

Enabling Health Technology Assessment (HTA) TA Readiness Through Real-Time AI-Assisted Living Systematic Literature Reviews (REAL-SLR): A Breast Cancer (BCa) Case Study

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OBJECTIVES

→ To evaluate the value of a Real-Time AI-Assisted Living Systematic Literature Reviews (REAL-SLR) as an enabling infrastructure for HTA readiness, using Breast Cancer as a case study

CONCLUSIONS

→ REAL-SLR reduced time to HTA-relevant evidence access to on-demand, delivering >90% time savings through daily searches, automated deduplication, and immediate availability of structured, PICO-aligned data

→ REAL-SLR enables a shift from episodic SLRs to a continuously maintained HTA evidence foundation

→ By supporting real-time incorporation of emerging data and rapid alignment to HTA requirements, REAL-SLR improves preparedness, reduces rework, and enhances transparency for oncology HTA decision making

BACKGROUND

- Health technology assessment (HTA) bodies increasingly require timely, transparent, and comprehensive evidence packages aligned to evolving standards of care
- Traditional de novo systematic literature reviews (SLR) are resource-intensive, slow to update, and often misaligned with the dynamic evidence needs of HTA processes

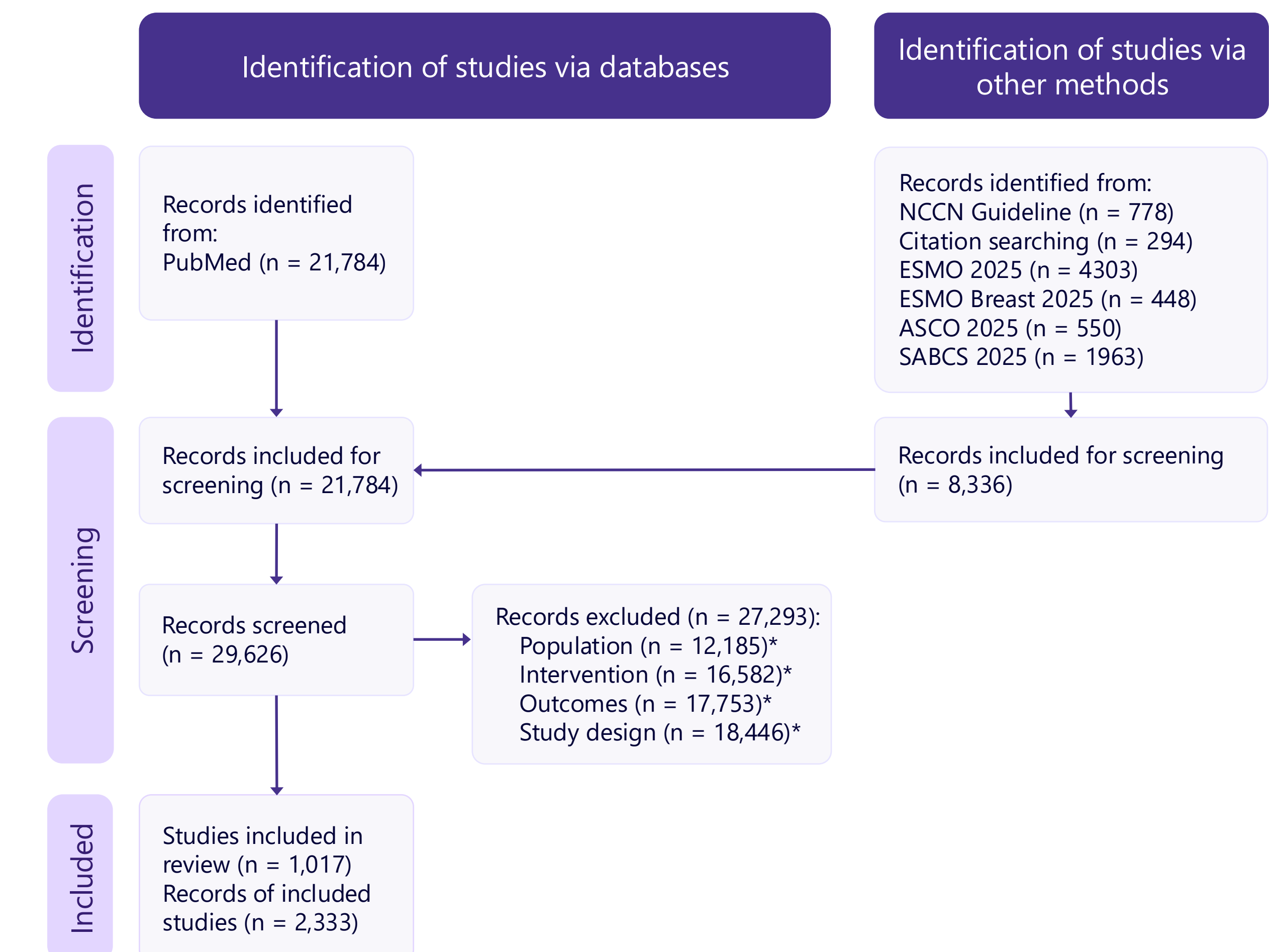
METHODS

- A breast cancer REAL-SLR was developed using PROSPERO-published protocol compliant with PRISMA and Cochrane guidelines for studies published in 2021-2025 including the abstracts from ESMO, ASCO and SABCS congresses
- AI review/extraction against the Population, Intervention/Comparator, Outcomes, and Study design (PICOS) framework (**Table 1**) was conducted with 100% human quality assurance
- Workflows, staffing requirements, and timelines for HTA-relevant evidence access via REAL-SLR were compared with those of a traditional manual systematic literature review (SLR)
- Evidence growth in the breast cancer REAL-SLR was assessed based on abstracts added during the 2025 calendar year and compared with estimated times to complete a tradition SLR
