Preparing for Joint Clinical Assessments:

How Early PICO Planning Ensures Smoother Submissions

What is the JCA and why does it matter?

The European Union's (EU) Regulation 2021/2282 on health technology assessment (HTA) seeks to enhance access to innovative health technologies by **minimizing duplication among national HTA bodies** and improving resource efficiency. Beginning in 2025 for cancer treatments and advanced therapy medicinal products (ATMPs), with **full implementation by 2030**, the regulation introduces significant changes to the EU market access ecosystem.

The Joint Clinical Assessment (JCA) **will streamline evaluations by consolidating data submissions** across member states, reducing redundancy and enabling companies to focus on generating high-quality evidence for faster market entry and reimbursement. However, the **JCA will not assess cost-effectiveness** or make statements on product value, and while it is **nonbinding**, it should inform member states' decision-making.

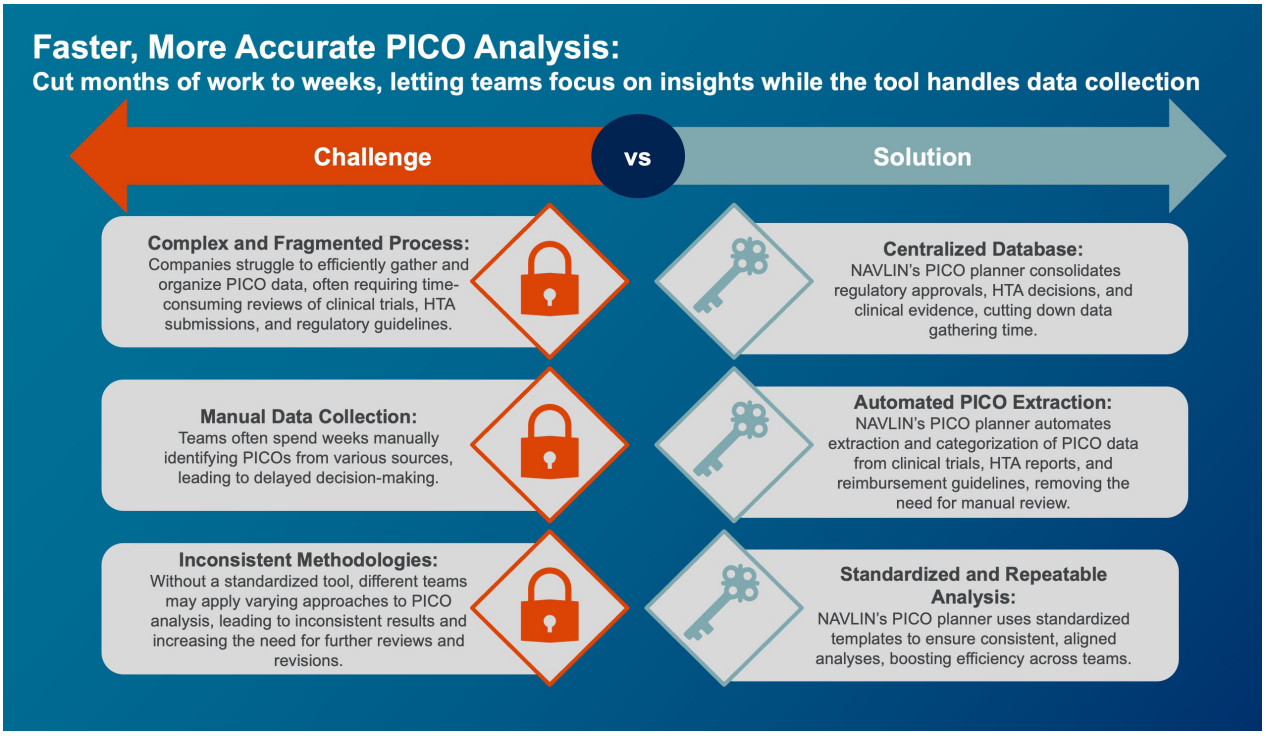
What is the scoping process in the JCA, why is it important and what challenges does the PICO bring?

