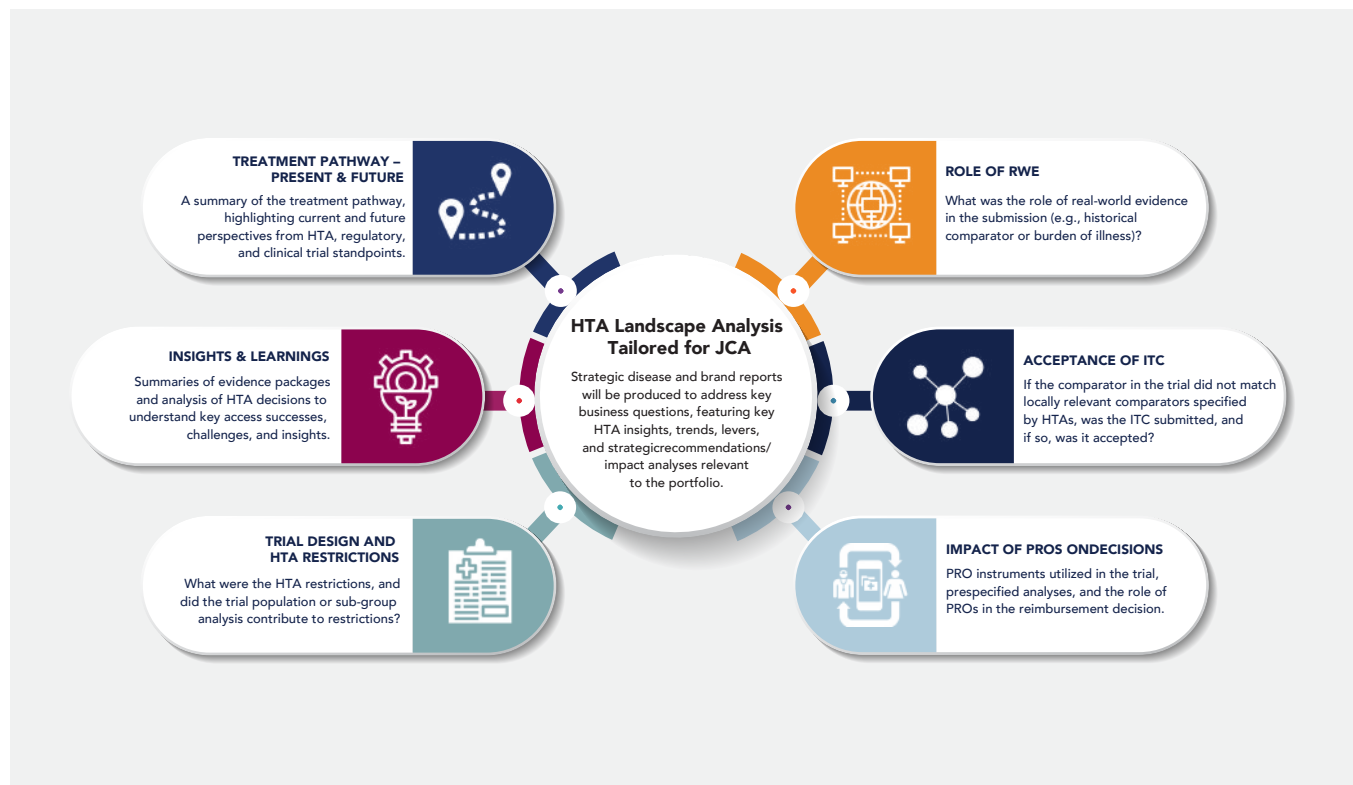


# Strategic PICO Planning: Enhancing Early-Phase Development for Market Access

## Overview

In an increasingly competitive and complex healthcare landscape, early and strategic PICO (Population, Intervention, Comparator, Outcome) planning has become a cornerstone of successful evidence generation. On top, latest regulatory updates like the European JCA do use PICO to create EU-wide consensus for therapy assessments. NAVLIN by EVERSANA's PICO Planner methodology enables clients to anticipate HTA requirements, align internal stakeholders, and make informed decisions across the asset lifecycle.

The following case study illustrates how NAVLIN by EVERSANA supported a distinct client scenario - in early-phase development - by delivering tailored, actionable PICO strategies.



## Case Study: Early PICO Prediction for Pre-Phase II Assets

A global pharmaceutical company managing a diverse pipeline sought support in predicting PICOs for several pre-Phase II assets across multiple therapeutic areas. The challenge was that the Target Product Profiles (TPPs) were not finalized, yet there was a need to align early trial design with future EU Joint Clinical Assessment (JCA) requirements and market access considerations.

