White Paper

EU HTA in Action

How HTDs can prepare for a successful JCA

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Introduction

The adoption of the Health Technology Assessment Regulation (HTAR) marks a transformative milestone in the European Union (EU) market access landscape,[1] and is one of many policy evolutions that health technology developers (HTDs) are currently navigating: EU Critical Medicines and Biotech Acts,[2,3] EU General Pharmaceutical Legislation reform,[4] unfolding US-EU pricing dynamics, and rising use of health technology assessment (HTA) frameworks globally, e.g., Association of Southeast Asian Nations (ASEAN) harmonisation,[5] Middle East and North Africa (MENA) cooperation,[6] etc. The evolving nature of these reforms, and their complex interdependencies, are raising critical strategic questions for HTDs:

- How do we balance EU Joint Clinical Assessment (JCA) against competing global evidentiary needs?
- How can EU HTA readiness be shaped in a way that brings organisational efficiency and benefits to other regions?
- How do we align our regulatory, market access, and JCA strategies, given what we can learn from the first JCAs in 2025/26?
- How do we envisage JCA readiness evolving as the Coordination Group (CG) undertakes a review of the regulation in 2028?

Drawing on IQVIA's experience from 90+ engagements since the inception of the EU HTAR, this white paper delivers strategic guidance and actionable steps for HTDs to navigate the evolving JCA landscape.

EU HTAR 101

- EU HTAR entered into force on 12th January 2025, bringing two new processes:
  1. JCA is currently applicable for new oncology and Advanced Therapeutic Medicinal Agents (ATMPs), for selected medical devices from 2026, orphan drugs from 2028 and all drugs, IVDs and high-risk medical devices from 2030.
  2. EU HTAR is Joint Scientific Consultation (JSC), which is non-binding HTA advice from at least two EU bodies (and optionally in parallel with European Medicines Agency [EMA]), before the start of the registrational clinical trial.
- The scope of the JCA will encompass the clinical evidence needs of all 27 EU member states (MS) in the form of PICOs (Population, Intervention, Comparator, Outcomes); given the heterogeneity clinical management among the 27 MS, the number of PICOs is expected to be large for most indications. HTDs have no involvement in formal scoping process.
- JCA runs in parallel to the EMA regulatory submission, with very short timelines to submit the dossier once the scope is confirmed (up to 100 days under standard EMA procedure and 60 under accelerated).
- The JCA report will evaluate the relative treatment effect but will not provide any value judgement or conclusions on the overall clinical added value; the report will be publicly available 30 days post European Commission (EC) decision.
- MS should give due consideration to the JCA report and not request the same information, data, analyses or other evidence that has been submitted in the JCA dossier.
- MS remain responsible for drawing conclusions on the value added for their health systems and for pricing and reimbursement (P&R) decisions.

Where do you begin? Prepping for JCA success

A successful JCA submission begins long before the dossier is initiated. Irrespective of company size or asset specifics, HTDs need to implement new ways of working that bring JCA to life. This is easier said than done: HTDs should not underestimate the time needed for internal alignment and change management.

Asset-level preparations must also begin early while there is still a window of opportunity to influence the clinical development programme — a shift in organisational thinking that can be challenging. The nature of JCA requires nuanced predictive work to simulate the PICO scope, engage with external stakeholders, adapt integrated evidence plans (IEP) accordingly and develop new materials with cross-functional teams, including a JCA statistical analysis plan (SAP) and JCA Patient Reported Outcome (PRO) strategy.

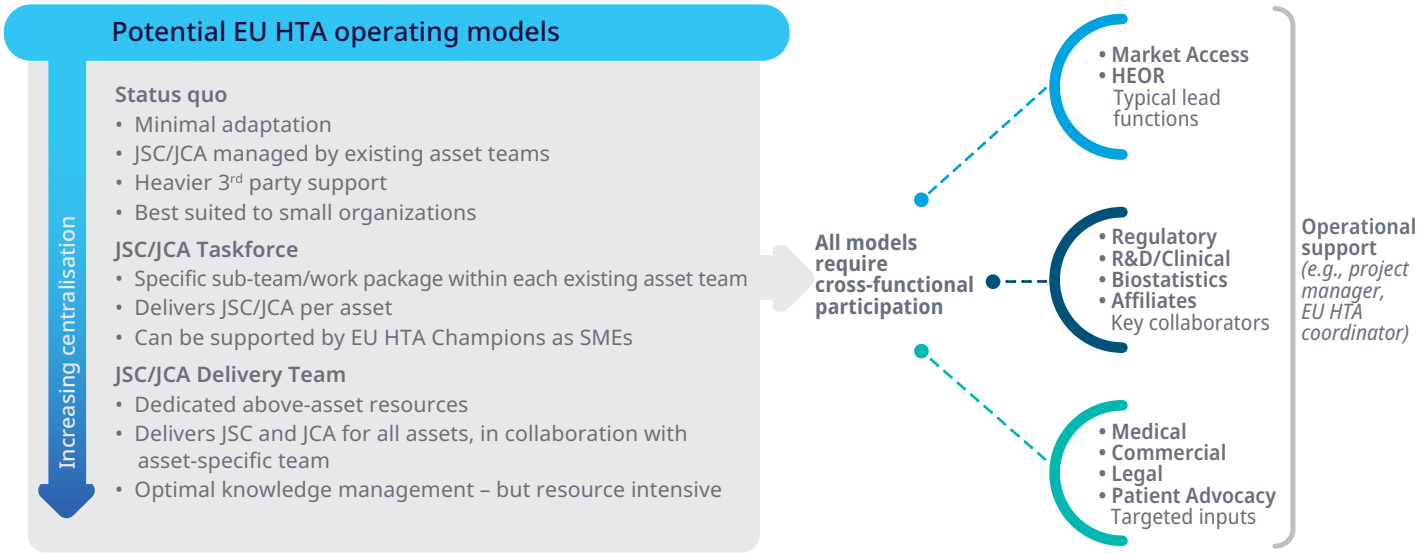
Working backwards from your first JCA-eligible asset's target EMA filing date provides a clear roadmap to prioritise EU HTA readiness activities and identify critical gaps where additional focus is needed.

