



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



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EUROPEAN NETWORK FOR HEALTH TECHNOLOGY ASSESSMENT

## Parallel Consultations

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Parallel Consultations Feedback Questionnaire

Preliminary results and initial reflections.

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Senior Scientific Officer – Scientific Advice Office





# Parallel Consultations Feedback Questionnaire

The results shared in this presentation were based in 15 contributions to the Parallel Consultations Feedback Questionnaire received by EMA and are related to Parallel Consultations that took place between August 2017 and August 2018. The response rate to the first batch of questionnaires was 68% (15 out of 22).

## Parallel Consultation pathway requested and allocated

PC pathway	Requested	Allocated
Consolidated (PCC)	15	6
Individual (PCI)	0	9

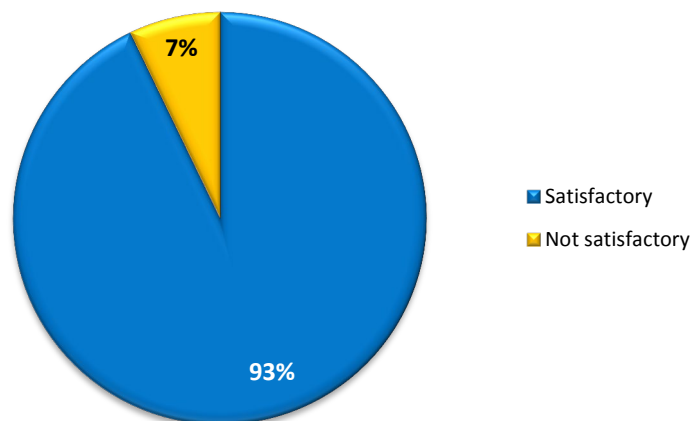
**Table 1.** Parallel Consultation pathway requested and allocated, ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

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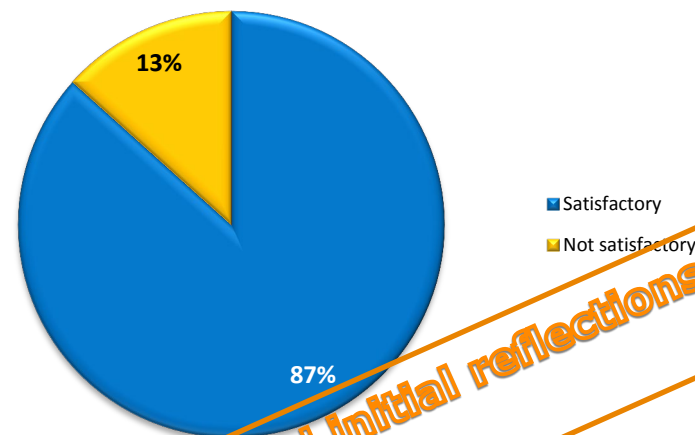
Please classify the quality of communications during the entire procedure, in terms of timely and useful answers to queries

