**[Notes:**

**In this document the NICE text from the consultation website [https://nice.researchfeedback.net/s/consultation\_2021] is in Black.**

**Our suggested potential responses are in Purple, for you to use and change as you see fit, it would be really helpful to the wider community if you make additional or different points that you share them.**

**Our notes and comments to try and help are in Green]**

**Please select the consultation(s) that you would like to comment on below:**

Methods (including questions on valuing the benefits of health technologies and understanding and improving the evidence base)

Processes (including questions on alignment, new ways of working and Commercial and Managed Access)

Topic selection (including questions on highly specialised technologies routing criteria and the eligibility criteria for devices, diagnostics and digital)

**[Note: if you can bear it, please tick all three!]**

**Methods: Valuing the benefits of health technologies**

  We would like to understand more about your perspectives on core themes relating to valuing the benefits of health technologies.

Please read and review the consultation document (Proposals a to o and appendix paras 1.1 to 1.52) then answer the questions below and add any comments you have on the themes on the next page.

  **How strongly do you agree or disagree with the proposals related to:**

Strongly agree. | Agree. | Neither agree nor disagree. | Disagree. | Strongly disagree. | Don't know / NA

A modifier for severity of disease            **Strongly disagree**

  Consideration of uncertainty within decision-making            **Strongly** **disagree**

  Health inequalities            **Strongly disagree**

  Aligning modifiers across programmes            **Strongly disagree**

  Discounting            **Strongly disagree**

|  |
| --- |
| **Methods: A modifier for severity of disease** |

|  |  |
| --- | --- |
|   | Two alternative options for a modifier for severity of disease are presented in proposal g and h: |

|  |  |
| --- | --- |
|   | **Of the 2 alternative options presented in proposal g and h (and appendix 1 paragraphs 1.18 and 1.19), which do you prefer?** |
|

|  |  |
| --- | --- |
|  | Option 1 |

 |
|

|  |  |
| --- | --- |
|  | Option 2 |

 |

**[Note: fill your boots with this one they both suffer from the same criticism (see below)]**

|  |  |
| --- | --- |
|   | **Please use this space to share any comments on the options:** |
|  |

**Please use this space to share any comments on the proposals related to:**

  A modifier for severity of disease

**The principle of additional consideration being given to more severe diseases is welcome. The current proposals (g & h - with supporting sections 1.15 - 1.25) are opaque and do not appear to have any transparent process or basis for their application (see section 1.24 “The application of the severity modifier will be considered on a case-by-case basis by individual committees, based on the totality of evidence and the precise condition and indication under consideration.”). This is unclear how it will be used, what evidence base for the values is, why these values and these cut-offs and how this is designed to do anything for people affected by the conditions that the technologies are under consideration for. This proposal appears to be nothing more than mathematical fiddling for which the approach and genuine intentions remain obscure.**

  Consideration of uncertainty within decision-making

**The current proposals (with supporting sections 1.26 - 1.35) are unclear and fall short of an explicit understanding of the nature of evidence uncertainty. Much of the focus appears to with consideration to perfect information. There are many diseases where perfect (or even near perfect) information is impossible, improbable, or unrealistic within a reasonable timeframe. Currently ERGs and committees appear to structurally discriminate against population for which evidence generation is particularly difficult, so it is excellent that four of these populations have been recognised (rare disease, children, innovative and complex technologies). There needs to be a process in which best plausibility collectable evidence is considered, i.e. what evidence could realistically be collected, for technologies where the realistically collectable evidence falls short of that which would normally be expected then a totally different approach to decision making is needed. The current and proposed methods and process simple do not and will not fairly and transparently evaluate these technologies.**

**It is concerning when the proposal talks about “this must not overlap with other modifiers”, when these four populations can occur together and the consideration of the impact of plausible evidence collection on uncertainty multiples with the addition of each of these populations (i.e. an innovative and complex technology for a rare disease affecting children will suffer from difficulties in evidence collection several orders of magnitude greater than a technology without those four characteristics).**

