EUnetHTA 21 Public Consultation
Of D5.3.2 on HTA body technical expert working groups

Comments should be submitted not later than 20 May 2022, 23:59 CET

Name organisation & abbreviation	Country
European Union of General Practice Family Medicine UEMO	Belgium
Lumanity	The Netherlands
German Medicines Manufacturer´s Association (BAH)	Germany
Bayer AG	Germany
EFPIA (European Federation of Pharmaceutical Industries and Associations)	Belgium
Eurordis – Rare Diseases Europe	France

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
D5.3.2	Union Européenne de Médecine Générale/ de Famille UEMO	6	91-92	Information specialist has to include the idea that understanding of processes is as important as statistical appraisal. For example the understanding of practical use of devices. For this, we need also qualitative methodologies and mixed methods. We suggest to add: … or other evidence syntheses including mixed methods (quantitative and qualitative).	Thank you for your comment. Your comment has not been considered, as systematic reviews and evidence syntheses are not limited to specific types of studies.
D5.3.2	Lumanity	6	Line 88/97	An agreed minimum requirement of qualifications for experts is needed. The document notes that experts should be highly trained but to have acceptance around the table agreement on what this means and how much practical experience experts have of health technology assessment within their geographies to input confidently on discussions and recommendations is required. Suggest adding a minimum requirement for qualification and years of experience.	Thank you for your comment. The minimum requirements are already stated in the text (please see section 1. "Background").

Please add extra rows as needed.

EUnetHTA 21 Public Consultation
Of D5.3.2 on HTA body technical expert working groups

Comments should be submitted not later than 20 May 2022, 23:59 CET

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
D5.3.2	Lumanity	6	Line 95	Consider having a list of volunteer "other experts" who can be called upon to support as a first step.	Thank you for your comment. A list of volunteer "other experts" is not planned. However, as stated in the text (please see section 1. "Background"), if there is a need for additional roles within the HTAb, it should be possible to form additional HTAb working groups.
D5.3.2	Lumanity	6	Line 120	The document states that the working groups will answer questions on an ad-hoc basis and a "Q&C form for ad-hoc methodological questions within assessments" has been included in the appendix. Suggest to also inform the working group at the start of an assessment what input might be required and when so that appropriate people in the working group can hold time. Otherwise, there may be issues with capacity which could cause delays to timelines.	Thank you for your comment. The request for these issues is already in the Q&A form (please see appendix 2). Further details of the HTAb working groups (e.g. regarding timelines, availability and workload) will be described in the "rules of procedure". We have amended the text under 2.2 "Purpose and Scope".
D5.3.2	Lumanity	6	Line 121	It is not clear whether there will be different working groups for the different areas mentioned. For example, will there be both a statistics working group and an information specialist working group concentrating on medical devices; then different groups for pharmaceuticals etc.? Or is there only one group which has representatives from all of these areas within it? If the latter, suggest adding information on how experts with different specialisms will be included.	Thank you for your comment. It is planned to initially implement two working groups (statisticians and information specialists). The groups will ensure that the necessary experience and skills are covered. Further details of the HTAb working groups will be described in the "rules of procedure".

Please add extra rows as needed.

EUnetHTA 21 Public Consultation
Of D5.3.2 on HTA body technical expert working groups

