THE EVOLVING LANDSCAPE OF EUROPEAN UNION JOINT CLINICAL ASSESSMENT (JCA): SUBMISSION PATTERNS AND KEY LEARNINGS

HTA408

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INTRODUCTION

- The Regulation on Health Technology Assessment (EU 2021/2282) established an EU-level JCA framework to scientifically assess the relative clinical effects of health technologies and support national HTA processes[1]
- JCA implementation began in January 2025 for new oncology medicines and ATMPs, with phased expansion to orphan medicines in 2028 and all new medicines by 2030[2]
- The HTACG's JCA Subgroup conducts assessments through assessors from different Member States, focusing exclusively on clinical evidence without value judgements or reimbursement recommendations, with reports endorsed within 30 days of EC marketing authorization
- With the first few JCA reports now published, emerging evidence requirements, submission approaches, and assessment outcomes offer valuable insights into what sponsors need to demonstrate to meet JCA expectations

OBJECTIVES

- This study aim to characterize the evolving JCA landscape, evaluate assessment outcomes, and identify key implementation learnings from the first wave of submissions

METHODS

- A structured desktop landscape assessment was conducted using publicly available JCA activity lists maintained by the European Commission under Article 30(3)(h) of Regulation (EU) 2021/2282 (health.ec.europa.eu)
- As the JCA database is continuously updated, the landscape was assessed at two predefined time points (during abstract and poster development) to capture the evolving evidence landscape; database cut-off dates for this poster: Ongoing JCAs, October 15, 2026; Completed JCAs, September 7, 2026; Discontinued JCAs, September 17, 2026
- Descriptive analysis of submission patterns including disease areas, substance types, and assessor/co-assessor allocation, and key learnings were extracted

RESULTS

- As of the latest updates (October 15, 2026), a total of 27 JCA procedures had been initiated. Of these, 19 are ongoing (18 at abstract development), 4 has been discontinued, and 4 has completed assessments



- The distribution of JCAs by therapeutic area, technology type, MAA validation year, Member State roles (assessor/co-assessor), and final assessment status is summarized in **Table 1**

Drug (INN)	Indication	Type	EMA MAA validation date	Assessor	Co-assessor	Status
Autologous melanoma TIL[3]	Melanoma	ATMP	Mar 2025	France	Poland	Discontinued
Tovorafenib[4]	Paediatric LGG	Chemical	Mar 2025	Ireland	Germany	Completed
Onasemnogene abeparvovec[5]	5q SMA	ATMP	May 2025	Ireland	France	Completed
Sasanlimab[6]	High-risk NMIBC (with BCG)	Biological	May 2025	Netherlands	Denmark	Discontinued
Lurbinectedin[7]	ES-SCLC	Chemical	Jun 2025	Germany	Portugal	Completed
Camizestrant[8]	Locally advanced / metastatic breast cancer	Chemical	Jun 2025	Austria	Belgium	Ongoing
Tarlatamab[9]	ES-SCLC	Biological	Jul 2025	Germany	Hungary	Completed
Catequentinib[10]	Synovial sarcoma / leiomyosarcoma	Chemical	Jul 2025	Sweden	Norway	Discontinued
Senaparib[11]	Advanced high-grade ovarian cancer	Chemical	Aug 2025	Germany	Slovenia	Ongoing
Relacorilant[12]	Platinum-resistant ovarian cancer	Chemical	Oct 2025	Portugal	Sweden	Ongoing
Ensartinib[13]	ALK+ NSCLC	Chemical	Nov 2025	Austria	Spain	Ongoing
Zopapogene imadenovec[14]	Resp. papillomatosis	ATMP	Nov 2025	Denmark	Austria	Ongoing
Sintilimab[15]	NSCLC (non-squamous)	Biological	Dec 2025	Germany	Slovakia	Discontinued
Sonrotoclax[16]	Mantle cell lymphoma	Chemical	Jan 2026	Belgium	Sweden	Ongoing
Taletrectinib[17]	ROS1+ NSCLC	Chemical	Mar 2026	Sweden	Germany	Ongoing
Zamtocabtagene autoleucel[18]	Large B-cell lymphoma	ATMP	Mar 2026	Netherlands	Ireland	Ongoing
Cosibelimab ★[19]	cSCC	Biological	May 2026	Germany	France	Ongoing
Lunsotogene parvec ★[20]	OTOF hearing loss	ATMP	May 2026	Germany	Norway	Ongoing
Rezvilutamide ★[21]	High-volume mHSPC	Chemical	Jun 2026	Netherlands	Ireland	Ongoing
Mezigdomide ★[22]	R/R multiple myeloma	Chemical	Jun 2026	Germany	Poland	Ongoing
Bioengineered skin† ★[23]	Partial deep dermal and full-thickness burns	ATMP	Jul 2026	France	Belgium	Ongoing
Bifikafusp/onfekafusp alfa ★[24]	Melanoma	Biological	Aug 2026	Sweden	Poland	Ongoing
Pelabresib ★[25]	Myelofibrosis	Chemical	Oct 2026	Norway	Estonia	Ongoing
Lirafugratinib ★[26]	Cholangiocarcinoma	Chemical	Oct 2026	Sweden	Austria	Ongoing
Rebisufligene etisparvovec ★[27]	MPS IIIA	ATMP	Oct 2026	Austria	Hungary	Ongoing
Fuzuloparib ★[28]	mCRPC	Chemical	Oct 2026	Germany	Netherlands	Ongoing
Daraxonrasib ★[29]	Pancreatic cancer	Chemical	Phased	Germany	Denmark	Ongoing

