ECKER ECKER

Market Access and Pricing for Pharmaceutical Products and Medical Devices

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How to prepare for a JCA?
Observations and learnings from +3 submissions

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Our learnings from early JCA submissions (I/II)

1.

Patient and clinical expert input remains underutilised

Current engagement mechanisms do not consistently capture patient perspectives, unmet need, or clinical practice realities.

2.

JCA increases evidence generation requirements

The level of detail expected for evidence submissions, particularly for SLRs and evidence justification, exceeds traditional European HTA requirements and requires substantial additional resources from HTDs.

3.

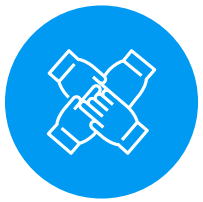
Assessment begins during completeness check

Completeness checks assess not only dossier completeness but also methodological choices, search strategies, and the feasibility of the proposed evidence approach.

4.

Operational readiness is critical

Short response timelines for requests for information require dedicated cross-functional teams, rapid decision-making processes, and readily available expert resources throughout the assessment.



Our learnings from early JCA submissions (II/II)

5.

JCA reports already shape evidence interpretation

Assessment reports do not merely summarise submitted evidence but also influence which analyses are considered relevant and discussed within the assessment.

6.

The fact-check process offers no opportunity for contextualisation

HTDs have only restricted opportunities to provide context and interpretation of assessment findings, highlighting the importance of a transparent and structured response mechanism.

7.

The JCA process continues to evolve

Recent procedural refinements have improved interaction between assessors and HTDs. However, variability in implementation and the need for clearer communication channels suggest further process optimisation is still required

PICO scoping: first insights of ongoing JCA projects (n=3)

PICO Scoping Process and Predictability

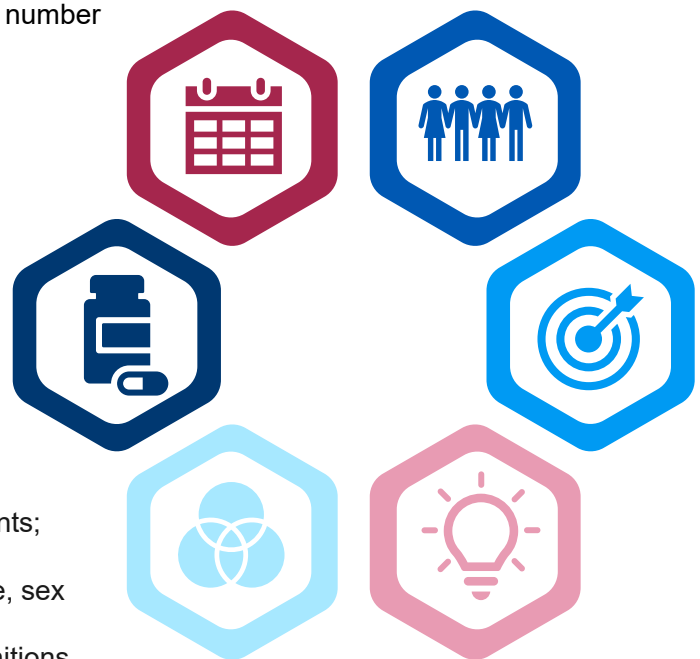
- PICO scoping completed within **<80 days**
- **<5, <10, or <15 PICOs** per assessment
- **High predictability** for population and comparator, but declining with increasing number of PICOs

Comparator

- Number of PICOs largely driven by number of relevant comparators
- The following pattern can be observed: all potential comparators are listed as individual PICOs, likely due to an AND linkage, and then the same comparators are repeated as a separate PICO connected via an OR linkage
- Unexpected off-label comparators included (not guideline-recommended) [n=1]

Subgroups

- Number and relevance vary widely across assessments; methodology appears **inconsistent**
- Common national HTA subgroup standards (e.g., age, sex for G-BA) are not systematically included
- Cut-off values sometimes differ from clinical trial definitions
- Cut-off values are not defined for all subgroups (inconsistent)
- Requested subgroup analyses can differ between the defined populations within the same assessment
- Certain country-specific requirements can still be identified (e.g., Germany-specific subgroup or comparator structures)



Population

- 1-4 populations per assessment
- Subpopulation mainly defined by **prior therapies**

Outcomes

- Some outcomes are specifically defined (e.g., generic HRQoL “preferably via SF-36”), others remain very broadly defined (e.g., “symptoms of disease”)
- Outcomes sometimes requested beyond those assessed in clinical trials
- AESIs not requested in detail
- No specific analytical requirements (e.g., TTE analysis, MID definitions)
- Outcome list is focused and limited (QoL, symptoms, key indication-specific outcomes)
- Outcome list is specified across all PICOs

Overall

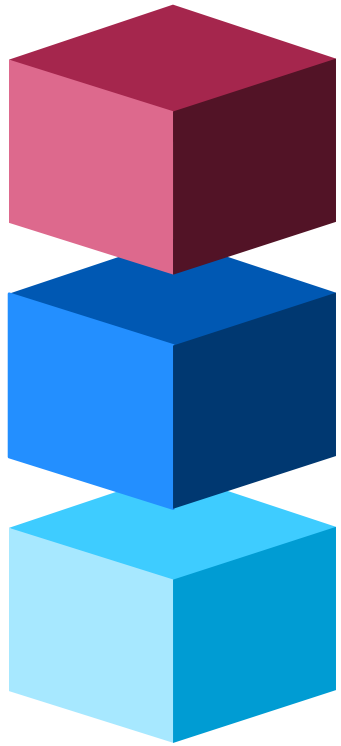
- Predictability becomes particularly challenging when multiple comparators are involved, especially given the limited transparency on how the CG approaches comparator selection.
- Country-specific requirements allow for the identification of the German PICOs

Statistical leadership is becoming a critical success factor for EU HTA

Statistical expertise is becoming essential to align clinical development, HTA requirements, and patient access.

Addressing evidence gaps through advanced evidence synthesis

Robust indirect treatment comparisons are increasingly required to address JCA PICOs when head-to-head evidence is unavailable.



Bridging clinical development and market access

Statisticians play a critical role in ensuring evidence generation strategies address both regulatory and HTA requirements from an early stage.

Ensuring scientific rigor in complex decision-making

Statistical expertise is essential to assess uncertainty, challenge assumptions, and support credible evidence interpretation.

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HTA – JCA Insights unleashed: What statisticians can learn from the first JCA procedures

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