Are Approved Therapies Always The Most Relevant Comparators?

A Living Evidence Analysis of Regulatory-Guideline-Reimbursement Divergence Across Six Oncology Indications



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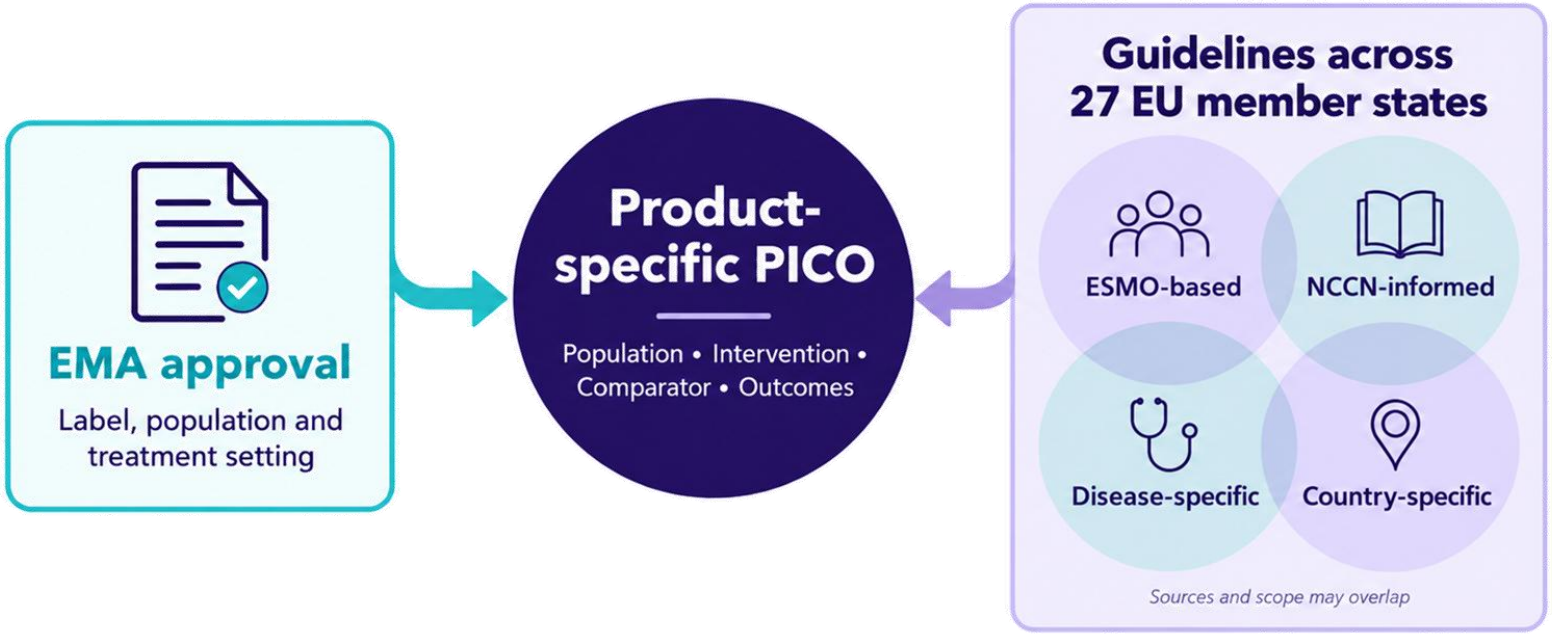
Background