★ New since abstract cut-off · † Living bilayered bioengineered skin · Phased: under EMA phased review; EMA MAA validation date = date the EMA validated the marketing authorisation application (not an opinion or approval date). Months follow the validation date, e.g. TIL and tovorafenib 27 Mar 2025; sasanlimab 22 May 2025; lurbinectedin 19 Jun 2025; tarlatamab and catequentinib 17 Jul 2025; sintilimab 25 Dec 2025.
Discontinuation reasons: sasanlimab = EMA application withdrawn 13 Feb 2026; catequentinib, sintilimab and the TIL product = incomplete JCA dossier (Art. 9(2)-(4), Reg. (EU) 2021/2282). The TIL product is listed by Delta-Dossier as "Tacquell"; confirm the name on the EC discontinuation page before adding it.
HTA bodies: HAS = Haute Autorité de Santé (France, FR); AOTMiT = Agency for HTA and Tariff System (Poland, PL); NCPE = National Centre for Pharmacoeconomics (Ireland, IE); IQWiG = Institute for Quality and Efficiency in Health Care (Germany, DE); G-BA = Federal Joint Committee (Germany, DE); ZIN = National Health Care Institute (Netherlands, NL); DMC = Danish Medicines Council (Denmark, DK); INFARMED = National Authority of Medicines and Health Products (Portugal, PT); FSI = Federation of Social Insurances (Austria, AT); AIHTA = Austrian Institute for HTA (Austria, AT); NIHDI = National Institute for Health and Disability Insurance (Belgium, BE); NCPHP = National Centre for Public Health and Pharmacy (Hungary, HU); TLV = Dental and Pharmaceutical Benefits Agency (Sweden, SE); SBU = Swedish Agency for HTA and Assessment of Social Services (Sweden, SE); NoMA = Norwegian Medical Products Agency (Norway, NO); SQHCA = Slovenian Quality Health Care Agency (Slovenia, SI); AEMPS = Spanish Agency of Medicines and Medical Devices (Spain, ES); NIHO = National Institute for Value and Technology in Health (Slovakia, SK); Univ. of Tartu (Estonia, EE).
Abbreviations: NMIBC = non-muscle-invasive bladder cancer; ES-SCLC = extensive-stage small cell lung cancer; LGG = low-grade glioma; mHSPC / mCRPC = metastatic hormone-sensitive / castration-resistant prostate cancer; cSCC = cutaneous squamous cell carcinoma.

