WORKSHOP SYNOPSIS

Navigating National Decision Making Post Joint Clinical Assessment (JCA): Enablers, Barriers and the Path Forward

27th November 2025
Renaissance Amsterdam Schiphol Airport Hotel, The Netherlands

Utrecht University

CIRS Centre for Innovation in Regulatory Science

GRAPHIC SUMMARY

Navigating National Decision Making Post Joint Clinical Assessment

A CIRS-Utrecht University workshop explored different stakeholders' early experiences of Joint Clinical Assessment (JCA), considering practical implementation of JCA outputs into national decision making.

Key learnings and recommendations

PICO coordination

- Developers require earlier and broader PICO discussions, with clearer communication of national needs.
- JCA reports should transparently reflect uncertainties, such as evidence gaps for informing specific PICOs and potential lack of robust or recent clinical trials.

EMA-HTA collaboration

- EMA shares major clinical objections with JCA subgroups without narrative commentary.
- Operational and evidence level collaboration will continue to be strengthened through workshops, daily coordination with the HTA Secretariat, and follow up work with the HTA Coordination Group.

Capacity building

- Maturing HTA agencies continue to strengthen internal JCA capability by leveraging external expertise and receiving Commission technical support to update national HTA processes and methods.
- HTA Regulation training and capacity building for all stakeholders should be implemented and regularly updated.

Feedback loops

- Systematic evaluation of early JCA experiences is needed to refine methods, guidance, and address challenges.
- Trust and transparent communication between stakeholders are key.
- CIRS research will continue to quantify timelines from regulatory approval to patient access.
- The official HTA Regulation evaluation by the Commission is expected by January 2028.

Background

Since January 2025, national HTA agencies, industry and other stakeholders have been actively adapting to a new era of Joint Clinical Assessment (JCA) of medicines. The aim is to reduce duplication, improve consistency, and enhance efficiency across Member States. However, the successful integration of JCA outputs into national decision making remains an evolving challenge.

Building on insights from the CIRS JCA workshop in 2024, this workshop explored different stakeholders' experiences of early JCAs in oncology and advanced therapy medicinal products (ATMPs), looking deeper at the challenges of post-JCA transition at the national level.

In this co-hosted workshop, CIRS and Utrecht University brought together EU HTA agencies, industry, patient organisations, payers, academics, the European Medicines Agency (EMA) and the European Commission to examine how Member States are adapting their HTA processes to integrate JCA outputs into decision making.

The aim was to make recommendations on how to facilitate practical implementation of JCA outputs and improve the efficiency and effectiveness of JCA.

Workshop format

This multi-stakeholder workshop consisted of a series of plenary sessions (see programme), featuring presentations and panel discussions. In addition, there were three parallel breakout discussions, guided by questions prepared by CIRS. These focused on identifying actions to align national HTA processes with JCA and to strengthen stakeholder collaboration.

Key points from plenary sessions

Session 1: Input into the JCA process

HTA agency perspectives

All JCA procedures begin with Population, Intervention, Comparator, and Outcomes (PICO) scoping, which can potentially generate multiple PICOs from Member States. The short timeline for PICO preparation is a common challenge across HTA agencies, putting pressure on internal resources and external stakeholder engagement.

The Dutch HTA agency's experience as a JCA co-assessor demonstrated the complexity of consolidating the lowest number of PICOs while still reflecting Member State needs. Consolidation involves distinguishing between "need to have" and "nice to have" Member State requirements through bilateral discussions via the online HTA platform. When it comes to deciding whether to be involved as a JCA assessor or co-assessor, the Dutch agency has found that this decision must occur much earlier than its national agenda-setting process.

Maturing HTA agencies continue to build their internal capacity and capability to facilitate implementation of JCA, leveraging external expertise through networks and partnerships. The Greek and Slovenian agencies secured technical support from the European Commission to strengthen their national HTA systems by updating processes and methods. In addition, evaluators from the Slovakian agency have participated in internships at the German agency (IQWIG).