ADAPT YOUR ORGANISATIONAL MODEL

EU HTA requires an evolution of processes across the organisation from market access, health economics and outcomes research (HEOR) and biostatistics, to regulatory, medical, commercial, patient advocacy and legal functions. Strategic cross-functional alignment across global, (regional) and local levels of an organisation, beginning early in the asset lifecycle, is therefore critical. Establishing a clear above-asset operating model that outlines roles, responsibilities, and interdependencies, while connecting to existing governance processes, is also essential (Figure 1). A granular task-level RACI (Responsible, Accountable, Consulted, Informed) matrix is recommended given the complexity of bringing together cross-functional stakeholders much earlier than previously. Developing and aligning on any new working model can take time, so having this in place ahead of your first JCA-eligible asset helps manage uncertainty about changes to workload or impact on current ways of working.

Figure 1: EU HTA organisational models

Organisational models for EU HTA oversight and delivery have variable levels of complexity and centralization, but all are cross functional, and many have operational support roles.



Source: IQVIA expertise.

Equally important to structural alignment is the engagement of internal stakeholders throughout the organisation. To achieve JCA success, organisations must prioritise education and regular, open communication across all internal stakeholders. Many HTDs have run internal EU HTA trainings, developed tactical playbooks, established an EU HTA shared document repository, and brought cross-functional perspectives into the shaping of operating models. This internal stakeholder engagement should also encompass the sharing of learnings from industry, and after-action review to refine processes following first JCA experiences.

An asset-level EU HTA readiness plan ideally should cover three strategic domains: i. Evidence generation and JCA strategy; ii. Internal and external stakeholder engagement; and, iii. JCA dossier development. It should remain dynamic and extend all the way to asset launch and beyond. A cross-functional JCA/JSC team can be set up to lead, coordinate the readiness plan, and collect and socialise learnings from internal and external experience; this could use dedicated above-asset resources in collaboration with asset teams (most centralised approach), or be defined by asset, with or without functional EU HTA champions where feasible (Figure 1). Many organisations have also created operational roles to support with the complex project management of integrating JCA into existing launch readiness.

IMPLEMENT BEST PRACTICES FOR PICO PREDICTION

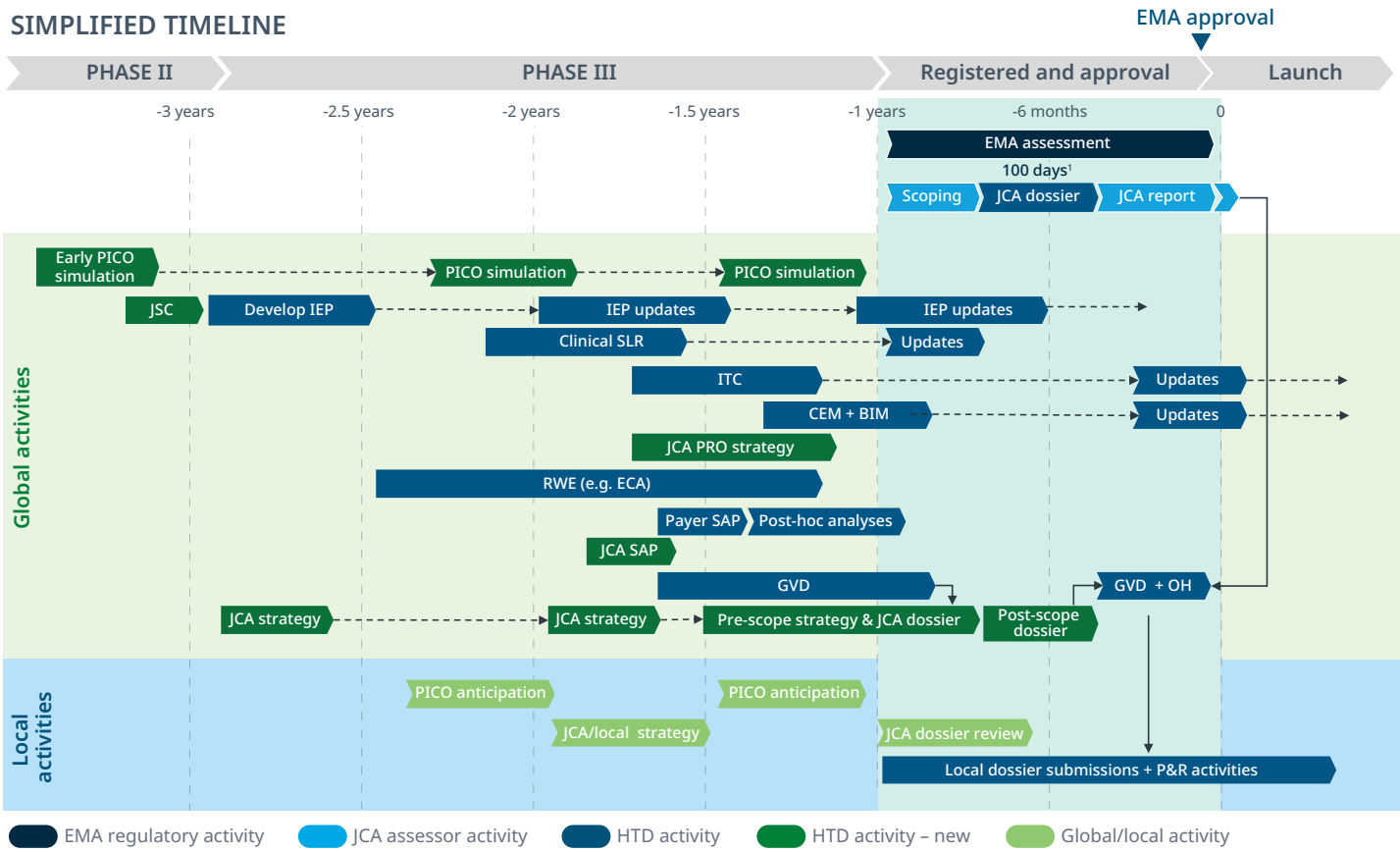
Early anticipation of the JCA scope through PICO simulation is the cornerstone of effective JCA planning (Figure 2). This process involves generating plausible PICO combinations based on the target regulatory label, current and future EU-level and local treatment paradigms, simulating likely population and sub-populations, comparators, outcomes and subgroups, and refining these combinations throughout development milestones to align with latest developments. Increasingly, artificial intelligence (AI)-augmented simulations are enhancing efficiency and accuracy, but outputs must be validated by cross-functional experts and updated alongside the IEP.

