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JCA in the EU:

A roadmap for sponsors

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Introduction

The Joint Clinical Assessment (JCA) framework (Regulation (EU) 2021/2282) was implemented on January 12, 2025 for all new medicinal products for oncology, and advanced therapy medicinal products (ATMPs). From 2028, this process will apply to orphan medicinal products, and from 2030 onwards, for all other products not previously included. Biosimilars, generics, and all products with existing marketing authorization by European Medicines Agency (EMA) in the European Union (EU) are excluded, even if applications are submitted for new indications.

The goal of the JCA framework is to improve the process for evaluating the clinical evidence of new medicines across the 27 EU member states, addressing concerns regarding equity, timeliness and access.

The output of the JCA process is a report that provides a single, harmonized evaluation of the clinical evidence for new treatments for all EU countries. It is a factual description of the relative effects observed for analyzed health outcomes, including numerical results, confidence intervals, and an analysis of scientific uncertainty and evidence quality. The report is expected to deliberately avoid value judgments, rankings, conclusions on overall benefit or clinical added value, and recommendations on the medicinal product's use or positioning within therapeutic strategies.

Member states retain responsibility for determining the clinical added value of medicinal products within their specific healthcare contexts, as the relevance of analyses in the JCA report may vary by country. This approach allows for flexibility in considering local factors while utilizing the JCA report as a foundation. The JCA report is intended to lay the groundwork for pricing and reimbursement negotiations with HTA bodies at the member state level, facilitating timely decisions within each market.

Who are the 27 EU member states?

The countries participating in the EU JCA: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden

While not EU members, Norway, Iceland and Liechtenstein (as part of the European Economic Area) also participate in the EU Health Technology Assessment (HTA) cooperation.

JCA is expected to increase collaboration and efficiency by avoiding duplication of efforts. This approach could facilitate more equitable and timely access to new, innovative treatments across member states, particularly benefiting smaller markets that historically face delays in product launches or have limited resources for conducting their own HTA evaluations.

As of July 2025, the JCA process is underway for six oncology products, including ATMPs, with assessments expected to be published in 2026. For 2025, it is estimated that 17 oncology products and eight ATMPs will undergo JCA evaluation.

Areas of challenge for sponsors

Based on our experience, we recognize six main areas of challenge for sponsors (known as health technology developers or HTDs in JCA nomenclature):

1. **Identifying and defining the PICO (Population, Intervention, Comparator, Outcome) relevant to each member state**

   The standard of care may vary across member states, leading to variations in the PICO elements requested by different EU member states and HTA bodies. The diversity in healthcare practices and priorities often results in a high number of requested PICOs in the final scope, even after JCA consolidation. Additionally, the final scope will not specify which member states requested particular PICOs. Consequently, sponsors will need to proactively anticipate HTA requirements to effectively prioritize and facilitate the generation of relevant evidence.

What is PICO?

The PICO framework provides a standard format for specifying research questions:

- **P (population)** – including full patient population and/or relevant subpopulations
- **I (intervention)**
- **C (comparator[s])** – including approved or off-label comparators
- **O (outcomes)**

If a comparison against multiple comparators is required, each will have a separate PICO.

2. Preparing evidence simultaneously for all member states

As JCA includes evidence requirements for all 27 European member states, evidence will need to be generated at the same time (e.g., indirect treatment comparisons), where previously, evidence generation could be stepwise, with a prioritization of key market requirements. This stepwise approach also allowed for learnings from one HTA interaction to be leveraged and addressed in subsequent HTA submissions, creating opportunities for further evidence generation.

3. Managing tight submission timelines and potential scope changes

With the requirement for the final dossier to be submitted within 100 days after the final scope is received (60 days for the accelerated process, and at the latest 45 days prior to EMA's Committee for Medicinal Products for Human Use (CHMP) opinion), there is limited scope and time for JCA evidence generation, synthesis and dossier strategy. This may be particularly challenging when developing robust, comparative effectiveness analysis within the 100-day timeframe using systematic literature review methodologies for evidence generation.

The JCA process may face additional complexities if the therapeutic indication changes during EMA evaluation. In such cases, if the change impacts the JCA scope, the JCA Subgroup may prepare a new assessment scope proposal. Consequently, the sponsor may be asked to submit an updated dossier, potentially leading to delays in the production of the final JCA report.

4. Navigating stakeholder management and limited interaction opportunities

The JCA process presents challenges for sponsors in managing multiple stakeholders across member states, with limited opportunities for direct engagement during the evaluation. While the process involves various stakeholders, their selection is primarily based on recommendations from member states or the HTA secretariat. The restricted involvement of sponsors during the evaluation phase may hinder timely clarifications or additional context provision. This approach could also limit input from patient organizations, clinical experts, and other interested parties, potentially narrowing the range of perspectives considered in the assessment.

5. Addressing resource and organizational challenges

Smaller sponsors may be particularly impacted by the growing resource demands of the JCA process, that runs alongside the regulatory process and includes providing additional data requested, meeting submission timelines and preparing evidence/strategy in advance – particularly without a European or local Market Access and Health Economics and Outcomes Research (HEOR) function.

