

The PICO Problem

Europe's Joint Clinical Assessment in its
First Twenty Months

Regulation (EU) 2021/2282 promised one clinical assessment in place of twenty-seven. This paper checks that promise against what has actually happened since January 2025: which products cleared the process, how the scoping step is really working, what the first reports and discontinued procedures reveal about the evidence standard, and what a pharma company should do differently because of it.

1. Where the JCA stands

Health technology assessment used to be an entirely national affair in Europe. A company filing in Germany, France, Italy, and Poland ran four separate clinical evidence reviews, often years apart, each built around its own preferred population, comparator and outcome measure. Regulation (EU) 2021/2282 set out to replace the clinical half of that work with one assessment, run once at EU level, ahead of any national pricing or reimbursement decision.

It arrived in stages, and the stages matter more than most readiness guides let on. Oncology medicines and advanced therapy medicinal products have been in scope since January 12, 2025. Selected high-risk medical devices and in vitro diagnostics have been in scope since January 2026, chosen through a recommendation of the HTA Coordination Group, the first-time device makers have faced anything like this at EU level. Orphan-designated medicines follow in 2028. Every other medicine with a new active substance authorized through the centralized procedure joins from 2030, and nothing already in scope ever leaves it. By the turn of the decade, the JCA will stop being about cancer medicines and advanced therapies and will become the standard gate for every new medicine authorized centrally. For medical devices and IVDs it remains a targeted procedure for a small number of selected high-risk products.

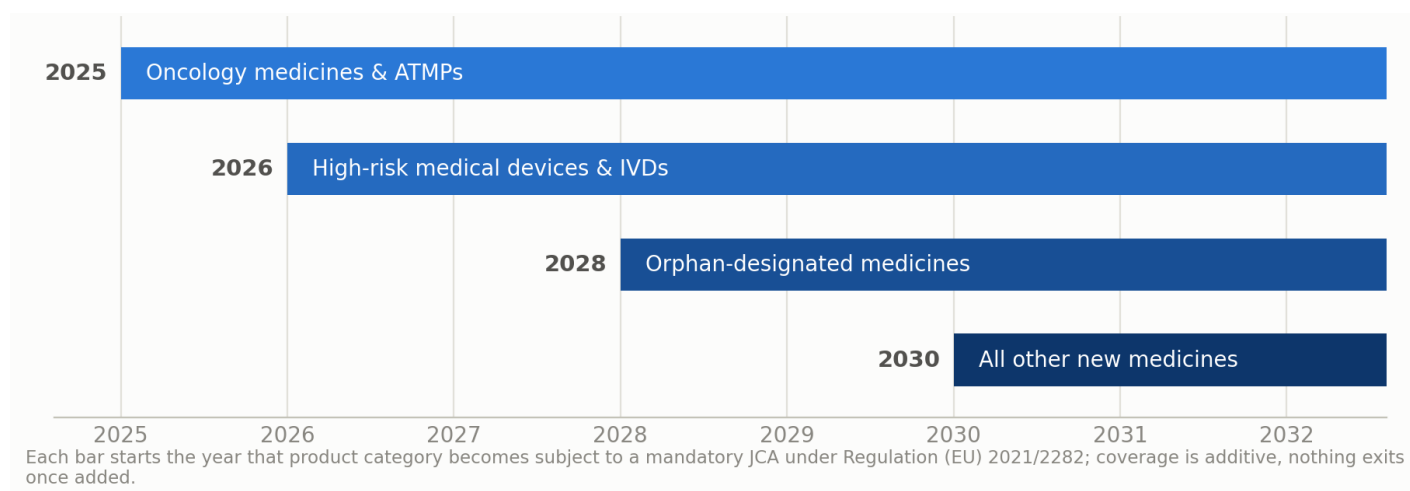


Figure 1. Product categories enter the joint clinical assessment on a rolling basis; coverage only ever expands. Source: European Commission

What the JCA does not do matters just as much as what it does. It produces one clinical assessment report, endorsed by the HTA Coordination Group and published after the European Commission's marketing authorization decision. It says nothing about price, and nothing about whether any given country will actually reimburse the product. Germany still runs AMNOG and France still runs HAS's appraisal, but member states must give due consideration to the JCA report and may not request information already submitted at EU level.

2. The PICO problem

Every JCA opens with a scope, written as a PICO: population, intervention, comparator, outcomes. An assessor and a co-assessor, drawn from two different member states' HTA bodies, draft it, and other member states feed in their own preferences before it is finalized. The scope reaches the sponsor with the Commission's first request, and from that notification the sponsor has 100 days to submit a dossier answering it in full. The deadline shortens to 60 days where EMA assesses the application under its accelerated procedure, or where the JCA concerns a new therapeutic indication.

EMA marketing
authorisation
application field



Assessor and co-
assessor draft the
PICO scope



Dossier due:
100 days (60
accelerated or
new indication)



Assessor review
+factual accuracy
check

**JCA report endorsed:
30 days post-
authorisation**

Figure 2. The JCA clock, from EMA filing to a published, endorsed report.