PICO simulation is not enough in isolation: it must translate into a JCA strategy that is developed early and is clearly aligned to wider market access goals for the asset. Given the high volume of PICOs for JCA (based on IQVIA predictions, the first JCA scopes coming out of the JCA subgroup, and statements by the HTACG themselves), such a strategy must prioritise PICOs for evidence generation, considering likelihood, evidence availability, and local pricing and reimbursement (P&R) implications. Affiliate engagement is also critical to avoid misalignment between EU-level and local dossiers. The JCA strategy, i.e. which PICOs to address through evidence submission and which PICOs to justify lack of evidence, will steer decisions on supplemental evidence, objection handling, and balancing EU and local HTA requirements.

IQVIA, through collaboration with HTDs, has seen several of the first consolidated scoping documents, and while the number of JCAs in process is still small, some initial learnings can be called out:

1. The number of PICOs remains high, driven by requests for sub-populations and different comparators
2. One can anticipate the PICO scope — our PICO simulation methodology closely predicted those that are in scope
3. As anticipated, the proposed EMA label statement is key in determining the JCA scope and even small changes in wording can have a big impact on the number of PICOs
4. MS-level PICO requests can best be predicted based on previous HTA body (HTAb) assessments in related indications, alongside clinical guidelines
5. Subgroups will be requested separately to be applied to all PICOs, and the definition of subpopulation versus subgroup is not always clear
6. The list of outcomes requested seems relatively standardised for oncology, with shorter lists than expected
7. There is a strong emphasis on PROs, similar to the German requirements, with health-related quality of life (HRQoL), measured by both disease-specific and generic instruments, health status and symptoms of disease being requested.

Figure 2: Overview of Key Global and Local JCA activities



Notes: [1]100 days if standard EMA procedure, 60 days for accelerated procedure.

Abbreviations: BIM – Budget Impact Model; CEM – Cost-effectiveness Model; ECA – External Comparator Study; EMA – European Medicines Agency; GVD – Global Value Dossier; IEP – Integrated Evidence Plan; ITC – Indirect Treatment Comparison; JSC – Joint Scientific Consultation; OH – Objection Handler; PICO – Population, Intervention, Comparator, Outcome; P&R – Pricing & Reimbursement; RWE – Real World Evidence; SAP- Statistical Analysis plan; SLR – Systematic Literature Review

PICO BEST PRACTICES

Based on these learnings our PICO best practices include:

- Planning for multiple lifecycle PICO simulations to account for evolving business questions
- Using analogues with published HTA reports from EU MS HTAbs and national/international guidelines to inform assumptions
- Engaging affiliates beyond EU4 to capture diverse local nuances
- Carefully reviewing the pivotal trial design for the intervention and relevant analogues to understand likely subgroups
- Ideally conducting the first simulation early enough to influence pivotal trial design — Phase I is ideal to allow exploration of PRO hypotheses in Phase II, but recognising that this may not always be feasible
- Continuously refining PICOs based on regulatory shifts, evolving standards of care, and competitor activity
- Validating AI-driven outputs with expert human-in-the-loop review.

Drawing on our learnings from 40+ PICO simulations, it is evident that HTDs are making substantial and proactive efforts to conduct these exercises robustly, despite insufficient clarity on the PICO consolidation process from the JCA Subgroup. Further, initial experience from ongoing submissions demonstrates the benefits of robust PICO simulations, which align closely with the confirmed assessment scope, with minimal revisions in the JCA dossier required post-scope confirmation.

PRIORITISE JCA AND JSC EXTERNAL STAKEHOLDER ENGAGEMENT

Integrating JCA and JSC into existing external engagement plans — or adapting those plans where needed — is critical to ensure alignment with the evolving EU HTA requirements. External stakeholder engagement is necessary to pressure-test assumptions related to JCA strategy and evidence generation, anticipate objections, and ensure that evidence generation plans and JCA dossier development are informed by evolving HTA expectations. Opportunities include:

Pressure testing your proposed trial design through JSC or HTA scientific advice: To align clinical development with evolving HTA expectations, HTDs should establish a strategic framework to define a scientific advice strategy. This scientific advice strategy should be embedded within the broader EU HTA readiness plan and revisited as the asset evolves, capturing both "early" and "late" scientific advice. Early engagement (prior to pivotal trial protocol lock) enables alignment on critical elements of the trial design using the PICO framework and helps to reconcile potential divergent regulatory and HTA requirements. As part of the scientific advice strategy, HTDs should evaluate eligibility and optimal timing of EU early scientific advice through either standalone JSC or parallel HTA CG/ European Medicines Agency (EMA) JSC, ideally at least 12 months before pivotal trial protocol lock, to allow sufficient time for incorporating feedback into trial design.[7] Planning for late scientific advice (post-protocol lock) or other local scientific advice processes should also be considered to ensure alignment with any emerging expectations prior to JCA submission.

Anticipating evidence requirements and local PICOs by engaging with MS HTAbs, clinicians and PAGs: Beyond JSC, where possible, HTDs should maintain ongoing dialogue with HTAbs across MS to validate assumptions and monitor evolving HTA expectations. This includes formal and informal exchanges and tracking national guidance updates. Such engagement helps HTDs anticipate scope-setting trends, understand local nuances, and refine their evidence strategy accordingly. It also supports alignment between JCA and local HTA submissions.

HTDs should also engage with external stakeholders such as key opinion leaders (KOLs), clinical experts, and patient advocacy groups (PAGs) to strengthen the relevance and credibility of the JCA strategy. JCA conflict of interest (CoI) rules must be carefully navigated to ensure the right stakeholders are still able to participate in the JCA itself.

