What is the Joint Clinical Assessment (JCA)?

The JCA is a mandatory process introduced by the European Union (EU) Health Technology Assessment (HTA) Regulation - it looks at how effective and safe a new medicine is compared to existing treatments used across Europe.

The goal of a JCA is to ultimately support faster, more equitable access to new medicines across Europe.

Instead of each Member State doing their clinical assessment separately, one joint assessment is done at an EU-level with input from all 27 Member States.

What You Need to Know

JCAs are conducted by a new EU body called the EU HTA Coordination Group (HTACG).

Each JCA will be led by two national HTA agencies from the JCA Subgroup (part of the HTACG), acting as assessor and co-assessor.

The JCA report is not binding - however, national authorities must give it "due consideration" when making their national decisions.

Patient experts and patient organizations are key stakeholders who will be consulted during the JCA process.

The JCA does not involve decisions about a medicine's pricing or reimbursement – these decisions still take place at a national level.

Any reference to a 'patient expert' in the timeline below refers to the individual(s) selected to participate in the JCA.

The Stakeholder Network

A network of EU-level organizations — including patient organizations — that support the implementation of the Regulation. These members may be asked to provide input on the disease and therapeutic area for a JCA.

Interested in JCA participation? Reach out to your EU-level patient organization to get involved.

How can patient experts and patient organizations participate in the JCA process?

Patient experts can be directly involved in JCAs, contributing insights based on their own experiences or representing the collective views of their patient community. This helps ensure the patient point of view is reflected in the assessment.

EU-level patient organizations may contribute to JCAs through their participation in the Stakeholder Network, which is consulted at key stages of the process. Their input may cover aspects such as the disease context, outcomes important to patients, and the acceptability of the health technology.

National patient organizations usually do not take part directly in the JCA, which is managed at the EU level. However, they can support patient identification and early scoping by consulting with their EU-level counterparts, and may be involved in national-level scoping activities. Their main role is in the national decisions that follow the JCA.

Patient organizations play a key role in finding and nominating patient experts with relevant lived experience.

They are also key in **providing training and support to prepare patient experts** for participation in the JCA process.

JCA Timeline

KEY

- Indicates steps where patient experts are involved
- EU ORG — involvement of European-level patient groups
- NATIONAL ORG — involvement of country-level patient groups

1. Pre-Submission

- Around 7 months before a medicine's application for EU marketing authorization, the company developing the medicine, referred to as the Health Technology Developer (HTD), notifies the European Medicines Agency (EMA) and the HTACG.

2. Start of JCA process at EMA submission

- The JCA officially begins.
- Two national EU HTA bodies are appointed to lead the assessment – one as the assessor and the other as the co-assessor.

EU ORG

- **A unit called the HTA Secretariat creates a shortlist of patient and clinical experts by consulting:**
  - **Patient organizations in the Stakeholder Network**
  - **The EMA**
  - **The European Reference Networks**
  - **Orphanet**
  - **National contact point for clinical trials**
- **A conflict-of-interest check is done to check if these experts are eligible to participate.**
- **The JCA Subgroup then selects the patient experts who will take part in the JCA.**
  - **Priority is given to experts who have relevant expertise across the Member States in the therapeutic area being investigated.**

Scroll down to read more about the Stakeholder Network!

3. Before Scoping Begins

- The scoping process defines the evidence required for the JCA of a medicine.

EU ORG

- **Patient organizations in the Stakeholder Network may be consulted before scoping begins to provide general input on the disease area and treatment landscape (via a standardized questionnaire, completed in written format).**

NATIONAL ORG

- **Stakeholder Network members may consult local patient organizations, but this is neither required nor certain.**
- Their insights are used to support the development of the assessment scope proposal.

4. Assessment Scope Proposal & PICO Survey

- **Selected patient experts may be asked by JCA assessors to provide insight on the indication under assessment (via a standardized questionnaire, completed in written format).**
- **They may also be asked follow-up questions by the assessors to help provide context for parts of the scope proposal.**
- Their input is used to support the development of the assessment scope proposal.
- The PICO survey is then sent to all 27 EU Member States to complete.

NATIONAL ORG

- National-level patient involvement may occur via local HTA procedures *(not JCA-managed)*.