### Objective

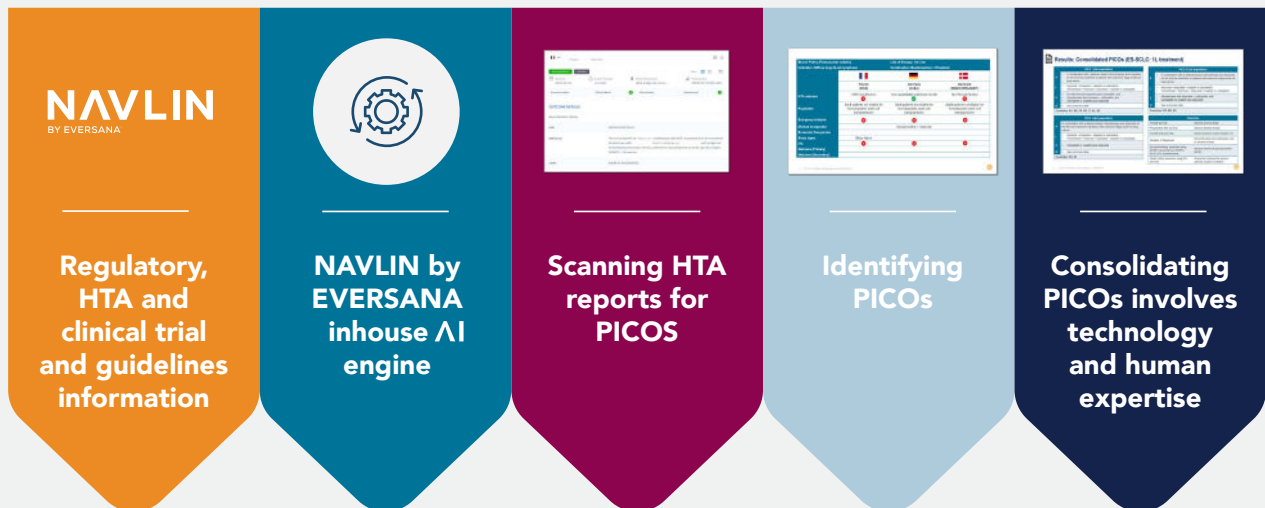
To develop a strategic PICO framework that could guide Phase II/III trial design and long-term evidence strategy, ensuring early-stage development remained adaptable to evolving HTA requirements and competitive dynamics.

### Approach

NAVLIN by EVERSANA applied its PICO planner methodology to:

- ✓ Review Clinical Guidelines, HTA Decisions, and Trial Data across 27 EU member states to identify payer-relevant endpoints and comparators.
- ✓ Develop a Comprehensive PICO Set ranked using a feasibility-and-prioritization framework, ensuring that initial PICOs could evolve as data matured.
- ✓ Conduct Retrospective HTA Analyses of analogous products to anticipate country-specific parameter requirements and their impact on HTA outcomes.
- ✓ Group Countries by Parameter Criticality (high, moderate, or low impact) to inform trial design choices and endpoint selection.

## Extraction of PICO Elements and Consolidation of PICOs



## Results:

- ✓ Delivered country-specific and consolidated PICO, tailored to pre-Phase II development realities, providing a clear path for optimization as TPPs evolved.
- ✓ Created a future roadmap identifying triggers for PICO updates—such as competitor loss of exclusivity, new guideline publications, and emerging clinical evidence—before JCA submission.
- ✓ Provided strategic trial design recommendations to optimize patient population definitions, comparator selection, and outcome measures.
- ✓ Enabled cross-functional teams to align on evidence generation priorities well before trial initiation, ensuring long-term market access readiness.

## Key Outputs:

- ✓ **Strategic Framework:** Comprehensive PICO set ranked for feasibility and prioritization.
- ✓ **Future Trial Design:** Cross-country HTA parameter comparison to guide endpoint and comparator selection.
- ✓ **Future Roadmap:** Pipeline tracking and PICO update triggers, with actionable next steps for JCA preparation.

“  
**Client Feedback:**  
You delivered both, all details in a trackable Excel and strategic recommendations in a leadership-ready format.  
”

## Conclusion

This case study demonstrates the versatility and impact of NAVLIN by EVERSANA's PICO planner methodology. Whether navigating crowded oncology markets or shaping early-phase development, we equip clients with the tools to make evidence-driven decisions—early, strategically, and confidently.

### Validating NAVLIN by EVERSANA's PICO Simulation Approach Using PICO, from Pluvicto and Pombiliti (EU netHTA Scoping Exercises)



#### Population

100% accuracy: All sub-populations and full populations were identified

100% accuracy: All sub-populations and full populations were identified

#### Comparator

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



EVERSANA is the leading provider of global commercialization services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, providers, channel partners and payers. The company serves more than 650 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences services for a healthier world. To learn more about EVERSANA, visit [EVERSANA.COM](https://EVERSANA.COM) or connect through [LinkedIn](#) and [X](#).