Comments should be submitted not later than 20 May 2022, 23:59 CET

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
D5.3.2	Lumanity	6	Line 123/124	It is not clear how disagreements will be handled within the group. There will be different HTA representatives with potentially different methodological approaches and while this goal is to encourage discussions and resolution of any disagreements there should be a formal process or decision-making route if no resolution can be found. Would recommend that the common methodologies are fully discussed and agreed upfront.	Thank you for your comment. Further details of the HTAb working groups (e.g. decision making within the HTAb working groups) will be described in the "rules of procedure".
D5.3.2	Lumanity	8	Line 158	The document does not state how the experts will be allocated across the country representatives and suggest including this detail. Must there be representation from the larger HTAbs given different methodological approaches?	Thank you for your comment. We have amended the text in table 2.
D5.3.2	Lumanity	8	Line 159	Working groups are to include experts with a wide range of expertise but no detail is given on how this will be achieved. Suggest including detail on how different expertise can be included in the group.	Thank you for your comment - the minimum requirements are already stated in the text (please see section 1. "Background"). We will consider your comment and propose additional text.
D5.3.2	Lumanity	8	Line 161	There is no guidance within this document on the time commitment that is expected for this role (perhaps that is not the remit at this time); but there is a need to understand what this will be, how frequent are meetings expected, how long will meetings take etc.	Thank you for your comment. Your comment has not been considered, since it lies beyond the scope of this deliverable.
D5.3.2	Lumanity	9	Line 172	As per a previous comment, there needs to be a much better definition of what the minimum standard is of specific expertise and experience that is agreed by all parties. What is expected of the promotion of exchange between HTAb technical experts – if there is a country specific methodology update would this be shared with the other members of the technical team? What	Thank you for your comment. The minimum requirements are already stated in the text (please see section 1. "Background"). The HTAb working groups aim to enable an exchange between the HTAb

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				is meant by facilitation of further training – is this purely related to the comment on line 163 about observers joining the working group as training; not overly clear.	technical experts in order to apply current international standards of evidence-based medicine (see HTAR article 4). The training organized by the HTAb working groups does not only address the observers mentioned in section 4.2, but should also address all HTAb technical experts involved in JCA/JSC.
D5.3.2	BAH	7	139	JCA/CA Assessor / JCA/CA Co-assessor: The BAH welcomes the explicit specification of the individual person instead of the institution itself as it was discussed before.	Thank you for your comment. We have adopted the definition of deliverable D5.3.1.
D5.3.2	Bayer	6	91-94	List of technical experts should be completed by a third bullet point: "Health economists with profound expertise in cost-effectiveness and budget impact analyses" - from the beginning, not just within a future update of this deliverable.	Thank you for your comment. As stated in the HTAR, a clinical assessment does not cover "cost and economic evaluation of a health technology".
D5.3.2	Bayer	8	154, 156	The role of health economist should be added to the list of technical experts (in Figure 1 and text in section 4.2)	Please see answer above.
D5.3.2	Bayer	9	172	The role of health economist should be added to the list of technical experts (Table 2).	Please see answer above.
D5.3.2	Bayer	6	93	Propose amendment: "Statisticians have experience in statistical data analysis for clinical trials and epidemiologic studies..."	Thank you for your comment. We have adapted the guidance.
D5.3.2	Bayer	General		RWE and alternative trial designs are likely to increase in prominence in the future, particularly for ATMP evaluation. Therefore, suggest adding a third technical expert category to provide expertise in RWE/epidemiology	Thank you for your comment. RWE will be covered by the statistician working group
D5.3.2	Bayer	6	126	Add "... and EMA"	Thank you for your comment. Your

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
					comment has not been considered, as the HTAb working groups are intended to facilitate an exchange between HTAb. However, the HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned. However, if needed, there will also be an exchange with other organisations (e.g. EMA).
D5.3.2	Bayer	9	173	Add bullet: "Monitor adherence and implementation of guidelines during JCAs and JSCs"	Thank you for your comment. Your comment has not been considered, as the HTAb working groups are not responsible for monitoring adherence and implementation of guidelines during JCAs and JSCs.
D5.3.2	Bayer	9	187-190	Unclear how EUNETHTA 21 can meet its objectives without appropriate technical experts.	Thank you for your comment. Technical experts in the HTAb are already involved in EUnetHTA21 (e.g. in CSCQ). The text describes the setup of the HTAb technical experts working groups within the framework of EUnetHTA 21.
D5.3.2	EFPIA	General		The guideline should define clear and predictable trigger points for updates of methodological guidelines as well as clearly defined rules for who can initiate a methodological review (Expert WG or Coordination sub-group or others?). Such updates of methodological guidelines should involve all relevant stakeholders (including industry). Furthermore, industry (and other stakeholders) should be able to ask for a	Thank you for your comment. Your comment has not been considered, since it lies beyond the scope of this deliverable. Nevertheless, it has been considered as a recommendation for the future.