In more established organizations, with global or regional functions alongside market affiliates, challenges will include sharing of information across functions and from global to regional to local levels. Identifying the correct stakeholders to input into the JCA strategy and submission will be required to ensure a streamlined approach and transparent communications across the organization. This will ultimately impact the success of HTA engagements at the member state level, and successful HTA engagements reimbursement and patient access.

6. Integrating JCA outcomes with national HTA processes and value frameworks

The JCA process focuses solely on clinical aspects, excluding economic, societal and organizational value considerations. As such, sponsors must communicate these broader value elements separately to HTA bodies at the member state level. As the JCA evaluation is not binding in the member states, companies face the challenge of integrating its outputs with local access requirements and national HTA processes. This disaggregation of clinical value from broader HTA value frameworks necessitates a multi-faceted approach to ensure comprehensive value communication across various stakeholders and jurisdictions.

How sponsors can prepare for the JCA implementation

We advise forward-thinking companies to proactively consider a set of strategic activities in anticipation of engaging with the JCA process, and to manage some of the common challenges identified. Aligning clinical development with JCA requirements and preparing comprehensive evidence dossiers that address both EU-level and national HTA bodies' requirements can lead to better preparation, smoother assessments, and ultimately, more efficient pathways to market.

The areas for proactive strategic focus include:

Early integrated evidence generation planning and gap analysis

Integrated evidence planning is crucial to address different stakeholder requirements and identify potential gaps in clinical and economic evidence. For example, while the EMA is generally more accepting of novel trial designs, HTA bodies may challenge the data package, with the JCA report potentially highlighting high degrees of uncertainty due to limited evidence. Consequently, individual member states may request additional evidence to substantiate the new drug's value in their specific healthcare systems. This could result in limiting the patient population to subgroups where clinical effectiveness is maximized or entering into value-based agreements that include provisions for future re-evaluation. These potential outcomes underscore the importance of conducting thorough evidence generation and gap analysis early in the development process to anticipate and address the diverse needs of regulatory bodies, HTA agencies, and individual member states.

Parexel's perspective:

In a recent analysis for our customer, we identified key evidence gaps in their oncology products and ATMPs that are in scope for the JCA process. Our integrated evidence generation plan recommends targeted studies, including real-world data and retrospective analyses, to close these high-value evidence gaps to meet the JCA's multi-stakeholder requirements.

Early engagement through Joint Scientific Consultation,[1] which seeks input from both EMA and HTA bodies on the Phase III clinical trial protocol in a single process, can also support the alignment of evidence requirements.

Scenario planning

Anticipate different potential requirements and outcomes of the JCA evaluation and prepare accordingly.

Parexel's perspective:

In the workshops we facilitate with biotech companies on scenario planning for different JCA evaluation outcomes, we include our own clinical, regulatory, RWE, HEOR and market access experts to critically assess the evidence package related to JCA and HTA requirements. This team also includes ex-EMA and HTA evaluators. Our customers' feedback is that this enhances their understanding of the potential issues, challenges, weaknesses and uncertainty in the evidence package, enabling them to prepare a robust JCA submission and HTA negotiation strategy.

Implement robust data management and submission preparation processes

Establish systems to ensure data quality, accessibility, and compatibility with JCA requirements.

Parexel's perspective:

With Parexel's bespoke AI platform to support JCA-related processes, we deliver dynamic, continuously updated evidence synthesis, including 'living' SLRs, 'living' NMA, 'living' economic models and 'living' dossier. The core concept is to continuously evaluate and update syntheses and insights as new evidence emerges regarding safety, efficacy, and cost-effectiveness. This proactive strategy helps our customers meet the stringent 100-day timelines for JCA submissions by ensuring that all evidence is current and readily available.

We also leverage AI to develop a PICO prediction tool. This essential component facilitates the scoping of evidence synthesis requirements for JCA submissions, further streamlining the process and supporting faster access to innovative drugs for patients.

Prioritize comprehensive stakeholder engagement

This should include early engagement with HTA bodies and regulatory agencies, as well as establishing strong relationships with European and local stakeholders, including patient advocacy groups and clinical experts.

Parexel's perspective:

Stakeholder engagement can be optimized through primary research; one-on-one interviews to validate the evidence package, advisory boards to address data gaps and challenges and focus groups to understand unmet needs and treatment impact.

The early development of economic models to demonstrate cost-effectiveness and budget impact across diverse European markets

After JCA dossier acceptance, all 27 member states will seek to assess the technology under their own HTA rules; this may occur simultaneously for reimbursement. Sponsors will require a sophisticated, flexible economic model that allows for customization to meet country-specific requirements and willingness-to-pay thresholds. Understanding the evidence challenges and coupling this with economic value will enable sponsors to facilitate the pricing and reimbursement negotiation with HTA bodies in each member state.