Communications with EMA



**Figure 1.** Communications with EMA ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

Communications with EUnetHTA ED Secretariat

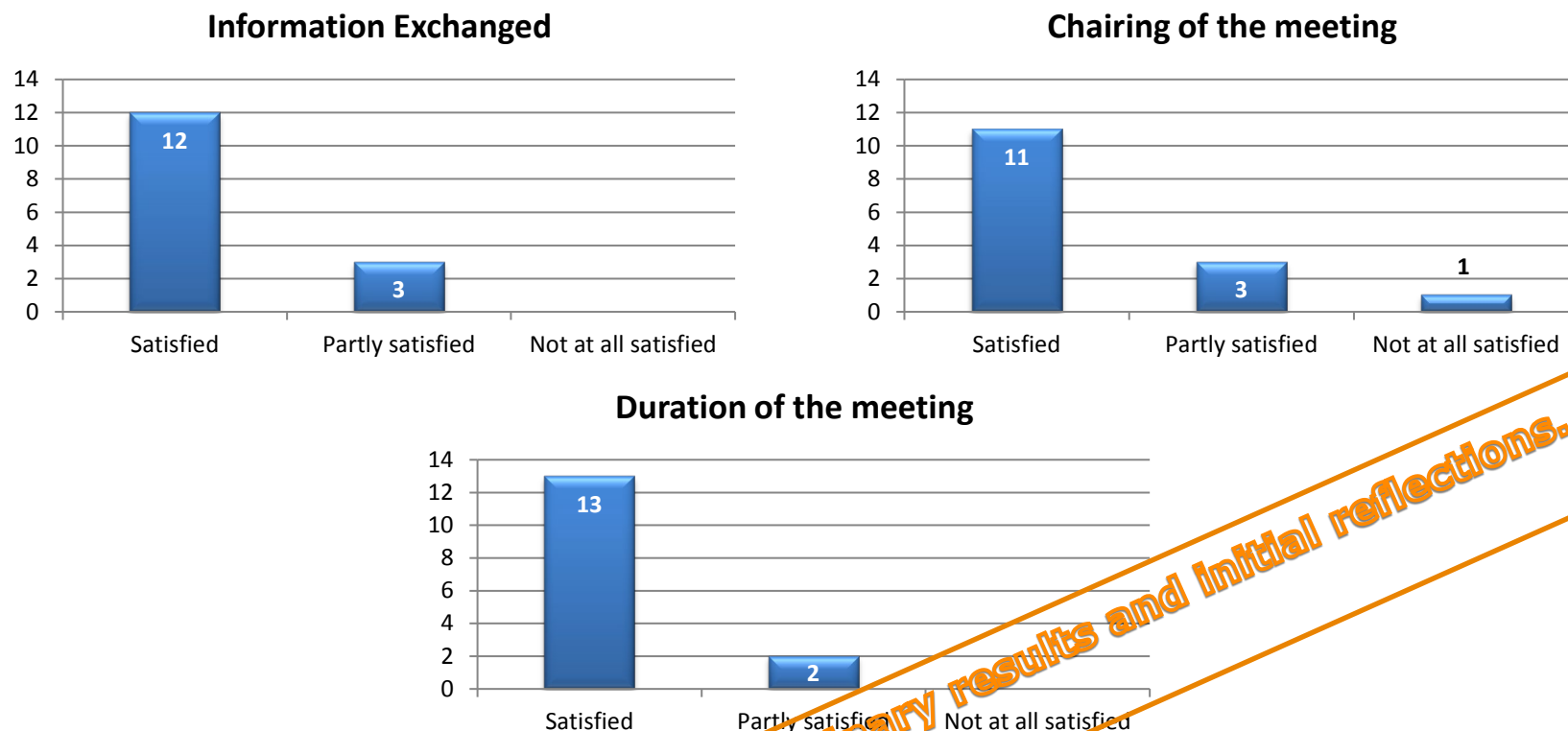


**Figure 2.** Communications with EUnetHTA ED Secretariat ( $n=33$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

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Regarding your experience related to the F2F meeting, please rate your satisfaction with the aspects below

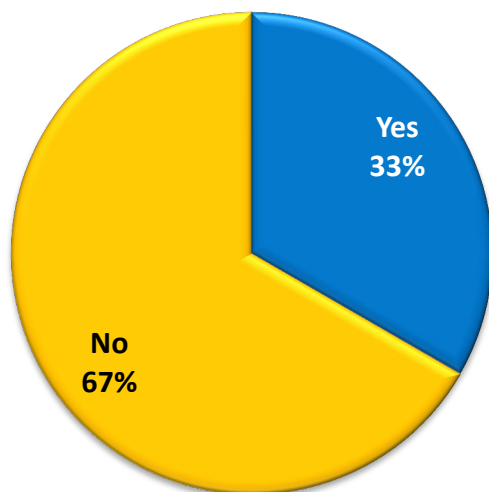


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**Figure 3-5.** Satisfaction with the experience related to the F2F meeting (information exchanged, chairing and duration of the meeting) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

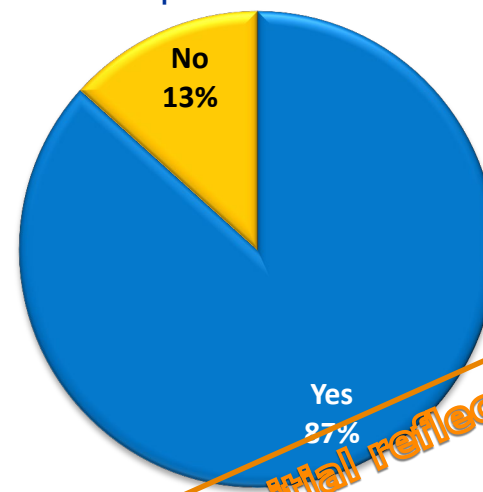


Were you satisfied with the number of HTAB taking part in your **PCI** procedure?