INTEGRATE JCA STRATEGY INTO EVIDENCE GENERATION PLANNING

The JCA strategy should be embedded within the global IEP, balancing EU requirements with other regions and documenting trade-offs where necessary. Truly accounting for the new EU-standard that JCA brings will require internal education on its complexity, and typical evidence approaches will need recalibration: JCA demands broader comparator baskets, granular subpopulation analyses, and inclusion of endpoints valued by MS and patients, such as validated PROs and disease-related symptoms.[8–10] Anticipated PICOs should be mapped against clinical plans to identify gaps early — and whether supplemental analyses, systematic reviews, indirect treatment comparisons (ITCs), or real-world evidence (RWE) is needed. External comparator arms (ECAs) using RWE will need to be considered much more frequently, especially where head-to-head randomised controlled trial data are unavailable or comparisons are unfeasible. HTDs must plan ECAs much earlier in the asset lifecycle to meet regulatory and HTA expectations, marking a significant shift in ways of working.

In summary, evolving current evidence generation strategies to incorporate JCA requires earlier planning: PICO simulations should inform global clinical systematic literature review (SLR) protocols to ensure comprehensive study capture; ITC feasibility assessments must be conducted with greater methodological rigour to meet JCA dossier and MPG guidance requirements; and a multi-network meta-analysis (NMA) programme with rolling updates, leveraging automation, may be required to support robust indirect comparisons. To meet the compressed timelines for JCA dossier finalisation, evidence generation activities must start early, with some activities conducted 'at risk', before final PICO scope confirmation (Figure 2).

In addition to evolving existing evidence generation strategies, JCA requires that every outcome is reported alongside confirmation of whether each statistical test conducted was statistically significant, pre-specified or not, and appropriately controlled for multiplicity.[10] As a result, a JCA SAP should be developed prior to trial read-out and submitted with the JCA dossier, in line with anticipated PICOs and JCA strategy. Alongside the above requirements, HTDs should consider including the following detail in the JCA SAP: cut-offs for conducting analysis for sub-populations or subgroups based on the number of patients/ events, subgroup analysis to be conducted across PICOs in alignment with the clinical SAP, minimal important differences (MID) for PROs, and a definition for symptoms of disease. When considering these components, in addition to meeting JCA requirements, the JCA SAP also serves to cross-functionally align and plan resources for the anticipated analysis burden for JCA.

Finally, JCA will also have downstream implications for health economic modelling. The PICO-driven framework may increasingly shape how economic models are constructed to support national HTA processes. While JCA formally excludes cost-effectiveness and budget impact analyses, the standardised clinical evidence it generates can inform survival analyses, ITCs, and subgroup definitions within modelling frameworks.

This has prompted a shift from single-country base cases toward modular, PICO-aligned strategies that deliver tailored yet consistent outputs across jurisdictions. Although a Joint Economic Assessment is not currently under discussion, deeper methodological alignment could enable more harmonised evaluations across Europe, while preserving national autonomy over P&R decisions.

BUILD A PRO STRATEGY THAT PUTS PATIENTS AT THE CENTRE OF YOUR JCA DOSSIER

In parallel to JCA strategy, a JCA PRO strategy is also recommended. Prior to JCA, a PRO dossier would usually be planned if the HTD wished to achieve a regulatory labelling claim. With JCA this has changed for two reasons:

1. The JCA dossier requires justification of the validity, reliability, and interpretability of PRO instruments

2. There is a strong emphasis on PROs in the outcomes requested for JCAs, including disease-specific and generic instruments, health status and symptoms of disease. A PRO dossier for JCA that articulates the PRO strategy and that also interprets the PRO analysis is therefore recommended to ensure a consistent narrative across both JCA and local HTA submissions, and to support patient-centric value framing.

The JCA strategy should be embedded within the global IEP; truly accounting for the new EU-standard that JCA brings will require internal education on its complexity, and typical evidence approaches will need recalibration.

Building your JCA Dossier: What hands-on experience has taught us

The most tangible learnings from developing end-to-end JCA dossiers focus on the need for early, proactive planning. To manage compressed timelines, HTDs should prepare a near-final draft based on predicted PICOs and closely aligned with the EMA common technical dossier before scope confirmation. Resources (internal/ external) should be allocated ideally 12 months before EMA filing. Consideration must be given to practical approaches for the large volume of data that is required to address the PICOs, such as automating the development and quality check (QC) of JCA tables.

Other JCA process observations go beyond early dossier readiness:

LEAD EARLY: HTDS ARE SHAPING JCA ENGAGEMENT PROACTIVELY

Although HTDs have limited formal influence over JCA scope, early experience shows engagement varies by assessor.[9] Some HTDs report informal interactions starting soon after Letter of Intent (LoI) submission, even before EMA validation. Increasingly, the LoI is seen as a strategic enabler, it opens dialogue with the HTA secretariat, grants access to the IT platform and creates opportunities for early engagement with the HTA CG. To maximise these benefits, HTDs should submit the JCA LoI alongside the regulatory LoI, ensuring the earliest possible involvement before scoping begins. HTDs should also consider proactive communication at the earliest opportunity regarding developments with the EMA process, anticipated data cuts or label changes to mitigate delays with the JCA report.

DO NOT SKIP THE SCOPING MEETING — PREPARE TO MAXIMISE ITS VALUE

Whilst HTDs are excluded from the scoping phase of JCAs, some MS offer some windows of engagement. Denmark, Norway, Poland, and Sweden permit HTDs to submit PICO proposals during the scoping phase, reflecting a more inclusive approach to defining local evidence needs. Belgium goes a step further by allowing a post-PICO survey meeting with HTDs, offering a rare opportunity for clarification and alignment prior to the JCA dossier submission. In Finland, engagement occurs later by providing the HTD with the HTAb response to the PICO survey. These emerging trends suggest more MS may follow suit in providing opportunities to engage with HTDs.

