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A Blueprint for Success: The Importance of Multi-Stakeholder Alignment for EU Health Technology Assessment (HTA)

Unresolved challenges in the Joint Clinical Assessment process could hinder timely and equitable patient access unless addressed through multi-stakeholder collaboration and refined processes

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Objectives

- Effective Jan 2025, the EU HTAR will align clinical assessments for new technologies across MS[1]
- Manufacturers are preparing by simulating evidence requirements, assessing their organisational resilience, and developing new working models to deliver high-quality EU HTA dossiers on time
- These preparations have highlighted unresolved challenges with the JCA process that may hinder the EC goal of accelerating and harmonizing access in Europe[2] unless they are addressed
- This research outlines the challenges and provides recommendations for improvement to the multi-stakeholder community responsible for EU HTA implementation

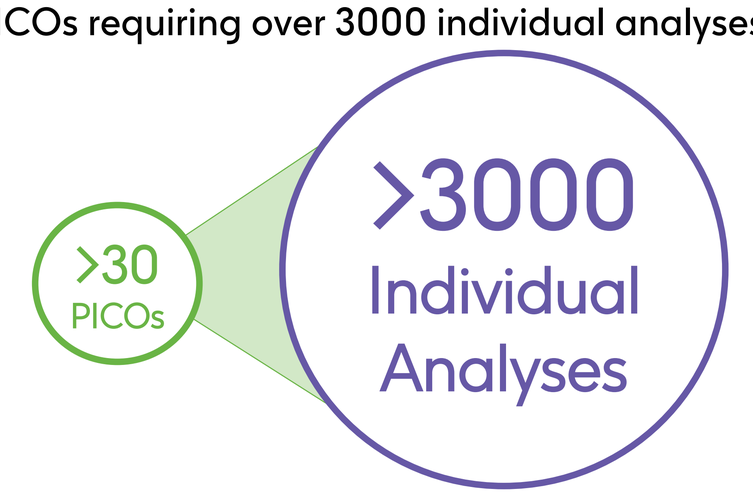
Methods

- A PICO (population, intervention, comparator, outcome) simulation for an oncology drug was conducted, accounting for local differences and anticipating evidence requirements by Member States[3]
- A review of internal adaptations to cross-functional ways of working was conducted, to identify how HTDs will need to evolve to successfully respond to EU HTA

Results

- The PICO simulation revealed that a single drug in a specific oncology indication required over 30 unique PICOs within the JCA scope, leading to more than 3000 individual analyses
  - This indicates a need for refining the JCA scoping process to reduce the burden on HTDs, MS, and JCA assessors
- The research also identified risks requiring adaptation by HTDs by responding quickly to the PICO process, streamlining data collection, and improving early engagement with MS
  - Risks include potential misalignment between MS and HTD on JCA expectations, which could lead to poor outcomes and delays in patient access
- Recommendations have been made for the EC, HTA Coordination Group, and JCA Subgroup to address these challenges with the current EU HTAR process

Figure 1: **Scale of analysis predicted; over 30 unique PICOs requiring over 3000 individual analyses**



Recommendations

Figure 2: **Recommendations for improving the EU JCA process**

Engage
HTACG and JCA subgroup should support pre-PICO survey engagement between MS and HTDs allowing for sufficient time for evidence generation

Refine
HTACG must acknowledge the need for early refinement of PICO survey methodology, based on initial learnings collated through a comprehensive review

Collaborate
JCA Subgroup should promote collaborative efforts to streamline PICO survey submissions by involving local payers and clinical experts from the outset. They should arrange initial workshops to gather input on survey design and key priorities

Integrate
HTACG should leverage technology to streamline the survey process: Utilize advanced data collection and analysis tools. For instance, adopt AI-driven platforms to analyse survey responses and identify key trends more efficiently

Discuss
EC should formalize the ability for HTDs to participate in scoping discussions prior to the finalization of the JCA scope – routinely, not only at the request of JCA assessors

Define
HTACG should encourage MS to set realistic and achievable goals for their PICO surveys, focusing on the most impactful elements that reflect the latest real-world treatments

Advance
HTACG should continue to provide training and resources for stakeholders involved in the PICO survey process. Offer online training modules and support hotlines to address questions

Conclusions

Early Planning: Essential for HTDs to avoid delays and mismatches in expectations with Member States and JCA assessors

Need for Change: Urgent rationalization of the scoping process is required to ensure efficient JCA outcomes and prevent overburdening all stakeholders

Enhanced Collaboration: Further cooperation between HTDs and HTAR stakeholders is necessary to ensure timely patient access to new technologies

Abbreviations

EC: European Commission; EU: European Union; HTA: health technology assessment; HTACG: HTA Coordination Group; HTDs: Health Technology Developer; JCA: Joint Clinical Assessment; MS, Member State; PICO: population, intervention, comparator, outcome.

References

1. European Commission - Implementation of the Regulation on health technology assessments
2. EUnetHTA – Scoping process practical guidelines
3. EUnetHTA – PICO FAQs

Disclosures

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