Tovorafenib [paediatric low-grade glioma]

- **Scope**: A single indication was expanded into 8 PICOs across 3 populations, defined by BRAF alteration type and age
- **Key challenges:**
  - Reliance on single-arm evidence (FIREFLY-1).
  - Unanchored MAIC with very small effective sample sizes and unadjusted confounders.
  - A comparator study excluded because only conference abstracts were available.
  - No relative estimates for OS, HRQoL or symptoms
- **Outcome:** Only 1 of 8 PICOs had comparative evidence included in the assessment, and its estimates may not represent true causal effects
- **Implication:** Sponsors of single-arm programmes need early planning of comparator evidence, along with full documentation and transparent confounder selection

Onasemnogene abeparvovec [Intrathecal onasemnogene abeparvovec in 5q SMA]

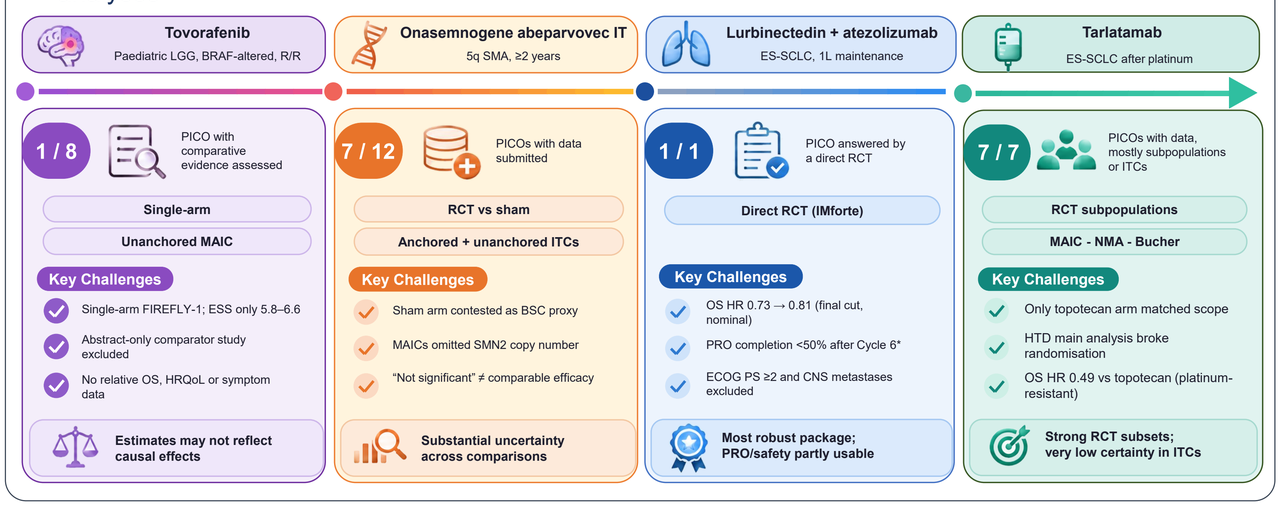
- **Scope:** Twelve PICOs across 6 populations after the indication was narrowed mid-procedure, from ≥6 months to ≥2 years
- **Key challenges:**
  - The sham control was contested as a proxy for best supportive care
  - MAICs omitted SMN2 copy number, leaving imbalance likely to favour the intervention
  - Analyses were split by prior DMT exposure, which the scope did not specify
  - Claims of "comparable efficacy" were based on non-significant results
- **Outcome:** Five of 12 PICOs had no data, and the remaining comparisons carry substantial uncertainty
- **Implication:** Trial populations should match the scope, sponsors should be ready to share individual patient data, and non-significance must not be presented as equivalence

