HTA62

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

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

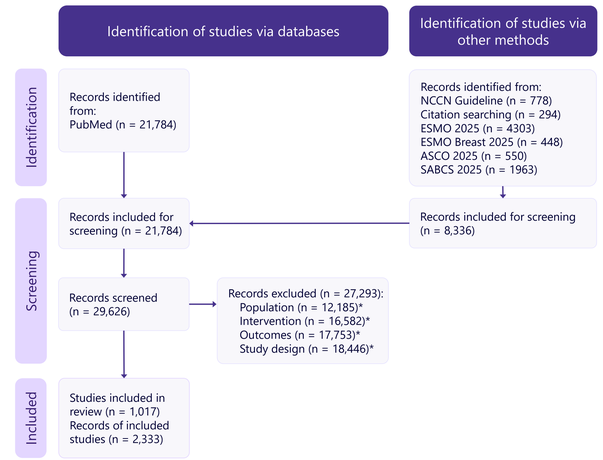
METHODS

- 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 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 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 REAL-SLR

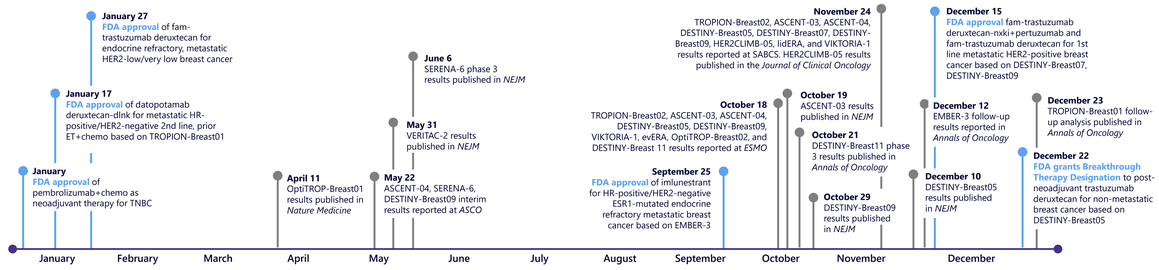


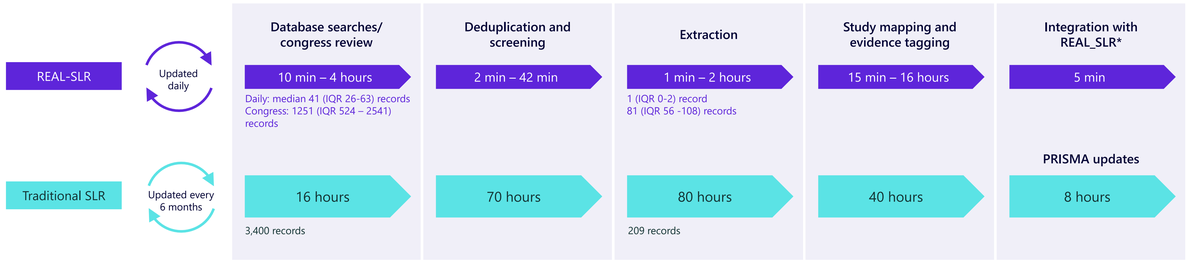
Table 2. Studies added to the REAL-SLR in 2025 supporting FDA approvals or NCCN guideline recommendations