**Figure 6.** Satisfaction with the number of HTAB taking part in the procedures ( $n=9$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from **PCI** procedures. Only put to PCI.

Were you satisfied with which HTABs took part in the **PCC or PCI** procedures procedure?



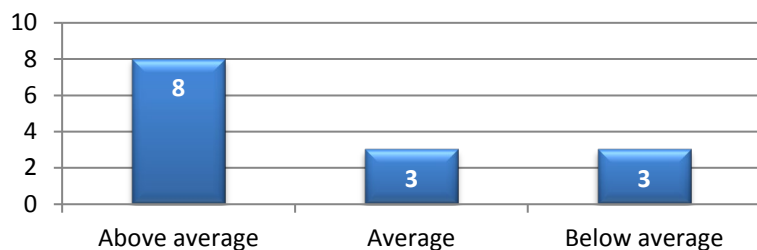
**Figure 7.** Satisfaction with which HTABs took part in the procedures ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both **PCC and PCI** procedures.

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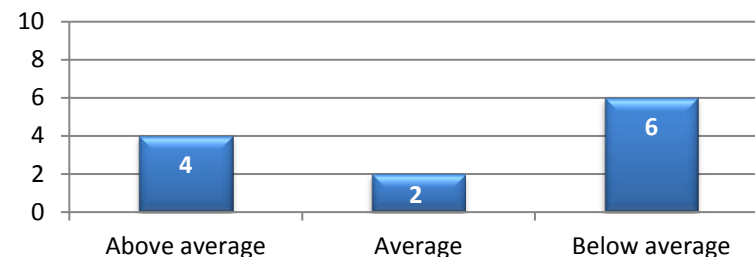
# Please rate the topics below regarding the alignment between EUnetHTA/HTABs' and EMA's opinion

### Population



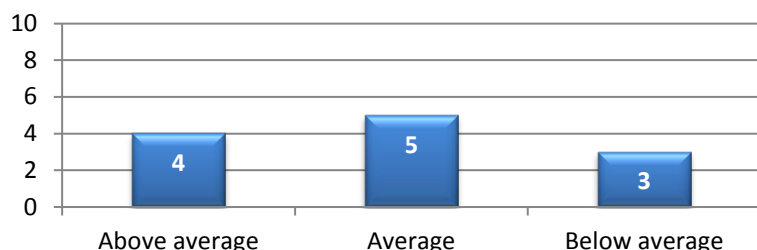
**Figure 8.** Alignment between HTABs' and EMA's opinion (Population) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. This question registered 1 "Not applicable" answer.

### Comparator



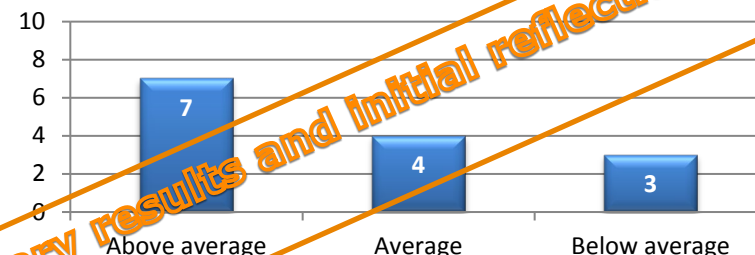
**Figure 9.** Alignment between HTABs' and EMA's opinion (Comparator) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. This question registered 3 "Not applicable" answers.

### Endpoints



**Figure 10.** Alignment between HTABs' and EMA's opinion (Endpoints) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. This question registered 1 "Not applicable" answer.

### Overall Package



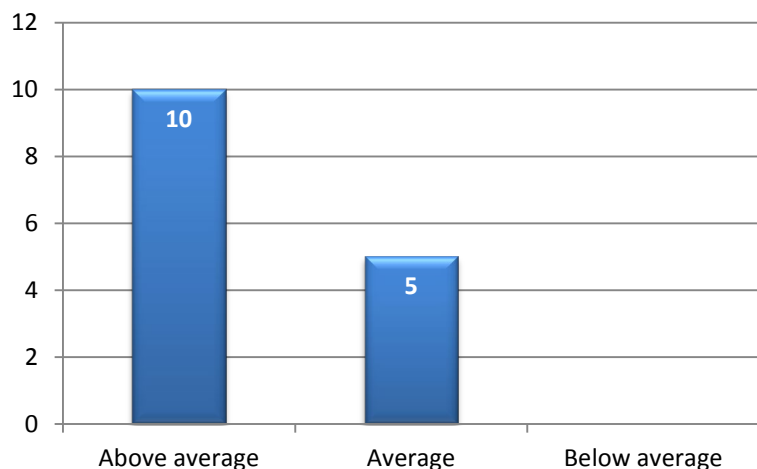
**Figure 11.** Alignment between HTABs' and EMA's opinion (Overall Package) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. This question registered 1 "Not applicable" answer.

