European Access Academy

# EAA Fall Convention

## *EU HTA – Procedural Insights & First Learnings*

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## Impulse Presentation


**Speaker name**

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**Title of the Talk**

*From Policy to Practice: The Health Technology Developer's Role, Experience and Expectations*


**Abstract**

The Joint Clinical Assessment (JCA) is unprecedented in ambition and scope in the field of health technology assessment (HTA), providing a significant opportunity to improve patient access to new medicines in the European Union (EU) and avoid duplication of work for both health technology developers (HTDs) and HTA bodies across the EU. Up until October, only 9 JCAs have started and the first completions are not expected until 2026. However, based on the experience to date, it is important that we celebrate where the process is working and become solution-focused where there may be barriers.

All stakeholders who have been part of an individual JCA procedure will have their own experience. From a HTD perspective, there will be rapid learnings within each individual company, but their experience of the JCA process itself may also not be reflective of others. This may be because of different levels of internal readiness, uniqueness of their evidence package, interpretation of the Regulation and procedural guidance documents; but it may also be due to differences in their interactions and information exchange with the HTA Secretariat and JCA assessors. For the latter two we are already seeing adaptation and efforts to both increase clarity on and improve the process.

But there remains much more to do, and we cannot sit still. We have now transitioned from "Policy into Practice", and it is only at this point that untested procedures are truly being challenged, and that unknown complexities have become known. From an HTD perspective, three criteria are essential for successful implementation:

1. **Improved health outcomes**: the fundamental measure of the Regulation's success is its ability to drive better health outcomes for patients across Europe.
2. **Streamlined national HTA and improved patient access:** the Regulation must not become another barrier for innovative medicines in Europe, particularly for SMEs; the additional investment and analyses required upfront by HTDs, compared to pre JCA, must be offset with usage of the report, more efficient national procedures and a shorter duration of the national decision-making process to improve availability and time to patient access.
3. **Process efficiency and workability**: HTDs need predictability and clarity throughout the JCA process, from the starting date and final scope delivery, through to submission deadline. HTD engagement before and during the process can make a difference too, ensuring high quality submission readiness. Crucially, HTDs also need to reliably predict requested PICOs to minimize substantial additional work beforehand. This requires clearer guidance on the scoping process and consolidation, and an optimization and convergence of PICOs over time.

To these ends, EFPIA and other HTD organisations in the EU HTA Stakeholder network are planning to track the process and experience of their members to provide regular feedback and solutions to ensure the Regulation delivers the performance envisioned, as well as inform the efficiency and added value of the Regulation for the Commission's 2028 evaluation.