**The current proposal also lacks transparency of application and process. It is unclear if committees will use this flexibility, however more concerning it the lack of clarity about what the flexibility actually is. That “innovative technologies and treatments for children or rare diseases have the potential to be recommended without barrier or delay” is welcome. However, just the *potential* is not enough. The current system has that same potential and yet exactly these technologies languish within the NICE process for YEARS. There is nothing in these proposals that suggests that they will be any difference in this going forward, i.e. the potential will remain but the reality will be continued anguish for patients and their carers.**

  Health inequalities

**The current proposals (with supporting sections 1.36 - 1.41) are unclear, it is not clear how NICE will evaluate inequalities, what NICE considers inequalities to be or what the modifier is or how it will work. The current approach NICE appears to take to inequalities appears to ignore them, perpetuate them or even make them worse. These proposals do nothing to address this.**

  Aligning modifiers across programmes

**The current proposals (specifically section 1.47) so a fundamental lack of understanding of the issues with the current HST process and a disappointing overlooking of it during this review. This section makes it unclear what the process and flexibilities within the current HST system are and what if any of the proposals in this consultation relate to HST. Implicit consideration is simply not good enough, because it does not appear to happen. Current ERGs and committees repeatedly show a singular lack of understanding of rare and complex diseases, their impact of peoples lives and the associated difficulties with evidence generation. It is great that HSTs are built on a different ethical framework and normative principles, but it is not clear what ethical framework and normative principles NICE are using for HST evaluation and the proposals from this review give no additional clarity. Given the continued insistence of a single manual it gives the rare disease communities immense cause for concern that HSTs are going to move further towards using the kind of approaches laid out from this review and cause further and increasing anguish and distress to patients and their carers. Please could there be a explicit, separate and distinct manual for HST evaluation that clearly and transparently lays out the approach and process used by HSTs.**

  Discounting

**The current proposals (with supporting sections 1.48 - 1.51) makes a compelling case for change to a 1.5% discount rate and then falls very short with the following statement (specifically section 1.51) “Until policy and system implications can be addressed, the existing reference-case discount rate of 3.5% will be retained.” This is not a proposal, this gives no timescale for change, nor assurances that the ‘implications’ can or will be addressed. False hopes raised, and as quickly dashed a deeply concerning a repeated theme from this review.**

**Methods: Understanding and improving the evidence base**

  We would like to understand more about your perspectives on some core themes relating to understanding and improving the evidence base.

Please read and review the consultation document (proposal P, appendix 1 paragraphs 2.1 to 2.16) then answer the questions below and add any comments you have on the themes on the next page.

  **How strongly do you agree or disagree that you support the proposals related to:**

Strongly agree. | Agree. | Neither agree nor disagree. | Disagree. | Strongly disagree. | Don't know / NA

  Implementing the proposed cases for change for sourcing, synthesising and presenting evidence, and considering health-related quality of life **Neither agree nor disagree**

  Considering real-world evidence            **Neither agree nor disagree**

  Calculating the costs of introducing health technologies           **Neither agree nor disagree**

  Analysing uncertainty            **Neither agree nor disagree**

**Please use this space to share any comments on the proposals on understanding and improving the evidence base:**

Implementing the proposed cases for change for sourcing, synthesising and presenting evidence, and considering health-related quality of life

**The current proposal (specifically section 2.2) contains no explicit methods or proposal**

Considering real-world evidence

**The current proposal (specifically section 2.4) contains no explicit methods or proposal “we therefore propose to articulate how and when RWE will be considered in decision-making and to explain what the expectations are around the identification of evidence and data”**

Calculating the costs of introducing health technologies

**The current proposal (specifically section 2.13) contains an excellent fundamental principle “that the price used must reflect as closely as possible the prices that are paid in the NHS for use in the population under consideration” however it seems unlikely with the current practice of redacted commercial-in-confidence prices that this principle will often be used. The proposal for the alternative approach lack clarity and transparency and it is unclear on how to effectively comment on this total arbitrary approach and acceptance of the by-passing of the principle.**

