WHITE PAPER

The EU Joint Clinical Assessment: Turning HTA reform into a market access advantage

A KEY QUESTION

What does the EU Joint Clinical Assessment mean for your market access strategy?

KEYWORDS

EU Joint Clinical Assessment (JCA), Health Technology Assessment (HTA), Market Access Strategy, Evidence Generation, Market Access Readiness

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The European Union (EU) Joint Clinical Assessment (JCA) changes how healthcare manufacturers must plan, generate and position evidence for health technology assessment (HTA) across Member States. It does not centralize reimbursement or pricing, and it does not replace national decision-making. Its importance lies elsewhere. It creates a common EU-level assessment of relative clinical efficacy and safety that is likely to shape how national HTA bodies first encounter the clinical case for a new medicine. National variation will remain, but the point of divergence is likely to move.

This creates a new planning challenge for manufacturers. Evidence strategy needs to be settled earlier, tested against a broader range of potential comparators and outcomes and built to withstand scrutiny across several Member State perspectives at once. For teams that prepare deliberately, the JCA can provide a clearer scientific platform for national submissions. For those that treat it as a late-stage filing requirement, it could expose evidence gaps across multiple markets simultaneously.

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This is particularly relevant for biotechnology companies, many of which make EU development, partnering or transaction decisions around Phase II/IIb proof of concept, before the pivotal evidence package is fully fixed. At that stage, a clearer view of likely EU evidence expectations can influence trial design, ancillary evidence generation, investor diligence, partnering discussions and the credibility of future access plans. Market access readiness and commercial potential may therefore depend less on any individual study than on how clinical trial evidence and real-world data are developed as part of a coherent evidence platform.

Understanding the role of the JCA in the EU HTA pathway

The JCA is the EU-level clinical assessment established under the Health Technology Assessment Regulation. It supports national HTA processes by providing a central scientific analysis of evidence on the relative effects of a health technology on clinical outcomes. For medicinal products, the process runs in parallel with the European Medicines Agency's (EMA) centralized procedure. Since January 2025, the framework has applied to new cancer medicines and advanced therapy medicinal products, and it is due to expand to orphan medicinal products by 2028 and to all new medicinal products by 2030.

Equally important is what the JCA is not. It is not an EU reimbursement decision, a pricing mechanism, a health economic assessment or a judgment of overall value. Those decisions remain national. Although EU Member States are expected to give due consideration to the published JCA report, they will continue to apply their own HTA processes and value frameworks. Historically, national HTA bodies have often reached different conclusions from broadly similar clinical evidence, reflecting differences in comparator expectations, endpoint preferences, tolerance for uncertainty and local standards of care.

What the JCA is not:

- An EU reimbursement decision
- A price recommendation
- A cost-effectiveness assessment
- A replacement for national HTA
- A guarantee of aligned access outcomes

For manufacturers, the practical lesson is straightforward. The JCA should not be managed as a substitute for national HTA, nor should it be treated as an administrative overlay. The extent of its influence will become clearer as implementation experience accumulates, but the JCA is already establishing a common reference point for EU clinical assessment. Even so, the clinical narrative established through the JCA is likely to become an important reference point for subsequent national discussions.

Why the JCA matters commercially

Despite implementation of the JCA, reimbursement outcomes will continue to differ across countries. National authorities will still apply different willingness-to-pay thresholds, budget constraints, clinical practices and policy priorities. A product may be broadly reimbursed in one market, restricted in another and rejected in a third.

The main change is the starting point. Core questions of relative efficacy and safety should, in principle, be debated once rather than re-opened repeatedly in each market. That will not produce harmonized access, but it should make the basis for disagreement more visible. Countries may still differ on the relevance of endpoints, the acceptability of uncertainty, the value of subgroups or the implications of local clinical practice, but those disagreements will be set against a shared EU clinical assessment.

