Early Experience with the European Union Joint Clinical Assessment (EU JCA): Implications for Oncology Products

HTA57

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BACKGROUND

Context: The European Union Joint Clinical Assessment (EU JCA), implemented under Regulation (EU) 2021/2282 on Health Technology Assessment (HTA), started in January 2025 for oncology and advanced therapy medicinal products (ATMPs) (**Figure 1**).[1, 2]

Why oncology: use of surrogate endpoints, single-arm trials, orphan designation and accelerated pathways make oncology prone to greater scrutiny.[3-6]

What changes: centralized multi-country assessment of population, intervention, comparator, and outcomes, to reduce duplication and improve consistency, increases evidence scrutiny (**Figure 2**).[7]

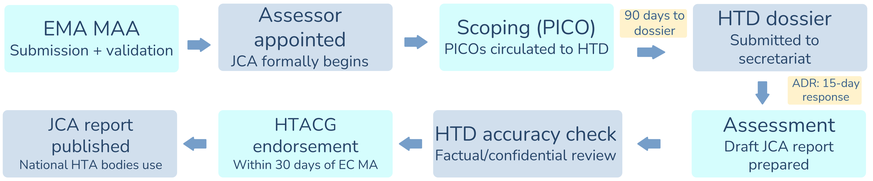
Significance: The new framework increases the need for early evidence planning.

OBJECTIVES

1. Review early JCAs conducted since January 2025 for oncology products
2. Assess how oncology products are evaluated under the new JCA framework
3. Identify key themes and methodological considerations emerging

The initial EU JCA experience (January 2025) reveals greater evidence scrutiny for oncology products: 60% carry orphan designation, 80% rely on RCTs, yet variability in PICO definitions and comparator selection, especially in 2L orphan settings, underscores the urgent need for early HTA alignment and robust evidence planning by manufacturers.

JCA process



EMA review runs in parallel. Marketing authorization decision triggers final HTACG deadline

Figure 2. EU JCA process

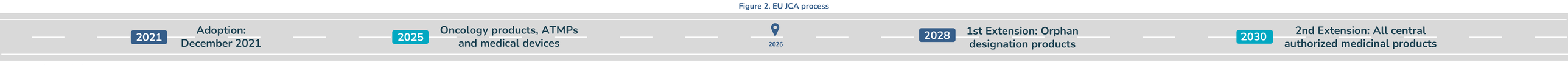
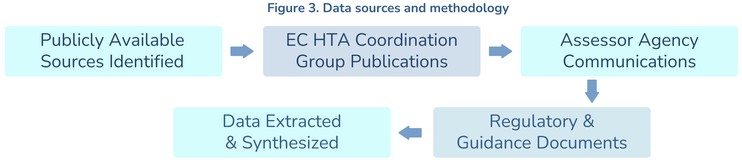


Figure 1. EU JCA timeline

METHODS

Figure 3. Data sources and methodology



- ✓ Public registry of ongoing EU JCAs searched to December 2025 (**Figure 3**)
- ✓ Included oncology EU JCAs initiated from January 2025
- ✓ Extracted domains: identification, process, evidence, regulatory anchors; cross-checked with European Medicines Agency (EMA) and US Food and Drug Administration (FDA) sources (**Figure 4**)

Figure 4. Extraction framework

Focus areas	Identification, JCA process, Evidence characteristics, Regulatory anchors		
Identification	Product name, therapeutic indication, line of therapy, substance type, orphan designation status	Evidence Characteristics	Clinical trial identifier(s), study design, sample size, endpoints, topline efficacy, safety results, use of indirect comparisons or external control arms
JCA Process	EMA MAA validation date, JCA status, assessor agency, co-assessor agency	Regulatory Anchors	EMA approval status, FDA approval status, utilization of accelerated or conditional pathways

Overview of results from the review

Figure 5. Study Design & Primary Endpoints Distribution

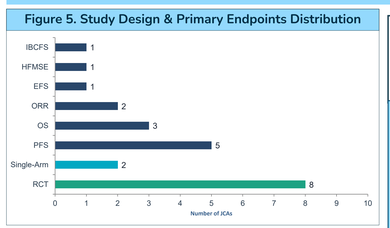
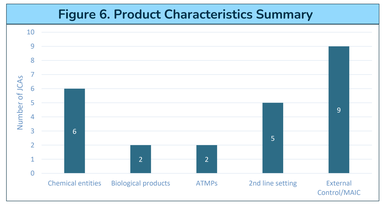


