518	Please remove '.. and other HTAbs ..' Such involvement would not be acceptable moving forward beyond EUnetHTA21, due to a lack of transparency and process. For any guidance beyond EUnetHTA21, this provision should be removed.	This comment seems to refer on the period after EUnetHTA 21, when only HTAb which are members of the Coordination Group will be allowed to participate to JCAs. In EUnetHTA21, their involvement will be made transparent in the JCA report, and they also need to sign a declaration of interest and confidentiality agreement forms.
BIOTRONIK SE & Co. KG	19	520	Pre-specify what '.. other relevant experts …' might be. Define how the language barrier will be addressed, and how education on HTA purpose / methodology / process etc will be provided to them, how confidentiality will be ensured.	There is a separate group developing guidelines and templates for the involvement of patients and HCPs (both as experts [|individually] and as stakeholders [associations]). The guidelines cover most, if not all, of the topics you have raised. These documents should respond to your comments and will be available for public consultation in August 2022.
BIOTRONIK SE & Co. KG	19	525	Please delete '.. and other HTAbs) …' as their involvement lacks transparency and process.	In EUnetHTA21, their involvement will be made transparent in the JCA report, and they also need to sign a declaration of interest and confidentiality agreement forms.
MTE	19	526	HTD review of 2nd draft fact check and confidentiality: Within the process, the HTD will only review the 2nd draft, which will result in intellectual property or confidential information included within the report, being exposed. This information will become accessible in the first round of review i.e. to	As indicated in section 3.1. confidentiality: "During EUnetHTA 21, any individual participating in JCA, including individuals representing HTAbs (including JCA CSCQ members and the consortium executive board (CEB)) and external experts, should fill out a EUnetHTA confidentiality agreement (ECA) form."

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			patients, clinical experts and relevant experts overall. An adjustment of the process will be needed.	Further information can be found in the D7.1. guidance for handling commercially confidential data.
MTE	19	534	HTD no review of scientific analysis. Given the JCA is limited to scientific analysis, the rationale to not consider the HTD scientific expertise and knowledge/expertise of the use of the innovation in clinical practices, as part of the review is unclear. Given the experience with the patient population, intervention and outcomes we consider an HTA involvement to be of value towards the quality of the report. HTD should be involved all along the JCA process from the scoping phase to the final JCA report. HTD's role should not be limited only to the fact checking of the final draft of the JCA report. The initial JCA draft report should also be shared with the HTD to avoid any disclosure of scientific in confidence information in the JCA report and in any other documents that will be published at the end of the process.	Further information can be found in the D7.1. guidance for handling commercially confidential data as well as in the D7.1. Practical guidance for interaction between the health technology developer and HTA bodies.
Edwards Lifesciences	20	558-560/ Section 4.6 JCA REPORT DISSEMINATION	The publication of the HTD submission dossier would expose the release of scientific in confidence information by EUnetHTA21 and/or the EU Commission. How will the confidentiality and intellectual property of the clinical evidence of the HTD be secured?	As mentioned in section 4.6 JCA report dissemination of the MD Framework guidance, the HTD submission dossier will be published as well once the final JCA report is published. This is a requirement from HTAR Art 12 (4) and Art 30 3 (d). Detailed information can be found in the D7.1. guidance for handling commercially confidential data.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
BIOTRONIK SE & Co. KG	20	569-572	Please add reference to the need for any AIC / CIC information to be redacted.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data. The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production.
MTE	20	546	**Endorsement of the report**. As part of the endorsement of the report, will the report be translated and how is this translation going to be validated? How is language, one of the key limiting factors going to be addressed?	So far, we are aware that the JCA report will be provided in English. It will be up for discussion in the coordination group under HTA R if translations will be provided.
BIOTRONIK SE & Co. KG	20	548	Please add 'In EunetHTA21' at the beginning of the sentence, to make the application period visible.	Thanks, added.
BIOTRONIK SE & Co. KG	20	558	Please clarify in which languages the JCA report will be provided and who is responsible for the accuracy of any translations.	So far, we are aware that the JCA report will be provided in English. It will be up for discussion in the coordination group under HTA R if translations will be provided.
BIOTRONIK SE & Co. KG	20	559	Please add reference to the need for any AIC / CIC information to be redacted.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
				The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production.
Silke Walleser Autiero Medtronic	20	559	As stated above, full publication of the HTD dossier submitted will be difficult for us as HTD as it might reveal details of our strategy to competitors. In addition, information in the dossier might be considered confidential scientific information if not fully published.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data.
Astellas Pharma Europe Ltd	20	559	If the HTD submission dossier is to be made publicly available, please include a step in the process for preparation of a redacted version to be able to remove potential proprietary information.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data.
BIOTRONIK SE & Co. KG	20	560	Please add reference to the need for any AIC / CIC information to be redacted.	Detailed information can be found in the D7.1. guidance for handling commercially confidential data. The handling of academic-in-confidence data was left out of the "D7.1. guidance for handling commercially confidential data". Apart from the fact that are not explicitly mentioned in the HTAR, we note that in May 2022 the International