In practice it is where the promise of one European assessment starts to come apart. Twenty-seven health systems do not share a single view of the right comparator or the right outcome measure, and the scoping step is built to reconcile that difference. EFPIA's own reflection on the first scoping cycles does not dress this up much: the rationale behind how member states' input gets folded into one consolidated PICO remains unclear in the published scoping guidance.

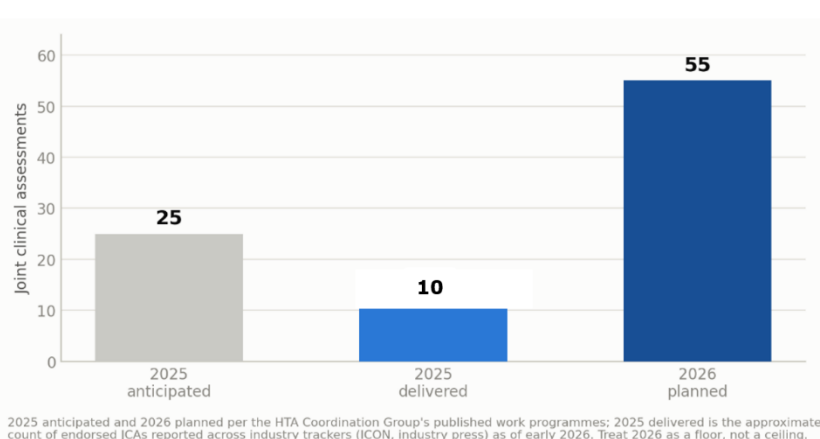
The Federation's specific ask, a formal, structured consultation with health technology developers while a PICO is still being drafted rather than after, remains just that, an ask, as of this paper's writing.

The first published reports show how wide the range already is. Tovorafenib, Ipsen's therapy for pediatric low-grade glioma, was assessed with Ireland's NCPE in the lead and Germany's IQWiG as co-assessor. Across the four reports published by September 2026, IQWiG acted as assessor or co-assessor three times, and the number of PICOs per assessment ranged from one (lurbinectedin) to seven (tarlatamab). Three further procedures were discontinued because the dossier did not meet the requirements, and one ended when the marketing authorization application was withdrawn. Same regulation, very different scopes.

3. Capacity against demand

The Coordination Group's own 2025 work programme anticipated roughly 25 joint clinical assessments. About 10 were initiated in 2025, and the first report was published only in June 2026. The gap to plan reflects how many in-scope applications companies filed, not a shortfall in system capacity. The 2026 programme asks for roughly 55: 35 oncology, 15 ATMP, and, for the first time, 5 medical device assessments.

Figure 3. 2025 estimate versus JCAs initiated, against the 2026 estimate. Sources: HTA Coordination Group annual work programmes



Scientific advice capacity is small. The Coordination Group has set aside 8 to 12 joint scientific consultation slots for medicines in 2026, and 2 to 5 for devices, a ceiling of 17. These slots serve products before their pivotal trials are designed; the products assessed in 2026 designed their trials years ago, before joint scientific consultations existed. Measured against the in-scope pipeline entering pivotal trials each year, capacity is scarce.

Treat a joint scientific consultation as one option, not the plan. Apply where the product meets the selection criteria and run national scientific advice in parallel in the markets whose comparator preferences are most likely to shape the consolidated PICO. Underpin both with a PICO simulation across member states, built from published national guidelines and recent JCA scopes. A multi-country advisory board can test clinical assumptions, but it reflects the views of individual experts, not the positions of the HTA bodies that will write the scope.

4. What this costs a pharma company

The direct cost is evidence generated on the wrong clock. Trial endpoints and comparators are typically locked at Phase II or early Phase III, years before a PICO scope exists to respond. A company that treats JCA readiness as a pre-launch, market access exercise is preparing for a test whose questions get written after the study answering them has already been designed.

The indirect cost is organizational. Companies that have run AMNOG, NICE or HAS submissions already have cross-functional HTA processes, but the JCA changes their timing: the dossier is due while EMA is still reviewing the application, so regulatory and HTA teams work on one clock while the label can still change, and they answer the combined questions of all member states rather than one. Responsibility also moves from national affiliates to global or EU-level functions. For smaller developers without a standing global HEOR function, which account for most JCA submissions so far, this capability often has to be built from scratch.

5. What changes for medical devices and diagnostics

For medicines, the JCA is a rule: every product in scope goes through it. For medical devices and in vitro diagnostics it is a selection. Since January 2026, the pool consists of class IIb and III devices for which an expert panel has issued a scientific opinion under the clinical evaluation consultation procedure, and class D IVDs for which expert panels have given their views. From that pool, the HTA Coordination Group recommends and the Commission selects, against the criteria in Article 7(4) of the Regulation: unmet medical need, novelty, impact on health systems, use of artificial intelligence, cross-border relevance, and major added value at EU level. The 2026 work programme foresees around five device assessments.