**Preliminary results and initial reflections.**



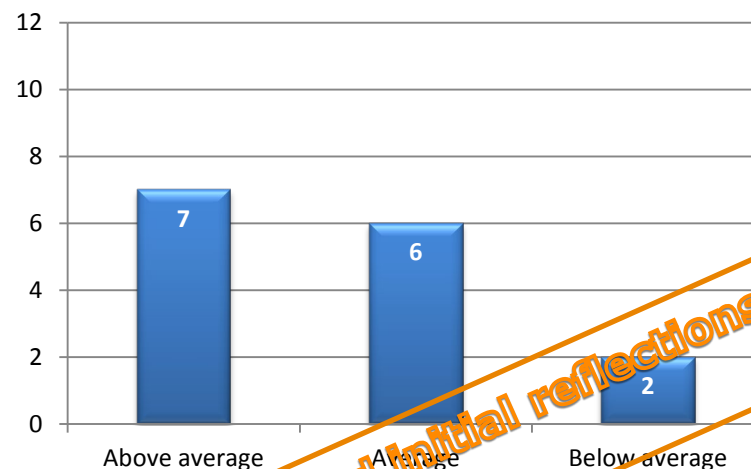
# Please rate the written advices received based on the clarity of the letters

### CHMP final advice letter



**Figure 12.** Clarity of the CHMP final advice letter ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

### EUnetHTA final recommendations (PCC) and HTABs written replies (PCI)

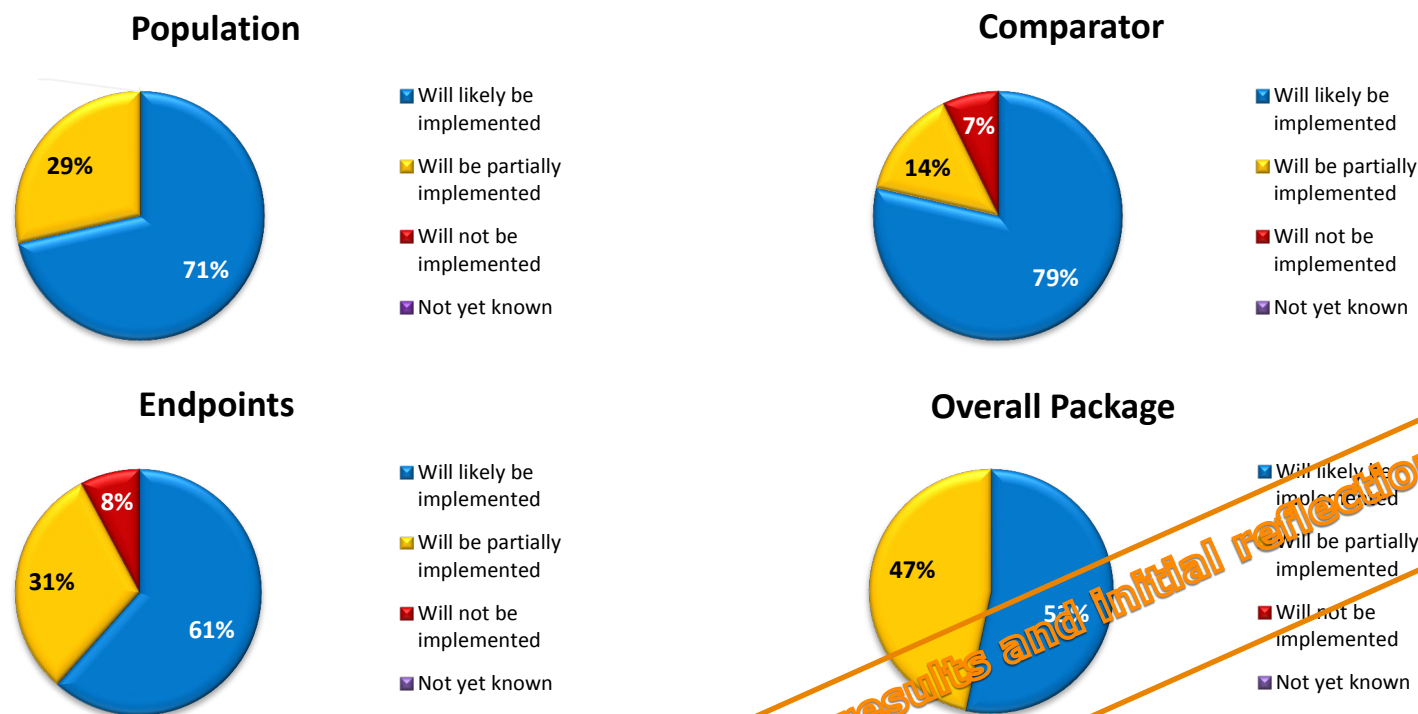


**Figure 13.** Clarity of the EUnetHTA final recommendations (PCC) and HTABs written replies (PCI) ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