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
				Committee of Medical Journal Editors (ICMJE) has extended their recommendations stating that: "The ICMJE does not consider results or data contained in assessment reports published by health technology assessment agencies, medical regulators, medical device regulators, or other regulatory agencies to be duplicate publication." Therefore, it is no longer necessary to describe the handling of academic-in-confidence data for HTA production.
Alexandra Poulsson, Norwegian Institute of Public Health	20	569	Typo – HDT should be corrected to HTD.	Thanks, corrected.
BIOTRONIK SE & Co. KG	20	577	Please add 'In EunetHTA21' at the beginning of the paragraph, to make the application period visible.	Thanks, corrected.
BIOTRONIK SE & Co. KG	20	586	The lack of an appeal option and process is unacceptable, as it is established procedure in HTA proceedings in MS. Please add an appropriate procedure to the guidance document.	Any appeal procedure is considered on national level. No appraisal will be done on EU level.
Silke Walleser Autiero Medtronic	21	6	Many related documents are still under development. We are looking forward to review these.	At the end of EUnetHTA 21, the current guidance (D4.7.1 & 2) will be reviewed, and then further recommendations/adaptations can be made, if needed. The other documents will also undergo a public consultation. Please provide your comments under the respective public consultation.
RedETS	21	593	Please consider engaging to Regulations: Regulation (EU) 2017/746 of the European Parliament and of the council of 5 April 2017 on In Vitro Diagnostic Medical Devices REGULATION (EU) 2017/ 746 OF THE EUROPEAN PARLIAMENT AND OF THE	Thanks, corrected.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			COUNCIL - of 5 April 2017 - on in vitro diagnostic medical devices and repealing Directive 98/ 79/ EC and Commission Decision 2010/ 227/ EU (europa.eu)	
BIOTRONIK SE & Co. KG	22	600	There seems to be doubled mentioning of Guideline D4.7.3/4 – here under Methodology but also under 'Other guidance documents' before (see line 598). Consider removing one or the other, for clarity.	Thanks, corrected.
BIOTRONIK SE & Co. KG	23	603 Under JCA CSCQ	Please change '.. *the JCA subgroup'* to '.. the JCA subgroup **on medical devices** … ', to add clarity.	Thanks, corrected.
BIOTRONIK SE & Co. KG	24	604 Under Project manager	If the project manager will be responsible for redacting confidential information from documents that will be made public, and should be noted here as a responsibility, as accidental disclosure of confidential information carries liability.	Detailed information regarding this process can be found in the D7.1. guidance for handling commercially confidential data.
RedETS	26	638-639	Please consider adding: Spanish HTA Agencies Network, RedETS (Spain) to the list of European HTA bodies	Thanks, we added RedETS with a note that information was provided during the public consultation.
RedETS	26	620	Please engage at the end: Spanish HTA Agencies Network (RedETS) provided information during the public consultation	Thanks, we added RedETS with a note that information was provided during the public consultation.
Silke Walleser Autiero Medtronic	13 and 14	Figure 4-1 Figure 4-2	For the initiation of the scoping process, it is also important to note that the coordination group, according to the regulation, has an annual workplan of JCA for medical devices, and that designated subgroup (of the coordination group) shall initiate the scoping process (Article 8 (6)). This raises the question of the timing of initiation of the scoping (and assessment process), that should be clarified. It is not clear how an	We suggested that the assessment phase will start in both options after the CE-marking. The initiation of the scoping depends on the TISP process, which is explained in further detail in the D4.7.3/D4.7.4. EUDAMED data reporting template / Guidance for EUDAMED-based TISP process.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			initiation of the JCA in parallel to the CE-marking is feasible, and why the development of the PICO needs to be commenced as per the intended use in the submission (and not in accordance with the final labelling).	
Silke Walleser Autiero Medtronic	13 and 14	Figure 4-1 Figure 4-2	We consider that 45 days to submit a dossier after the PICOs have been validated is too short and should be reconsidered given the large scope of information that is required.	The following clarification was added to the guidance: "The timelines proposed in this guidance are tentative and could be extended in EUnetHTA 21 for a specific JCA if need be. At the end of EUnetHTA 21, the present guidance will be reviewed based on the experiences made and timelines might be redefined as deemed appropriate."
RedETS	28	722	Please consider adding: Spanish HTA Agencies Network, RedETS (Spain)	Thanks, we added RedETS with a note that information was provided during the public consultation.
RedETS	28	722 and following	Comment: We would like to clarify that Spanish HTA Agencies Network (RedETS) is the body responsible for medical device assessments in Spain. Please consider adding: - Regarding to medical devices and other health technologies, there is a requirement to consider HTA results in health benefits package decisions (for common NHS portfolio)(Real Decreto 1030/2006, de 15 de septiembre, por el que se establece la cartera de servicios comunes del Sistema Nacional de Salud y el procedimiento para su actualización. (boe.es) - Assessing all health technologies but medicinal products is responsibility of RedETS, according to the Law	Thank you for providing the information. We added the main parts to the appendix.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
			16/2003 (Ley 16/2003, de 28 de mayo, de cohesión y calidad del Sistema Nacional de Salud (boe.es)) -The running of the Network is regulated by Order SSI/1833/2013 (Orden SSI/1833/2013, de 2 de octubre, por la que se crea y regula el Consejo de la Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud. (boe.es)) Autonomous Communities (Spanish regions) can include health technologies different from common portfolio in their complementary portfolios. Regions have to allocate their own financial resources for this complementary portfolio. The assessment of this technologies differs among regions.	