Analysing uncertainty

**The current proposal (sections 2.14 -2.16) do not contain a clear proposed approach to handling uncertainty, only a statement that (section 2.16) that EVPI would not be used and (section 2.15) that the visualisation framework will not form part of the manual (it is therefore difficult to comment on the proposal)**

|  |
| --- |
| **Methods: additional comments** |

|  |  |
| --- | --- |
|   | We understand you may have comments relating to the methods consultation document that have not been covered in our questions about valuing the benefits of health technologies or understanding and improving the evidence base.Please use the space below to share any equality considerations, or wider thoughts or comments.Each box allows for 9,999 characters (approximately 3.5 pages of A4) if you need additional space you can attach a word document using the upload icon at the bottom. Please note that the document should be kept to a minimum and must not repeat what you have included in the form. |

|  |  |
| --- | --- |
|   | **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.Please share any comments on whether the proposed methods will help to achieve this aim, or if the proposals raise any concerns with regard to equality:** |
|  |

|  |  |
| --- | --- |
|   | **Please share any other comments:** |
|  |

|  |
| --- |
|  |

  **You can attach a document here:**

**Processes**

  This section of the form focuses on the Processes consultation document.

In particular we would like to understand more about your perspectives on alignment, new ways of working and Commercial and Managed Access.

Please click next page to continue.

|  |
| --- |
| **Processes: alignment** |

|  |  |
| --- | --- |
|   | We would like to understand more about your perspectives on the alignment of processes within the consultation document.Please read and review the consultation document then answer the questions below and add any comments you have. |

|  |  |
| --- | --- |
|   | **Have the processes been aligned appropriately?** |
|

|  |  |
| --- | --- |
|  | Yes |

 |
|

|  |  |
| --- | --- |
|  | **No** |

 |

  **Please use this space to share any comments:**

 **It is not clear the degree to which the processes are aligned, and the consultation only allows for yes or no responses. This inappropriate channelling of responses is characteristic of how NICE currently behaves.**

|  |  |
| --- | --- |
|   | **Are there any remaining unwarranted differences in the processes of guidance development for Diagnostic Assessment, Highly Specialised Technologies, Medical Technology Evaluation and Technology Appraisal?** |
|

|  |  |
| --- | --- |
|  | **Yes** |

 |
|

|  |  |
| --- | --- |
|  | No |

 |

  **Please use this space to share any comments:**

 **It is unwarranted that the HST process has been left out of this consultation on methods. The HST process methods are currently, interim, unclear, non-transparent and serviced by people and committees who appear to have a limited understanding or appreciation of rare diseases or how to evaluate them in a equitable manner.**

 **Processes: New ways of working**

  We would like to understand more about your perspectives on some core themes relating to new ways of working.

Please read and review the consultation document then answer the questions below and add any comments you have on the themes on the next page.

  **How strongly do you agree or disagree with the proposals related to:**

Strongly agree. | Agree. | Neither agree nor disagree. | Disagree. | Strongly disagree. | Don't know / NA

  Technical Engagement            **Neither agree nor disagree.**

  Rapid review of guidance for biosimilars           **Neither agree nor disagree.**

  Treatment eligibility criteria            **Strongly disagree**

  Managing high company base case ICERs           **Strongly disagree**

  Alternative draft scope consultation timings            **Strongly disagree**

**Please use this space to share any comments on the proposals on new ways of working:**

Technical Engagement

 **It is not clear what the proposal actually is.**

Rapid review of guidance for biosimilars

 **It is not clear what the proposal is. There is no indication in the proposal paper of what the process will be, what is meant by rapid or how this will make any meaningful difference.**