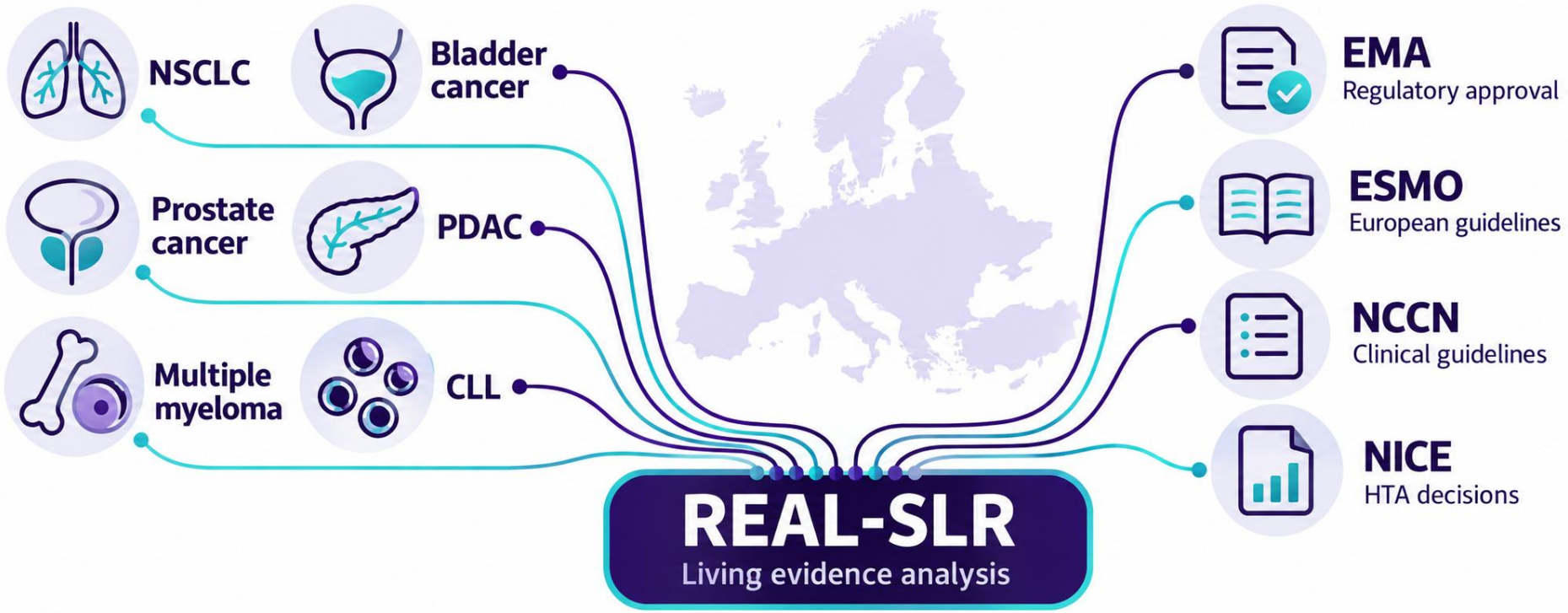
- **Health technology assessment** (HTA) and **Joint Clinical Assessment** (JCA) require identifying clinically relevant comparators.
- As standards of care evolve, **guideline recommendations may diverge from regulatory approvals** through biomarker-driven therapies, sequencing changes, and timing of events.



Comparator selection must reflect evolving standards of care alongside regulatory approval

Objective

- To evaluate the concordance between **EMA approvals**, **European guideline** recommendations and **NICE** decisions across six oncology indications and assessed implications for comparator selection through a Real-Time AI-Assisted Living Systematic Literature Review (**REAL-SLR**)



Six oncology indications, assessed through living evidence to inform comparator selection