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				methods guideline update.	
D5.3.2	EFPIA	General		The guideline should provide clarity and transparency around the process (including timing) for the input of Technical Expert Working Groups provided on specific methodological queries during a specific JCA/JSC. Furthermore, clarity and transparency should be provided, in the final assessment report, as to how the respective feedback is integrated. It is not clear when/for which questions the experts are included in the assessment / scientific consultations – EFPIA recommends that a standard operating procedure should be developed for their consultation. Important consideration should be given also to the time allowed for a response, so as to not un-necessarily delay the finalization of the respective assessment. It might be that the coordination group is not aware of a potential methodological issue that should be examined by an expert (e.g. statistician). In case of assessments using more complex methodologies an expert should (always) be consulted and proactively discuss some main topics/ methodologies (since some queries are only considered relevant by the respective expert) and ensure that methods are used in a standardized way.	Thank you for your comment. The tasks of the HTAb working groups are shown in Table 2. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope. Your request for technical experts to be involved in complex methodological issues is ensured, as each assessment team includes these technical experts; please see guidance D5.3.1. The HTAb working groups are additionally available for ad hoc questions.
D5.3.2	EFPIA	General		Members of the Working Groups should reflect HTA expertise spread across MS (not all experts from just one / two HTAb) and reflect the needs	Thank you for your comment. We have amended the text in table 2. Furthermore, the HTAR provides broad

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				of the HTAbs and adaptability to promote uptake of the JCA. Experts various need to reflect EU level methods rather than adopt the assumptions / positions of 'their national' HTAb. Expert groups should include independent external experts not part of HTAbs, providing additional objectivity and balance and insight of emerging state of the art methods.	involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned.
D5.3.2	EFPIA	General		Members of the Technical Expert Working Group should have life science training and experience in HTA (e.g. 10 years) to be able to provide advice on specific statistical issues with an understanding of HTA needs in a life science based context Guideline should consider building future capabilities/ emerging technology, e.g., artificial intelligence (AI) in retrieving and screening studies for inclusion in systematic literature reviews, and role that can play in assisting information retrieval.	Thank you for your comment. Your comment has not been considered, since the minimum requirements are already stated in the text (please see section 1. "Background"). New developments in information retrieval, such as automation in search strategy development and screening studies, will be covered by the HTAb working group of information specialists.
D5.3.2	EFPIA & Vaccines Europe	6	95	EFPIA strongly recommends that technical expert groups are formed around methodological issues rather than by discipline. These should be based around the current and potential methodological guidelines and include methodologists with different expertise and perspectives so as to enable greater applicability of the JCA report to MS. For example, Technical Expert Working Groups could be formed for safety, direct and indirect comparisons (include sub expertise needed for different types), the role of RWE and	Thank you for your comment. It is not planned to form additional HTAb working groups for individual methodological problems. However, the challenges mentioned will be addressed in the planned HTAb working groups. If there is a need for additional technical experts, it is possible to form additional HTAb working groups.

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				observational studies, development and validation of Patients Reported Outcomes (PROs) (including both qualitative and quantitative (e.g., psychometric analyses) stages of PRO validations, derivation of meaningful level of change, etc.), and clinical endpoints. Considering the specificities of vaccines, expertise on vaccinology and public health (to ensure that the direct and indirect impact of vaccines on individuals, society and public health will be properly assessed) should be included as well.	
D5.3.2	EFPIA	6	100	Please rephrase sentence, e.g. "The EU co-funded EUnetHTA JA3 ended in May 2021. On September 17th 2021, the European Health and Digital Executive Agency (HaDEA) signed....to further support European HTA collaboration.	Thank you for your comment. Your comment has not been considered, as it is the wording from the deliverable D5.3.1
D5.3.2	EFPIA	6	111	Please rephrase it is not clear what the deliverables are. Is the process of creating an SOP or is the SOP itself the deliverable?	Thank you for your comment. We have amended the text.
D5.3.2	EFPIA	6	114	Please rephrase it is not clear what the deliverables are. Is the process of designing a proposal or the proposal itself the deliverable?	Thank you for your comment. We have amended the text.
D5.3.2	EFPIA & Vaccines Europe	6	121	Please add "vaccines" as an example of expertise in different areas as follows "(…)ensure that methodological expertise in different areas is covered (e.g. medical devices, pharmaceuticals, vaccines, JSCs, emerging health technologies)"	Thank you for your comment. Your comment has not been considered, as the list should not be understood to be complete.
D5.3.2	EFPIA	6	121-122	The focus of this bullet point is primarily on technologies, of which the HTD will be the expert. We recommend that this bullet focus is changed	Thank you for your comment. Your comment has not been considered, as