- In the REAL-SLR, the time to complete the daily update was calculated based on our experience conducting updates from March 4, 2025 – December 19, 2025 with AI review and extraction and human quality assurance. The time required for congress updates was averaged based on ASCO 2025, ESMO 2025, ESMO Breast 2025, and SABCS 2025
- Time to complete a the traditional SLR update every 6 months was estimated based the number of records screened during a 6-month period from March 4, 2025 to September 4, 2025. The time required for congress updates was averaged based on ASCO 2025, ESMO 2025, ESMO Breast 2025, and SABCS 2025. Estimates were based on dual review

Table1. PICOS statement

Element	Inclusion
Patient population	• Patients diagnosed with BCa at any stage
Intervention and Comparators	• Any intervention used for the treatment of BC including procedures (such as surgery or radiotherapy) and drugs (including biologics, cell treatments, vaccines, etc.)
Outcomes measures	• Overall survival (OS) and mortality • Progression-free survival (PFS) • Other progression measures (such as time to progression [TTP] or time to treatment failure [TTF], or metastases free survival [MFS]). • Response rate (including objective response rate (ORR), and other response) • Quality of life (including patient reported outcomes [PRO] and EQ-5D utility) • Safety / toxicity (including adverse events [AEs] and discontinuations)
Study design	• Prospective Interventional studies including randomized (RCT), non-randomized (non-RCTs), single arm, Phase 1, Phase 1/2, Phase 2, Phase 2/3, Phase 3, Phase 4 • Pooled analyses of RCTs • Externally controlled trials (ECTs)
Restrictions	• English language

Figure 1. PRISMA diagram for the Breast Cancer REAL-SLR for records included in 2025



*Reasons for exclusion were not mutually exclusive

Figure 2. Landscape changes in 2025 represented by the publication of practice changing clinical trials, NCCN guideline updates, and FDA approvals captured in the breast cancer REAL-SLR