Legislation changes have been necessary in several Member States to facilitate implementation of the HTA Regulation. For example, Spain, Greece, Slovenia and Slovakia have implemented or are undergoing legislative reform to align their HTA frameworks with the EU HTAR.

Another challenge for some HTA agencies has been lack of awareness of JCA among national decision makers. In Slovakia, this has necessitated emphasis on JCA reports' significance for broader EU project involvement.

Company perspectives

The delivery of each JCA has considerable financial implications for companies, alongside significant staffing and analytical demands. Cross-functional collaboration, particularly involving local affiliates, is key. The compressed timeline from final scope receipt to submission means there is insufficient time for companies to complete the intensive preparatory work required, including systematic literature reviews and indirect comparisons. Therefore, companies must 'over-predict' PICOs, increasing workload, and be prepared to quickly pivot their evidence compilation strategy once the final scope is received. Timely sharing of national PICOs helps companies to prepare their national submissions more efficiently and effectively.

Utilisation patterns of JCA outputs so far suggest that not every Member State uses all the extensive analyses conducted, raising efficiency concerns. Nevertheless, the potential to accelerate decision making and reduce duplication offers significant long-term benefits for EU patient access.

Patient perspectives

Early experiences of patient involvement in JCA processes highlighted insufficient guidance to engage effectively and a lack of transparent feedback loops. While progress is being achieved through stakeholder collaboration, there must be systematic integration of patient input at relevant JCA stages from PICO definition to final JCA reports. Capacity building, transparent communication and monitoring progress are key.

Clinician perspectives

Continued collaboration between clinical societies, regulators and HTA agencies offers opportunities for improved evidence evaluation and decision-making processes. For example, The European Society of Medical Oncology (ESMO) developed the ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) to address concerns about differential cancer drug access across Europe and globally. It provides clinical perspective on evidence assessment, facilitating discussions about meaningful effect sizes whilst adapting to evolving regulatory and HTA landscapes.

Role of the EMA

While maintaining clear separation of regulatory and HTA remits, the European Medicines Agency (EMA) and HTA Secretariat closely collaborate at operational and evidence levels. Three key operational areas require ongoing attention: notification processes, timeline communication, and question sharing during centralised procedures. A joint position paper published in April 2025 provides recommendations to developers to address evidence challenges and manage uncertainties.

EMA shares major clinical objections with JCA subgroups without narrative or commentary whilst providing relevant information for PICO impact assessment. This process is expected to undergo review in 2026.

Planned initiatives include continued operational collaboration through regular workshops and daily coordination with the HTA Secretariat. Evidence-level collaboration will build on the April 2025 position paper and other initiatives, working with the HTA Coordination Group (CG) and Subgroups to enhance EU-level success in evidence development and evaluation.

Session 2: Output from the JCA process into national decision making

Company perspectives

A key challenge for industry lies in understanding how JCAs will be implemented at the national level. Company mapping exercises are assessing local HTA preparations such as legal reforms, dossier adaptation, visibility of PICOs, timelines, and inclusion of local stakeholders in JCA processes. The landscape remains highly fragmented, with countries at different preparation stages and varying levels of clarity regarding JCA integration into national frameworks.

Success of the JCA requires not only high-quality European procedures, dossiers, and outputs, but also clear, predictable national implementation pathways. Trust and transparent communication between industry and HTA agencies is key.

Agency perspectives

Various HTA agencies shared how they intend to integrate JCA outputs into their national decision-making processes. For example, in the Netherlands, the JCA report will be the starting point for national appraisal, and a shortened effectiveness report will be produced referencing the JCA PICO chapter. Belgium has mandated combining JCA outputs with national assessments in a single bilingual report, with consideration of added therapeutic value assessments from France and the Netherlands, when available. The Beneluxa partnership presents opportunities for informal exchange during JCA processes and enhanced collaboration in post-JCA national procedures.