Please add extra rows as needed.

Comments received outside EU/EEA countries

Name organisation & abbreviation	Country
College of Pharmaceutical sciences, Dayananda sagar university	India
PHMR Limited	UK
Intuitive	United States

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Dr K V Ramanath, Dayananda Sagar university	General	--	The entire document is written correctly	Thank you
Ayesha Naz PHMR		General	From the scope of the document, it is detailed the new HTA R process will be discussed however the EUnetHTA 21 service contract and conformity evaluation is integrated throughout the document. If these are to be included in this guideline this could be introduced into the scope and can be clearly differentiated from the HTA R process within the main body of the text.	Indeed, this general guidance defines the framework for the assessment of high-risk MDs during the EUnetHTA 21 service contract and proposes foreseen further adaptations to comply with the HTAR for MDs and IVDs.
Ayesha Naz PHMR		General	The guideline references many different regulations this could be integrated to an appendix.	We consider it more useful if the references are included in the running text.
Ayesha Naz PHMR		General	At two points the definition of the MDs and IVD's in scope for the HTA R are provided which includes the need for a scientific opinion/views from an expert panel – it should be highlighted that this is part of the conformity evaluation procedure. Section 2.3.1 also refers to expert panels in the HTA R and it should be clarified how this would relate to those experts partaking in the conformity evaluation process.	The regulatory process is independent from the HTA process. Points of cooperation still needs to be clarified.

Please add extra rows as needed.

Comment from	Page number	Line/ section number	Comment and suggestion for rewording	HOG response
Ayesha Naz PHMR	7	Line 134	It is stated that the elements applicable to IVDs will be highlighted but this does not appear later in the guideline	This sentence has been deleted.
Joshua Bao, Intuitive	16	409-413	Intuitive would like to emphasize that the MDs required for assessment will be selected in accordance with HTA R. This may provide additional distinction between HTDs selected for mandatory submission under HTA R and HTDs making a voluntary submission.	Yes, that is correct. The MDs selected for JCA will be selected in accordance with the HTAR. The scope of the present guidance document was the mandatory submissions for JCA.
Ayesha Naz PHMR	15 and 16	Lines 333,334, 395	The phrase 'acquisition activities' is used a few times however it is unclear what this means.	Thanks, an explanation was provided in the text.

Please add extra rows as needed.