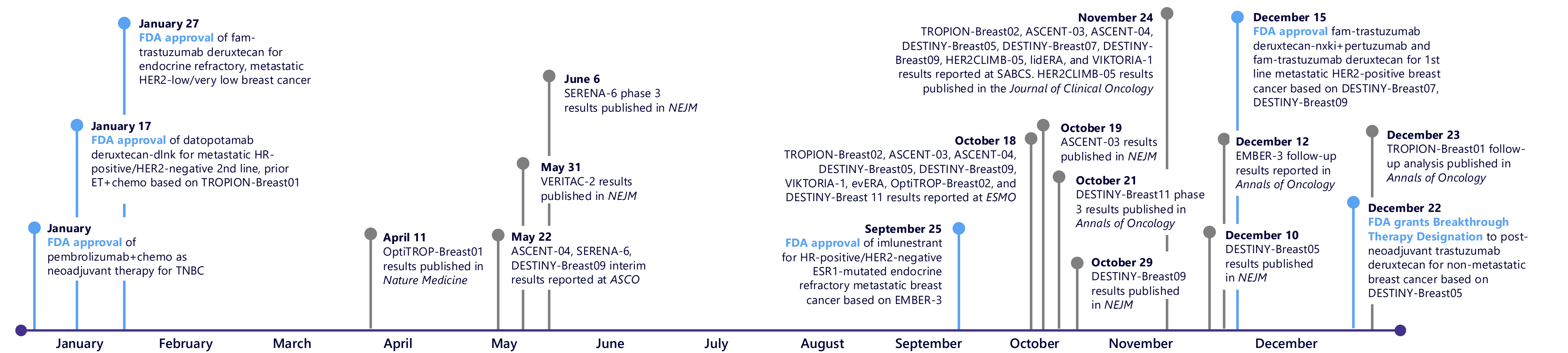


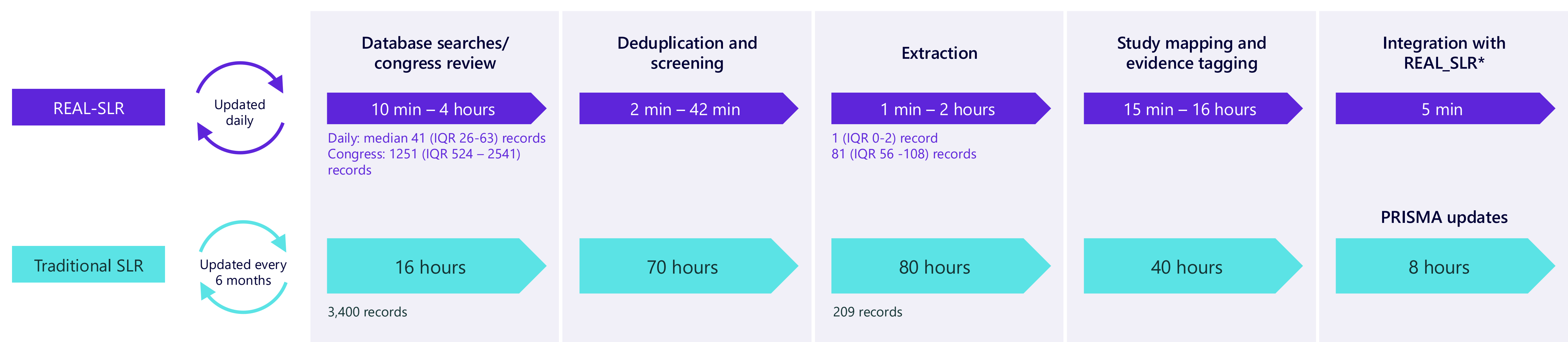
Table 2. Studies added to the REAL-SLR in 2025 supporting FDA approvals or NCCN guideline recommendations

Clinical trial	Intervention	Indication	Guideline recommendation	FDA approval	Efficacy results captured	QOL results captured	Subgroup analyses captured	Safety analysis captured
DESTINY-Breast07	Trastuzumab deruxtecan +pertuzumab	Metastatic HER2-positive 1 st line	Yes	Yes	OS, PFS, DOR, ORR	NR	NR	Grade ≥ 3 AE/Serious AE
DESTINY-Breast09	Trastuzumab deruxtecan +pertuzumab	Metastatic HER2-positive 1 st line, prior ET	Yes	Yes	OS, PFS, DOR, ORR	EORTC QLQ-C30; EORTC QLQ-BR45; PRO	Breast cancer subtype/Biomarker	Grade ≥ 3 TRAE/Serious TRAE
DESTINY-Breast05	Trastuzumab deruxtecan	Non-metastatic HER2-positive adjuvant	Yes	No	OS, DFS, IDFS	NR	NR	Grade ≥ 3 TRAE/Grade ≥ 3 AE
ASCENT-03	Sacituzumab govitecan	Metastatic Triple negative 1 st line	Yes	No	OS, PFS, DOR, ORR	EORTC QLQ-C30	NR	Grade ≥ 3 TEAE/Grade ≥ 3 AE
ASCENT-04	Sacituzumab govitecan	Metastatic PDL1-positive Triple negative 1 st line	Yes	No	OS, PFS, DOR, ORR	NR	NR	Grade ≥ 3 [Discontinuations]
TROPION-Breast01	Datopotamab deruxtecan	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+chemo	Yes	Yes	OS, PFS	EORTC QLQ-C30	NR	Grade ≥ 3 TEAE
NeoPACT	Pembrolizumab +carboplatin +docetaxel	Non-metastatic Triple negative Neoadjuvant	Yes	Yes	FFS, pCR	Treatment response	NR	Grade ≥ 3 Immune related AE
EMBER-3	Imilunstrant	Metastatic HR-positive/HER2-negative ESR1 mutant ≥2nd line, prior ET	Yes	Yes	OS, PFS, PFS2, ORR	EORTC QLQ-C30	Biomarker/Treatment path/ctDNA dynamics	Grade ≥ 3 TEAEs/grade 3/serious AEs