Because JCA represents only a small component of Norway's overall assessment process—which includes comprehensive cost-utility analyses—it may be less impactful than in countries that conduct clinical benefit assessments, such as France and Germany. This variation stems from the different types of uncertainty each HTA system addresses and the extent to which JCA outputs align with national requirements.

For those countries that perform comprehensive cost-utility analyses, the limitations of JCA outputs relative to comprehensive economic evaluations may raise questions about resource allocation and opportunity costs. Success will depend on developing complementary processes that maximise JCA value whilst acknowledging the substantial additional work required at national levels.

There are concerns that JCA reports could become outdated for countries where market launches can be delayed for years following EMA approval, such as in Eastern Europe. Furthermore, in rapidly moving therapeutic areas like oncology, national HTA processes may require the latest clinical data, potentially limiting the relevance of JCA reports.

Session 3: Ensuring a future proof HTA landscape in Europe and beyond

In the final session of the workshop, a multi-stakeholder panel reflected on the transformative nature of the HTA Regulation, positioning it within broader healthcare policy evolution in Europe and worldwide.

The current EU landscape presents significant change and opportunity through multiple regulatory initiatives including the pharmaceutical reform, targeted evaluation of the Medical Devices Regulation, and Critical Medicines Act. The EU HTA Regulation has elevated HTA to higher prominence within the wider healthcare ecosystem, and JCA should be viewed as part of addressing healthcare sustainability challenges. Building trust and learning through experience are essential. Official evaluation of the HTA Regulation will be shared by the European Commission by January 2028.

For companies, JCA requires significant investment and unprecedented coordination for global market access, demanding new approaches to evidence generation, submission preparation, and stakeholder engagement across multiple jurisdictions simultaneously. To ensure success, approaches to evidence evaluation must be flexible, and company-agency interactions during JCA need to shift from information exchange to active dialogue.

Consideration is being given for how JCA outputs can be leveraged beyond the EU. For example, the UK National Institute for Health and Care Excellence (NICE) envisages the JCA report (if available) being a key literature component in its evaluations. International collaboration remains key to addressing HTA methodological issues, beyond JCA.

European payers recognise the potential benefits of JCA but remain focused on maintaining national decision-making capabilities and ensuring healthcare system sustainability. The intense pressure on public budgets, combined with competing policy priorities and political pressures, creates an environment where HTA's future depends on demonstrating clear value in guiding wise investment decisions.

Recommendations from breakout discussions

Navigating national HTA processes in the context of JCA

- The HTA CG and industry should work together to conduct practical workshops sharing learnings of the JCA process and define future training for industry.
  - Questions remain about commercial sensitivity limitations and implementation timing whilst procedures continue.
- Industry should implement policy changes internally to enhance processes and collaboration, such as improving communication between regulatory and HTA departments and leveraging expertise from national affiliates.
- CIRS should explore the impact of JCA at the EU level, globally, and on clinical guidelines.
- Research is needed to evaluate whether the availability of national PICOs is timely enough for national submissions.

Methodological alignment between JCA and national processes

- HTA agencies could work together more closely to align and enhance guidance on interpreting evidence from subpopulations or small patient populations.
- HTA agencies should consider how to enhance communication on PICOs. An option could be to broaden the remit of PICO explanation meetings and have them earlier in the process.
- HTA agencies should aim for the published JCA report to provide sufficient detail on the uncertainties, such as evidence gaps for informing specific PICOs and the potential lack of robust or recent clinical trials.
- Companies and HTA agencies should collect lived experiences of using the JCA guidance issued by the HTA CG – are all stakeholders using the same language and interpretation?
- All stakeholders should reflect on JCA methodological learnings after the first four or five JCAs have been completed.

