



SSI Strategy Webinar

EU HTA Regulation: JCA in Practice - From Procedure to Evidence Generation

Webinar Hosts:

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The Joint Clinical Assessment (JCA) is a new cornerstone of the European Union's efforts to standardize the evaluation of therapies across its member states. As part of the newly implemented Health Technology Assessment (HTA) regulation, this centralized process ensures that medicines are assessed for their relative effectiveness and safety in a consistent manner across all member states. This harmonized system aligns the evaluation of clinical data with the regulatory approval process timeline, creating opportunities to streamline market access while also presenting new challenges. To succeed under the JCA framework, companies must understand its procedural requirements, adapt their evidence generation strategies, and carefully coordinate efforts across internal teams.

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Understanding the JCA Framework and Scope

Central to the JCA is the PICO framework, which defines the scope for assessing a therapy's relative effectiveness.

PICO breaks down into Population, Intervention, Comparators, and Outcomes, outlining the populations to be treated, the therapy under evaluation, relevant comparators, and the clinical outcomes required for analysis. This framework is not new but takes on heightened importance within the JCA context, as it serves as the foundation for dossier preparation and evidence generation.

The JCA process runs parallel to the EMA's regulatory timeline. Companies must submit key documents, including clinical trial data and supporting contextual information, at the time of their marketing authorization application. When regulators have validated the MA application, HTA assessors determine the PICO scope, and send a request for dossier to the company. Although the JCA is distinct from the regulatory process, the two are closely aligned in terms of timing.

The procedure is tightly structured, with minimal flexibility once it begins. Companies are given 100 days to prepare and submit their dossier. This timeline leaves little room for error or adjustments, making early planning essential. Any gaps in evidence must be justified, as incomplete submissions could result in the

discontinuation of the JCA process.

Comprehensive Dossier Requirements

The JCA dossier is notable for its depth and breadth, emphasizing transparency and justification at every stage. Companies must submit all relevant clinical trial results, along with detailed contextual information, including how data was gathered, reasons for excluding certain studies, and any limitations of the available evidence. The assessment is structured around each PICO, requiring separate analyses for every relevant population, comparator, and outcome.

One of the defining features of the JCA is its emphasis on robust indirect treatment comparisons when direct comparisons are unavailable. These comparisons often require advanced methodologies, and when study data is lacking, detailed real-world data might be needed to fill the gaps, underscoring the need for thorough planning and resource allocation.

The dossier structure is designed to ensure clarity and consistency, but the level of detail required can be overwhelming. Expert consultations and advice procedures are important in this process. By engaging early with EU HTA bodies and leveraging their feedback, companies can refine their strategies and address potential gaps before beginning the dossier preparation.

Evidence Planning

Evidence generation for the JCA should begin during clinical development, alongside the regulatory evidence planning. Trial designs should attempt to address both regulatory and HTA requirements, as far as possible. Any additional evidence generation needed to meet the anticipated PICO scopes of the JCA should be done in parallel with the pivotal trials. With compressed timelines, there's little opportunity to gather additional data once dossier preparation begins.

It is necessary to understand the therapeutic landscape. Companies should anticipate relevant comparators and outcomes based on treatment guidelines, HTA decisions, and advisory feedback from clinical experts. For rare diseases or emerging therapies, expert consultations can help identify data gaps and unmet needs.

Joint Scientific Consultations offer a structured way to refine evidence strategies and gather feedback on planned approaches. These consultations require careful preparation, including clarity on anticipated PICO scenarios and planned data collection efforts.

Lessons from a Case Study

A practical example involving a prostate cancer treatment highlights the complexity of aligning trial designs with JCA requirements. In this case, the therapy's pivotal trial provided evidence for certain populations and comparators but left gaps for others. The label population included multiple subpopulations, each with distinct treatment options and comparators, requiring supplementary analyses and indirect treatment comparisons to fill the gaps.

The case demonstrates the importance of early planning and scenario analysis to anticipate evidence requirements. It also emphasizes the value of designing trials that collect broader data sets, enabling flexibility in addressing varying requirements across the EU.

A Path Forward

The new regulation requires companies to present a complete, well-supported dossier from the outset and the compressed timelines of the JCA leave little room for adjustments. Early scenario planning and evidence generation can mitigate risks, while strategic advisory consultations can clarify expectations and requirements.

To ensure readiness for the JCA, companies should focus on actionable strategies that align with their long-term goals:

- 1. Start early:** Incorporate JCA requirements into clinical development plans from the outset, ensuring that trial designs address key populations, comparators, and outcomes as far as possible and plan any additional evidence generation needed.
- 2. Engage with advisory processes:** Use Joint Scientific Consultations to gather feedback on your evidence generation strategy and refine your approach based on HTA input.
- 3. Leverage real-world data:** Identify opportunities to collect supplementary data, such as natural history studies or patient-level data, to strengthen indirect comparisons.

4. Anticipate national preferences:

Analyze treatment landscapes and comparator expectations to align your dossier with the diverse needs of EU member states.

- 5. Build internal alignment:** Foster collaboration between departments to ensure a coordinated approach to dossier preparation, addressing both regulatory and HTA requirements.

The JCA represents a paradigm shift in how therapies are evaluated and approved in the European Union. While the process is designed to reduce duplication and streamline market access, it also raises the bar for evidence generation and procedural rigor. Companies that approach the JCA with a proactive and well-coordinated strategy will be better positioned to meet these challenges and seize the opportunities presented by this new regulatory landscape.

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About the hosts

Dr Chantal van Gils



Chantal is Vice President of Evidence and Value at SSI Strategy. She is a seasoned specialist in real-world research, epidemiology, and health economics. She brings extensive knowledge and a wealth of professional experience in harnessing population-specific analyses and quantitative methods to inform both interventional and observational clinical studies including pragmatic trials, natural history of diseases, registry-based data, patient-related outcome reports or multi-dimensional molecular medicine data.



Dr Sigrid Klaar



Sigrid is Medical Advisor & NDA Advisory Board Member. She is a former senior regulatory assessor and HTA agency medical advisor. MD, PhD, Specialist in Oncology. With HTA experience from the Swedish Dental and Pharmaceutical Benefits Agency (TLV), including national reimbursement applications as well as EUnetHTA and FINOSE joint clinical assessments. Deeply involved in the EU HTA regulation before and after its adoption, including under EUnetHTA 21. Extensive experience from oncology drug approvals of all drug types in the EMA centralised procedure, scientific advice at the Swedish Medical Products Agency, and drafting guidelines for industry in the EMA Oncology Working Party. Sigrid applies her knowledge to successfully support companies on the clinical and HTA aspects of drug development.





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