EU JOINT CLINICAL ASSESSMENT IN ONCOLOGY AND ATMPs: UPDATED EVIDENCE FROM THE FIRST 18 MONTHS OF IMPLEMENTATION

HPR21

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> **18 EU JCAs initiated in 18 months, but only one report published; and the evidence base is shifting: single-arm designs, surrogate endpoints, and indirect comparisons now dominate the pipeline.**

1 BACKGROUND

Since 12 January 2025, the European Union (**EU**) Health Technology Assessment (**HTA**) **Regulation** has required **Joint Clinical Assessments (JCAs)** for new oncology medicines and advanced therapy medicinal products (ATMPs).

- Each JCA assesses relative clinical effectiveness against population, intervention, comparator, outcome (PICOs) consolidated across Member States.
- Pricing and reimbursement stay national, and scope widens to orphan medicines in 2028 and all new medicines in 2030.[1]

Evidence gap: Published evidence on how JCAs operate in practice is limited, and our prior analysis ended in December 2025.[4]

2 OBJECTIVES

We updated our review of EU JCAs for oncology products, while also cataloguing ATMPs for context and completeness, extending coverage from **December 2025** to **June 2026**, with three aims.

1 COVERAGE
Identify every JCA initiated or completed to mid-June 2026.

2 CHARACTERISE
Describe the product, process, evidence and regulatory features of each JCA.

3 TRENDS
Compare with the prior analysis to identify emerging trends.

3 METHODS

Publicly available sources were searched to mid-June 2026, including European Commission HTA Coordination Group publications, assessor agency communications, regulatory documents, and HTA methodology and guidance documents.[2] Data were extracted across four domains and compared against our prior analysis (cut-off: December 2025).[4] (**Figure 1**)

Figure 1. EU JCA review process

SEARCH Public sources searched to mid-June 2026 → **IDENTIFY** Oncology and ATMP JCAs initiated since Jan 2025 → **EXTRACT** Structured tracker across four data domains → **COMPARE** Findings set against the prior analysis (Dec 2025) → **SYNTHESISE** Emerging trends and key themes

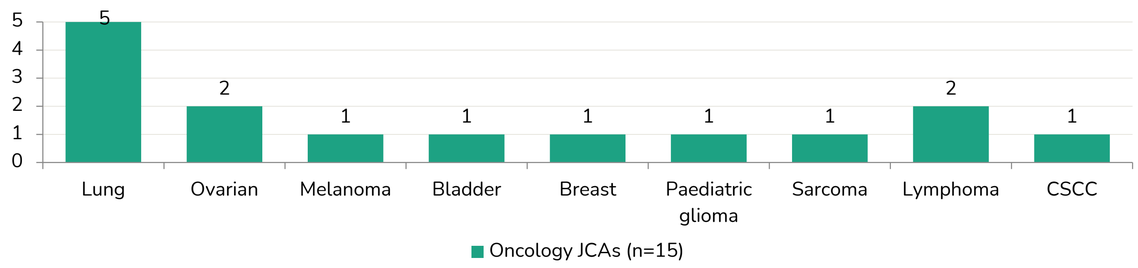
The tracker is refreshed at each data cut; this update extends the December 2025 analysis to mid-June 2026.

- **Product:** substance type, orphan designation, indication and line of therapy.
- **Scope:** Oncology was the primary focus; ATMP status was captured as a contextual product characteristic.
- **JCA process:** status, assessor and co-assessor agencies, and key procedural dates.
- **Evidence characteristics:** pivotal study design, primary endpoints, and proposed indirect comparisons or external controls.
- **Regulatory anchors:** European Medicines Agency (EMA) and Food and Drug Administration (FDA) status and accelerated or conditional pathways.

4 RESULTS

As of mid-June 2026, **18 JCAs** were identified (15 ongoing, 1 completed, 1 discontinued, 1 withdrawn), an **80% increase** from the prior analysis (n=10). Most addressed oncology indications (n=15), (**Figure 2**) 3 were non-oncology (ATMPs) and half carried orphan designation (n=9). Germany's IQWiG served as lead assessor for 1/3rd of JCAs.

Figure 2. Summary of JCAs by cancer type



Lung cancer was the most frequently assessed oncology indication.

Primary endpoints included Progression-Free Survival (PFS) (44%), Objective Response Rate (ORR) (27%) and Overall Survival (OS)(17%), with reliance on **surrogate endpoints** more frequent in single-arm submissions. (**Table 1**)

- **First report:** the first JCA report was published in June 2026, for tovorafenib in paediatric low-grade glioma.[3]

Table 1. JCA evidence characteristics

Evidence characteristic (N=18)	n (%)
Randomised controlled trial	**11 (61%)**
Single-arm study	**7 (39%)**
First-line positioning	**9 (50%)**
Chemical / biological / ATMP	**9 / 4 / 5**
Primary endpoint (not mutually exclusive): PFS / ORR / OS	**8 / 5 / 3**
Orphan designation	**9 (50%)**
Indirect comparison or external control	**14 (78%)**

Randomised evidence dominated, but 39% of JCAs relied on single-arm studies.

Key themes included **variability in comparator selection** (n=11), strict application of PICO criteria across states, and growing expectations for external control data and Real-World Evidence (RWE).

- **Update:** Four reports are now available; however, this poster covers only the first report because the remaining reports were published after the mid-June 2026 data cut-off.

5 DISCUSSION

In six months the JCA pipeline grew from 10 to 18 assessments, yet only one report is public. Early assessments already show the EU process **reshaping evidence expectations** particularly for oncology products.

- Single-arm studies and response-based endpoints sit uneasily with JCA's comparative focus, driving indirect comparisons and external controls.
- Half of JCAs (9/18) involved products granted at least one expedited regulatory pathway (e.g., breakthrough therapy, priority review), amplifying the mismatch between accelerated development timelines and the JCA's demand for mature comparative evidence.
- Divergent national standards of care multiply the PICOs that one evidence package must answer.
- With half of JCAs orphan-designated, evidence uncertainty at submission is structural.
- **Limitation:** public sources only; with most JCAs ongoing, assessment conclusions remain largely unknown.

Abbreviations: ATMP, advanced therapy medicinal product; CSCC, cutaneous squamous cell carcinoma; EMA, European Medicines Agency; FDA, Food and Drug Administration; HTA, health technology assessment; JCA, Joint Clinical Assessment; ORR, objective response rate; OS, overall survival; PICOs, population, intervention, comparator, outcome; PFS, progression-free survival; RWE, real-world evidence.

6 CONCLUSION

After 18 months of implementation, initial JCA assessments highlight heightened scrutiny of clinical evidence and increased demands on manufacturers regarding study design and comparator choice.

Implication: prospective PICO prediction and early regulatory–HTA alignment are critical for orphan-designated products, where evidence uncertainty at submission remains high.

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