ONCOSCOPE
REAL-TIME ONCOLOGY LIBRARY

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Are EU Joint Clinical Assessments (JCA) based on outdated evidence?

Tracking evidence evolution during active JCAs using Real-time AI-assisted Living Systematic Literature Reviews (REAL-SLRs)

BACKGROUND

EU JCAs are conducted over extended timelines during which new clinical evidence, regulatory decisions, and changes in standards of care may emerge.

However, evidence submissions are typically based on **static systematic literature reviews (SLRs)** that do not support ongoing evidence surveillance.

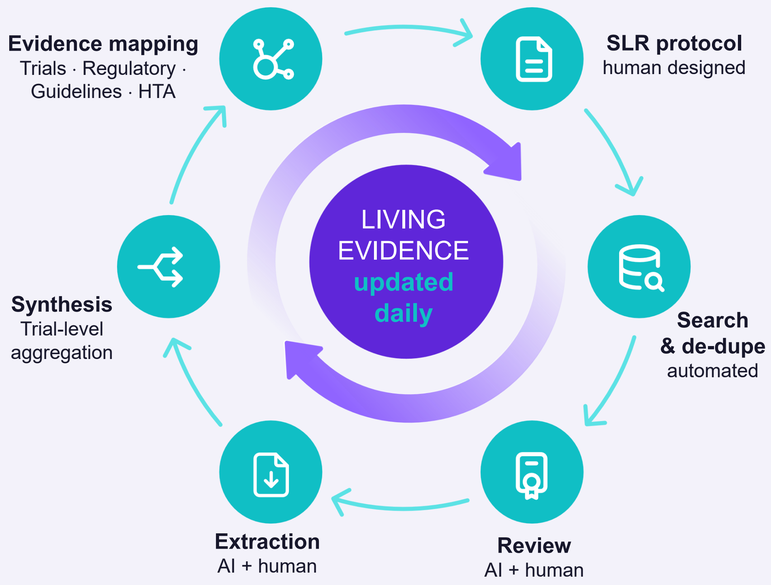
OBJECTIVES

This study evaluated evidence evolution during active oncology JCAs using **Oncoscope REAL-SLR database.**

METHODS

Oncoscope REAL-SLR oncology database contains continuously identified, screened, extracted, validated, and linked evidence from publications, conference abstracts, clinical trial registries, regulatory sources, clinical guidelines, and HTA documents by cancer. Four oncology products at different stages of JCA review in breast cancer and non-small cell lung cancer were selected. For each assessment, JCA duration, newly published evidence, regulatory developments, and emerging comparator evidence after JCA initiation were evaluated.

Figure 1. **Oncoscope REAL-SLR framework**



KEY TAKEAWAYS

Although JCA PICOs remain formally fixed during assessment, oncology evidence continues to evolve throughout the review period.

Living evidence surveillance identified new efficacy, safety, quality-of-life, regulatory, and comparator data after JCA initiation, demonstrating that evidence available for subsequent national HTA and reimbursement decisions may differ from that available at JCA submission.

Oncoscope REAL-SLR provide a practical framework for prospectively monitoring evidence evolution across the JCA-to-national decision-making pathway.

Results as of June 23, 2026

- The four JCAs represented surveillance periods of 89–369 days.
- Two of four assessments experienced clinically relevant evidence changes.
- For camizestrant, seven SERENA-6 publications reported updated progression-free survival, overall survival, quality-of-life, and safety outcomes, and a positive CHMP opinion was issued during the review period.
- For taletrectinib, two publications reported updated progression-free survival, objective response rate, duration of response, and patient-reported outcomes from TRUST-I and TRUST-II.
- Continuous monitoring also identified three new comparator therapies for camizestrant and five for sintilimab with phase 2/3 efficacy and safety data, creating additional potentially relevant PICO scenarios.
- No clinically relevant evidence changes were identified for the remaining two products.