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				to ensure expertise in different methodological areas (e.g. ITC, PRO, safety, use of RWE and observational data).	the list should not be understood to be complete.
D5.3.2	EFPIA	8	145	The guideline should be more specific and mention that it refers to changes in EU-wide methods / methods used in JCAs when referring to the need of experts to be aware of their evolution. It is not specified in detail if there are any regular exchanges between the experts and the different HTAb or even the pharmaceutical company/academia and the experts. A regular cross-functional meeting with participants from different HTAb, academia, and pharmaceutical companies might create awareness for new methodologies. Including not only HTAb but also academia might broaden the knowledge of the experts.	Thank you for your comment. Your comment has not been considered, since it lies beyond the scope of this deliverable. Nevertheless, the HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned.
D5.3.2	EFPIA	8	152	As methods are continuing evolving, the Coordination Group and its subgroup may identify the need to establish additional Expert Groups to support their work and answers questions during JSC and JCA.	Thank you for your comment. It is already stated in the background (please see section 1. "Background") that other roles may be added in the future.
D5.3.2	EFPIA	8	152 Figure 1	"Identification of emerging technologies" may be updated to "Identification of emerging technologies or statistical methods"	Thank you for your comment. Your comment has not been considered, as the figure refers to the subgroups stated in the HTAR article 3(7(k))
D5.3.2	EFPIA	8	157 - 163	Members of the Working Groups should reflect HTA expertise spread across MS (not all experts from just one / two HTAb) and reflect the needs	Thank you for your comment. We have amended the text.

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				of the various HTAbs and adaptability to promote uptake of the JCA. The Coordination Groups should reflect if a pool of 5-10 experts is sufficiently deep to answer complex methodological questions, also considering the expectation of the growing number of assessments as the scope of the Regulation is expanded. Line 241 mentions that assessors may contact the Expert Group with specific questions on ongoing assessments and that the Expert Group need to provide responses, in a consensus manner. The guideline should be mindful of potential bottlenecks if several assessments are carried out in parallel and advice is needed on all.	Further details of the HTAb working groups (e.g. on timelines) will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	8	157 - 163	Clarity should be provided as to whether or not the same individual can be part of both (multiple) Expert Working Groups.	Thank you for your comment. The 2 HTAb technical expert working groups of statisticians and information specialists have such different thematic focuses that this question will not arise.
D5.3.2	EFPIA	8	157	Information (names, institutions, short CV, areas of expertise and declaration of CoI) of the Working Group members should be made public on the IT platform because they have to be seen as members of a subgroup! Their FAQs should be public as well.	Thank you for your comment. Further details of the HTAb working groups (e.g. on timelines) will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	General and 8	159	Transparency of the selection criteria and the selection process for each individual in the expert team should be provided and, should a hierarchy of selection criteria be established, such hierarchy should be transparent and clarified in the	Thank you for your comment. Your comment has not been considered, as a strict definition of the selection criteria is not planned. However, the minimum

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				guideline Further definition of the terms "expertise" should be provided (e.g. relevant education, diploma level etc.). EFPIA recommends that members of the Technical Expert Working Group should have life science training and experience in HTA (e.g. 10 years) to be able to provide advice on specific statistical issues with an understanding of HTA needs in a life science based context.	requirements are already stated in the text (please see section 1. "Background").
D5.3.2	EFPIA & Vaccines Europe	General and 8	159	For the assessment of vaccine, the composition of HTAb technical expert working group should allow for the delegation of NITAGs' members.	Thank you for your comment. The HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned.
D5.3.2	EFPIA	General and 8	161	The guideline should define the role of the chair/co-chair in the group. Is it just administrative or does the co-/chair have authority to decide in case a consensus cannot be reached among the working group members? Please provide information on the selection of the chair/co-chair within the expert group. It is not clear in which form they are nominated and by whom. EFPIA believes chairs/co-chairs should also be responsible for providing transparency of the work of the WGs e.g. through publication of meeting minutes, topics for consultation, conclusion on method topics, etc.	Thank you for your comment. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.