Table 3. Studies published in 2025 reporting practice-changing evidence not yet incorporated into FDA approvals or NCCN guidelines

Clinical trial	Intervention	Indication	Efficacy results captured	QOL results captured	Subgroup analyses captured	Safety analysis captured
DESTINYBREA ST-11	Trastuzumab deruxtecan	Non-metastatic HER2-positive Neoadjuvant	FFS, pCR	EORTC QLQ-C30	Breast cancer subtype	Grade ≥ 3 AEs/Grade ≥ 3 TRAE
OptiROP-Breast 01	Sacituzumab trumotecan	Metastatic Triple negative ≥2nd line	OS, PFS, DOR, ORR	NR	NR	TRAE
OptiROP-Breast 02	Sacituzumab trumotecan	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+CDK4/6i	OS, PFS, ORR	NR	Biomarker/Breast cancer subtype	Grade ≥ 3 TRAEs/Grade ≥ 3 TRAEs leading to discontinuation
SERENA-6	Camizestrant +CDK4/6i	Metastatic HR-positive/HER2-negative ESR1 mutation 1 st line	OS, PFS, PFS2	EORTC QLQ-C30; EORTC QLQ-BR23; PRO	NR	TRAE leading to discontinuation
VIKTORIA-1	Gedatolizib +pabociclib +fulvestrant Gedatolizib +fulvestrant	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+CDK4/6i	OS, PFS	NR	NR	Grade ≥ 3 TRAEs/Grade ≥ 3 TRAEs leading to discontinuation
HER2CLIMB-05	Tucatinib +pertuzumab +trastuzumab	Metastatic HER2-positive Maintenance	OS, PFS	NR	NR	TRAE/Grade ≥ 3 TRAE leading to discontinuation
eVERA	Giredestrant +everolimus	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+CDK4/6i	OS, PFS	NR	Biomarker	Grade ≥ 3 AE/Discontinuations
lidERA	Giredestrant	Non-metastatic HR-positive/HER2-negative Adjuvant	OS, DFS, IDFS, dRFI	NR	NR	Grade ≥ 3 AE/Discontinuations

Figure 3. Comparison in SLR updates timelines between the REAL-SLR conducted daily and a traditional SLR conducted every 6 months



ABBREVIATIONS

AE, adverse event; ASCO, American Society of Clinical Oncology; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; ctDNA, circulating tumor DNA; DFS, disease-free survival; dRFI, distant relapse-free interval; DOR, duration of response; EFS, event-free survival; EORTC QLQ-BR45, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Breast Cancer 45; EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; ESMO, European Society for Medical Oncology; ESR1, estrogen receptor 1; ET, endocrine therapy; FDA, US Food and Drug Administration; HR-positive/HER2-negative, hormone receptor-positive/human epidermal growth factor receptor 2-negative; IDFS, invasive disease-free survival; IQR, interquartile range; NCCN, National Comprehensive Cancer Network; NR, not reported; ORR, overall response rate; OS, overall survival; pCR, pathological complete response; PFS, progression-free survival; PRO, patient-reported outcome; SABCS, San Antonio Breast Cancer Symposium; TRAE, treatment-related adverse event