That changes the planning problem. A drug developer knows its product will be assessed; a device maker knows only that it may be. The step to watch is the expert panel: a device that goes through the clinical evaluation consultation procedure enters the pool, and its manufacturer should plan as if selection will follow, because the selection criteria favor exactly the innovative, high-risk devices that reach that step.

Device evidence is built for a different question

Device evidence is generated for conformity assessment. A clinical evaluation report and post-market clinical follow-up answer whether a device is safe and performs as intended. A JCA asks how it compares with the alternatives patients would otherwise receive, on outcomes that matter to them, for each PICO the member states request. Randomized trials are the exception for devices, and operator learning curves, the difficulty of blinding and frequent design iterations weaken comparisons that are routine for medicines. For IVDs the gap is wider still: a performance evaluation demonstrates analytical and clinical performance, while a JCA asks whether using the test changes treatment decisions and patient outcomes. Diagnostic accuracy is not clinical utility, and the link between the two has to be argued explicitly.

The practical consequence mirrors the pharma case, only with fewer levers: the evidence conformity assessment requires and the evidence a JCA requires should be planned as one programme, so that clinical investigations and post-market studies collect the comparators and outcomes a PICO is likely to ask for.

Companion diagnostics sit between both worlds

Companion diagnostics are class C under the IVDR and therefore outside the device JCA scope. They still shape medicine JCAs. When a medicine's indication is defined by a biomarker, as with the BRAF-, ALK- and ROS1-targeted medicines among those assessed or under assessment, the test defines the population in every PICO. Differences in test method, threshold or sample type between the pivotal trial and routine care become questions about whom the assessment applies to. Medicine and diagnostic developers who align their test strategy before the pivotal trial avoid having that question raised at scoping.

6. Recommendations for pharma companies

The recommendations below should be treated as a working posture for the next two to three JCA cycles.

Move PICO thinking into the Phase II-to-Phase III decision point

By the time a formal scope exists, the trial that has to answer it is usually locked. Give market access and HEOR a real seat at the table where comparators and endpoints are chosen, not a review pass on a protocol that has already been finalized.

Do not wait on a joint scientific consultation slot to test your assumptions

With at most 17 slots a year, most companies developing in-scope products will not get one. Anticipate PICOs based on clinical pathway expertise, convene your own multi-country advisory board on the same pre-Phase III timeline, and pursue national scientific advice in your two or three most consequential markets in parallel.

Hold national HTA budgets and headcount steady through at least the next two JCA cycles

The JCA adds a layer. Reallocating AMNOG- or HAS-facing resource toward the new European process on the assumption it will do double duty is the single fastest way to be underprepared for a national decision in the same product cycle.

Build one internal PICO options library per major disease area before any specific product enters scoping

Catalog the comparators, subpopulations, and outcome measures your portfolio is likely to face, market by market, ahead of time. When a real 100-day dossier window opens, the work becomes retrieval and adaptation.

Price and staff external advisory relationships by JCA cycle milestone

Scoping request, dossier submission, and draft report review are the three moments that matter. A fixed multi-year contract signed today locks in a playbook built on guidance that the Coordination Group has already shown a willingness to revise mid-stream.

If you are a mid-cap or specialty biotech without a standing global HEOR function, borrow rather than build

Bring in senior, fractional expertise for a single JCA cycle rather than hiring permanently around a process whose long-run shape, particularly from 2028 once orphan medicines join, is still being shaped through guidance and implementing acts.

The joint clinical assessment will keep expanding whether the system around it is ready or not. Medical devices joined in 2026, orphan medicines follow in January 2028, and every other medicine with a new active substance authorized centrally by the turn of the decade. The procedures will keep evolving; the standard they apply is already clear. The first reports and discontinuations judge evidence by the same test: does it answer the questions in the scope, with comparisons whose assumptions are stated and defensible? That test will not soften as the Coordination Group refines its guidance. Companies that design their evidence for this standard before the pivotal trial will be able to meet it. Companies that wait for the process to settle will discover it when their trial can no longer be changed.

How we support JCA readiness

This section describes the authors' services. It is separate from the analysis above.

Evidence planning before pivotal trials. Testing comparator, population, and endpoint choices before protocol lock, using a PICO simulation across member states built from published national guidelines and recent JCA scopes, and preparing requests for joint scientific consultations and national scientific advice.

Dossiers and indirect comparisons. Preparing JCA dossiers against the HTA Coordination Group templates, with an indirect comparison strategy that states explicitly which assumptions each comparison rests on and in which direction any remaining bias is likely to run.

Medical devices and diagnostics. Assessing how likely a device is to be selected, aligning clinical evaluation, post-market clinical follow-up and performance evaluation with JCA evidence needs, building the clinical utility case for diagnostics, and aligning companion diagnostic test strategy with medicine JCAs.

From JCA to national filings. Carrying the JCA evidence into AMNOG, HAS and other national submissions with the same team, so that the European and national dossiers tell one consistent story.

Authors



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Ingenious e-Brain's healthcare and life sciences practice supports market access, HTA, pricing and evidence generation for pharmaceutical, biotech and medical device clients from offices in India, the US and the UK.

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