To date, the utility of the optional scope explanation meeting, which HTDs can request, remains unclear. Although scope explanation meetings do not provide formal validation, requesting them is advised — most HTDs have done so to date. To maximise their value, align internally cross functionally in advance and share an agenda or list of questions with assessors to make the output of the meeting more meaningful. In our experience, this has contributed to a slightly more substantive and impactful engagement with the assessors and JCA subgroup.

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START EARLY AND PLAN FOR WORST CASE SCENARIO

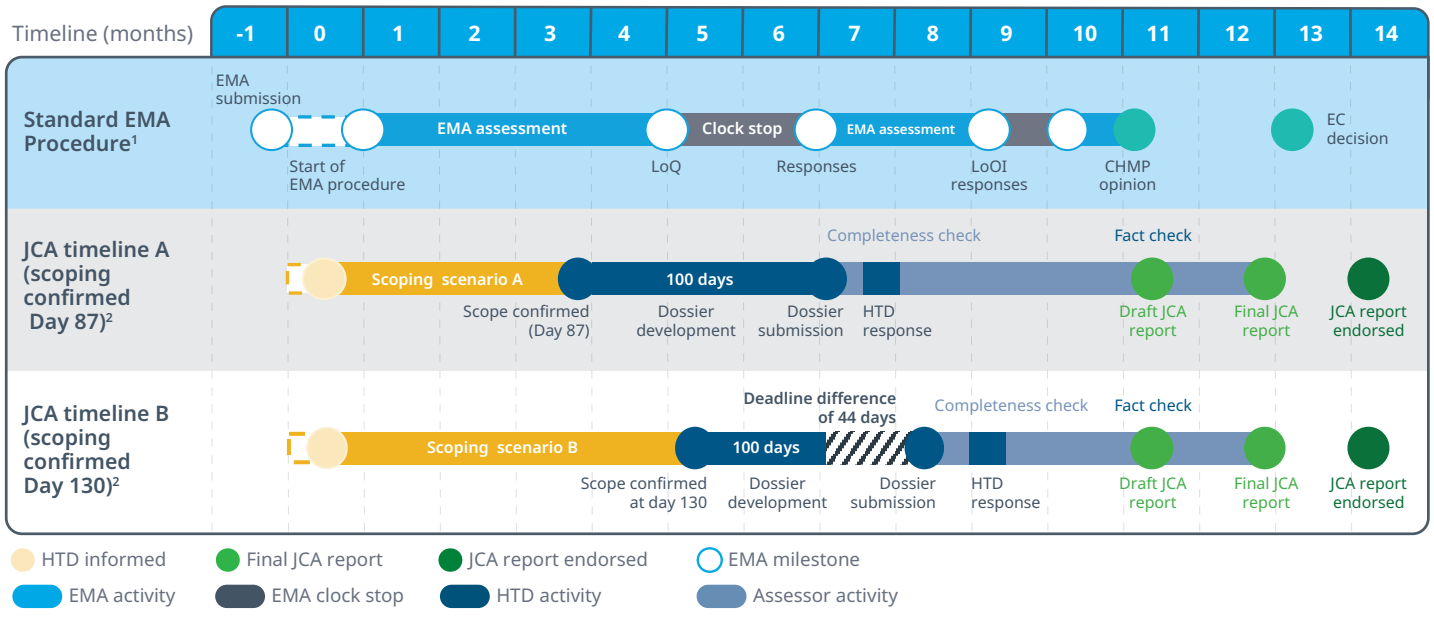
Under the EU HTAR, the JCA Subgroup must finalise the JCA assessment scope at the latest 10 days after the Committee for Medicinal Products for Human Use (CHMP) approval of the Day 120 List of questions, counting from the date of the validation of the EMA marketing authorisation (Day 1). From this point, the JCA dossier deadline is then up to 100 days or 60 days later depending on the EMA procedure (Figure 3).[1] Therefore, as both the timing of EMA Day 1 and the duration of the scoping is variable, the deadline for the JCA dossier submission can be difficult to predict. The JCA Subgroup has indicated that they will aim to share the scope around Day 87. However, based on our experience, this can shift by up to four weeks in either direction, which in turn affects the JCA dossier submission deadline, making it difficult to precisely predict. HTDs should therefore consider scenario planning and utilise the earliest point at which the scope could be received as the base-case to avoid time constraints with dossier finalisation. Additional variability stems from post-EMA submission communications on timelines and assessor assignments, reinforcing the need for proactive planning and flexibility.

DRIVE DELIVERY OF YOUR JCA DOSSIER THROUGH COLLABORATION

The JCA process requires a highly collaborative and well-coordinated internal effort, particularly during dossier development. Before initiating the process, it is essential to identify and engage all relevant stakeholders — such as extended market access teams (including local affiliates), regulatory, statistics, and others — and ensure they are aligned on roles and responsibilities throughout the JCA process.

This alignment becomes especially critical after scope confirmation and in the post-submission period, when rapid decision-making and agile dossier recalibration are needed under tight timelines.

Figure 3: JCA Timelines: Impact of scoping confirmation on dossier deadline



Notes: [1.] Timelines are estimated and depend on regulatory assumptions for EMA process e.g. stop clock durations etc.; average duration between submission (Day 0) and start of EMA procedure (Day 1) is 21 days but can take up to 30 days; [2.] Difference in delivery of final scope between timeline scenario A and B, results of 44 days for the dossier submission deadline for the same EMA procedure.

Abbreviations: CHMP – Committee for Medicinal Products for Human Use; D – Day; EC – European Commission; EMA – European Medicines Agency; HTD – Health Technology Developer; JCA – Joint Clinical Assessment; LoOI – List of Outstanding Issues; LoQ – List of Questions; NCE – New Chemical Entity.

Dossier development should begin approximately one year prior to the anticipated submission date (Figure 2). Given the compressed timelines post-scope confirmation, a full draft of the dossier and appendices should be completed and internally approved in advance. This pre-scope version should reflect the anticipated scope and align with both the JCA strategy and relevant sections of the EMA dossier.

The dossier template and accompanying guidance offer a structured format, including detailed methodological requirements and standardised tables for reporting results.[11–13] While adherence to the template is expected, minor adaptations may be appropriate to improve clarity and interpretation.