The scoping process in JCAs is critical, as it defines the research questions manufacturers must address in their submissions, using the PICO – population, intervention, comparator outcome – framework. This process gathers input from all EU member states, consolidating their needs into a unified scope for manufacturers. However, the **challenge lies in predicting and aligning with the potentially diverse requirements** of each country, making it difficult to ensure compliance.

A key challenge with the PICO framework is the **uncertainty surrounding how member states' input will be consolidated**. The number of PICOs can vary significantly, from as few as six to as many as 30, which increases the workload for manufacturers, who must provide comprehensive evidence for each. This unpredictability, along with tight timelines, has led to concerns in the industry about adequately preparing for unforeseen research questions and the potential impact on market access in Europe. Effective **early PICO precision and careful planning are essential to avoid delays** in submissions and reimbursement.

Steps companies should consider for efficient PICO planning:

1. **Analyze the current and future treatment landscape:** Perform an in-depth review of existing treatment options, and forecast potential changes to stay proactive in a shifting market.
2. **Understand payer decision-making:** Investigate how payers in Europe approach reimbursement decisions for your drug class and indication, ensuring your strategy aligns with their priorities.
3. **Identify PICOs early in the process:** Collaborate with clinical and market access experts across Europe to anticipate possible PICO requests and adjust your evidence strategy accordingly.
4. **Report risks and opportunities:** Communicate the strategic implications for your JCA approach, covering aspects such as evidence selection, comparators, outcomes and costs, to ensure all stakeholders are on the same page.



How can NAVLIN by EVERSANA's PICO planner help with your PICO planning process?

NAVLIN's PICO planner is a comprehensive tool designed to simplify the evidence planning process, supported by advanced data insights and AI-driven analysis.

With the PICO planner, you can:

- **Streamline PICO identification:** Leverage AI-powered insights to predict and identify relevant PICOs based on your drug's indication and payer needs.
- **Enhance global evidence planning:** Anticipate global HTA requirements by integrating evidence from multiple regions, simplifying the preparation of submissions.
- **Simulate future scenarios:** The PICO planner allows companies to simulate future payer requests, helping you refine your strategy before submissions.

Why is simulation important, and when should a PICO planner be used?

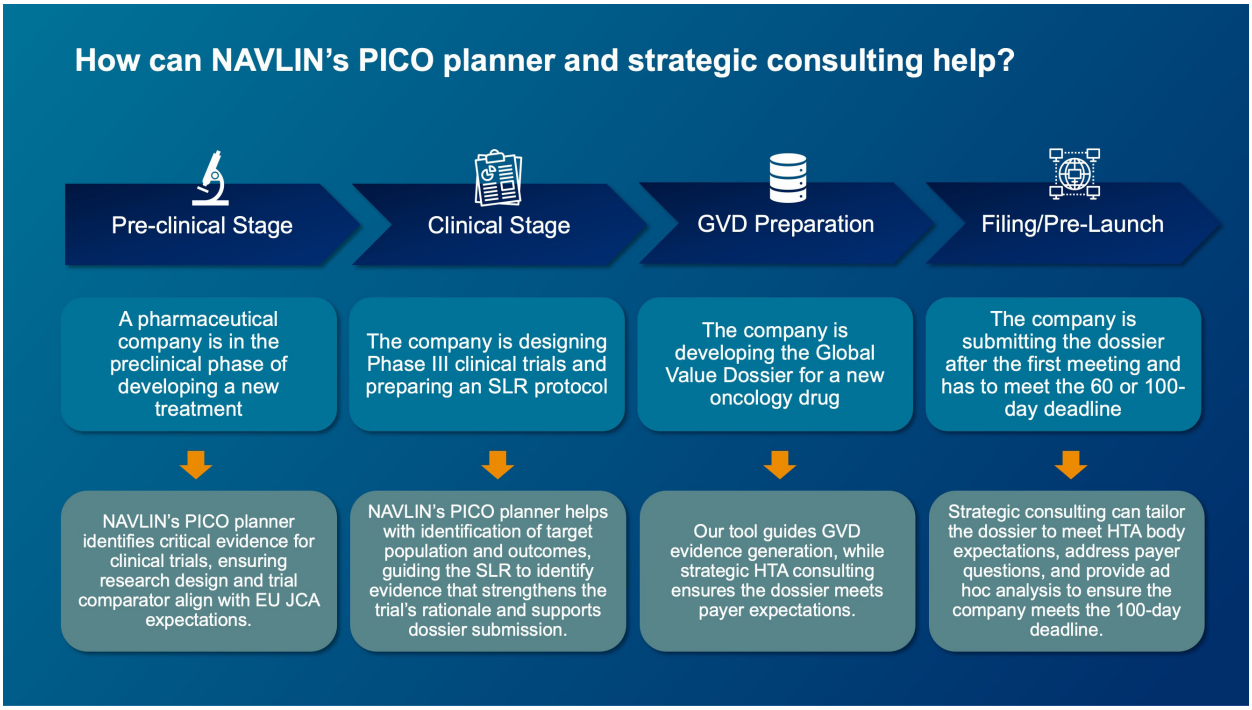
PICO simulations are essential for a strong submission and avoiding surprises in the regulatory process.