Treatment eligibility criteria

**It is not clear what the proposal is or how or when it will be used. Just that it may be used.**

Managing high company base case ICERs

**It is not clear what the proposal is, the use of significantly and sufficiently are unspecified. “May pause” is not a transparent process with actionable criteria. “reserve the right” appears to be used here to imply ‘ignore all stakeholders’ whenever felt like. What is NICE’s meta-equivalent of “fully informed” and “rationale” because currently the communication and explanations of NICE meet neither of these from a pragmatic, dictionary or standard use point of view, and there is nothing within this consultation or proposal to suggest the future will be different.**

Alternative draft scope consultation timings

**It is not clear what the proposal is.**

|  |
| --- |
| **Processes: Commercial and Managed Access** |

|  |  |
| --- | --- |
|   | We would like to understand more about your perspectives on the proposals relating to Commercial and Managed Access.Please read and review the consultation document then answer the questions below about how clear or unclear you find them and add any comments. |

  **How clear or unclear are the proposals related to:**

   Very clear   Clear   Neutral   Not very clear   Not clear at all   Don't know / NA

  Commercial activity             **Not clear at all**

  Managed access activity             **Not clear at all**

  **Please use this space to share any comments on the proposals:**

  Commercial activity

**The proposal is unclear, the scheme is unclear, opaque and appears of little or no benefit to patients as currently presented.**

  Managed access activity

**The proposal is unclear, the eligibility for such a scheme is unclear, 5.12.11 States this scheme is “**applying NICE’s usual standards and processes” **how are HST technologies that are explicitly not using standard processes ever going to achieve these valuable and much needed MAAs. In fact these technologies are exactly the one for which MAAs should be designed, but here they appear specifically disadvantaged.**

 **Processes: additional comments**

  We understand you may have comments relating to the processes consultation document that have not been covered in our questions about alignment, new ways of working or Commercial and Managed Access.

Please use the space below to share any equality considerations, or wider thoughts or comments.

Each box allows for 9,999 characters (approximately 3.5 pages of A4) if you need additional space you can attach a word document using the upload icon at the bottom. Please note that the document should be kept to a minimum and must not repeat what you have included in the form.

  **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Please share any comments on whether the proposed processes will help to achieve this aim, or if the proposals raise any concerns with regard to equality:**

  **Please share any other comments:**

  **You can attach a document here:**

|  |
| --- |
| **Presentation of the guidance manual** |

|  |  |
| --- | --- |
|   | The draft guidance manual brings together the proposals from the methods and processes consultation documents as an illustrative example of the proposals put into practice.Please read and review "Developing NICE technology guidance: The draft manual" and share your thoughts below. |

|  |  |
| --- | --- |
|   | **What are your initial impressions of how the guidance manual is presented?** |
|  |
|   | You have ? characters left |

|  |
| --- |
| **While written in straight-forward language the implications of the words are consistently obscured. Every page, nearly every paragraph as unspecified language, words that have an implied meaning. However, the meaning that we as stakeholder would hope for is unlikely to be the meaning. This consultation is too short for every instance (several examples are used in earlier responses and additional ones will be included below) of this to be drawn to your attention and it is a principle that should be corrected immediately and for all future consultations.** |

  **If you have any comments on the chapters in the guidance manual please provide these here: (otherwise please click next)**

  Involvement & participation

 **It is apparent to patient representative that currently many committee members do not read the documents sufficiently to understand the disease, the issues or be allowed to be in a position to make or contribute to what, for patients, is a life changing decision. There is nothing in this that appears to address this fundamental issue.**

**With respect to 1.2.17 - bullet point 3 - it is not sufficient that a purported expert simply has knowledge of…this criterion has lead committees to select clinicians with little insight into the disease/technology interaction and ignore clinicians (put forward by other stakeholders) who have extensive experience of using the technology in real patients. 1.2.27 - allowing experts to opt out if their views are adequately reflected in the papers is not acceptable because many committee members do not read or understand the papers.**

**Section 1.2.30 why do the EAG limit themselves to “**creates a report that independently synthesises the evidence from published information and any evidence submissions about the clinical and cost effectiveness of the technologies” **only for MTA, surely this would be equally valuable in HSTs.**

