

Predicting PICOs for EU HTA: The validated PICO planner approach based on retrospective analysis

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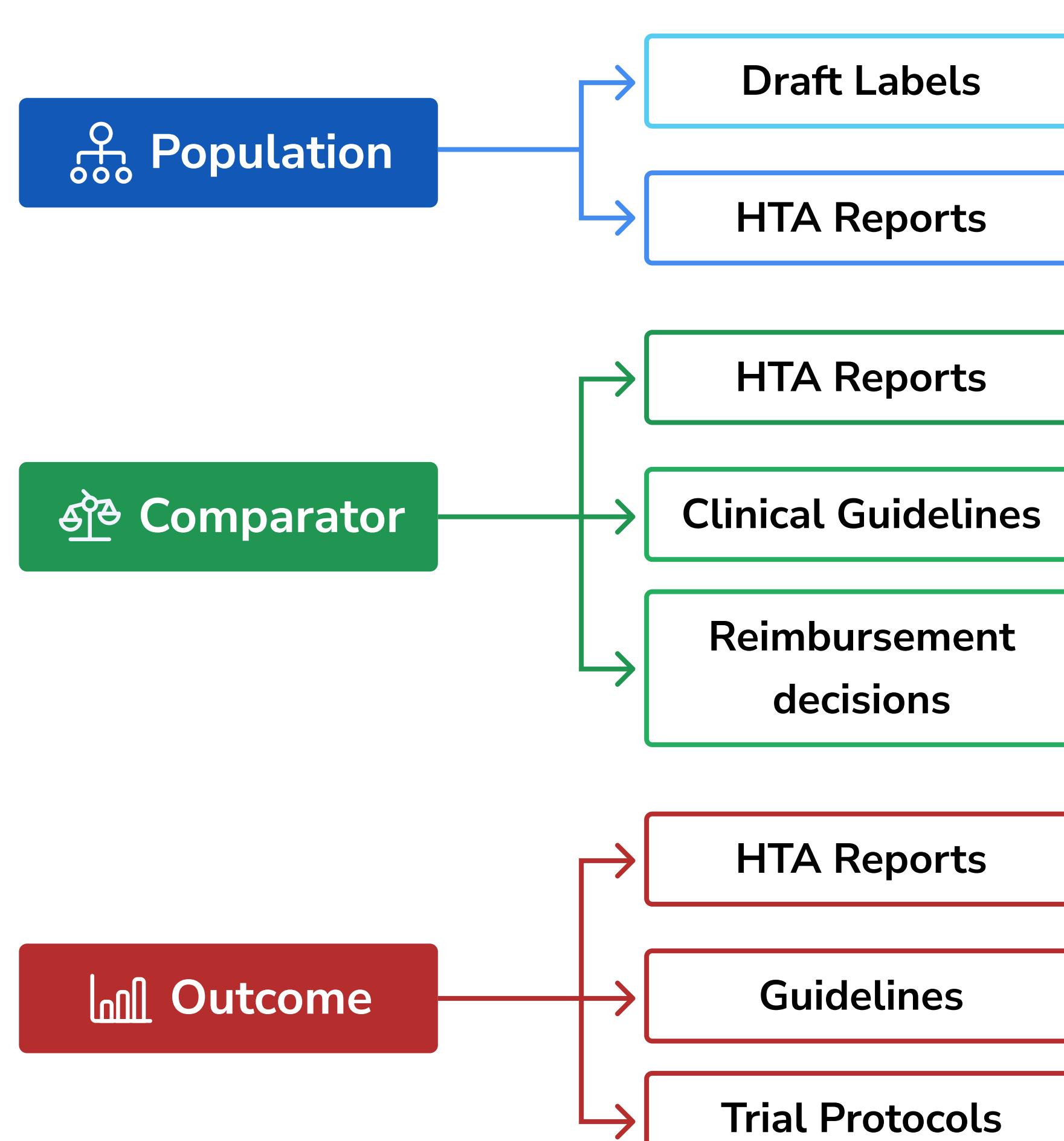
BACKGROUND AND OBJECTIVE

The European Union Health Technology Assessment Regulation (EU HTAR) and Joint Clinical Assessment (JCA) aim to harmonize clinical evaluations while allowing national Health Technology Assessment (HTA) decisions.

