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EU HTA Joint Clinical Assessments Webinar - Questions and Answers

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This document contains a comprehensive Q&A report with questions from attendees and insights from the panelists.

PICO

Q1. How many PICOs will a JCA have?

The number of PICOs will be highly dependent on the indication and how clinical practice varies across the 27 member states for the specific indication. The goal of the scoping process is to consolidate the PICO requirements of the 27 member states into a manageable number. However, recent case studies have shown the number of PICOs could exceed 20 in some situations. The number of needed PICOs is still an area of contention and requires further clarity as discussions evolve, as it will have a significant impact on resourcing.

Q2. What provisions will be made for relevant comparators, e.g., if current reimbursed comparators are not aligned across the EU?

As part of the JCA process, each of the 27 member states will be given the opportunity via the PICO survey to provide the relevant comparators for their country. Non-approved (off-label) comparators can also be considered.

Q3. How will the findings of the JCA be interpreted at a national level?

The findings of the JCA will be presented per PICO. The intention is that the need of any given member state will be covered in one of the consolidated PICOs. It may be possible that member states require additional analyses for their national submissions, but the concept behind the JCA is to reduce this potential duplication of effort.

Resourcing, timeline and alignment

Q1. How should companies prepare for the JCA in 2025?

As presented during the webinar, the key is to begin early. Companies should already have started piloting the JCA process to understand what is needed for successful collaboration across departments (regulatory, access, HTA) internally, as well as with key external stakeholders. There also needs to be a seamless feedback loop between teams conducting SLRs and ITCs to ensure efficiency and management of timelines.

Implications of the JCA (e.g., at national levels)

Q1. How does the EU HTA regulation differ from EUnetHTA 21?

EUnetHTA 21 was commissioned to develop a set of guidelines on joint HTA clinical assessments across Europe. The EU HTA regulation entered into force in January 2022 and applies as of January 2025. The implementing acts for the EU HTA regulation will consider the guidelines developed and pilot assessments conducted by EUnetHTA 21.

Q2. Will it be mandatory for member states to adopt the findings of the JCA?

The EU HTA regulation covers only the clinical assessment and is not an appraisal/ reimbursement decision. While it will be mandatory for HTDs to meet the requirements for a JCA submission, it will not be legally binding for member states to adopt the findings of the JCA.

Q3. Will any of the member states carry more weight than others in the PICO scoping?

Based on the EUnetHTA 21 guidelines, there will be no ranking of PICOs, and the idea of the JCA is that all 27 member states will have equal input into the selection of PICOs.