Key stages include:

- **End of Phase 2:** Align Phase 3 trials with European HTA requirements.
- **18 months pre-submission:** Refine PICO predictions based on the current landscape.

NAVLIN's PICO planner helps test and validate evidence, ensuring it meets JCA standards. It also allows you to simulate payer reviews, validate findings and identify risks to adjust your evidence plan.

> **"Early simulations are crucial for ensuring strong submissions and preventing regulatory surprises. By leveraging technology, such as NAVLIN's PICO planning tool, this exercise can be completed in weeks instead of months, enabling faster decision-making and timely submissions."**



Navigating Change: The Road Ahead for Pharma

The implementation of JCA and early PICO planning present several implications and challenges for pharmaceutical companies:

- **Focus on Europe:** The JCA highlights Europe as a key market, prompting early integration of PICO planning into Phase 3 development. However, while PICO evaluations will be consolidated, individual member states may still request additional evidence, complicating submissions.
- **Risk of resubmission:** Changes in PICOs following the CHMP opinion could require a repeat of the JCA process, leading to potential delays and increased workload.
- **Equity in market access:** While the JCA does not directly address pricing, it may empower smaller markets to negotiate better based on evidence, potentially enhancing patient access to innovations across Europe.
- **Cross-functional collaboration:** All teams involved in evidence development need to align with the new EU HTA processes. Early education and engagement are essential.
- **Early PICO integration:** Companies should integrate PICO predictions into Phase 3 planning and refine them 12 to 18 months before submission to ensure thorough preparation.
- **Navigating national procedures:** Despite the JCA's regional focus, national processes remain crucial for reimbursement decisions, necessitating tailored strategies for each country.

NAVLIN's PICO planner assists companies by delivering faster and more accurate PICO analysis. Traditionally, companies have conducted this analysis manually; however, the PICO planner uses technology to accomplish months of work in just weeks, facilitating quicker decision-making and timely submissions. This enables teams to concentrate on insights and actions while efficiently managing data collection and analysis.

References

1. European Commission. Health technology assessment: Joint clinical assessments of medicinal products. Accessed October 28, 2024, from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13708-Health-technology-assessment-joint-clinical-assessments-of-medicinal-products

2. European Commission. Health technology assessment: Cooperation with the European Medicines Agency. Accessed October 28, 2024, from https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14164-Health-technology-assessment-cooperation-with-the-European-Medicines-Agency_en