# Implementation of EU Joint Clinical Assessment: An Early Landscape of Submission Patterns and HTA Involvement

HTA37

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## INTRODUCTION

- The Regulation on Health Technology Assessment (EU 2021/2282) established a framework for Joint Clinical Assessments (JCA) at the EU level[1]
- These assessments support Member States' national HTA processes by providing a scientific analysis of clinical evidence on the relative effects of a health technology on health outcomes
- From 12 January 2025, new oncology medicinal products and advanced therapy medicinal products (ATMPs) became subject to JCA. The scope will expand to include orphan medicinal products from January 2028, and all new medicinal products from January 2030[2]
- The JCA Subgroup of the Health Technology Assessment Coordination Group (HTACG) conducts assessments by appointing an assessor and a co-assessor from different Member States. The assessment focuses on clinical domains only, without value judgements or conclusions on reimbursement. The JCA report must be endorsed no later than 30 days after the Commission grants marketing authorization
- As JCAs move into early implementation, the submission and assignment patterns may offer insight into disease priorities and assessment leadership

## OBJECTIVE

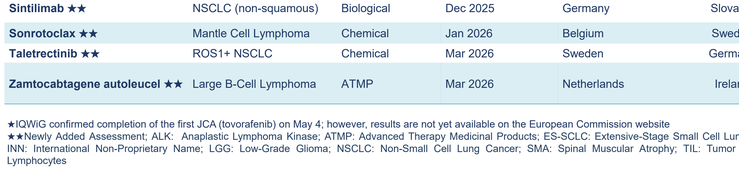
- This study presents a landscape assessment of ongoing JCA submissions, focusing on disease areas and assessor-co-assessor allocations

## METHODS

- A structured desktop landscape assessment was conducted using publicly available data from the European Commission website (health.ec.europa.eu)
- The European Commission's HTA publishes and maintains lists of JCA activities in accordance with Article 30(3)(h) of Regulation (EU) 2021/2282
- The JCA database is dynamic and subject to ongoing updates; therefore, the landscape assessment was conducted at two predefined time points, during abstract development (January 6, 2026) and poster preparation (May 4, 2026), to ensure a comprehensive and contemporaneous representation of the evidence
- The landscape assessment was categorized into three groups: ongoing, completed, and discontinued JCAs
- Descriptive analysis of submission patterns, including disease areas, substance types, and assessor/co-assessor allocation, etc., was extracted

## RESULTS

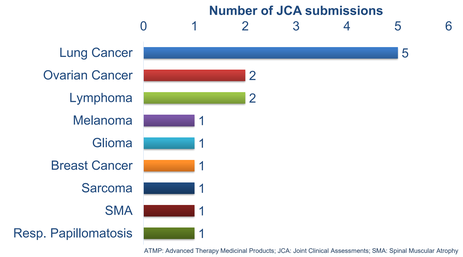
- At the time of abstract development (January 6, 2026), a total of 12 ongoing JCA submissions were identified, the majority of which were in oncology (n=9), encompassing indications such as small-cell lung cancer, melanoma, glioma, bladder cancer, prostate cancer, and breast cancer
- As of the latest update (May 4, 2026), with a JCA cut-off date of 14 April 2026, a total of 16 JCA procedures had been initiated. Of these, 14 are ongoing, 1 has been discontinued, and 1 has completed assessments[3]
- In terms of the indication, oncology predominates within the JCA landscape, accounting for 13 of the 14 ongoing assessments (93%)




*IQWiG confirmed completion of the first JCA (tovorafenib) on May 4; however, results are not yet available on the European Commission website

- Lung cancer represents the most frequent indication (n=5; 33%), followed by ovarian cancer (n=2) and lymphoma (n=2), with single assessments in melanoma, glioma, breast cancer, and sarcoma. The two non-oncology assessments are advanced therapy medicinal products (ATMPs), targeting spinal muscular atrophy and respiratory papillomatosis **(Figure 1)**
- By substance class, chemically synthesized products constitute the majority (n=9; 60%), followed by ATMPs (n=4; 27%) and biologics (n=2; 13%) **(Figure 2)**
- Germany, through Institute for Quality and Efficiency in Health Care (IQWiG), serves as the lead assessor in four JCAs. Overall, the assessments involve a broad geographic distribution, encompassing nine assessor countries and 13 co-assessor countries, reflecting the collaborative, EU-wide nature of the framework **(Table 1, Figure 3)**

**Figure 1: Disease Area Distribution (n=15)**




ATMP: Advanced Therapy Medicinal Products; JCA: Joint Clinical Assessments; SMA: Spinal Muscular Atrophy