Clinical trial	Intervention	Indication	Guideline recommend-dation	FDA approval	Efficacy results captured	QOL results captured	Subgroup analyses captured	Safety analysis captured
DESTINY-Breast07	Trastuzumab deruxtecan| Trastuzumab deruxtecan +pertuzumab	Metastatic HER2-positive 1st line	Yes	Yes	OS, PFS, ORR			Grade ≥3 AE|Serious AE
DESTINY-Breast09	Trastuzumab deruxtecan +pertuzumab	Metastatic HER2-positive 1st line|≥2nd line, prior ET	Yes	Yes	OS, PFS, DOR, ORR	EORTC QLQ-C30; EORTC QLQ-BR45; PRO	Breast cancer subtype|Biomarker| Treatment path	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 1st line	Yes	No	OS, PFS, DOR, ORR	EORTC QLQ-C30	NR	Grade ≥ 3 TEAE|Grade ≥ 3 AE
ASCENT-04	Sacituzumab govitecan +pembrolizumab	Metastatic PDL1-positive Triple negative 1st 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	EFS, pCR	Treatment response		Grade ≥ 3 Immune related AE
EMBER-3	Imlunestrant	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|any-grade Aes|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
DestinyBREAST-11	Trastuzumab deruxtecan	Non-metastatic HER2-positive Neoadjuvant	EFS, pCR	EORTC QLQ-C30	Breast cancer subtype	Grade ≥3 AE|serious AE|TRAE
OptiTROP-Breast 01	Sacituzumab tirumotecan	Metastatic Triple negative ≥2nd line	OS, PFS, DOR, ORR	NR	NR	TRAE
OptiTROP-Breast 02	Sacituzumab tirumotecan	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+CDK4/6i	OS, PFS, ORR	NR	Biomarker|Breast cancer subtype	Grade ≥ 3 TRAEs|TRAE leading to discontinuation
SERENA-6	Camizestrant +CDK4/6i	Metastatic HR-positive/HER2-negative ESR1 mutation 1st line	OS, PFS, PFS2	EORTC QLQ-C30; EORTC QLQ-BR23; PRO	NR	TRAE leading to discontinuation
VIKTORIA-1	Gedatolisib +palbociclib +fulvestrant Gedatolisib +fulvestrant	Metastatic HR-positive/HER2-negative ≥2nd line, prior ET+CDK4/6i	OS, PFS	NR	NR	Grade ≥ 3 TRAEs|TRAE leading to discontinuation
HER2CLIMB-05	Tucatinib +pertuzumab +trastuzumab	Metastatic HER2-positive Maintenance	OS, PFS	NR	NR	TRAE|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 timelines between SLR updates between the REAL-SLR conducted daily and a traditional SLR conducted every 6 months



RESULTS

- During 2025, the Breast Cancer REAL-SLR screened 29,626 records and incorporated 2,333 new publications, including 33 from ESMO Breast, 95 from ASCO, 68 from ESMO, and 159 from SABCS, with an approximately 5-day turnaround following major congresses (**Figure 1**)
- Achieving equivalent coverage through a manual SLR would require >16 weeks of effort from two junior and one senior researchers, delaying HTA readiness
- The REAL-SLR captured multiple practice-changing Breast Cancer updates in 2025 relevant to HTA evaluations (**Figure 2**).
- In 2025, we identified 16 clinical trials (**Tables 2 and 3**) reporting practice changing evidence. Eight of those trials (Table 2) led to FDA approvals or guideline updates based on results published in 2025. Figure 1 outlines the dates of publication and corresponding FDA approvals
- Table 3 outlines the publications reporting practice changing evidence that did not yet lead to FDA approvals or guideline updates
- Each publication was added to the REAL-SLR within 5 days (1-2 days for publications indexed on PubMed and <5 days for conference abstracts)
- Following screening and extraction of the records included in the Breast Cancer REAL-SLR, each record was mapped to create a tagged evidence library of clinical trials including data on guideline recommendations and regulatory body approvals
- Additionally, each trial record in the REAL-SLR includes the most up-to-date results including efficacy outcomes, QOL outcomes, safety outcomes, and subgroup analyses (**Tables 2 and 3**)
- As a comparison, we compared the amount of time it takes to fully update the Breast Cancer REAL-SLR daily with the time it takes to update a traditional SLR (**Figure 3**)
- The REAL-SLR is run daily including a median number of 1 studies (IQR 0-2) and takes approximately 1 hour depending on the number of studies included. Congress reviews are conducted when abstracts are released, with records added to the REAL-SLR within 5 days depending on the congress size
- A traditional SLR update conducted every 6 months was estimated to include 3400 records based on our experience updating the breast cancer REAL-SLR in 2025. Congresses would only be included if they fell within the period between the first SLR and the SLR update. With dual human review, updating the Breast Cancer REAL-SLR using traditional methods would take ~5 weeks
- The REAL-SLR captures the rapidly changing landscape in Breast Cancer and integrates published studies into an HTA-ready database that can be easily queried using PICO criteria to identify relevant comparators

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

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, pathologic complete response; PFS, progression-free survival; PRO, patient-reported outcome; SABCS, San Antonio Breast Cancer Symposium; TRAE, treatment-related adverse event

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