Figure 2. **Evolving evidence landscape during ongoing JCA reviews**

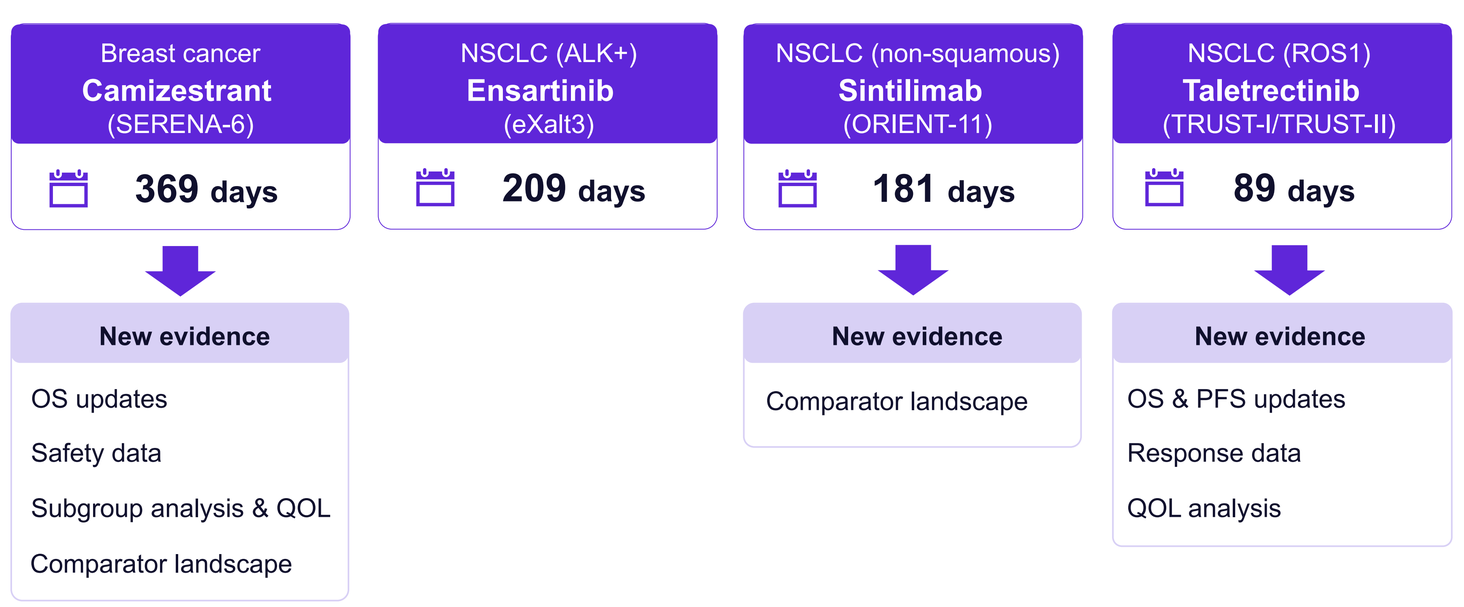


Table 1. **Four ongoing JCA reviews in breast cancer and NSCLC**

	Camizestrant	Ensartinib	Sintilimab	Taletrectinib
Intervention category	ET (SERD)	ALKi	ICI	ROS1-Targeted
Sponsor	AstraZeneca	Xcovery	Innovent Biologics / Eli Lilly	Nuvation Bio
Population	**BC / Metastatic / HR+ HER2- / ESR1 mutation**	**NSCLC / Metastatic / ALK+/ 1L**	**NSCLC / non-squamous / 1L**	**NSCLC / metastatic / ROS1**
Trial	NCT04964934 (SERENA-6) P3 RCT	NCT02767804 (eXalt3) P3 RCT	NCT03607539 (ORIENT-11) P3 RCT	NCT04919811 (TRUST-II), NCT04395677 (TRUST-I) P2 non-RCT
EMA date	2025-06-19	2025-11-27	2025-12-25	2026-03-26
How long has JCA been as of June 23, 2026	**369 days**	**209 days**	**181 days**	**89 days**

Table 2. **Oncoscope updates on the four ongoing JCA reviews**

	Camizestrant	Ensartinib	Sintilimab	Taletrectinib
Regulatory updates	Positive CHMP opinion – May 22, 2026; EC decision pending	None	None	None
FDA status	Not approved	FDA approved 2024 Dec	Not approved	FDA approved 2025 Jun
New publications	QOL analysis: PubMed 41125211 Oct 20, 2025	None	None	TRUST-I Follow-up: PubMed 42013573 Apr 21, 2026
New congress abstracts	• QOL analysis: ESMO 2025 528P Oct 13, 2025 • QOL analysis: ESMO 2025 486MO Oct 13, 2025 • Follow-up, QOL analysis: SABCS 2025 PS5-02-11 Nov 24, 2025 • Safety analysis: SABCS 2025 PD10-04 Nov 24, 2025 • Follow-up: SABCS 2025 RF7-03 Nov 24, 2025 • Follow-up, Subgroup analysis: ASCO 2026 LBA1007 May 22, 2026	None	None	TRUST-II QOL analysis: ASCO 2026 8629 May 22, 2026
New clinical data	OS; Safety; subgroups, QOL	X	X	ORR, DOR, PFS, QOL
Comparator changes	• Giredestrant (Genentech) • Imlunestrant (Eli Lilly) • Inavolisib (Roche)	None	• Pumitamig (BioNTech) • Brigatinib (Takeda / AriadPharmaceuticals) • Cemiplimab (Regeneron) • Osimertinib (AstraZeneca) • Pralsetinib (Roche)	None

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ABBREVIATIONS

1L, first-line treatment; **ALK**, anaplastic lymphoma kinase; **ALK+**, ALK-positive; **ASCO**, American Society of Clinical Oncology; **CHMP**, Committee for Medicinal Products for Human Use; **EMA**, European Medicines Agency; **ESMO**, European Society for Medical Oncology; **ESR1**, estrogen receptor 1; **ET**, endocrine therapy; **EU**, European Union; **FDA**, US Food and Drug Administration; **HER2−**, human epidermal growth factor receptor 2-negative; **HR+**, hormone receptor-positive; **HTA**, health technology assessment; **ICI**, immune checkpoint inhibitor; **JCA**, joint clinical assessment; **NCT**, National Clinical Trial; **NSCLC**, non-small cell lung cancer; **ORR**, objective response rate; **OS**, overall survival; **PICO**, population, intervention, comparator, outcome; **PFS**, progression-free survival; **QoL**, quality of life; **RCT**, randomized controlled trial; **REAL-SLR**, Real-time AI-assisted Living Systematic Literature Review; **ROS1**, ROS proto-oncogene 1; **SERD**, selective estrogen receptor degrader; **SLR**, systematic literature review.