5. Assessment Scope Finalization

- PICO responses are consolidated into a draft scope.
- The consolidated scope proposal is reviewed by the JCA Subgroup.
- **The consolidation scope proposal will be shared with selected patient experts who will have the opportunity to provide input.**
- **They may also be invited to a dedicated part of a scope consolidation meeting.**
- The scope is finalized.

6. Dossier Preparation by HTD

- The HTD uses the PICO scope to prepare the JCA dossier, which includes all the relevant clinical evidence about the medicine.
- The dossier must be submitted at least **45 days** before Committee for Medicinal Products for Human Use (CHMP) opinion.

45

7. Development of Draft JCA Report & Additional Questions

- The co-assessors develop a draft report and share this with the JCA Subgroup for their feedback.
- **During this time, the selected patient experts may be asked to clarify their earlier input or be asked follow-up questions as the assessors draft the report. All of their responses must be provided in a written format.**

8. Revision of JCA Report

- The co-assessors share the draft report with the JCA Subgroup for feedback.
- **A revised report and summary report must be shared with the patient and clinical experts who contributed to give them the opportunity to provide input (this is mandatory)!**

9. Finalization of JCA Report

- The JCA Subgroup has a discussion meeting to review feedback from the Member States, as well as from the patient and clinical experts.
  - **Patient experts might be invited to join a specific part of this meeting.**
- The final JCA report is prepared.
- The HTACG must endorse the JCA report by consensus at the latest **30 days** after regulatory approval of the medicine in the EU.

30

10. Publication after EU regulatory approval

- Following endorsement, the report is submitted to the European Commission for a procedural review, which can take up to **10 working days**. If approved, the JCA report is published in English.
- The report highlights the strengths and gaps in the evidence for the medicine but it does not include any recommendation on whether the medicine should be reimbursed.

11. National HTA Submissions

- The process moves to the national level.
- National HTA bodies will use the JCA report as part of their own assessment about pricing and reimbursement of the medicine.
- Key changes to national submissions include:
  - HTDs must not duplicate clinical data already submitted in the JCA.
  - They can submit supplementary clinical evidence if needed.
  - All economic and pricing data included here.

NATIONAL ORG

The opportunity for patient organizations to contribute to these national assessments varies by country.

Explore the procedural guidance:

- Joint Clinical Assessments
- Joint Scientific Assessments

Explore useful training materials:

- HTACG webinar – insights for patients and clinical experts
- EUCAPA training program – focusing on the Regulation and supporting patient experts involved in JCAs and JSCs

This is a high-level, non-exhaustive summary. The information is sourced and controlled by third parties.

Glossary:

- **Assessor/Co-Assessor:** two national HTA agencies from the JCA Subgroup appointed to lead the JCA assessment.
- **Health Technology Developer (HTD):** the pharmaceutical company submitting the medicine or technology for assessment.
- **Health Technology Assessment (HTA):** a multidisciplinary process that evaluates a health technology, such as a medicine, device or procedure, to inform healthcare decision-making.
- **HTA Coordination Group (HTACG):** made up of 27 EU Member States, the HTACG is responsible for conducting Joint Clinical Assessments, Joint Scientific Consultations and horizon scanning.
- **HTA Secretariat:** a unit within the European Commission that supports and coordinates the EU HTA procedures. They help to manage exchange of information between the HTD and JCA Subgroup/assessors.
- **JCA Subgroup:** a subgroup of the HTACG who oversee the conduct of JCAs.
- **Member States:** the 27 countries who are part of the European Union.
- **PICO:** used during scoping to help define the policy or decision question the assessment is trying to answer, and to guide what evidence is needed. It's defined by:
  - **P**opulation – who is eligible for the drug?
  - **I**ntervention – what treatment or technology is being assessed?
  - **C**omparator(s) – what are the alternatives?
  - **O**utcomes – what endpoints matter?

Sources:

1. https://health.ec.europa.eu/publications/procedural-guidance-jca-medicinal-products_en
2. https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment_en

This material has been developed in collaboration with Cancer Patients Europe and Digestive Cancers Europe. Funded by Takeda Pharmaceuticals.

C-ANPROM/EUC/NON/0036 | August 2025