ONCOSCOPE
REAL-TIME ONCOLOGY LIBRARY

Stacy Grieve[1], Anna Forsythe[1], Saro Sarkisian[2]

[1]Oncoscope, Miami, FL, USA; [2]Frederick Health, Frederick, MD, USA

ISPOR Europe 2026
8-11 November 2026
Vienna, Austria

HPR181

Are tumor-agnostic approvals sufficient for tumor-specific reimbursement decisions?

A pancreatic cancer case study using living evidence

BACKGROUND

Tumor-agnostic approvals represent a major shift in oncology, enabling treatment recommendations based on molecular biomarkers rather than tumor histology. However, **health technology assessment (HTA)** and **reimbursement decisions** are typically made within specific cancer types, creating uncertainty regarding the transferability of evidence from pooled multi-tumor populations to individual tumor settings.

OBJECTIVES

To evaluate the evidence supporting tumor-agnostic treatment recommendations in pancreatic ductal adenocarcinoma (PDAC) and identify evidence gaps for HTA decision-making using the **Oncoscope** Real-Time AI-Assisted Living Systematic Literature Review **(REAL-SLR).**

METHODS

The Oncoscope REAL-SLR, a **PRISMA-compliant** and continuously updated database was used to map PDAC interventional evidence by biomarker, treatment pathway, intervention category, regulatory status, and guideline inclusion. Regulatory approvals, US/EU guidelines, and clinical trials supplemented the evidence map.

Studies were classified as **tumor-specific evidence** when pancreatic cancer data were available and **supporting evidence** when recommendations were primarily derived from tumor-agnostic approvals.

REFERENCES

1. https://**www.asco.org**/news-initiatives/policy-news-analysis/hfda-grants-accelerated-approval-dabrafenib-combination
2. https://**www.fda.gov**/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-her2
3. https://**www.fda.gov**/drugs/fda-approves-larotrectinib-solid-tumors-ntrk-gene-fusions-0
4. tps://**www.asco.org**/practice-policy/policy-issues-statements/asco-in-action/fda-approves-entrectinib-ntrk-solid-tumors
5. https://**www.fda.gov**/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-repotrectinib-adult-and-pediatric-patients-ntrk-gene-fusion-positive
6. https://**www.fda.gov**/drugs/resources-information-approved-drugs/fda-approves-selpercatinib-locally-advanced-or-metastatic-ret-fusion-positive-solid-tumors
7. https://**ascopost.com**/issues/february-10-2018/pembrolizumab-in-msi-h-or-dmmr-solid-tumors-first-tissuesite-agnostic-approval-by-fda/
8. https://**www.fda.gov**/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-advanced-solid-tumors
9. https://**www.fda.gov**/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-adults-and-children-tmb-h-solid-tumors

KEY TAKEAWAYS

Oncoscope REAL-SLR database IDENTIFIED substantial GAPS between tumor-agnostic approvals and pancreatic cancer-specific evidence.

LIVING evidence STRATIFICATION may help sponsors, HTA agencies, and payers assess evidence transferability, prioritize evidence generation, and support reimbursement decisions in BIOMARKER-defined populations.

Figure 1. **Continuously updated PRISMA (REAL-SLR framework) in pancreatic cancer**
(updated Jun 15, 2026)