Parexel's perspective:

Our development of a flexible economic model for our customer with a novel oncology treatment proactively incorporates various scenarios for different European markets, aligned with the different PICOs and comparative effectiveness analyses (e.g. indirect treatment comparisons, matching-adjusted indirect treatment comparisons) present in the JCA dossier. This proactive approach will enable rapid adaptation to country-specific requirements post-JCA, significantly reducing the time to market in key EU countries, and any conflicts in messaging as the clinical evaluation is incorporated into clinical and economic value for the individual healthcare systems.

For a rare disease therapy: early economic model development with modular components that can be easily adjusted for different healthcare systems enables our customer to swiftly demonstrate value across multiple EU markets, from cost-effectiveness-focused Nordic countries and BeNeLuxA, to budget impact-centric Southern European nations.

The early development of an economic model that allows for detailed subgroup analyses (aligned with the respective PICOs required during the JCA process, for instance) enables our customer to identify patient populations where their technology offers the most value across different EU markets, informing targeted market access strategies and potentially supporting higher prices in specific subgroups.

Emphasize strategic pricing activities and innovative contracting

Foster early collaboration with payers, utilizing data, real-world evidence, and robust clinical evidence to articulate product value effectively.

Parexel's perspective:

Companies could consider the appropriateness of value-based/outcome based pricing agreements vs. simple discounting models, in advance of the member state engagements to facilitate faster negotiation, implementation and acceptance of the new treatment. ATMPs such as cell and gene therapies for rare diseases or oncology are particularly suitable for these pricing agreements as the risks are associated to the perceived high initial cost and the uncertainty related to long-term outcomes.

CASE STUDY

JCA preparation in action

Parexel is supporting a biotech company in their preparations for JCA submission in oncology, ensuring that the regulatory strategy is aligned with their JCA and HTA strategy, so that the evidence package is acceptable to all assessment bodies.

The process is ongoing, with initial actions completed:

- Identification of potential PICOs in anticipation of the final JCA scope
- Review of the treatment landscape and guidelines across the member states to identify relevant treatment comparators
- Pipeline assessment to identify upcoming comparators, which may become relevant before the final scope

Next steps include:

- Survey with external experts from the member states to validate PICOs
- PICOs then to be assessed based on priority, ability to generate comparative evidence, and JCA strategy

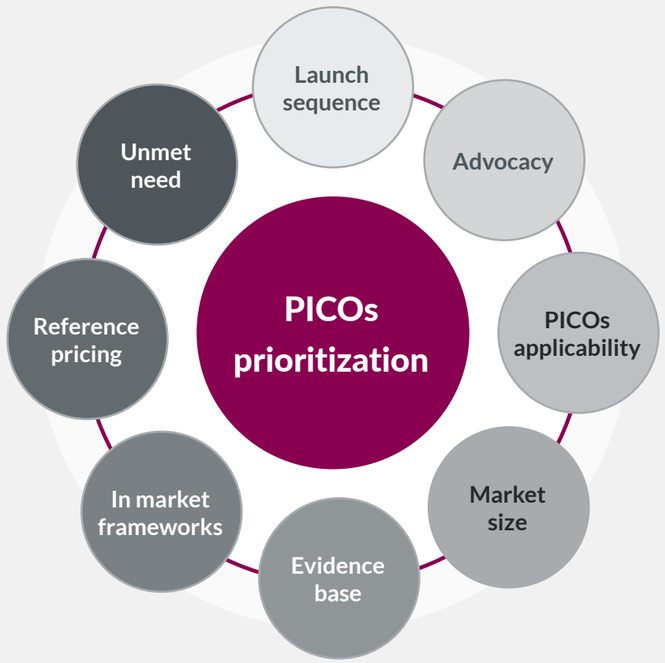

Figure 1. Insights that can be used to develop PICO predications and input into prioritization and launch sequence

Upcoming actions: Following the PICO validation survey, comprehensive gap analysis should be conducted to prioritize evidence generation strategies, alongside JCA dossier compilation, while considering scientific advice from relevant bodies. Other areas of focus are:

- Preparation for stakeholder involvement
- Internal alignment across teams
- Refinement of the product's value proposition
- Development of a post-submission strategy to address potential scenarios and requests for additional information during the assessment process

Expected outcome: A strategically aligned and robust evidence package that seamlessly integrates regulatory, JCA, and HTA requirements for the oncology product. This harmonized approach should result in a JCA submission that not only meets regulatory standards but also anticipates and addresses the diverse needs of HTA bodies across EU member states.

Optimize your JCA readiness

At Parexel, we have a proven track record of supporting pharmaceutical and biotech companies in evidence planning and strategy, developing submission dossiers and other assessment documents. To address the implementation of the JCA processes, our integrated service offering holistically meets the needs of biopharma companies.

Our expertise includes early assessment of PICOs across the member states, facilitating early interactions with multiple stakeholders, advisory engagements, and developing strategic market access and reimbursement strategies to meet JCA requirements.

Please get in touch, we're always available for a conversation.

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Unlock product value through access and reimbursement to bring therapies to patients, faster:

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››› Could a partnership like that put your product ahead?
We're always available for a conversation.

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