**Session: EU HTA in 2025: Finish line or starting gate?**

*Chair: Lara Wolfson, MSD*

The first EU-level Health Technology Assessment (HTA) submissions will kick off on the other side of January 2025, mandating submission of EU-level HTA evidence dossiers as part of the EU HTA Joint Clinical Assessment (JCA) process. The evidence dossiers will inform decisions about access to innovative treatments for patients across Europe and will necessitate the use of both conventional and innovative statistical methods on a scale, scope, and speed never seen before.

However, what exactly does this mean for statisticians involved in the EU HTA JCA? Does this mark the end of preparations, or is it the starting gate of an ultra-marathon? What part will statisticians play in one of the most significant policy changes to affect the pharmaceutical industry in the last decade?

With implementing acts, evidence dossier templates, and learnings from the EUnetHTA JCA pilots at hand, we can now piece together a projection of what lies ahead. Join this session to learn about how statisticians can help enhance the relevance of JCA for decision-making at the member-state level.

**Presentation 1 - Overview of implementing acts and dossier templates**

*Thomas Ecker, Ecker & Ecker*

As per HTA Regulation (HTAR) the Implementing Acts (IA) are intended to provide key documents for the upcoming HTA process, including the dossier template as well as the template for JCA report. Now the first IA is being published as a draft. Whereas the timelines for the health technology developer (HTD) remain unchanged, some (optional) opportunities for interaction between the HTD and the relevant HTA institutions have been defined. And the scoping process has been streamlined, as indicated in the updated deliverable D4.2. Compared with deliverable 5.1 (dossier template) and 5.2 (report template), both documents have been considerably simplified and shortened. Even though this will simplify dossier preparation, the value of the dossier for the subsequent national processes might suffer. National implementation of HTAR will only be discussed after the IA are adopted, which is expected for 2nd half of 2024, causing additional challenges for the first companies undergoing EU HTA.

**Presentation 2 - EU HTA, the future is here - what did we learn from the EUnetHTA Joint Actions and will it be a bumpy ride?**

*Sandro Gsteiger & Per-Olof Thuresson, Roche*

The EU HTA regulation formalises the HTA collaboration in Europe, building on two decades of voluntary cooperation within the framework of the European Network for Health Technology Assessment (EUnetHTA). The Relative Effectiveness Assessments (REAs) performed as part of the so-called EUnetHTA Joint Actions can be seen as precursors to the Joint Clinical Assessments defined in the regulation.

 We will briefly summarise the REA process and share some of our experiences from participating in three REA pilots. This includes challenges and lessons learned for a number of areas such as European PICOs, timelines, and local usage. Conducting REAs in parallel with regulatory assessments is inherently uncertain since the final label is not known at the time of analysis. This second-guessing increases the assessment scope as one needs to ensure that our population definition covers the population expected in the final label. In addition, EU level PICOs must balance local differences with the need for harmonising the decision problem to keep it manageable. Additionally, we will explore the incorporation of REA dossiers into local decision-making processes, especially in countries where cost-effectiveness models heavily influence appraisals.

 These topics are highly relevant also for EU HTA as set forth by the regulation. We will draw connections between past REA experiences and the proposed framework, specifically considering insights from the Implementing Act on JCA and the evolving methodological guidelines. Finally, we will conclude with some considerations on the implications for (industry) statisticians and for the broader HTA community in general.

**Presentation 3 - The relevance of JCA for national decision-making: the Dutch perspective**

*Jelena Stevanovic, BMS*

| EU HTA Regulation represents an opportunity to streamline evidence assessment across Europe. When carrying out a national HTA on a health technology for which JCA reports have been published or for which a JCA has been initiated, MS are expected to give due consideration to the published JCA reports in their local HTAs, while maintaining their competence to draw conclusions on the overall clinical added value of a health technology in their local healthcare system. Dutch HTA consists of clinical benefit assessment and economic assessment including both a cost-effectiveness and budget impact analyses. We will briefly summarize how comparative effectiveness/safety analyses have been traditionally used in the Dutch market vs. how they might be impacted in the future by the JCA process once EU HTA regulation becomes effective in 2025.  |
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