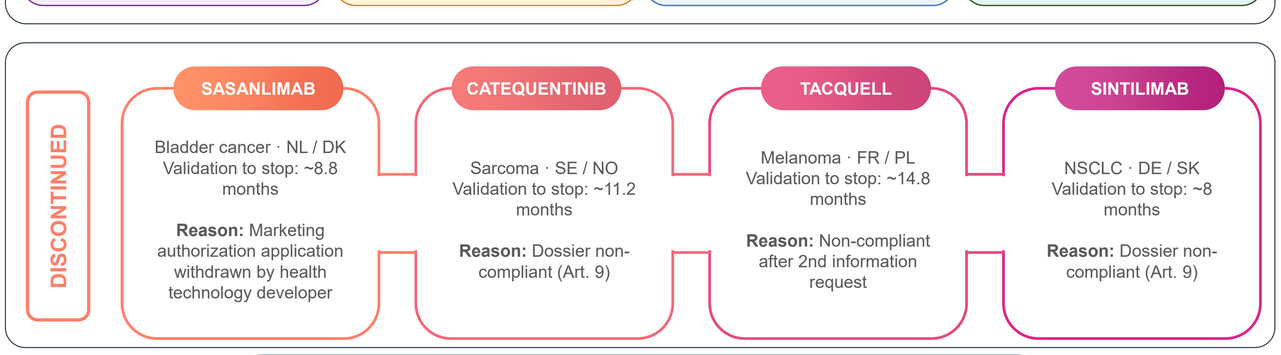
Lurbinectedin [ES-SCLC]

- **Scope:** One PICO, directly addressed by a single RCT (IMforte) against the scope comparator.
- **Key challenges:**
  - The OS benefit weakened at the final data cut (HR 0.81, nominal)
  - PRO completion was overstated by using an on-treatment denominator, and observation was unequal between arms
  - The immune-related AE selection was post hoc and incomplete
  - Patients with ECOG PS ≥2 and CNS metastases were excluded from the trial
- **Outcome:** This was the most robust evidence package of the four, but PRO and safety evidence were only partly usable
- **Implication:** An RCT alone is not sufficient. Prespecified PRO and AE analyses and full population coverage are critical

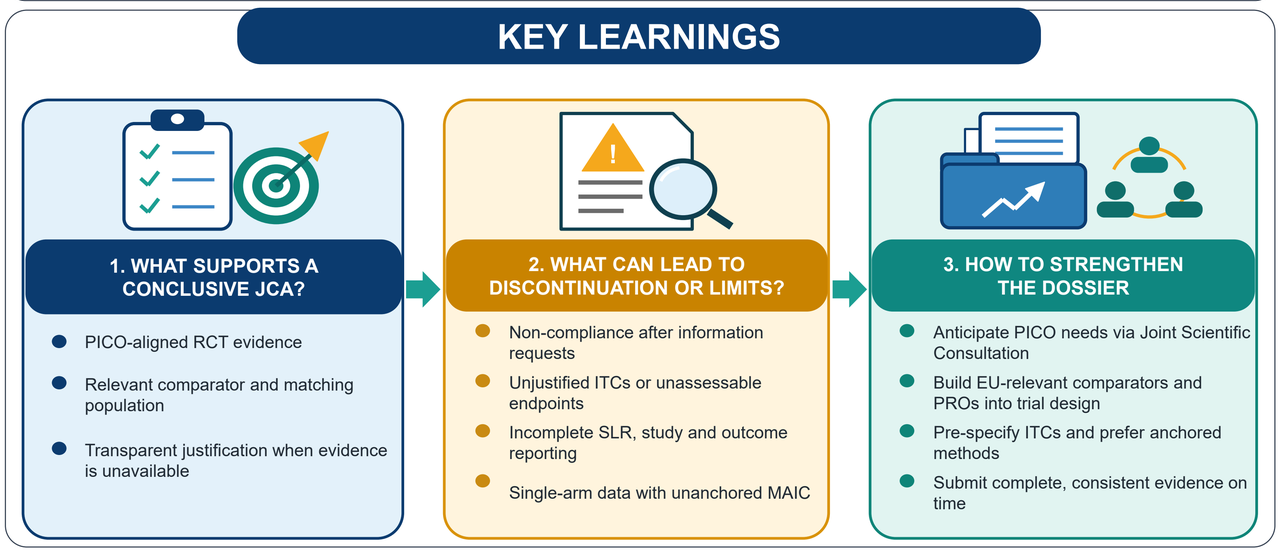
Tarlatamab [ES-SCLC]

- **Scope:** Seven PICOs across 4 overlapping populations, defined by different platinum-free interval cut-offs
- **Key challenges:**
  - Only the topotecan option in the RCT's control arm matched the scope
  - The HTD's main analyses broke randomization
  - Indirect comparisons versus CAV and platinum rechallenge had very low certainty
  - Treatment beyond progression confounded OS
- **Outcome:** There was strong RCT evidence in the topotecan-comparable subgroups (e.g., OS HR 0.49 in the platinum-resistant population), but low or very low certainty elsewhere
- **Implication:** Stratifying by intended comparator before randomization enables valid scope-specific analyses