**Section 1.2.37 really contain no tangible information on the actual value and use to which a committee will put information from expert patients. There is not included framework for the evaluation and use of these data and as such it is likely that NICE committees will continue to undervalue or subtly (or explicitly) ignore them.**

  The scope

**2.2.1 begins with a typical example of unspecified language “appropriate information”, define appropriate, because what appear appropriate to the people affected by conditions is often disregarded by NICE committees.**

**2.2.3 appears to make it very difficult for technologies that might additionally treat very rare conditions from being assessed.**

**2.2.5 “at NICE’s discretion” what on earth does this mean, practically. How can any external stakeholder be expected to work with this unspecified, one-sided, opaque criterion.**

**2.2.8 “Excluding people from the scope does not mean that the technology is inappropriate for these people”, but how, specifically by what mechanism, will they access if not included in the scope. Essentially this paragraph appears to boil down to “Because resources for evaluation are limited…” patient populations have to be disadvantaged.**

**2.2.17 “**For evaluations where QALYs are calculated…” **please could NICE be explicit about when and which evaluations will not include QALY calculations**

**2.2.20 “should be” do they have to be? “appropriately validated” define appropriately. What does this mean for populations where this validation is not practical or possible?**

**2.3.1 great to have the obligation to “seek views”, but where is the obligation to give those views, fair, transparent and equitable consideration.**

**2.3.4 appear to directly contradict 2.2.5**

**2.4.8 “**if they meet the eligibility criteria to be a stakeholder in the evaluation”  **it is not clear what these criteria are. On a more fundamental level if someone or an organisation requests to be a stakeholder then they feel they have an interest, what would be the basis for denying them.**

**2.5.3. Who defines need.**

**2.7.1 this appears to be shifting the goal posts for MAAs. Surely an MAA is set up to address specific uncertainties. How is it fair that a new scope essential starts again ignoring the evaluation to date.**

**2.8.4 what is the time that constitutes a ‘significant’ length? What extent determines further engagement? What happens if NICE are not ready, or cannot be ready in a timely manner.**

  Evidence

**3.1.1 We agree, so why does 1.2.30 appear to limit this only to MATs**

**3.4.4 What method for systematic reviewing will be done to “assemble all the relevant evidence” when It is recognised by experts within the rare disease community, that standard processes e.g. GRADE, not fit for use in systematic reviews of evidence for tiny populations e.g. [Tischkowitz M, Colas C, Pouwels S, Hoogerbrugge N; PHTS Guideline Development Group; European Reference Network GENTURIS. Cancer Surveillance Guideline for individuals with PTEN hamartoma tumour syndrome. Eur J Hum Genet. 2020 Oct;28(10):1387-1393. doi: 10.1038/s41431-020-0651-7. Epub 2020 Jun 12. PMID: 32533092; PMCID: PMC7608293.] and [Frebourg T, Bajalica Lagercrantz S, Oliveira C, Magenheim R, Evans DG; European Reference Network GENTURIS. Guidelines for the Li-Fraumeni and heritable TP53-related cancer syndromes. Eur J Hum Genet. 2020 Oct;28(10):1379-1386. doi: 10.1038/s41431-020-0638-4. Epub 2020 May 26. PMID: 32457520; PMCID: PMC7609280.]**

**3.3.13 How will NICE handle diseases where tools/frameworks such as ROBIN-I or GRADE do not and cannot discriminated between the existing studies, when the studies are the highest quality existing in the world, and the highest quality possible or likely and these tools classify them as at high-risk of bias.**

**Sections 3.3.20 to 3.3.22 do not really explain the value or use to which NICE will put these data or how it will be aggregated with and compared to other data sources**

 **Sections 3.3.23 to 3.3.25 do not really explain the value or use to which NICE will put these data or how it will be aggregated with and compared to other data sources**