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# Regarding the advice received from the CHMP and related to specific topics below

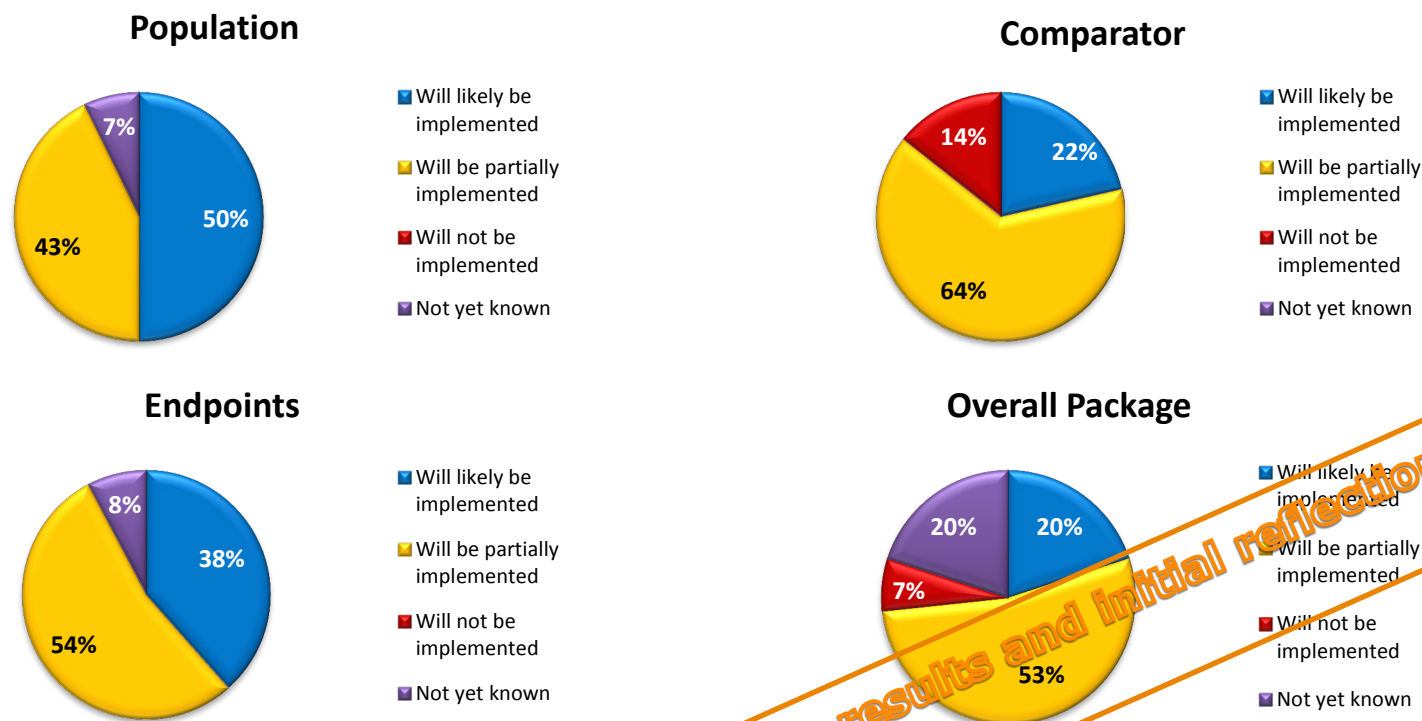


**Figure 14-17.** Implementation of specific topics (Population, Comparator, Endpoints and Overall Package) regarding the advice received from the CHMP ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. Each of the following topics registered 1 "Not applicable" answer: Population, Comparator. Each of the following topics registered 2 "Not applicable" answers: Endpoints.