**Figure 2: Substance Type Distribution (n=15)**

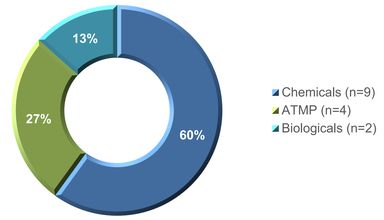



**Figure 3: Assessor Allocation by Country (n=15)**

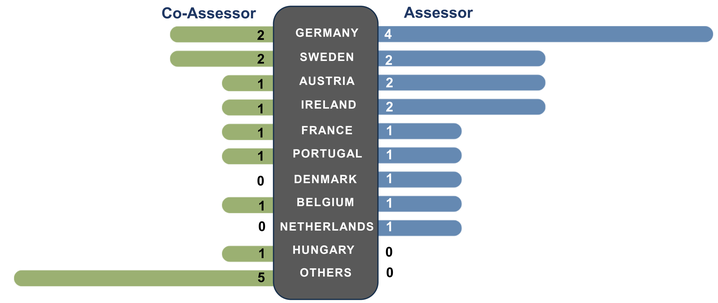



**Table 1: Ongoing and Completed Joint Clinical Assessments (n=15)**

| Drug (INN) | Indication | Type | EMA Date | Assessor | Co-Assessor |
|---|---|---|---|---|---|
| Autologous melanoma TIL | Melanoma | ATMP | Mar 2025 | France | Poland |
| Tovorafenib★ | Paediatric LGG | Chemical | Mar 2025 | Ireland | Germany |
| Onasemnogene abeparvovec | SMA | ATMP | May 2025 | Ireland | France |
| Lurbinectedin | ES-SCLC | Chemical | Jun 2025 | Germany | Portugal |
| Camizestrant | Breast Cancer | Chemical | Jun 2025 | Austria | Belgium |
| Tarlatamab | ES-SCLC | Biological | Jul 2025 | Germany | Hungary |
| Catequentinib | Sarcoma | Chemical | Jul 2025 | Sweden | Norway |
| Senaparib | Ovarian Cancer | Chemical | Aug 2025 | Germany | Slovenia |
| Relacorilant | Ovarian Cancer | Chemical | Oct 2025 | Portugal | Sweden |
| Ensartinib | ALK + NSCLC | Chemical | Nov 2025 | Austria | Spain |
| Zopapogene imadenovec | Resp. Papillomatosis | ATMP | Nov 2025 | Denmark | Austria |
| **Sintilimab ★★** | NSCLC (non-squamous) | Biological | Dec 2025 | Germany | Slovakia |
| **Sonrotoclax ★★** | Mantle Cell Lymphoma | Chemical | Jan 2026 | Belgium | Sweden |
| **Taletrectinib ★★** | ROS1+ NSCLC | Chemical | Mar 2026 | Sweden | Germany |
| **Zamtocabtagene autoleucel ★★** | Large B-Cell Lymphoma | ATMP | Mar 2026 | Netherlands | Ireland |

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★★Newly Added Assessment; ALK: Anaplastic Lymphoma Kinase; ATMP: Advanced Therapy Medicinal Products; ES-SCLC: Extensive-Stage Small Cell Lung Cancer; INN: International Non-Proprietary Name; LGG: Low-Grade Glioma; NSCLC: Non-Small Cell Lung Cancer; SMA: Spinal Muscular Atrophy; TIL: Tumor Infiltrating Lymphocytes

**★ RECENT UPDATES IN LATE 2025 / EARLY 2026**

**COMPLETED**

- **Tovorafenib** Paediatric low-grade glioma
- **Assessor:** Ireland **Co-assessor:** Germany
- **IQWIG** Confirmed on May 4, 2026
- Four additional JCA* completions are anticipated by the end of 2026

**NEW ADDITIONS**

- **01** **Sintilimab** Non-squamous NSCLC (Biological, Dec 2025)
- **02** **Sonrotoclax** Mantle Cell Lymphoma (Chemical, Jan 2026)
- **04** **Taletrectinib** ROS1+ NSCLC (Chemical, Mar 2026)
- **03** **Zamtocabtagene autoleucel** Large B-Cell Lymphoma (ATMP, Mar 2026)

**WITHDRAWN**

- **Sasanlimab** Treatment of Bladder Cancer
- **Assessor:** Netherlands **Co-assessor:** Denmark
- **Reason:** Withdrawal of marketing authorization application by the health technology developer

*Lurbinectedin (Q3 2026), Tarlatamab (Q3 2026), Senaparib (Q3 2026), Sintilimab (Q4 2026) are anticipated to complete their JCA assessment

## CONCLUSIONS

- ❖ The early landscape evidence from ongoing JCA submissions highlights a strong focus on oncology and a centralized yet collaborative assessor structure
- ❖ As the JCA process matures and additional submissions are evaluated, these patterns are expected to evolve, underscoring the need for continued monitoring of disease focus and assessor allocation, alongside early strategic evidence planning to enable successful EU-wide HTA outcomes. With scope expansions ahead, early strategic evidence planning aligned to JCA requirements is no longer optional but a competitive imperative.

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