KEY LEARNINGS



CONCLUSION

- This landscape assessment shows a growing JCA pipeline of 27 intended submissions to date, which remains oncology-centric (81%), with ATMPs accounting for all non-oncology assessments and Germany holding one-third of lead assessor roles
- Early completed JCAs show that the strength of an assessment depends on how well the evidence matches the PICO scope: scope-relevant RCTs supported robust conclusions, whereas single-arm data, indirect treatment comparisons and methodologically flawed analyses left major gaps and uncertainty
- Early HTA engagement through joint scientific consultation, combined with scope-driven evidence planning, from trial design and comparator selection through ITC strategy and prespecified outcome reporting, will be key to future JCA success

Abbreviations: ATMP: Advanced Therapy Medicinal Product; cSCC: Cutaneous Squamous Cell Carcinoma; EMA: European Medicines Agency; ES-SCLC: Extensive-Stage Small Cell Lung Cancer; G-BA: Federal Joint Committee; HTA: Health Technology Assessment; IQWiG: Institute for Quality and Efficiency in Health Care; ITC: Indirect Treatment Comparison; LGG: Low-Grade Glioma; MAA: Marketing Authorisation Application; MAIC: Matching-Adjusted Indirect Comparison; NMA: Network Meta-Analysis; NSCLC: Non-Small Cell Lung Cancer; PICO: Population, Intervention, Comparator, Outcome; RCT: Randomised Controlled Trial; SLR: Systematic Literature Review; SMA: Spinal Muscular Atrophy; TIL: Tumour-Infiltrating Lymphocytes

References: 1. Regulation (EU) 2021/2282 on health technology assessment. OJ L 458, 22.12.2021. 2. European Commission (EC). Joint clinical assessments of medicinal products: JCA tracker, JCA reports and lists of missing information (health.ec.europa.eu; accessed October 15, 2026). 3. EC JCA tracker: autologous melanoma TIL (Tacquell), discontinued 22 Jun 2026. 4. HTACG. JCA report MP-202406: tovorafenib (Ojemda); 9 Jun 2026. 5. HTACG. JCA report MP-202412: onasemnogene abeparvovec (Itvisma); 7 Sep 2026. 6. EC JCA tracker: sasanlimab, discontinued 13 Feb 2026; EMA, Zumrad withdrawal. 7. HTACG. JCA report MP-202416: lurbinectedin (Zepzelca); 8 Jul 2026. 8. EC JCA tracker: camizestrant. 9. HTACG. JCA report MP-202417: tarlatamab (Imdylltra); 8 Jul 2026. 10. EC JCA tracker: catequentinib, discontinued 22 Jun 2026. 11. EC JCA tracker: senaparib. 12. EC JCA tracker: relacorilant. 13. EC JCA tracker: ensartinib. 14. EC JCA tracker: zopapogene imadenovec. 15. EC JCA tracker: sintilimab, discontinued 16 Sep 2026. 16. EC JCA tracker: sonrotoclax. 17. EC JCA tracker: taletrectinib. 18. EC JCA tracker: zamtocabtagene autoleucel. 19. EC JCA tracker: cosibelimab. 20. EC JCA tracker: lunsotogene parvec. 21. EC JCA tracker: rezvilutamide. 22. EC JCA tracker: mezigdomide. 23. EC JCA tracker: bioengineered skin. 24. EC JCA tracker: bifikafusp alfa/onfekafusp alfa. 25. EC JCA tracker: pelabresib. 26. EC JCA tracker: lirafugratinib. 27. EC JCA tracker: rebisufligene etisparvovec. 28. EC JCA tracker: fuzuloparib. 29. EC JCA tracker: daraxonrasib. EC JCA tracker: https://health.ec.europa.eu (ongoing list extracted 15 Oct 2026; discontinued list 17 Sep 2026). JCA reports: health.ec.europa.eu/publications.

Correspondence

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