EU HTA Regulation: Expert, Integrated Support

Health Technology Developers (HTDs) are facing new challenges on both sides of the Atlantic. In the US, focus is on the impact of the Inflation Reduction Act, while in Europe, the Health Technology Assessment Regulation (HTAR) and the revision of the general pharmaceutical legislation will significantly change the pricing and reimbursement landscape.

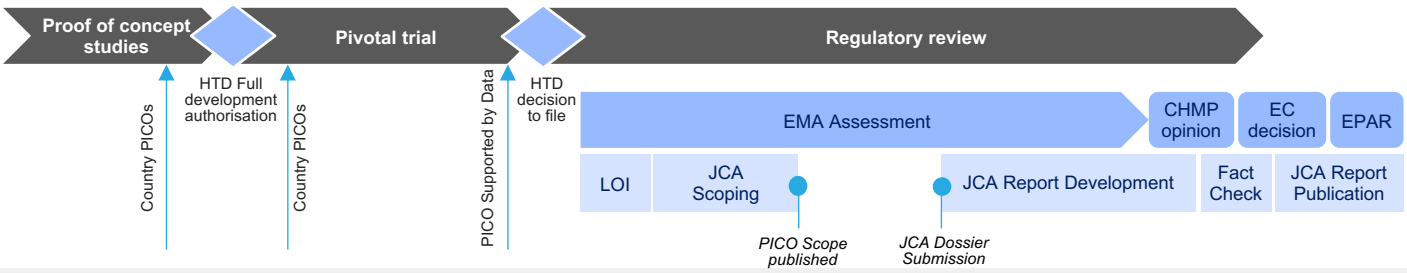
The EU HTAR aims to improve the availability of innovative health technologies for patients across the EU, ensure the efficient use of resources, and strengthen the quality of health technology assessments (HTAs). It introduces an EU-wide Joint Clinical Assessment (JCA) of relative effectiveness of new medicines, requiring HTDs to develop a new type of submission dossier. A JCA will be required for all new oncology therapies and advanced therapy medicinal products (ATMPs) from 12 January 2025 with a phased introduction to apply to all new therapies in 2030. The JCA report will likely form the core relative effectiveness assessment of new medicine for all EU countries.

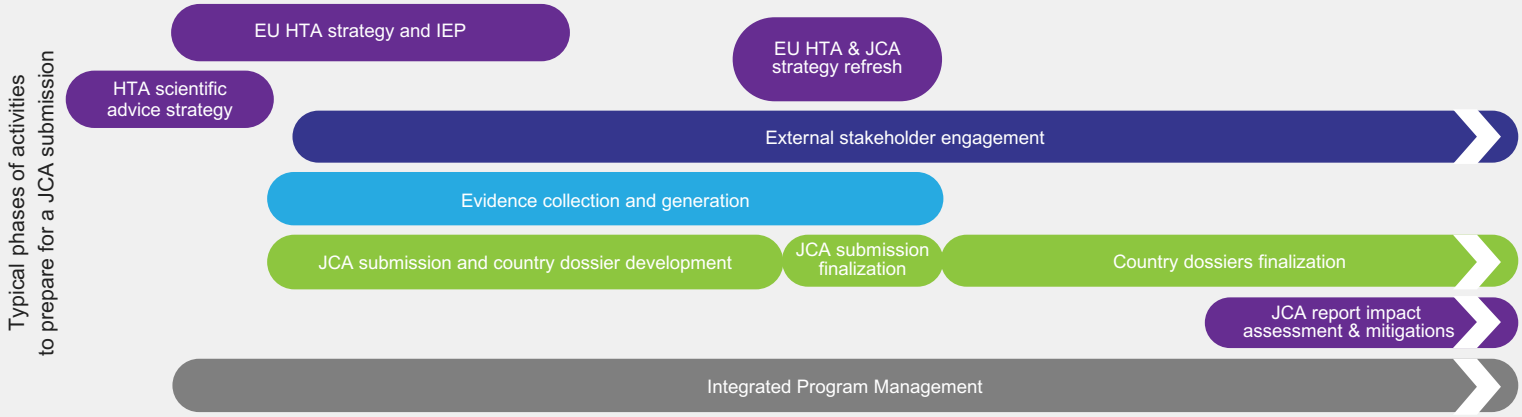
While the new regulation creates opportunities to optimize market access in Europe, it also introduces additional complexity and creates new challenges for HTDs:

- Need for EU-wide HTA strategy and Integrated Evidence Planning (IEP)
- Policy-driven (vs data-driven) JCA scope and uncertain evidence requirements
- Regulatory and EU HTA strategies need careful alignment
- Strategic approach required to Integrated Scientific Advice (ISA) and Joint Scientific Consultation (JSC)
- JCA methods and preferences will create new considerations throughout clinical development
- HTD resource challenges and new governance requirements
- Limited time for development of JCA submission
- Minimal involvement of HTDs beyond JCA dossier submission
- Uncertain impact on reimbursement and pricing across EU and non-EU markets

