

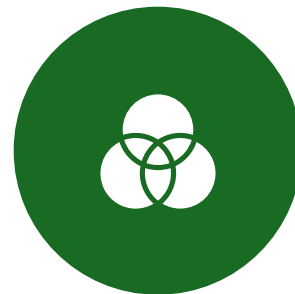
Ataxia Patient Conference: 28 October 2025

# JCA Framework and Process

# EU Joint Clinical Assessment – Overview



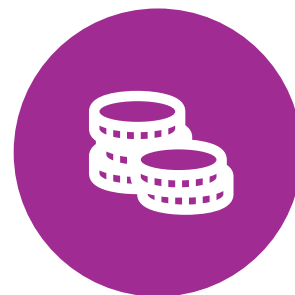
Regulation (EU) 2021/2282, implemented Jan 2025 for oncology and ATMPs.



Harmonises clinical evidence evaluation across the EU.



Conducted by HTA Coordination Group (HTACG).



Focus: comparative clinical evidence (not economics).

# JCA Process Flow

Triggered upon EMA marketing authorisation submission, with developers submitting Summaries of Product Characteristics and clinical overviews to HTACG.

Assessor and co-assessor appointed → definition of PICO framework (Population, Intervention, Comparator, Outcomes).

Draft and final reports produced using the HTA IT platform to ensure secure information exchange.

Timeline aligned with EMA processes for efficiency and transparency.

# Implementation Timeline

Oncology and ATMPs.

**2025**

All new centrally authorised medicines.

**2030**

**2028**

Orphan drugs.

# How the JCA Works



a. Scoping (defining PICOs).



b. Dossier submission (parallel to EMA regulatory review).



c. Assessment and consultation.



d. Publication of final JCA report.



Identify governing bodies: Coordination Group, assessors, EMA collaboration.

# Stakeholder Implications

# Intended Impact on Stakeholders

01

For companies:  
early alignment  
with HTA evidence  
needs; mandatory  
EU dossier. PICO

02

For HTA bodies:  
shared clinical  
base supporting  
national  
appraisals.

03

For patients: faster  
and more  
consistent access  
across EU Member  
States.

# Embedding Patients in JCAs

Patients and caregivers recognised as key stakeholders under EU HTA Regulation.

Involvement spans the Joint Scientific Consultation (JSC) and JCA stages:

Early input on unmet needs and desired outcomes during JSC.

Contributions to scoping and draft JCA reports (PICO relevance, real-world perspectives).

Mechanisms for input include Stakeholder Network participation, written contributions, and plain-language summaries.

# Impact & Future of Patient Participation

**Unified Framework:**  
Establishes EU-level standards for consistent participation.

**Empowerment:** Enhances rare disease and oncology patient advocacy influence.

**Representation Equity:**  
Reduces Member State disparities in patient voice inclusion.

**Transparency:** Improves legitimacy through multilingual feedback and open summaries.

**Access Impact:** Anticipated acceleration of time-to-patient access as engagement evolves.

**Future Outlook:** Patients expected to shift from observers to co-creators of evidence; ongoing capacity-building initiatives aim to position Europe as a global model for participatory HTA.

# EUHTA Conflict of Interest Principles

- All representatives and experts involved in EU JCA must submit a Declarations of Interest and CV before participation
- COIs encompass financial or other direct/indirect interests in health technology developers in both current and recent past roles, consultancy, strategic advisory capacity, financial holdings, academic research, and immediate family interests.
- DOIs are reviewed by the European Commission, enforcing exclusions where interests are incompatible with participating, including for specific roles, products, or therapeutic areas.

# Derogations

- Independent experts in rare disease HTA are scarce due to a small specialist pool and unavoidable conflicts of interest.
- Allowing derogations includes vital clinical and patient expertise, enhancing scientific quality and HTA relevance.
- Transparent procedures inform stakeholders of conflicts, supporting public trust and dialogue on access.
- This approach balances independence with limited expert availability, adapting HTA to rare disease needs.

# Key Challenges and Future Outlook

Challenges: varying national cost and value frameworks; PICO alignment issues.

Outlook: Joint Scientific Consultations, early dialogue, and cross-country learning.

Strategic message: importance of collaboration and adaptive evidence planning.



This Photo by Unknown Author is licensed under [CC BY-SA](https://creativecommons.org/licenses/by-sa/4.0/)