Commercially, this changes where manufacturers need to make their argument. Once the JCA assessment is published, national discussions are more likely to focus on translation into local value: Affordability, unmet need, clinical practice, budget impact and the trade-offs each health system is prepared to accept. This has implications beyond dossier preparation. If the JCA creates an earlier shared clinical reference point for Europe, then decisions about when and how to plan for EU access become more consequential.

Launch sequencing is one area where this may become visible. Some biotechnology companies may be tempted to defer the EU in favor of the United States or Asia-Pacific. Delay may reduce near-term complexity, but it can also increase later misalignment as standards of care, comparator expectations and clinical practice evolve. A strong JCA will not guarantee national reimbursement success. A weak or poorly anticipated JCA, however, can leave manufacturers defending the same clinical weaknesses repeatedly across national HTA processes.

The JCA does not determine national reimbursement, but it may shape how reimbursement discussions begin.

A shift in timing, not just in workload

For many manufacturers, the hardest adjustment is not conceptual; it is chronological. The JCA pulls important evidence and narrative decisions earlier in the development process. Once a JCA has been initiated, scoping moves quickly and the manufacturer dossier follows on a fixed timeline. Manufacturers need to have considered how they will define populations, justify comparators, prioritize endpoints, handle subgroup analyses and explain major sources of uncertainty. These choices cannot be left until after key regulatory milestones. They require earlier coordination between regulatory, clinical, Health Economics and Outcomes Research (HEOR) and market access teams.

The "PICO problem"

In the JCA process, scoping defines the assessment PICO (Population, Intervention, Comparator and Outcomes). Member States can propose PICOs that reflect the evidence they need to assess the product relative to their national clinical practice and evidence expectations, and these inputs are consolidated into a single assessment scope.

In practice, this can create a "PICO expansion" challenge. What was once addressed through separate national HTA submissions may now need to be addressed in parallel within the JCA dossier, particularly where pivotal trial comparators are not aligned with standard of care in all markets. The result is often a larger set of evidence questions and a greater need for comparative analyses and evidence synthesis to support a shared EU clinical narrative.

Early JCA experience suggests this can translate into a substantial number of potential PICO assessment scenarios, with published examples indicating scopes ranging from single-digit numbers to more than ten PICOs.

Why it matters: Scoping decisions made early in the JCA process can influence evidence expectations across multiple markets at once, leaving less opportunity to adjust framing later.

The workload question is therefore more nuanced than whether the JCA adds work or removes it. Some activity will be brought forward, and some may become more demanding because it must address several Member State perspectives at once. At the same time, a well-built clinical argument can be reused across national submissions, leaving local teams to focus on epidemiology, treatment pathways, cost inputs, economic modeling and payer engagement. The opportunity is not workload reduction in the abstract; it is better sequencing, prioritization and less avoidable rework.

Turning JCA into a strategic advantage

Manufacturers that get value from the JCA will be those that use it to discipline evidence planning, rather than those that simply build a dossier on time. The task is to connect trial design, ancillary evidence generation, regulatory strategy and market access requirements early enough for choices to remain adjustable.

Start early. Manufacturers should consider likely JCA implications by late Phase II/Phase IIb at the latest, while pivotal trial design and evidence generation plans remain adaptable. This should include early review of comparator choices, endpoint strategy, subgroup definitions, uncertainty management and the role of supporting real-world evidence.

Anticipate the JCA scope. During early clinical development, manufacturers should pressure-test likely consolidated PICOs, comparator challenges, Member State evidence expectations and evidence gaps that could materially affect priority markets or intended positioning.

Create one clinical narrative. Global, regional and local teams should work from a shared account of clinical performance, key uncertainties and evidence limitations. The objective is not to eliminate local nuance, but to prevent repeated reopening of core scientific questions.

Invest in process readiness. Under the JCA, analytical quality is necessary but not sufficient. Teams also need clear ownership, rapid decision-making, disciplined escalation of evidence trade-offs and a shared view of which compromises are acceptable across regulatory and access objectives.

