



How to respond to the EU Joint Clinical Assessment

Changes are underway

The **Joint Clinical Assessment (JCA)** is an initiative to streamline and centralize the evaluation of health technologies. Launched in January 2025, stakeholders have expressed concerns about the complex analytics and documentation required, the challenge of producing submissions that comply with the regulations, and the tight timelines for submission. The JCA introduces additional challenges:

- Ensuring alignment between the outcomes required by JCA and national regulatory bodies
- Transferring clinical and technical data between the JCA system and individual Health Technology Assessment (HTA) agencies
- Streamlining the submission process
- Increasing transparency and engagement opportunities for stakeholders during JCA negotiations.

What is HTAR?

The JCA is part of the **European Health Technology Assessment Regulation (HTAR)**, established by Regulation (EU) 2021/2282. The goal of this legislation is to improve cooperation and consistency in HTAs.

The main objectives of these policies:

- Increase transparency and efficiency in the HTA process
- Reduce duplication of efforts and strengthen cooperation among member states
- Ensure consistent quality standards and speed up patient access to safe, effective treatments.

Support to negotiate JCA challenges

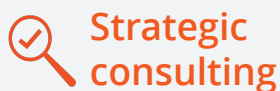
At Genesis Research Group, we believe **advanced planning** and **evidence generation** are needed to support submissions. Stakeholders who are willing to reassess existing strategies and **adapt quickly** will have an advantage.

The breadth of our **expertise** and **agility** of our partnerships make us ideally suited to support these needs. Our teams of scientists and consultants are accustomed to providing strategic advice, integrating insights, and generating evidence in a continually changing regulatory environment. Many of our scientists and consultants have been where you are.

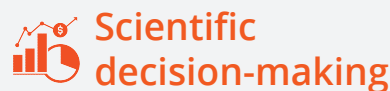
JCA readiness solutions



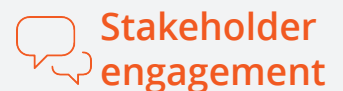
Evidence strategy



Strategic consulting



Scientific decision-making



Stakeholder engagement

- A data-agnostic approach to real-world evidence
- Evidence synthesis
- Insight generation
- Workshops and coaching
- Project management
- Submission strategy and guidance
- PICO-based decision-making
- Comparative effectiveness research and economic models
- Value dossiers
- RPR-powered stakeholder insights



Leverage our online stakeholder engagement platform and a network of 3500+ payers, clinicians, and KOLs to secure robust insights quickly. Test and refine your submission strategy, ask questions on PICO, comparator appropriateness, or other key topics.



Our Flexible Integrated Team engagement model provides dedicated cross-functional teams that integrate seamlessly with your own to fill experience gaps or supplement resources. With no need for further contracting, the teams can pivot quickly to respond to an ever-changing regulatory environment.

Ask how we can help you with JCA preparation. Contact solutions@genesisrg.com