Stakeholder collaboration for effective JCA implementation

- The European Commission and HTA Stakeholder Network should implement and continuously update training and capacity building activities on the HTA Regulation for all stakeholders.
- CIRS should conduct research into how best to measure timelines from regulatory approval to patient access (e.g. prescriptions), so that the impact of JCA and national decision making can be quantified.
- Research is needed to track the evolution of human resource available in national HTA agencies for JCA and Joint Scientific Consultation (JSC) activities.

Workshop programme

Session 1: Input into the JCA process - Learnings from national HTA agencies and companies

Chair: Prof Wim Goettsch, Professor of HTA, Utrecht University

Lisette Vernooij, Senior Advisor, European Joint Clinical Assessments of Medicinal Products, National Health Care Institute, The Netherlands
Dr Tomas Tesar, Director, National Institute for Value and Technologies in Healthcare (NIHO), Slovakia
Dr Flora Bacopoulou, Head, HTA Committee, Ministry of Health, Greece
James Ryan, Director, Global HTA Policy, HTA and Modelling Science, AstraZeneca, UK
Dr Michael Berntgen, Head of Scientific Evidence Generation Department, EMA
Belén Torres Garrido, Therapeutic Positioning Report and Health Technology Assessment Area, Medicines for Human Use Department, Spanish Agency of Medicines and Medical Products (AEMPS), Spain
Antonella Cardone, CEO, Cancer Patients Europe, Belgium
Prof Elisabeth de Vries, Professor of Medical Oncology, University Medical Center Groningen, The Netherlands

Session 2: Output from JCA process into national decision making - Processes, methodologies and strategic considerations

Chair: Prof Wim Goettsch, Professor of HTA, Utrecht University

Francine Brinkhuis, PhD Candidate, Utrecht University
Eelko Den Breejen, Senior Director, Global Access & Value, Head of Oncology Portfolio & Market Engagement Team, Pfizer, The Netherlands
Katarina Beravs Bervar, HTA Unit, Ministry of Health, Slovenia
Dr Anja Schiel, Senior Adviser; Lead Methodologist in Regulatory and Pharmacoeconomic Statistics, Norwegian Medical Products Agency (NOMA), Norway
Dr Marc van de Casteele, Chair of Beneluxa Domain Task Force HTA, and Coordinator HTA Pharmaceuticals, Belgian Health Care Institute (RIZIV-INAMI)

Session 3: Breakout discussions and the future HTA landscape

Chair: Dr Brian O'Rourke, Chair, CIRS HTA Steering Committee

Breakout discussions

A) Navigating national HTA processes in the context of JCA
Chair: Niklas Hedberg, Chief Pharmacist, TLV, Sweden
Rapporteur: Anne Willemsen, Co-Chair of JCA Subgroup, and Senior Advisor, National Health Care Institute, The Netherlands

B) Methodological alignment between JCA and national processes
Chair: Dr Christine Leopold, Assistant Professor of Drug Regulatory Science, Utrecht University
Rapporteur: Dr Antonia Morga, Head, New Product Planning, Global Value Evidence, Medical Affairs, Astellas Europe

C) Stakeholder collaboration for effective JCA implementation
Chair: François Houyez, Director of Treatment Information and Access, EURORDIS-Rare Diseases Europe
Rapporteur: Dr Peter Pemberton-Ross, Head, HE & HTA Strategy, Biogen, Switzerland

Panel speakers

Dr Nick Crabb, Chief Scientific Officer, National Institute for Health and Care Excellence (NICE), UK
Shane Kavanagh, Vice President, Health Economics and Real-World Evidence, Johnson & Johnson, Belgium
Maya Matthews, Head of Unit Health Technology Assessment, European Commission
Yannis Natsis, Director, European Social Insurance Platform (ESIP), and European Health Forum Gastein Board member

About CIRS

The Centre for Innovation in Regulatory Science is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. CIRS provides an international forum for industry, regulators, HTA bodies and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, and grants.

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