Please add extra rows as needed.

EUnetHTA 21 Public Consultation
Of D5.3.2 on HTA body technical expert working groups

Comments should be submitted not later than 20 May 2022, 23:59 CET

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
D5.3.2	EFPIA	General and 8	163	It will be important to appropriately train the technical experts to ensure that the advice they give is consistent with EU methodologies and not reflect bias from their national level methodologies.	Thank you for your comment. We agree that training will be an essential responsibility of the HTAb working groups. Please see tasks listed in table 2
D5.3.2	EFPIA	8	160	The rules of procedure and the workplan for the Technical Expert Working Groups should be public. A public consultation for this code of conduct/rules of procedure should be put in place as well.	Thank you for your comment. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	General and 8;9	160; 172	The Expert Groups are only nominated for a specific period of time. Due to the limited period, it might occur that one joint assessment is not finished. Consequently, an exchange of experts who have worked on the assessment so far might take place. It would be preferrable if the knowledge and expertise acquired during the time period / one assessment will be submitted to the next nominated expert group. A transitional phase ensuring that all queries concerning the methodology of one assessment are solved by one expert group might be an option. It is not clear from the document how the consistency of the contributions of these expert working groups will be maintained. A suggestion would be to add a subsection that will indicate where the produced documents will be stored and how to access them.	Thank you for your comment. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	9	164 - 169	The guideline should provide a clear distinction	Thank you for your comment. Since the

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				and transparency of roles and responsibilities of Technical Expert Working Groups vis-a-vis Coordination sub-group on Development of methods.	establishment of the structures resulting from HTAR has only just begun, we cannot provide any further details on this.
D5.3.2	EFPIA	9	172 Table	In addition to promotion of exchange between HTAb technical experts, the expert group should promote coordination with EMA-HMA methodological experts, in particular the EMA Methodological domain.	Thank you for your comment. Your comment has not been considered, since it lies beyond the scope of this deliverable. However, if needed, there will also be an exchange with other organisations (e.g. EMA).
D5.3.2	EFPIA	9	172 Table	The mandate of an expert for 3 years should be renewable. Every three years, after the chair has been elected, the subgroup shall re-examine and confirm the composition of the entire expert group, based on expected activities and expertise required	Thank you for your comment. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	9	178	Beyond the resourcing needs for the Expert Groups coming from the EU level, Members of the Technical Expert WG should be empowered, by their respective national HTAb, to prioritize and allocate sufficient resources (e.g. time) for EU level work.	Thank you for your comment. Since the establishment of the structures resulting from HTAR has only just begun, we cannot provide any further details on this.
D5.3.2	EFPIA	9	181	The wording "The funding of HTAb working groups may be part" needs additional clarification. If the funding is not ensured by the European Commission what are the	Thank you for your comment. Since the establishment of the structures resulting from HTAR has only just begun, we cannot provide any further

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				consequences for the expert groups - will expert groups still be part of the joint assessment/ joint scientific consultations/ identification of emerging health technologies? Although it is stated that this funding will be ensured when implementing the HTAR, the weak formulation "may be" within the guideline remains the reader with some questions.	details on this. However, the HTAb working groups will be part of the subgroup "development of methodological and procedural guidance" and will deal only with scientific issues.
D5.3.2	EFPIA	9	187	Please clarify, sentence (whole paragraph) is confusing. Please rephrase, e.g. "The implementation of HTAb technical working groups was not initially considered within EUnetHTA21. Therefore, a decision regarding the implementation of these groups is required at the level of CSCQ or CEB."	We have deleted this paragraph since it is misleading.
D5.3.2	EFPIA	12	241	Please provide more guidance on the consensus process, in particular, what happens if a consensus cannot be reached.	Thank you for your comment. Further details of the HTAb working groups will be described in the "rules of procedure". We have amended the text under 2.2 Purpose and Scope.
D5.3.2	EFPIA	12	245	Potential conflict of interest is checked. It might occur that all experts have a conflict of interest regarding the respective assessment, particularly for special diseases. In the case of arising methodological queries that require the support of the expert group, please outline how such a situation will be dealt with.	Thank you for your comment. Your comment has not been considered, since it lies beyond the scope of this deliverable. However, please see the procedure guidance for DOI (D7.5), which was updated to cover exceptional circumstances of orphan diseases.
D5.3.2	Eurordis	7	132-4	Where it is written: " Whilst focusing on statisticians and information	Thank you for your comment. It is not