**Section 3.4.22 does not say or explain how these methods “should take into account…” these challenges**

**Section 4.2.13-15 does this mean in the future NICE will genuinely consider any HRQL data on children collected using a well-documented process with supporting rationale. If so, this is welcome, as this has not been the experience in the past.**

**The whole of section 4.5 (and section 4.6) is a black box that will compound (not clarify) uncertainty in diseases with significant evidential challenge. When are models not needed or not useful (4.5.2)? We believe there is a strong argument for not using them in HST evaluation. And the guidance enclosed within this section will not result in models that help HST decision-making especially when those models are built on the types of evidence typical available. We strongly suggest to NICE that the HST process is revisited.**

  Developing the guidance

**Section 5.1.8 this is true and currently the decision-making does not appear transparent.**

**5.1.9 we fully agree with this. The rationale is not currently always clear, and at times appears based on factors not available for public consideration. It can be difficult to understand how when presented with the evidence that is put in the public domain the committee made a decision that is at odds with the apparent evidence.**

**5.2.11 it is excellent to see acknowledge that QALYs are not necessarily equivalent and there are important factor not measurable or included in QALYs. But what, operationally does ‘take into account’ (5.2.12) mean? The proposed approaches (5.2.14 and 5.2.15) appear very arbitrary and not based on any evidence or even principle.**

**5.2.23 ignores, undervalues or does not care about the structural uncertainties within QALYs that become apparent in combination with challenge in collecting evidence. This approach is arbitrary and only addresses one small aspect of issues that face HSTs. This problem is compounded by the black-box, measure ‘what you can’, model ‘what you can’t’ approach when the outputs of such models e.g. QALYs are treated as somehow real, and comparable, not as the aggregation and hiding of uncertainties and flawed assumptions that they are.**

**5.2.29 This approach appears to take aggregated population data and extrapolate to predict the future outcomes of individuals. We see this often in HSTs and it is based on flawed logic and is a fundamentally discriminatory approach. It is particularly galling when a committee expresses extreme uncertainty about the available evidence and is equally certain that the sub-group they have selected as ‘better’ is.**

**General point this whole approach is designed to, or will at very least have the effect to, classify treatments, especially those rare complex diseases not meeting HST criteria, cost-ineffective, when their efficacy is clear to recipients, and it is only a failure of this process to handle evaluation in the face of evidence uncertainty.**

  Finalising and publishing the guidance

**What are the principles to be followed when NICE does not have a process or when it is obvious that the process being followed is flawed or discriminatory**

  Guidance surveillance

**Topic selection**

  This section of the form focuses on the Topic Selection consultation document.

In particular we would like to understand more about your perspectives on how clear certain elements are.

Please click next page to continue.

|  |
| --- |
| **Topic selection: Highly Specialised Technologies** |

|  |  |
| --- | --- |
|   | We would like to understand more about your perspectives on the HST evaluation programme.Please read and review the consultation document and draft topic selection manual, page 10 - section 6, then answer the questions below and add any comments you have. |

  **How clear or unclear is the aim of the HST evaluation programme?**

   Very clear   Clear   Neutral   Not very clear   Not clear at all   Don't know / NA

  The aim of the HST evaluation programme is...

**Very clear**

  **Please use this space to share any comments on the proposals on the aim of the HST evaluation programme:**

 **The aim is clear, really clear, limit the number of topics considered by HST and make decisions based not on benefit to patients but on how much it can save NHSe money, wrapping up every NO in obscured decision-making and hiding behind the false logic of QALYs**

|  |
| --- |
| **Topic selection: Highly Specialised Technologies (HST) routing criteria** |

|  |  |
| --- | --- |
|   | We would like to understand more about your perspectives on the routing criteria.Please read and review the consultation document and draft topic selection manual, page 10 – section 6, then answer the questions below and add any comments you have. |

  **How clear or unclear is the refined routing criteria for HST?**

   Very clear   Clear   Neutral   Not very clear   Not clear at all   Don't know / NA