Plan for national value overlays. The JCA will not replace local economic models, budget impact analyses, affordability discussions or payer engagement strategies. However, if the clinical case is well established at the EU level, national teams can focus more of their effort on what remains truly national: Local burden of disease, treatment pathways, willingness to pay and access mechanisms.

These are familiar principles, but the JCA raises the cost of getting them wrong. Early misalignment is no longer confined to one national process. Manufacturers may view broader PICO requests as an expanded evidence burden; Member States may view them as necessary to reflect diverse health system contexts.

Manufacturers best positioned under the JCA will be those that approach it as an organizing principle for launch readiness, not merely a filing requirement.

What effective JCA preparation requires in practice

Effective JCA preparation starts well before dossier writing. By the time formal scoping begins, manufacturers should already have stress-tested the likely assessment scope, including plausible comparators, endpoint expectations, subgroup questions and sources of uncertainty. This is difficult to do well from a single functional perspective; it requires an integrated view of clinical development, regulatory strategy, HEOR, HTA and market access.

Preparation also requires a clinical evidence package that can do two jobs. It must support a credible EU-level assessment of relative efficacy and safety, while remaining usable for national HTA pricing and reimbursement discussions. The objective is unlikely to be complete evidentiary certainty across every possible assessment scenario. Rather, manufacturers need a clear view of which populations, comparators, outcomes and uncertainties are most likely to influence access decisions in priority markets. That prioritization should be anchored in the commercial strategy for the product: Target launch markets, intended positioning, relevant standards of care, anticipated treatment pathways and the evidence gaps most likely to affect reimbursement outcomes. In this environment, evidence strategy and commercial strategy become increasingly interdependent.

This is where experienced cross-functional support can add value. By pressure-testing evidence plans against likely JCA requirements, identifying gaps before they become fixed and helping teams decide which trade-offs need to be resolved while choices remain adjustable.

The practical value of integrated support is not simply dossier production. It lies in helping manufacturers connect development decisions with downstream access consequences, expose avoidable evidence risks earlier and improve the starting position for national reimbursement discussions.

How Fortrea can support JCA readiness

- Stress-testing likely JCA scope, including potential PICO requirements, priority-market comparators, endpoint expectations, subgroup questions and uncertainty risks before formal scoping begins
- Assessing whether pivotal trial design, indirect treatment comparison feasibility, external comparator feasibility and real-world data sources can support a coherent comparative evidence strategy
- Identifying evidence gaps and trade-offs early, and distinguishing those most likely to affect reimbursement and access outcomes from those that may be managed through explanation, supplementary evidence or national adaptation

Why it matters: Fortrea's integrated clinical development, regulatory, HEOR, HTA and market access capabilities can help manufacturers prepare earlier, expose evidence risks before they become fixed and build a stronger starting point for JCA and national access discussions.

Conclusion

The JCA is not a European reimbursement decision in disguise. Pricing, reimbursement and value judgments remain national. Its importance is that it creates a shared EU assessment of relative clinical efficacy and safety that national bodies are expected to consider.

For manufacturers, that changes the access conversation. The clinical case may be framed earlier, more visibly and across more markets at once. National discussions will still determine affordability, cost-effectiveness, budget impact and practical access, but they are likely to begin from a more common clinical reference point.

Biotechnology companies have a particular reason to prepare early. They often face EU access decisions while pivotal evidence plans are still forming, partnering discussions are active and internal resources are stretched. By late Phase II/Phase IIb, likely scope expectations, comparator risks, endpoint choices and supporting evidence needs should already be visible enough to inform development and transaction planning.

The manufacturers best positioned under the JCA will not be those that wait for the formal timetable and then mobilize around dossier production. They will be those that use the reform to sharpen evidence planning throughout asset development by anticipating scope, building a defensible clinical narrative, making evidence trade-offs explicit, investing early in the comparative evidence infrastructure that matters most and preserving enough flexibility for national value arguments.

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