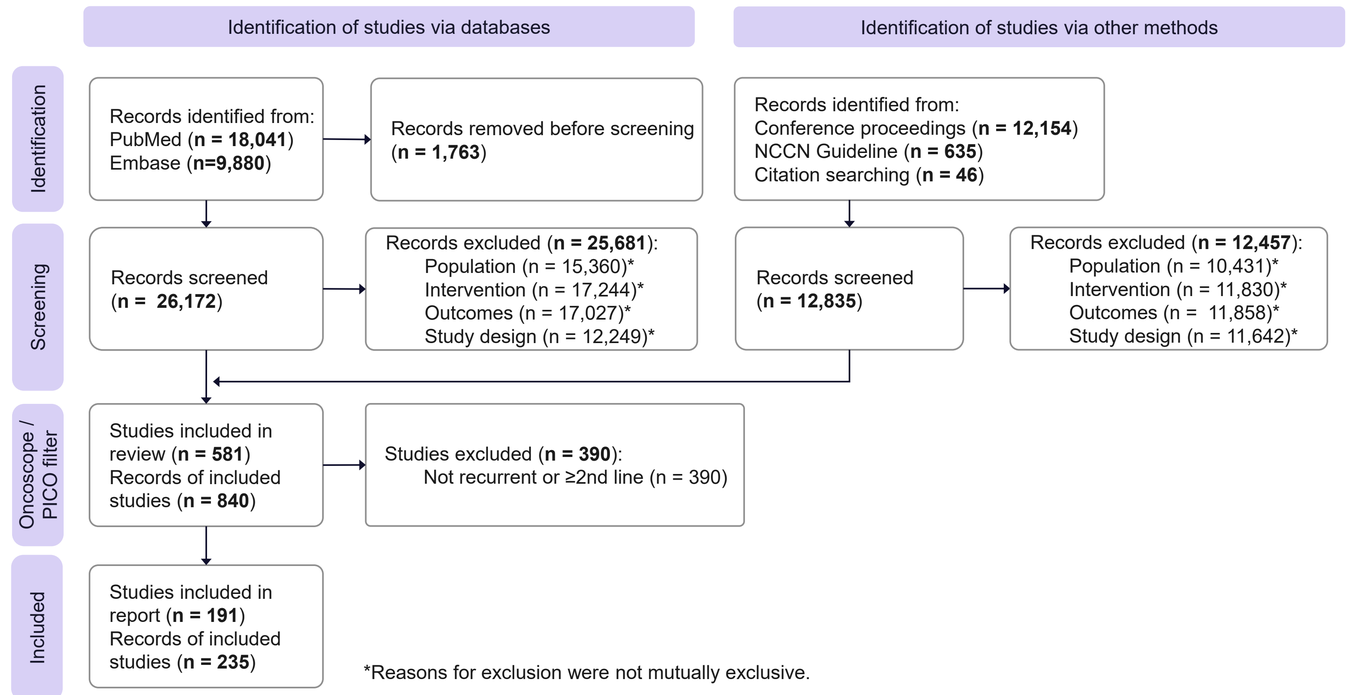
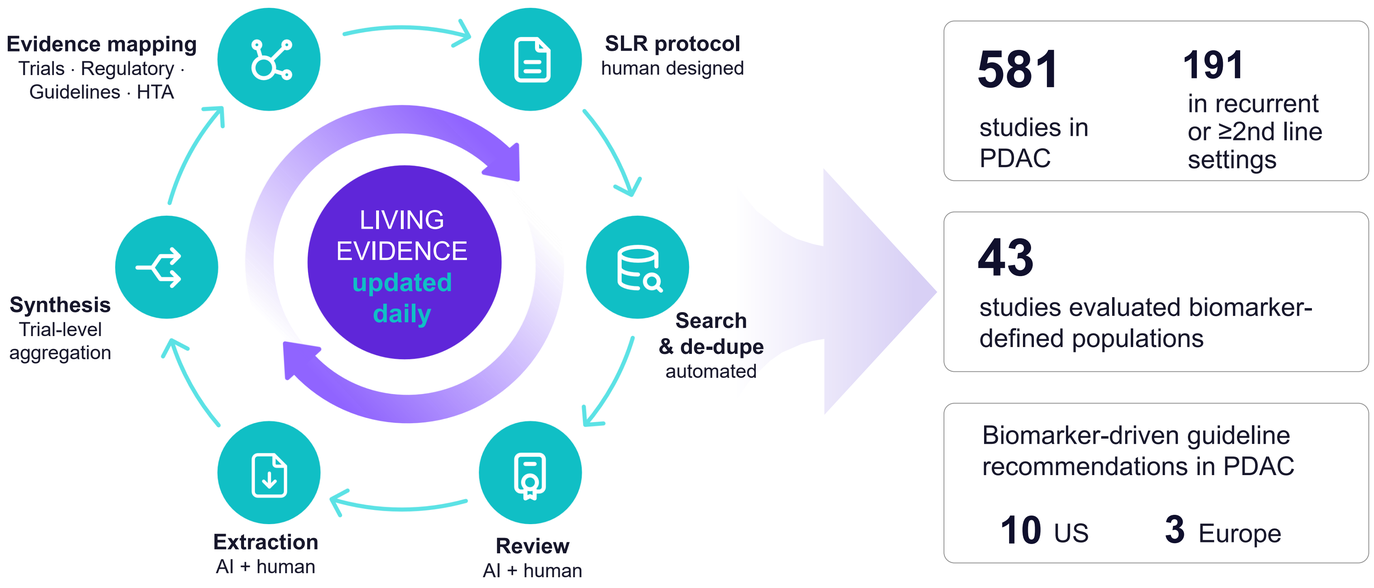