To ensure compliance with both the template and Methods and Procedural Guidance (MPG) guidance, using a checklist is recommended. Automation tools can support the creation of results tables — which are numerous and prone to human error — covering both direct and indirect evidence. This is particularly helpful in the post-scope period, when updates to SLR/ITC and potentially new data need to be incorporated with extremely tight timelines. These tools offer clear advantages in processing speed, flexibility for last minute updates, and improved accuracy and consistency of reported data. Appendices require comprehensive documentation of the evidence base and form a substantial part of the JCA dossier that must not be overlooked or left to the last minute.

The dossier template and accompanying guidance offer a structured format for reporting results; whilst adherence to the template is expected, minor adaptations may be appropriate to improve clarity and interpretation. Automation tools can also support with the creation of results tables.

Although the JCA dossier can draw from the Global Value Dossier (GVD), it cannot replace it — and vice versa. The GVD serves as an internal, centralised document presenting the core clinical and economic evidence and value narrative for global markets. It is more concise (~100–200 pages), whereas the JCA dossier is publicly available, defined by EU scope, and significantly more detailed (~600–1,000 pages depending on scope). To ensure strategic alignment, the JCA dossier's background section may be developed using early chapters of the GVD, although in practice, both are often developed in parallel. Once finalised, a chapter on the JCA scope and a summary of results can be added to the GVD to support broader affiliate communication (Figure 2).

Comparisons between the JCA dossier and Germany's Federal Joint Committee (G-BA) dossier are common, but the two differ significantly in scope and complexity. While some elements — such as the emphasis on PROs — reflect German influence, the JCA dossier demands broader expertise, particularly with evidence generation (ITCs) across multiple EU markets. The JCA dossier's strategic importance is underscored by its publication in English and its role in shaping EU-level access decisions, whereas AMNOG is often viewed as a 'data-heavy' national submission. Other differences include stricter ITC methodology requirements and a higher number of PICOs, making the JCA dossier more complex and resource-intensive than AMNOG.

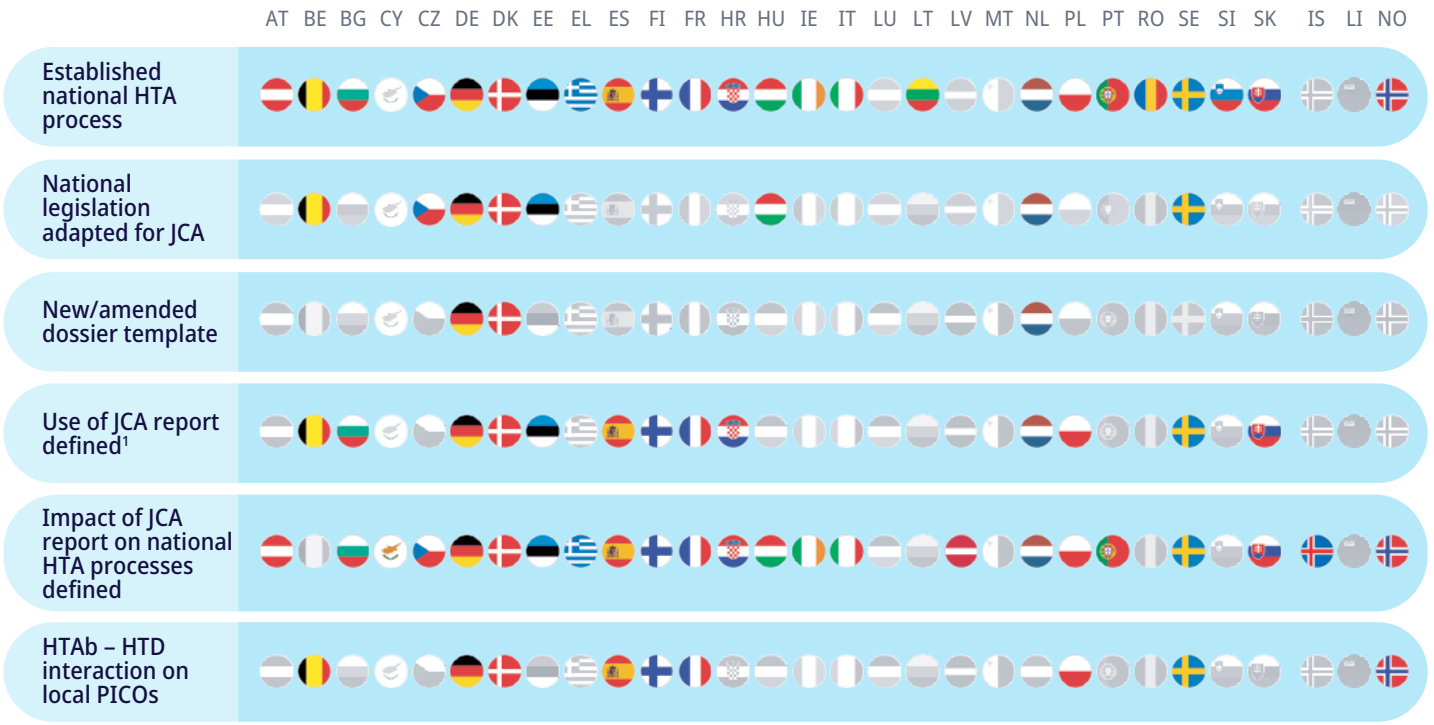
Following scope confirmation, the dossier should be refined to reflect any strategic realignment on PICOs, including additional analyses if required. Although the specifics of the completeness check remain unclear, the template requires a robust rationale for any PICOs not addressed. Automation tools are especially valuable at this stage, enabling swift updates to reflect additions or removals of specific PICOs.

Successful JCA dossier development hinges on early planning, cross-functional alignment, strategic integration with global materials, and the agile use of automation — supported by experienced HTA writers who can navigate complex methodological requirements and ensure clarity, consistency and compliance throughout.