Evidera offers a flexible, comprehensive approach to help our clients achieve optimal market access and reimbursement across the EU's 27 countries

- Evidera is a leader in EU HTAR readiness programs, having supported multiple HTDs to adapt their ways of working, providing cross-functional team awareness and training, defining PICO scoping and currently supporting JSC and JCA submissions
- Evidera has been a leader shaping new HTA methods, strategy, and delivering robust submissions across the EU
- Evidera has more than 1,000 experienced consultants and scientists to support our clients in EMA regulatory strategy and submissions, JSC, and JCA





Abbreviations: CHMP = Committee for Medicinal Products for Human Use; EC = European Commission; EPAR = European Public Assessment Report; HTA = Health Technology Assessment; HTD = Health Technology Developer; IEP = Integrated Evidence Planning; JCA = Joint Clinical Assessment; LOI = Letter Of Intent; PICO = Population, Intervention, Comparators, Outcomes

Discuss the implications of the EU HTAR and how you can prepare for it with our experts…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EU HTA Strategy & Integrated Evidence Planning

Approaches to value appraisal, and reimbursement and pricing decisions vary across EU countries. HTDs need to consider the opportunities and risks of evidence presented in the JCA submission to each country, especially major markets. HTDs need to develop an EU HTA strategy and a strategic approach to JCA submissions, including an integrated evidence generation plan capturing data generation needs for the EU.

Our consultants have focused on navigating HTA trends and ISA since 2009. We have supported many HTDs to prepare for the changes the EU HTAR will introduce, especially the JCA, and are supporting HTDs to define their EU HTA strategy for assets launching from 2025 onward.

Evidera offers the following solutions to our clients:

- EU HTA and regulatory strategy
- JSC, other ISA, and JCA strategy
- Population, intervention, comparators, outcomes (PICO) prediction

External Stakeholder Engagement

Preferred evidence generation approaches for JCAs may not be possible or could be extremely challenging. HTDs need to engage with HTA and payer stakeholders before the start of a JCA to ensure the rationale for decisions taken during clinical development are understood and accepted. Patients, experts, and clinical and learned societies play important roles in JCAs, and early engagement will be essential alongside careful navigation of the conflict-of-interest rules.

Our consultants and established network of experts across Europe will support HTDs to successfully engage stakeholders to ensure optimal JCA outcomes.

Evidera offers the following solutions to our clients:

- Stakeholder identification
- External stakeholder engagement planning
- Tailored key stakeholder messages and engagement materials

Evidence Collection and Generation

The central requirement of the JCA is comparative effectiveness. In the absence of sufficient head-to-head trial data, systematic literature reviews (SLRs) to gather evidence and indirect treatment analysis (ITC) to assess relative effectiveness are required. These SLRs and ITCs go well beyond the requirements of individual nations as they encompass requests from every one of the 27 member states. The SLR and ITC need to be finalized rapidly following publication of the final PICOS scope.

Our scientists are global leaders in evidence synthesis with a rich heritage in providing SLRs and ITCs. These have resulted in successful HTAs and reimbursement for hundreds of treatments in recent years.

Evidera offers the following solutions to our clients:

- JCA-compliant clinical SLRs for efficacy and safety
- ITC with feasibility assessment aligned with JCA methods
- Network meta analysis and ITC for single-arm studies

JCA Submission and Country Dossiers

The JCA requires HTDs to develop an additional submission dossier with distinct requirements and standards under significant time pressure. Currently, HTA markets in Europe differ substantially in the complexity and evidence requirements for their submissions. Further evolution of these requirements in response to the JCA Report is expected in EU markets.

Our team of specialized market access writers bring their extensive experience in global value dossier (GVD) and HTA submission development to meet the requirements of the JCA submission and adapt to evolving market-specific submission processes. We translate product strategy and an optimized evidence package into compelling submissions that convey the unmet need for patients and the product value story to payers.

Evidera offers the following solutions to our clients:

- JCA-ready GVDs
- JCA and country HTA submissions
- Advisory boards and mock committee meetings
- Post-submission support

Integrated Program Management

The JCA and JSC require careful program management and internal stakeholder engagement over several years to ensure all the elements and analyses are coordinated and developed on time, forming a high-quality JCA submission. This is in addition to existing pre-launch activities and development and submission of country dossiers.

Evidera has a dedicated team of highly experienced and qualified program managers to support client cross-functional teams and our consultants and scientific staff, ensuring the most efficient processes and optimized program delivery.

Evidera - a thought leader in EU HTAR

Scan the QR code to learn more about the EU HTAR

Stop by booth #901 to speak with us about our solutions!