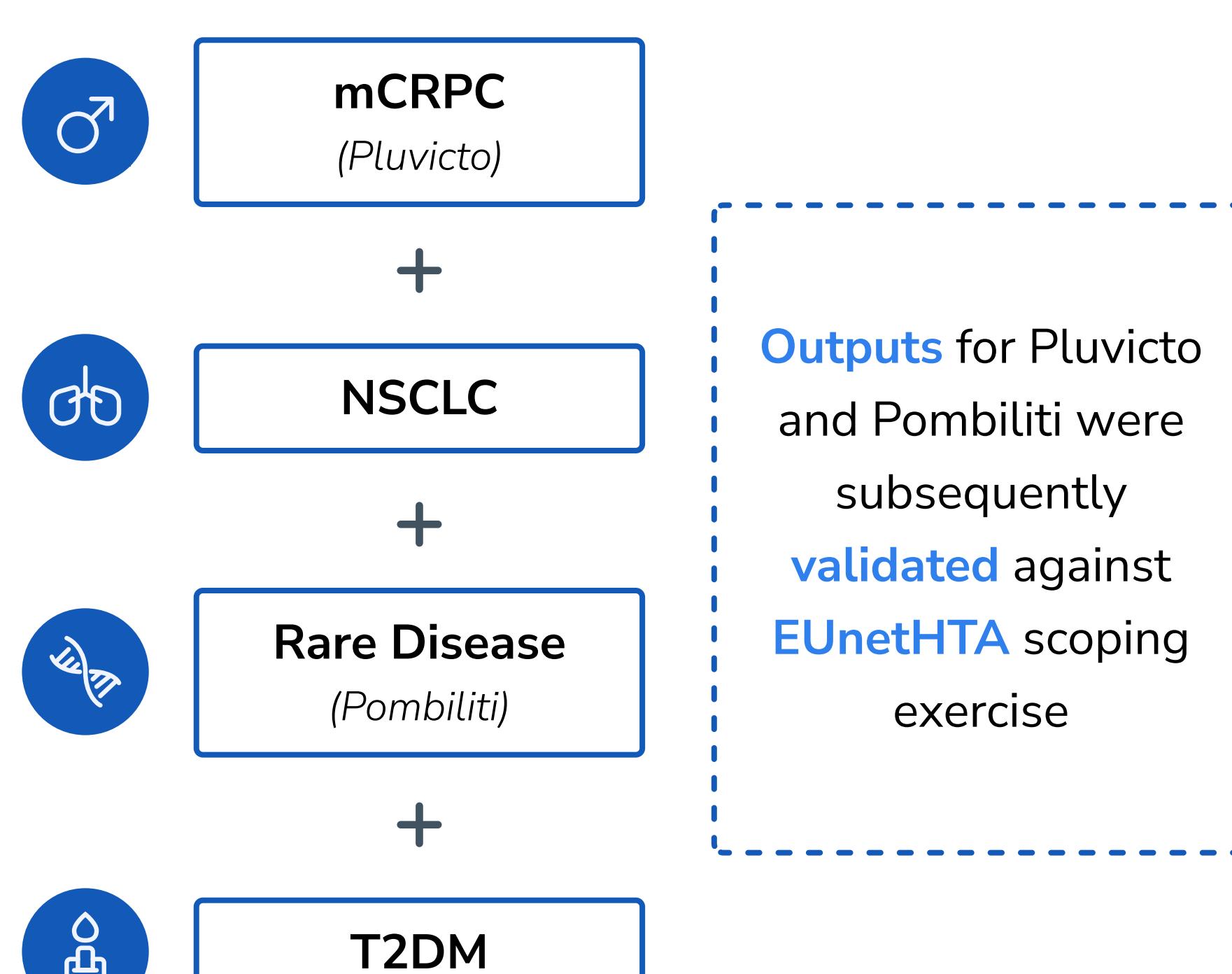
Each country defines its own Population, Intervention, Comparator, and Outcomes (PICO). This research evaluated how targeted literature reviews using HTA reports, clinical guidelines, and reimbursement decisions—combined with a structured “PICO planner” methodology—can anticipate national and EU-level PICO requirements.

METHODS

1 PICOs were developed independently based on secondary research, without knowledge of EUnetHTA results, using a **3-step consolidation process** aligned with HTA Coordination Group (HTACG) Scoping Guidelines.



2 Exercises were conducted across 4 products



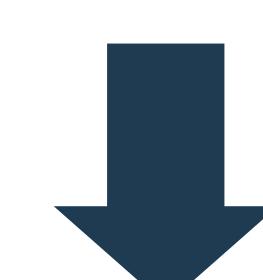
3 Country specific PICOs for all 27 EU member states were collected, and further were consolidated in line with JCA guideline

RESULTS

A consistent methodological approach and **3-step consolidation process** effectively predicted PICOs for all four drugs, with steps unchanged across products.

VALIDATION AGAINST EUNETHA SCOPING EXERCISE

	PLUVICTO [®] lutetium Lu177 vipivotide tetraxetan INJECTION FOR INTRAVENOUS USE	POMBILITI [®]
Population	100% accuracy: All sub-populations and full populations were identified	100% accuracy: All sub-populations and full populations were identified
Comparators	93% accuracy: All comparators were captured except apalutamide, which was off-label and not mentioned in guidelines or HTA documents.	100% accuracy: All comparators were identified
Outcomes	100% accuracy: All the outcomes were predicted	93.75% accuracy: Some PROs unique to the client trial were not included by the PICO Planner. Future updates will address this



REAL LIFE CASE STUDIES

Oncology (NSCLC)	Late-stage PICO Planning	7-10 Consolidated PICOs
Cardio- metabolic (T2DM)	Early-stage PICO Planning, TPP not defined	25-28 Consolidated PICOs

KEY TAKEAWAYS:

- The validated PICO planner approach demonstrates high predictive accuracy across multiple therapeutic areas, supporting its reliability for EU HTA alignment.
- Early-stage PICO planning yields broader and more comprehensive PICOs, enabling better design of phase III trials and evidence generation strategies.
- Late-stage planning allows for more focused and streamlined PICOs, supporting clear strategic alignment.

CONCLUSION

The findings demonstrate that a structured, **data-driven approach to evidence collection and consolidation** can predict PICOs.

- Further supported through validation with **country affiliates** and **SLRs**.
- Fosters **collaboration with HTA stakeholders**, enhances evidence planning.
- Enhances evidence planning and **accelerates reviews**.
- Promotes equitable, **value-based access**.
- Positions **secondary research** as a **driver of patient-centered innovation** across Europe.

DISCUSSION

- The PICO planner cuts months of manual work into weeks by **automating data collection and standardizing analysis**—freeing teams to focus on insights and strategy.
- Future research will validate PICOs developed using this approach against **JCA dossiers** expected in 2026, offering prospective confirmation of its accuracy and strengthening its role in early evidence planning for EU HTA.

REFERENCES

- NAVLIN HTA database
- NAVLIN Price and access database
- ESMO/EASD guidelines
- EUnetHTA PICO exercises of Pluvicto and Pombiliti

DOWNLOAD POSTER