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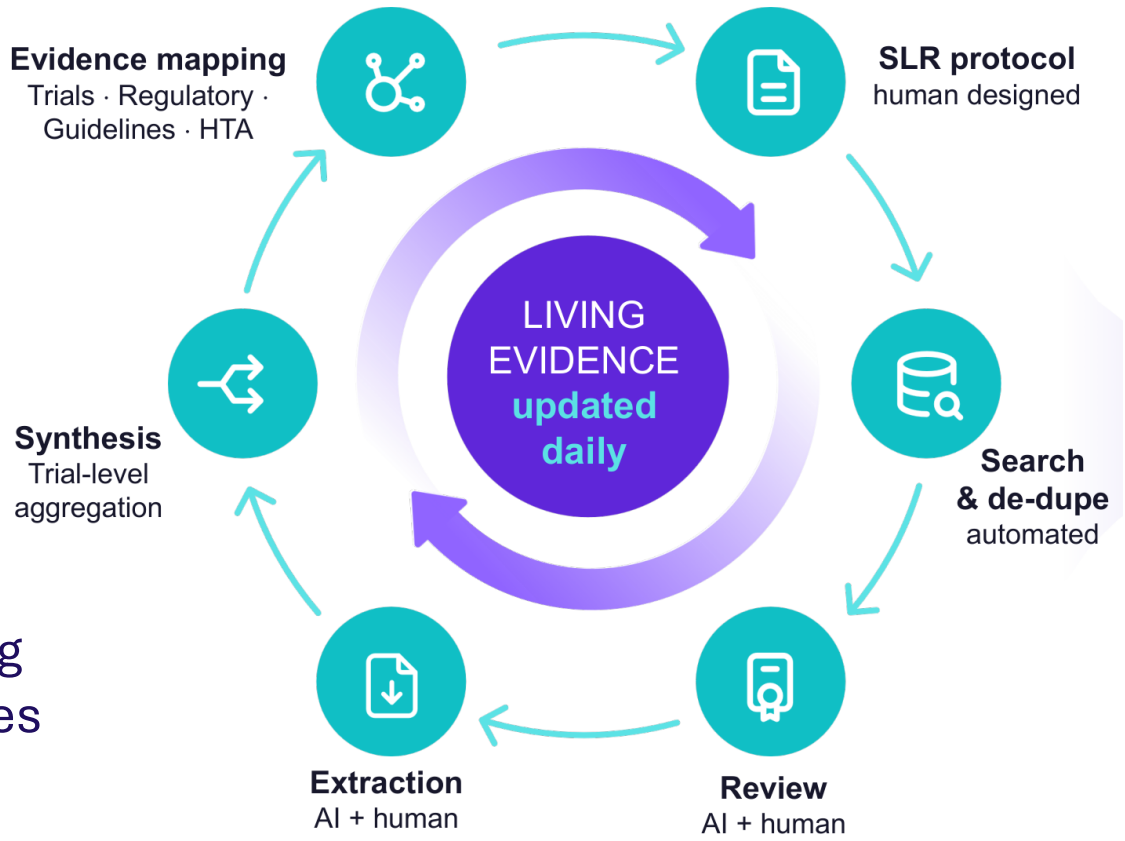
Methods: Living SLR Database*

- A PRISMA-aligned living SLR updated daily:
  - ✓ Publications
  - ✓ Conference abstracts
  - ✓ FDA/EMA
  - ✓ Guidelines
  - ✓ HTAs
- AI-assisted review and data extraction combined with 100% human oversight.
- Study-level synthesis and evidence mapping across trials, regulatory approvals, guidelines and HTA.



A continuously updated evidence base for tracking changes in clinically relevant comparators

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*Analysis cutoff: 17 June 2026

Evidence base across six indications

- The current REAL-SLR database contains **>250K records**, each tagged with **its PICO set** to ensure data reusability.
- The table presents the evidence available across **six indications as of June 17, 2026,** including studies evaluating EMA-approved and/or guideline-recommended therapies.

Indication	All studies	EMA and/or guideline subset
NSCLC	1,726*	412
Prostate	862	128
Multiple myeloma	751	182
PDAC	582	72
Bladder	554	28
CLL	341	97



At any time, a snapshot provides a current, comprehensive disease map integrated across multiple data sources