KEEP ON TOP OF LOCAL IMPLEMENTATION

One of the most important but overlooked elements of the JCA process is the successful integration of the JCA report into local P&R processes. For most MS, integration of the EU HTAR remains ongoing, with only one-third of those with existing HTA legislation/frameworks having formally adapted national legislation to incorporate the EU HTAR. Of these, just three MS have published a new national dossier template (Figure 4).[14] This uncertainty has important implications for affiliates who prepare local submissions in parallel with JCA, making ongoing global-local strategic alignment critical as MS implement and adopt the new process, alongside legacy (pre-JCA) P&R pathways.

Figure 4: Local implementation of JCA



Source: Publicly available statements from individual MS HTAb.

Notes: [1] Within national decision-making processes/pricing & reimbursement/health economic assessments
Greyed out flags indicate that the Member States' position has not formally been defined yet (as of October 2025).

Abbreviations: HTA(b) – Health Technology Appraisal (body); HTD – Health Technology Developer; JCA – Joint Clinical Assessment; PICOs – Population, Intervention, Comparator, Outcomes.

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How to navigate JCA beyond the obvious

Whilst the need for organisational readiness, early evidence planning, and proactive JCA dossier development is well understood, there are some less-obvious considerations that can inadvertently impact a HTDs workload, timelines for JCA report publication, and downstream pricing and market access activities, creating hurdles or opportunities if considered strategically.

UNIFY REGULATORY AND ACCESS STRATEGIES

The plan and timeframes for submitting data cuts to regulators, as well as what data is reserved for specific MS P&R/HTA processes only, is made more complex in Europe with the arrival of JCA.

HTDs need to be mindful that the release of new clinical evidence at all stages of launch — before JCA dossier submission, during dossier evaluation, and after JCA report publication — has the potential to impact JCA timelines or even re-trigger the process after completion, with knock-on impacts on time to patient access. Scenario planning and close collaboration with medical and regulatory are essential to map-out the data submission strategy, including determining whether to submit an addendum to the JCA dossier or adjust the dossier strategy to avoid unintended re-initiation of the JCA process. Some key scenarios include:

Scenario 1: Late data cut submission to EMA

After EMA filing, the regulatory team decides to submit a later data cut for the registrational study to strengthen the marketing authorisation application, e.g., during a clock stop. The HTD must notify the HTA Secretariat and JCA assessors will request submission of the new data within five days, leading to a significant surge in effort to update the JCA dossier, or potentially extend the dossier submission deadline (on a case-by-case exceptional basis, to be requested by the HTD). It should also be noted that assessors are only obligated to include this data in the JCA report if it is received no later than seven days post-CHMP opinion. To avoid this, HTDs should proactively communicate any plans for updated data cuts, so both the HTD and assessors can agree on a timeline that avoids a delay to the JCA report but ensures the latest data is considered by the assessors.

Scenario 2: Mature data submitted to EMA years after original application

Mature data may become available well after the JCA report is published — for example, overall survival (OS) data submitted to the EMA for Summary of Product Characteristics updates two years later. HTA CG will determine on a case-by-case basis whether such updates warrant re-evaluation of the JCA in their annual workplan. To mitigate these risks, global market access teams must proactively align with regulatory counterparts to assess the timing and impact of emerging data.

CLOSE THE GLOBAL-LOCAL GAP TO REDUCE RISK

A key component of the EU HTAR that can be overlooked is the MS obligation to report back to JCA stakeholders how the JCA report was utilised and any additional data submitted locally as part of national HTA/P&R negotiations. This requires a much greater level of global/regional to local coordination on dossier submission strategy, illustrated in this scenario:

Scenario 3: PICO declared unfeasible for JCA, later submitted locally: An HTD does not address a PICO in the JCA on the basis of the absence of data. Post-JCA, this data is submitted as part of local P&R processes. This will be reported back to the HTA Secretariat, and assessors can decide to re-open the JCA process and require the HTD to resubmit the dossier.

HTDs will need to establish internal governance to track post-JCA-submission data changes and align cross-functionally with EU affiliates on evidence strategy to avoid conflicting submission strategies. By embedding such processes into EU HTA readiness plans, HTDs can also reduce the likelihood of re-triggering evaluations and protect downstream access timelines.

BE AWARE OF REMAINING PROCESS UNCERTAINTIES
Hands-on experience of JCA implementation has clarified most questions that were left unanswered in the implementing acts and guidelines, but some open areas remain that should be part of scenario planning:

Confidentiality appeal process: What information will be published in the JCA report and summary report? If a HTD raises a confidentiality appeal, will publication be deferred? How long does the appeal process take, and what are the implications for launch timelines and public perception?

Requirement for future JCA updates: Under what conditions will assessors request a future update to the JCA report? Will this be limited to confirmatory studies under conditional marketing authorisation, or could it apply to mature data such as OS?

PLAN FOR THE GLOBAL AUDIENCE OF THE JCA REPORT
EU HTA will have ripple effects far beyond EU market access, reshaping global strategies and stakeholder perceptions.[15] JCA reports — publicly available in English and based on internationally-recognised methodologies — will likely influence decisions in major markets such as the United States (US), Canada, Australia, Japan, and China, highlighting the importance of the JCA dossier from a global standpoint. HTDs should therefore see JCA as an opportunity to accelerate patient access, balanced against any international reference pricing implications. Capitalising on this opportunity will require strategic alignment with global affiliates to ensure the JCA report is interpreted and leveraged for a broader set of P&R processes.

These dynamics, combined with proposals under the upcoming EU General Pharmaceutical Legislation reform, may incentivise launching in all EU MS, challenging traditional sequencing.[4] JCA visibility will influence payer sentiment, guideline inclusion, and brand perception globally, requiring EU launch to be prioritised alongside FDA and other regulatory milestones. HTDs should proactively incorporate these broader strategic consequences — or "halo effects" — of JCA, which extend to global planning, commercial operations, and pricing governance in EU HTA readiness plans.

Are you ready to make the most of EU HTA?

