Ensure JCA success

IQVIA EU HTA Solutions: Your partner at global, regional and local level

The implementation of the new European Health Technology Assessment (EU HTA) regulation represents a fundamental turning point for health technology developers (HTDs), HTA bodies, payers, and patients.

Since 12th January 2025, the HTA clinical assessment of new cancer drugs and Advanced Therapy Medicinal Products (ATMPs) are conducted centrally. These Joint Clinical Assessments (JCAs) aim to streamline HTA efforts across EU Member States and ultimately accelerate patient access to innovative medicines. By 2030, the new HTA process will be rolled out for all drugs, vaccines, in-vitro diagnostics and high-risk medical devices.

What this means for you

Although this new era holds significant promise for all stakeholders, HTDs need to adjust their current market access strategies and launch preparations to align with the evolving environment. This will ensure they maximize the benefits of the new HTA process.

Although all guidance documents on the EU HTA process and assessment methodology for medicinal products have been published, uncertainty remains around their implementation. HTDs need to accommodate these uncertainties in their evidence and tactical planning, not just for assets eligible for the EU JCA in 2025, but also for their pipeline products, to ensure future EU HTA success.

How the new EU HTA process impacts the way health technology developers prepare for market access

Planning	Evidence & Analysis	Stakeholder Engagement	Access
Complex JCA dossier needs to be prepared **in parallel to EMA dossier** Alignment needed on **regulatory and access strategy** **Resource intensive** process with **tight timelines**	Impact on **evidence needs** expected to be **exponential** Early planning required to **anticipate HTA evidence needs** via **JSC** **Patient-reported outcomes** to become more prominent Many **post-hoc analyses** and **indirect treatment comparisons** required	Local teams need to be engaged to anticipate components of the **PICO** and to align on **JCA strategy** **External stakeholder engagement** needed to help anticipate PICOs and any local JCA implementation uncertainties	New process may impact **launch timelines** and sequencing Earlier launch may impact **international reference pricing** and parallel trade More **concise local 'delta' dossier** development required

Although this new era holds significant promise for all stakeholders, HTDs need to adjust their current market access strategies and launch preparations to align with the evolving environment.

Abbreviations: EU: European Union; HTA: Health Technology Assessment; HTD: Health Technology Developer; ITC: Indirect Treatment Comparison; JCA: Joint Clinical Assessment; JSC: Joint Scientific Consultation; PICO: Population, Intervention, Comparator, Outcome

How IQVIA can help you

With hands-on experience in the development of European HTA dossiers (500+ in the last five years, >100 in Germany alone), IQVIA can be the right partner for you to successfully work through the uncertainties of the new process.

Our dedicated EU HTA Solutions team can support you with robust preparation for EU HTA through end-to-end services, ranging from global strategy development and evidence generation, including JCA statistical analysis plan development and analysis, to dossier development and local execution. As recognized thought leaders in EU HTA, we understand that you need a holistic and cross-functional approach to ensure that you and your organization are ready in time — at a global, regional and local level.

Our offering connects IQVIA's broad European network of >1,800 local "on-the-ground" market experts, our proprietary data sources and tools, and our unique combination of expertise ranging from HEOR, evidence synthesis and market access to clinical and technical expertise and organizational redesign, to create an effective solution tailored to your needs. Our centralized management ensures efficient and integrated delivery while building a close partnership on your EU HTA journey.

IQVIA's offering connects in-depth local HTA expertise, strategic thinking and technical expertise.

IQVIA's EU HTA Solutions team provides end-to-end support

Advisory Services	Scientific Advice Strategy	JCA Strategy & Evidence Generation	JCA Dossier Development	Local HTA Support
JCA impact assessment on portfolio	JSC/AMNOG/NICE/ CADTH eligibility assessment	Early PICO simulation, prioritisation and JCA strategy development	Late-phase PICO simulation, final JCA dossier strategy development	Delta dossier landscaping and mapping
Operating model design	Trade-off analysis and strategic planning for scientific advice	Evidence generation strategy development, incl. gap analysis	End-to-end dossier development support, from early draft to post-submission	Local external engagement mapping
JCA inclusion in PMA strategy	Application and briefing book development	Execution of JCA evidence generation strategy, incl. • Global value dossiers • Systematic literature review • Indirect treatment comparison • External comparator studies • Post-hoc analyses	Objection handling for non-addressed PICOs/JCA report	Local PICO simulation and country-specific post-JCA strategy
Governance and SOP development	Advice meeting preparation and support	JCA Statistical Analysis Plan development		Delta dossier development and complementary analyses
External stakeholder engagement strategy	Advice meeting debrief and strategic recommendations for pivotal trial design			Mock HTA meetings and meeting attendance
Readiness assessment, incl. peer benchmarking				Post-submission full P&R support and negotiation
JCA KPI tracking				
JSC/JCA training development and roll-out				
Change management and PMO support				

Abbreviations: EU: European Union; HTA: Health Technology Assessment; HTAR: HTA Regulation; HTD: Health Technology Developer; JCA: Joint Clinical Assessment; JSC: Joint Scientific Consultation; KPI: Key Performance Indicator; PICO: Population, Intervention, Comparator, Outcome; PMA: Pricing & Market Access; SOP: Standard Operating Procedure; PMO: Project Management Office; P&R: Pricing & Reimbursement.

We are ready for JCA — are you?
Reach out to the IQVIA EU HTA Solutions team to discuss your needs at: EUHTASolutions@iqvia.com

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