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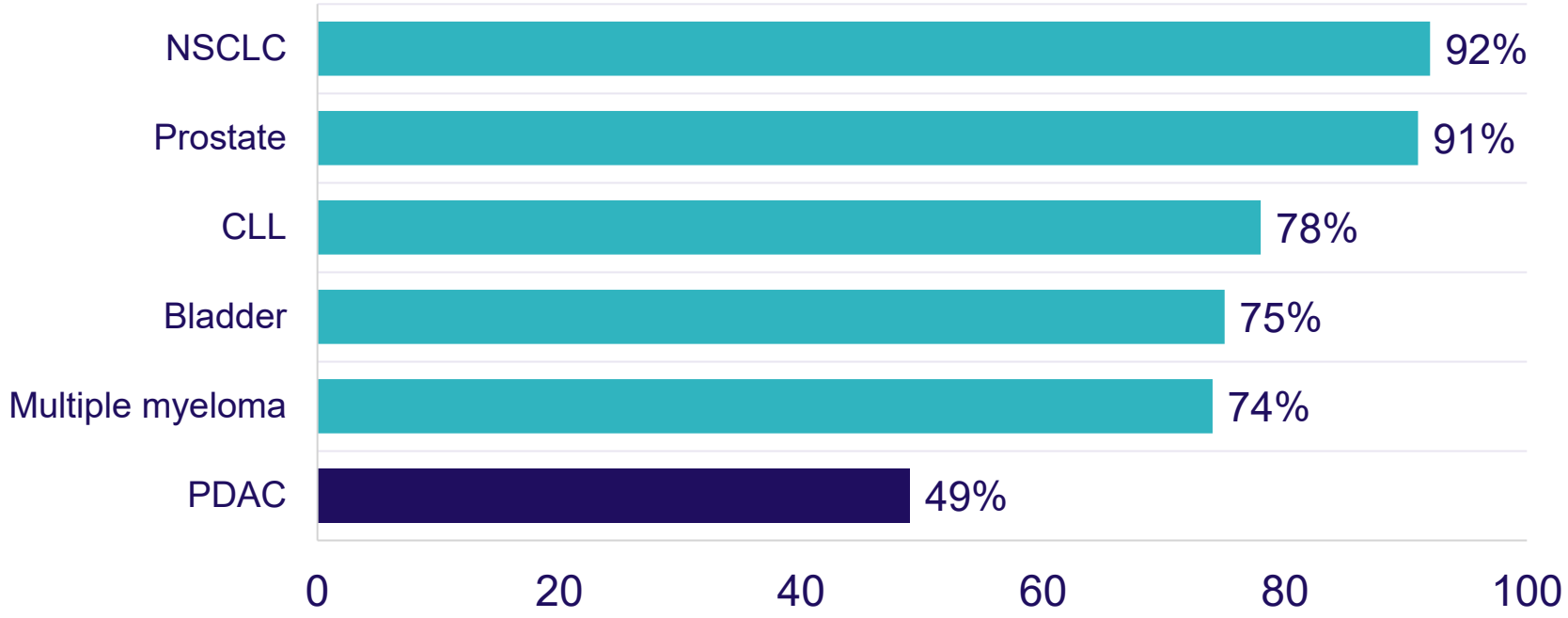
* Snapshot - NSCLC has 1922 studies as of Nov 5th

Approval–guideline alignment varied by indication

- Among studies evaluating EMA-approved therapies, alignment with European guidelines varied across indications.

Studies evaluating EMA-approved therapies also supported by European guidelines (%)