  The routing criteria for HST is...            **Very clear**

|  |  |
| --- | --- |
|   | **Please use this space to share any comments on the proposals on the routing criteria for HST:** |
| **Very clear and wrong, arbitrary and going to limit effective treatments for tiny vulnerable populations being available in the UK** |
| **Topic selection: eligibility criteria** |

|  |  |
| --- | --- |
|   | We would like to understand more about your perspectives on the eligibility criteria.Please read and review the consultation document and draft topic selection manual, page 3 – section 4 then answer the questions below and add any comments you have. |

  **How clear or unclear is the eligibility criteria (section 4) for devices, diagnostics and digital technologies?**

   Very clear   Clear   Neutral   Not very clear   Not clear at all   Don't know / NA

  The eligibility criteria (section 4) for devices, diagnostics and digital technologies is...

|  |  |
| --- | --- |
|   | **Please use this space to share any comments on the proposals on the eligibility criteria:** |
|  |

|  |
| --- |
| **Topic selection: additional comments** |

|  |  |
| --- | --- |
|   | We understand you may have comments relating to the topic selection consultation document (and manual) that have not been covered in our questions about highly specialised technologies or the eligibility criteria for devices, diagnostics and digital.Please use the space below to share any equality considerations, or wider thoughts or comments.Each box allows for 9,999 characters (approximately 3.5 pages of A4) if you need additional space you can attach a word document using the upload icon at the bottom. Please note that the document should be kept to a minimum and must not repeat what you have included in the form. |

  **NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

Please share any comments on whether the proposals for Topic Selection will help to achieve this aim, or if the proposals raise any concerns with regard to equality:**

|  |
| --- |
|  |

|  |  |
| --- | --- |
|   | **Please share any other comments:** |
|  |

|  |  |
| --- | --- |
|   | **You can upload a document here:** |
|  |

|  |
| --- |
| **The topic selection manual** |

|  |
| --- |
|  |

  **Please provide comments on the following chapters in the topic selection manual**

  Eligibility, selection and routing criteria

  Highly specialised technologies

**The criteria in this section are wrong, arbitrary and going to limit effective treatments for tiny vulnerable populations being available in the UK. These criteria are a subtle shift in the principles that the HST programme was set up to operationalise and show a fundamental lack of understanding of the reason for an HST programme and how to approach the decision-making under uncertainty needed to make the patient centred evaluations required for tiny populations affected by complex diseases.**

  The Topic Selection Oversight Panel (TSOP)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|

|  |
| --- |
| **Profile** |

|  |
| --- |
|  |

|  |  |
| --- | --- |
|   | This is our final section of questions before you can submit your form. |

|  |
| --- |
|  |

|  |  |
| --- | --- |
|   | **To enable us to confirm safe receipt of your comments, and follow up for clarification if necessary please confirm your:** |
|   | Name: |  |   |
|  |
|   | Email: |  |   |
|  |
|   | Organisation: |  |   |

|  |
| --- |
|  |

|  |  |
| --- | --- |
|   | **Which of the following best describes you/your organisation:** |
|

|  |  |
| --- | --- |
|  | Academic body |

 |
|

|  |  |
| --- | --- |
|  | Committee member |

 |
|

|  |  |
| --- | --- |
|  | Device Industry |

 |
|

|  |  |
| --- | --- |
|  | Diagnostic Industry |

 |
|

|  |  |
| --- | --- |
|  | Industry body |

 |
|

|  |  |
| --- | --- |
|  | Life sciences consultancy |

 |
|

|  |  |
| --- | --- |
|  | NHS organisation |

 |
|

|  |  |
| --- | --- |
|  | NICE staff |

 |
|

|  |  |
| --- | --- |
|  | Patient organisation |

 |
|

|  |  |
| --- | --- |
|  | Pharmaceutical Industry |

 |
|

|  |  |
| --- | --- |
|  | Professional organisation |

 |
|

|  |  |
| --- | --- |
|  | Public/individual |

 |
|

|  |  |
| --- | --- |
|  | Other |

 |

 |   |
|  |  |