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				specialists, the proposed process could be applied to other HTAb technical expert working groups as necessary" We suggest: Technical expert working groups might be proposed and organised on topics of interest from a methodological, scientific, and general point of view for the centralised cooperation, such us (e.g.): - Significant benefit for OMPs - PROMs - QoL - Patient elicitations and engagement - Artificial Intelligence - New trial design - Payment model (under the voluntary cooperation) A technical expert working group might be specifically composed of HTAb and external experts/specialists, depending on the topic, such as (e.g.): - Patient representatives - Professional representatives - Payers - Information Technology / Artificial Intelligence / Data experts - Consumers/patient intelligence experts	planned to form additional working groups for individual methodological issues. However, the challenges mentioned will be addressed in the planned working groups. The HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned. However, if needed, there will also be an exchange with other organisations (e.g. EMA).

Please add extra rows as needed.

EUnetHTA 21 Public Consultation
Of D5.3.2 on HTA body technical expert working groups

Comments should be submitted not later than 20 May 2022, 23:59 CET

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
D5.3.2	Eurordis	7	Table 1	"An HTAb technical expert working group comprises a limited number of HTAb technical experts delegated from the HTAbs who are responsible for fulfilling the tasks of the working group for a defined period of time" We suggest adding: "A technical expert working group comprises a limited number of HTAb delegates, who are responsible for driving the work of the group, and a limited number of external experts and specialists, who are responsible for the service provided under their field of expertise for the time of their appointment"	Thank you for your comment. The HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned. However, if needed, there will also be an exchange with other organisations (e.g. EMA).
D5.3.2	Eurordis	8	151-2	Where it is written: "Two dedicated working groups, one for statistics and one for information specialists, should be created when the Coordination Group forms the subgroup". We suggest: Five dedicated working groups should be created when the Coordination Group forms the subgroups - Statistics - Information specialists - Significant benefit for OMPs - PROMs - Patient elicitation and engagement	Thank you for your comment. It is not planned to form additional HTAb working groups for individual methodological issues. However, the challenges mentioned will be addressed in the planned HTAb working groups. In addition, there will be a deliverable on patient involvement (D7.2 - guidance on patient & healthcare professional involvement).
D5.3.2	Eurordis	8	163	We suggest adding:	Thank you for your comment. The HTAR

Please add extra rows as needed.

Sub-deliverable	Comment from	Page number	Line/ section number	Comment and suggestion for rewording	Editorial comment?
				"External experts or specialists should be selected through a public call for expression of interest and upon validation of their declaration of interest"	provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned.
D5.3.2	Eurordis	9	Table 2. Structure	We suggest adding: - External experts (e.g. patient, clinicians, specialists, academics) - Selected upon public call for expression of interest and upon validation of their declaration of interest	Thank you for your comment. The HTAR provides broad involvement of external experts. For this, please see D7.2 and D7.3. Further involvement in the HTAb working groups is not planned.
D5.3.2	Eurordis	9	Table 2. Task	We suggest adding: "Supporting the coordination group and subgroups members by replying to ad hoc questions and informing them of the state of the art in a specific domain of interest"	Thank you for your comment. This is an important issue. However, these activities are already covered in the guidance document. Please see section 4.2.
D5.3.2	Eurordis	9	177-183	We suggest adding : "Technical expert working groups might cover – at the willingness of Member States – topics that will continue to fall under the voluntary cooperation".	Thank you for your comment. Your comment has not been considered, because "voluntary cooperation" is already addressed in the guidance (see, for example, Appendix 2, Q&A Form).

Please add extra rows as needed.