43

percentage-point difference

Between NSCLC and PDAC

Guideline alignment ranged from 49% in PDAC to 92% in NSCLC

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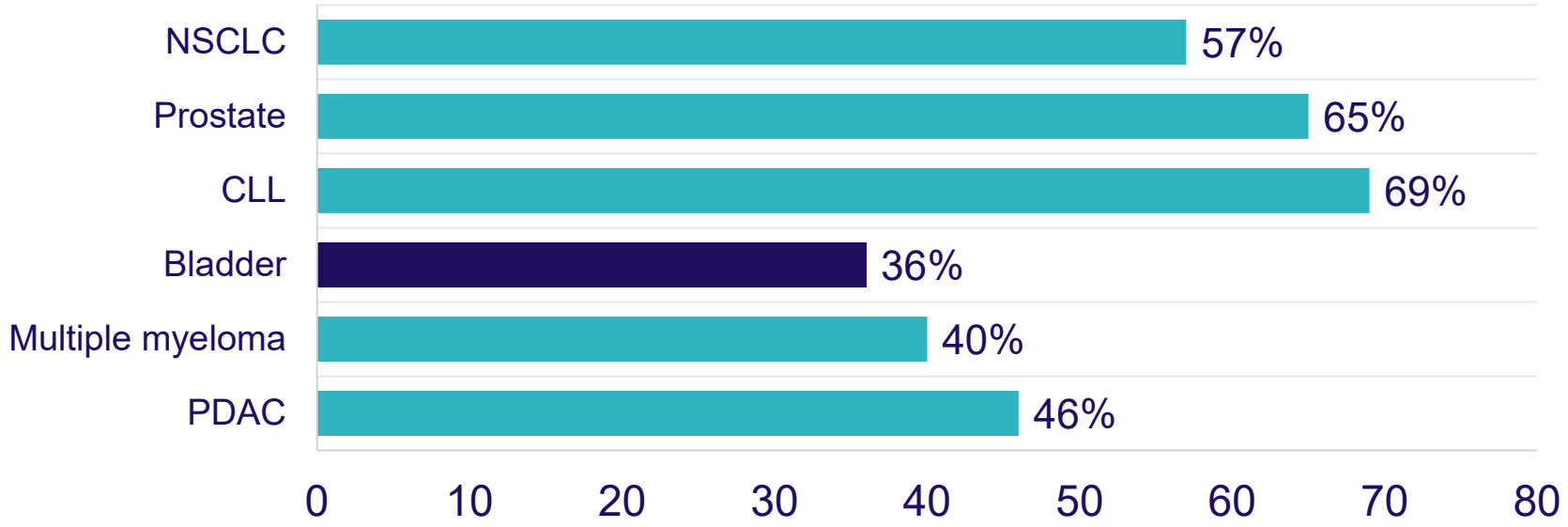
EMA, guideline and NICE alignment

EMA approval
Regulatory status

EU guidelines
Clinical recommendations

NICE positive decisions
HTA recommendations

- Percentage of studies evaluating EMA-approved therapies with both EU guideline support and positive NICE decisions



36–69%

Alignment across all three sources

NICE represents one reimbursement context

Only 36%–69% aligned with both EU guidelines and positive NICE decisions

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Drivers of divergence



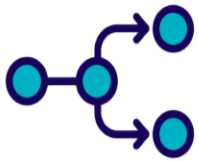
Older therapies

Approval persists after guidelines move toward other options



Emerging therapies

Guideline recommendations may precede regulatory approval



Sequencing changes

Comparator relevance changes by treatment line and prior exposure



Biomarker strategies

Tumor-agnostic approvals may precede guideline adoption



The relevant comparator set can change while regulatory approvals remain in place

Implications for comparator selection

PICO mapping integrates evidence, clinical expertise and local access

Current relevance

SLR evidence



- Review guideline position alongside regulatory status
- Use real-time evidence from multiple sources

Clinical setting

HCP input



- Assess disease stage, biomarker, treatment line and prior therapy
- Validate with disease-specific oncologists in each country

Local access

Payer input



- Assess jurisdiction-specific reimbursement and availability
- Incorporate payer perspectives on each country's access landscape

Document the rationale for including or excluding each comparator within the relevant PICO

Conclusions and next steps

- **Regulatory approvals, European guidelines and NICE decisions showed substantial divergence across six oncology indications**

Study limitations

A snapshot already outdated

- The analysis reflects June 17, 2026. Evidence and treatment standards have continued to evolve.

NICE-only HTA comparison

- Expand comparisons across national HTAs to capture differences in local access.

Living evidence today

Substantially more studies

The continuously updated database now contains a much larger evidence base.

All EU/UK HTAs – 28 HCP + 28 Payers panels

Broader coverage enables an updated comparison across HTA settings.

Comparator selection needs living evidence that reflects evolving care and local access

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Thank you

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