Figure 2. **REAL-SLR evidence capture summary (as of June 15, 2026)**



60% **of biomarker-driven US recommendations were supported by tumor-agnostic evidence (Table 1)**

Pancreatic cancer-specific evidence remain LIMITED
with small sample sizes and lower response rates compared to overall mixed tumor populations (Table 2).

Table 1. **Tumor-agnostic FDA approvals supporting PDAC-specific guideline recommendations**

	Biomarker	Tumor-agnostic FDA therapy (8 unique interventions)	Initial tumor-agnostic approval	FDA reference
1	**BRAF V600E**	Dabrafenib + trametinib	**2022** · Jun 22	FDA documentation explicitly identifies this as a **tumor-agnostic accelerated approval** for unresectable/metastatic BRAF V600E solid tumors. [1]
2	**HER2 IHC 3+**	Fam-trastuzumab deruxtecan-nxki (T-DXd)	**2024** · Apr 5	FDA accelerated approval for unresectable/metastatic **HER2-positive (IHC 3+) solid tumors**, irrespective of tumor origin. [2]
3	**NTRK fusion**	Larotrectinib	**2018** · Nov 26	FDA accelerated approval for **NTRK gene fusion-positive solid tumors**; FDA explicitly described this as its second tissue-agnostic cancer approval. [3]
4	**NTRK fusion**	Entrectinib	**2019** · Aug 15	FDA accelerated approval for **NTRK gene fusion-positive solid tumors**. [4]
5	**NTRK fusion**	Repotrectinib	**2024** · Jun 13	FDA accelerated approval for adult and pediatric patients ≥12 years with **NTRK gene fusion-positive solid tumors**. [5]
6	**RET fusion**	Selpercatinib	**2022** · Sep 21	FDA accelerated approval for locally advanced/metastatic **RET fusion-positive solid tumors**. [6]
7	**MSI-H/dMMR**	Pembrolizumab	**2017** · May 23	This was the landmark first FDA tissue/site-agnostic oncology approval, for unresectable/metastatic **MSI-H/dMMR solid tumors**. [7]
8	**dMMR**	Dostarlimab-gxly	**2021** · Aug 17	FDA accelerated approval for **dMMR recurrent or advanced solid tumors**. [8]
9	**TMB-high (≥10 mut/Mb)**	Pembrolizumab	**2020** · Jun 16	FDA accelerated approval for unresectable/metastatic **TMB-H solid tumors ≥10 mut/Mb**. [9]

Table 2. **Pancreatic-specific vs. tumor-agnostic response data**

Biomarker	Sample size, n		Overall response rate (ORR), %	
	PDAC-specific	Tumor-agnostic	PDAC-specific	Tumor-agnostic
HER2 +	**~25**	**267**	**12%**	**37%**
MSI-H	**~25**	**155**	**18%**	**38%**

View all Oncoscope posters at ISPOR Europe 2026

ABBREVIATIONS

BRAF, B-Raf proto-oncogene, serine/threonine kinase; **dMMR**, deficient mismatch repair; **EU**, European Union; **FDA**, Food and Drug Administration; **HER2**, human epidermal growth factor receptor 2; **HTA**, health technology assessment; **IHC**, immunohistochemistry; **MSI-H**, microsatellite instability-high; **mut/Mb**, mutations per megabase; **n**, sample size; **NTRK**, neurotrophic tyrosine receptor kinase; **ORR**, overall response rate; **PDAC**, pancreatic ductal adenocarcinoma; **PICOS**, population, intervention, comparator, outcomes, study design; **PRISMA**, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; **QC**, quality control; **REAL-SLR**, Real-Time AI-Assisted Living Systematic Literature Review; **RET**, rearranged during transfection; **SLR**, systematic literature review; **T-DXd**, trastuzumab deruxtecan; **TMB-H**, tumor mutational burden-high; **US**, United States; **V600E,** valine-to-glutamic acid substitution at codon 600.