JCA represents a pivotal shift towards harmonised clinical evidence evaluation across Europe. The first wave of EU JCA implementation has made one thing clear: a successful JCA submission demands strategic planning to start much earlier in an asset's lifecycle, ideally from Phase 1 onwards. HTDs must embed JCA readiness into every stage of asset development: Robust PICO simulations, cross-functional alignment, early evidence generation coordination and scenario planning are critical success factors to navigating compressed timelines and JCA scope. JCA success will be achieved by HTDs that plan early, foster efficient collaboration and proactively adapt to changing landscapes.

Whilst the HTA CG may make refinements to the process following the 2028 review, it is already clear that the JCA process will continue to evolve. Companies that proactively engage in the process and view the JCA as a strategic platform to demonstrate the value and patient relevance of their innovations — while translating operational learnings into strategic foresight — will not only meet regulatory requirements but also lead the way in accelerating equitable patient access and achieving sustainable commercial success across Europe and beyond.

JCA represents a pivotal shift towards harmonised clinical evidence evaluation across Europe. The first wave of EU JCA implementation has made one thing clear: a successful JCA submission demands strategic planning to start much earlier in an asset's lifecycle, ideally from Phase 1 onwards.

Glossary

ABBREVIATION		EXPLANATION
AI		Artificial Intelligence
ASEAN	Association of Southeast Asian Nations	A regional organisation that promotes economic, political, and security cooperation among Southeast Asian countries
ATMP	Advanced Therapy Medicinal Product	Medicines based on genes, tissues or cells
CG	Coordination Group	Body consisting of representatives from Member States' HTA authorities and bodies, responsible for overseeing the conduct of JCAs and other joint work within the scope of the HTAR
CHMP	Committee for Medicinal Products for Human Use	Scientific committee within EMA responsible for preparing opinions on medicines for human use, including their evaluation and approval
CoI	Conflict of Interest	A person's personal, financial, or professional interests could compromise — or appear to compromise—their judgment or actions in a given role
EC	European Commission	An executive branch of the European Union responsible for proposing legislation, implementing policies, and managing the EU's day-to-day operations
ECA	External comparator arm	A control group in a clinical study that use data from outside the trial (e.g., previous studies or real-world evidence) instead of enrolling participants directly
EMA	European Medicines Agency	Agency responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU
EU	European Union	Political and economic union of 27 European countries that collaborate on legislation, trade, health, and other policy areas
FDA	Food and Drug Administration	U.S. agency responsible for regulating and supervising the safety and efficacy of drugs, medical devices, and food products
GVD	Global Value Dossier	A comprehensive document compiling clinical, economic, and value-based evidence to support HTA submissions across multiple countries
G-BA	German Federal Joint Committee	
HRQoL		Health Related Quality of Life
HTA	Health Technology Assessment	Systematic evaluation of the properties, effects, and impacts of health technologies, used to inform policy and decision-making
HTAb	Health Technology Assessment body	Organisation or authority responsible for conducting HTAs and providing recommendations on health technologies
HTAR	HTA Regulation	Regulation (EU) 2021/2282 which was adopted in December 2021 and came into force in January 2022 that sets out the procedures and the rules for carrying out joint work and establishing a framework on HTA at EU-level
HTD	Health Technology Developer	The company developing the technology subject to JCA and submitting the dossier

ABBREVIATION		EXPLANATION
IEP	Integrated evidence plan	A strategic roadmap that aligns evidence generation activities across clinical, regulatory, and market access needs to support a product's development and lifecycle
ITC	Indirect Treatment Comparison	Analytical method used to compare treatments that have not been directly compared in head-to-head trials, using data from separate studies
JCA	Joint Clinical Assessment	Health technology assessments covering four domains which are transferable across MS: health problem and current use of the technology, description and technical characteristics of technology, safety and clinical effectiveness. Not JCAs do not include other domains including cost-effectiveness, budget impact or organisation aspects, and JCA does not include an appraisal of the evidence (i.e. it will not provide evidence rating or recommendations on added value / reimbursement)
JSC	Joint Scientific Consultation	Opportunity for Industry to consult with both the EMA and EUnetHTA 21 (from 2025 onward the HTA CG) to obtain feedback from regulators and HTA bodies in EU MS on their evidence generation plans
LoI	Letter of intent	A formal document indicating a company's commitment to participate in the JCA process and outlining its intent to submit relevant evidence for evaluation
KOL	Key Opinion Leader	Expert in a specific field whose views are highly respected and can influence clinical practice, policy, or market adoption
MENA	Middle East and North Africa	Geographic region encompassing countries
MID	Minimally important difference	The smallest change in score that patients perceive as meaningful in their health status
MPG	Methodological and Procedural Guidance	Document outlining the methods and processes to be followed in joint HTA work under the HTAR
MS	Member State	The 27 countries that form the political and economic European Union: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and Sweden
NMA	Network Meta-Analysis	Statistical method that compares multiple treatments across different studies by analysing both direct and indirect evidence
OS	Overall Survival	Measure of the length of time from either diagnosis or treatment start that patients are still alive
P&R	Pricing & Reimbursement	Policy and negotiation processes that determine the price of a medicine and whether it will be covered by healthcare systems
PAG	Patient Advocacy Group	Organisation that represents patients' interests, often involved in healthcare policy, research, and access to treatment
PICO(s)	Population, Intervention, Comparator(s), Outcomes	Framework used to define the scope of the JCA, by defining the patients or population(s) of interest, the intervention being assessed, the relevant comparator(s) against which the intervention under assessment should be compared and the outcomes of interest

ABBREVIATION		EXPLANATION
PRO(s)	Patient Reported Outcome(s)	Health outcomes directly reported by the patient, reflecting their experience with symptoms, treatment, or quality of life
QC	Quality Control	Process of ensuring that products or data meet defined standards and specifications through systematic checks and procedures
RWE	Real-World Evidence	Data on the use and outcomes of health interventions collected outside of controlled clinical trials, such as from electronic health records or registries
SAP	Statistical Analysis Plan	Detailed document outlining the statistical methods and procedures to be used in analysing clinical trial data
SLR	Systematic Literature Review	Structured review of published studies using predefined criteria to identify, evaluate, and summarise evidence
UK	United Kingdom	
US	United States	

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