Figure 6. Product Characteristics Summary



Map of Assessor and Co-assessor agencies

Figure 7. Map of the associated countries of the agencies

Abbreviations: 2L: Second-Line; ADR: Adverse Drug Reaction; ATMP: Advanced Therapy Medicinal Products; CNS: Central Nervous System; EC MA: European Commission Marketing Authorization; EFS: Event-Free Survival; EMA: European Medicines Agency ; EU: European Union; FDA: Food and Drug Administration; HFMSE: Hammersmith Functional Motor Scale-Expanded; HTA: Health Technology Assessment; HTACG: Health Technology member state Coordination Group; HTD: Health Technology Developer; IBCFS: Invasive Breast Cancer-Free Survival; JCA: Joint Clinical Assessment; MAA: Marketing Authorization Application; ORR: Objective Response Rate; OS: Overall Survival; MAIC: Matching-Adjusted Indirect Comparison; PFS: Progression-Free Survival; PICO: Population, Intervention, Comparator, Outcome; RCT: Randomized Controlled Trial; SCLC: Small Cell Lung Cancer; SMA: Spinal Muscular Atrophy.

RESULTS

JCAs by Cancer Type (n=10 JCAs reviewed. 9 ongoing, 1 withdrawn)

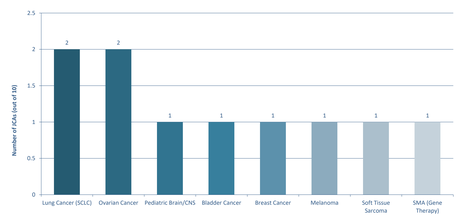


Figure 8. JCAs by Cancer Type

60% (n = 6) Orphan Designation

80% (n = 8) RCT Evidence

50% (n = 5) First-Line

Figure 9. Key findings

- ✓ 10 EU JCAs were identified by mid-December 2025 (1 withdrawn, 9 ongoing) (**Figure 8**)
- ✓ 60% (n = 6) had orphan designation and 50% (n = 5) were in first-line setting (**Figure 9**).
- ✓ Evidence was mainly from randomized controlled trials (80%) (n = 8); 20% (n = 2) used single-arm trials. (**Figure 5, 9**)
- ✓ Comparator selection for second-line orphan products showed greater heterogeneity across assessments.

DISCUSSION

- ✓ Early EU JCA experience shows that oncology evidence packages often do not align easily with expectations for direct comparative evidence. (**Figure 5**)
- ✓ Indirect treatment comparisons and external controls are being used, but their suitability across multi-country Population, Intervention, Comparator, Outcome (PICO) requirements remains unresolved.
- ✓ Orphan-designated and accelerated products face difficulty because evidence uncertainty is high at Marketing Authorization Application (MAA), while JCA timelines run in parallel with EMA review. (**Figure 2**)
- ✓ Differences in assessor participation may affect future consistency across assessments. (**Figure 7**)

Implications for manufacturers: These findings reinforce the need for earlier comparator planning and closer regulatory-HTA alignment for future oncology and non-oncology submissions.

Reference

1. EU Regulation 2021/2282 on Health Technology Assessment. *Off J EU*. 2021
2. European Commission. JCA Scope & Timeline. ec.europa.eu/health.2025.
3. EUnetHTA21. JCA Methodological Guidelines: Direct Comparisons. v1.0.2022
4. Julian E, et al. *Health Econ Rev*. 2022;12(1):30. (PMC9161501)*
5. Toumi M, et al. *J Mark Access Health Policy*.2022; 10(1):2055567*
6. Michaeli DT, et al. *Eur J Health Econ*. 2024;25(6):979-997*
7. EUnetHTA21. JCA Procedural Guidance. 2022.
8. Bouvy JC, et al. *Pharmacoeconomics*. 2023;41:139-148
9. Horgan D, et al. *Public Health Genomics*. 2023;26:1-10.
10. European Commission. Ongoing JCA List. Health.ec.europa.eu. 2025
11. European Commission. (n.d.). Joint clinical assessments. health.ec.europa.eu/health-technology-assessment
12. European Medicines Agency. (n.d.). Amtagvi: Overview. ema.europa.eu
13. NCBI. Article on joint clinical assessment. pmc.ncbi.nlm.nih.gov/articles/PMC12551043/

*Note: References of studies included in the review

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