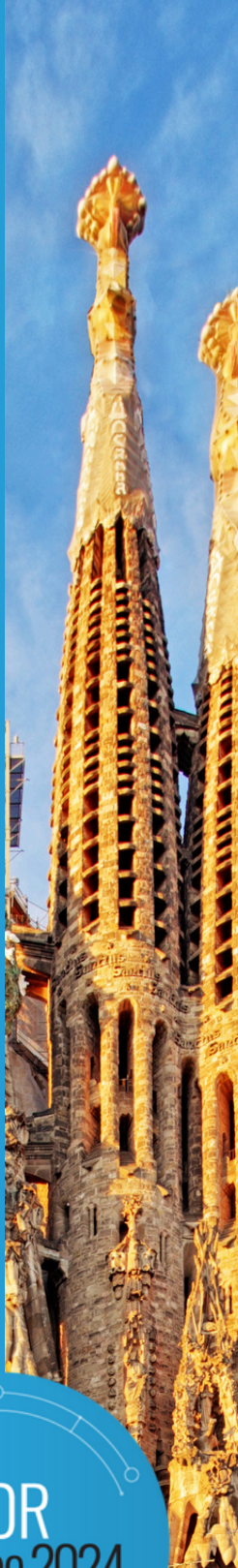
# TODAY AT ISPOR



## Our overview of the plenary session from Tuesday 19th November 2024

ISPOR Europe 2024 Presenter

Remap

# Plenary 200b: Ready, Set, Go: The Last Sprint for the EU HTAR

**SPEAKERS**: Anne Willemsen, Roisin Adams, Vanessa Schaub, Michal Stanak, Valentina Strammiello

## INTRODUCTION

The plenary began with opening thoughts from the panel members, expressing optimism about the European Health Technology Assessment Regulation (EU HTAR). They highlighted hopes for faster, broader, and more equitable patient access to innovative drugs, which could build trust in the system. Expectations included timely, high-quality assessments to reduce uncertainty and enable member states to make smarter decisions. The chair of the coordination group emphasised a pivot towards producing high-quality evidence, critical for achieving these objectives.

## SHORT-TERM IMPLEMENTATION AND READINESS

Discussions moved to the short-term readiness for EU HTA implementation. The chair of the coordination group stated that the EU is prepared; supported by implementing acts and guidance documents. The first 30 Joint Clinical Assessments (JCAs) are anticipated in 2025, with publications starting in late 2025 or early 2026. While flexibility in guidance is limited, a pragmatic approach was encouraged to handle diverse scenarios while ensuring equity. A review of processes is planned for 2028.

From a national perspective, less established HTAs view this as an opportunity to develop more robust processes despite an increased resource burden. Roche shared insights into their internal reorganisation to prepare for JCAs, emphasising new cross-functional working methods, improved communication between global and affiliate teams, and increased statistical resources.

## PATIENT ADVOCACY AND PICO SCOPING

Patient advocacy groups have been focusing on raising awareness and providing training to diversify patient representation in EU HTA.

Efforts are also underway to align patient needs across member states to reduce fragmentation in PICOs (Population, Intervention, Comparison, Outcomes).

From a health technology developer (HTD) perspective, Roche has already conducted PICO scoping exercises for assets expected to undergo JCAs in 2025. These exercises revealed a high number of PICOs, with over 20 for each asset. However, the HTD is not involved in PICO scoping, leaving only 100 days to develop the JCA submission dossier after receiving PICOs. Joint Scientific Consultations (JSCs) were highlighted as invaluable for preparing HTDs, with a call for more meaningful scientific advice.

## ADDRESSING LONG-TERM IMPLEMENTATION CHALLENGES

The panel discussed long-term implementation, including the challenge of timeliness. Concerns about JCAs becoming outdated due to delayed submissions and the need for updated data cuts were raised.

There is hope that alignment among countries will reduce the number of PICOs over time, streamlining processes. Sustainable patient involvement is essential, requiring continuous updates to tools and training and upskilling HTA bodies. For HTDs, the upfront investment in EU HTA could result in reduced duplication and resource use in the future.

Ultimately, alignment of evidence requirements at the national level could strengthen the EU's voice in healthcare decision-making, enabling more efficient and impactful systems.

## CLOSING THOUGHTS

The panel's closing remarks emphasised the need for a smooth transition in January 2025, with collaboration from all stakeholders to improve decision-making across the EU. In the long term, the panel aspired for the EU to set a global example in HTA, demonstrating how unification can enhance healthcare systems, access, and patient outcomes. Increasing the quality of evidence was highlighted as a key priority, with the hope for smarter trials designed to answer critical questions for healthcare systems.

## THE 3 KEY TAKEAWAYS

1. The EU HTAR aims to reduce duplication and align evidence requirements, benefiting both HTDs and member states
2. Producing relevant, high-quality evidence is essential for smarter decision-making and equitable patient access
3. Continuous training and tools are needed to maintain meaningful patient engagement across diverse member states

# We always welcome your thoughts and opinions on the topics raised at ISPOR.

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