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# Regarding the written advices received from EUnetHTA/HTABs that took part in your procedure and related to the specific topics below



**Figure 18-21.** Implementation of specific topics (Population, Comparator, Endpoints and Overall Package) regarding the written advices received from HTABs that took part in the procedures (n=15). It represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures. Each of the following topics registered 1 "Not applicable" answer: Population, Comparator. Each of the following topics registered 2 "Not applicable" answers: Endpoints.

*Preliminary results and initial reflections.*



# Themes for reflection based on feedback

## EMA-EUnetHTA Communication and organisation

- Communication regarding logistics?
- Procedure duration, timelines, PRIME scheme?
- Coordination between EMA and EUnetHTA/HTA Bodies regarding List of Issues?

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# Themes for reflection based on feedback

## EMA-EUnetHTA Communication and organisation - F2F Meeting

- Participants, topics and questions?
- Organisation of the F2F meeting?
- Including clinical experts and payers?

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# Themes for reflection based on feedback

## Re EMA-EUnetHTA Outcomes

- Follow-up mechanisms (to further address differing evidence needs)?
- Challenges in addressing the evidentiary needs of the involved stakeholder when there are remaining divergences between EUnetHTA's/HTA Bodies' and EMA's opinions

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# Themes for reflection based on feedback

## HTA Bodies participation in Parallel Consultations

- Decision criteria for the allocation of the Parallel Consultation procedure pathways (Individual or Consolidated); feedback?
- HTA Bodies participation; more/representativeness?

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# Themes for reflection based on feedback

## HTA Bodies deliverables

- Consolidation of HTA validation comments?
- Scientific discussion section for HTA in List of Issues for context?
- Addressing variability amongst the HTA Bodies involved in the procedures?

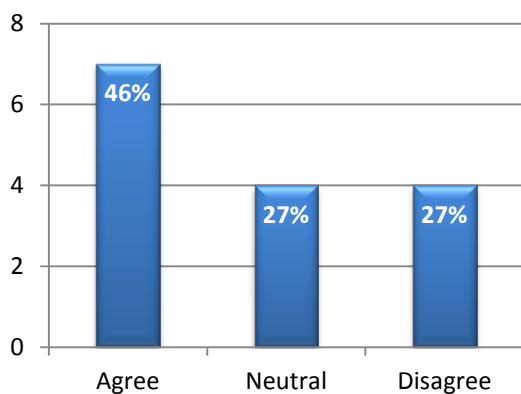
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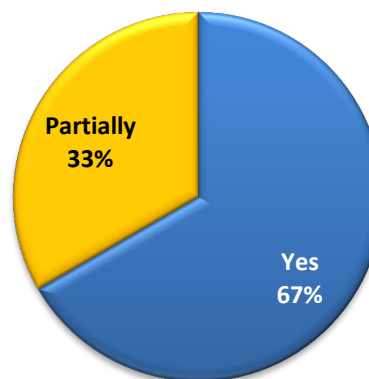


PC facilitated a single development trial/plan approach for our product to meet the evidentiary needs of the involved stakeholders



**Figure 22.** Facilitation of a single development trial/plan approach for the product to meet the evidentiary needs of the involved stakeholders ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

Did the advice meet your expectations?



**Figure 23.** Did the advice meet your expectations? ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

Would you repeat the process for another product/indication?



**Figure 24.** Would you repeat the process for another product/indication? ( $n=15$ ).  $n$  represents the number of contributions to the Parallel Consultations Feedback Questionnaire from both PCC and PCI procedures.

**Preliminary results and initial reflections.**



# Conclusions

Important to strive for continuous improvement; feedback is helpful

There are areas for further reflection – Admin. TCs EMA and EUnetHTA

Overall positive message on benefits of parallel consultation:

- “Aligned feed-back was received from the CHMP & HTABs on many topics”
- “The procedure itself ran efficiently from both the EMA & EUnetHTA”
- “The procedure was beneficial even though the outcomes may at points not be satisfactory or be challenging. It is important to be aware of the implications of the development plan on the post-approval phase. HTAs may have a different set of expectations than the Regulators”

**Preliminary results and initial reflections.**



# Thank you for your attention

## Further information

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