**HTA ESIG Townhall**

**EU HTA: readying ourselves for the road to 2025 and beyond**

*Session Chair: Lara Wolfson, MSD*

Health Technology Assessment (HTA) has historically been a topic for the select few statisticians specializing in HTA, and something that took place relatively siloed from regulatory statistical work. Once regulatory statisticians had argued efficacy and safety of a new treatment, HTA statisticians could take over to help quantify the added clinical and economic value.

With healthcare systems increasingly moving towards a value-driven approach, HTA will demand the attention of statisticians across the product life cycle. Cross-border initiatives like EU HTA will very literally put HTA side by side with regulatory assessment, requiring statisticians to carefully consider how to integrate HTA needs in pivotal trials, and how to manage complex HTA and regulatory statistical work simultaneously. The road ahead has challenges, but also unique opportunities for statisticians to break down silos and take leadership - as experts in strategically anticipating and mitigating uncertainty across many different types of evidence.

Join this session to hear reflections from key institutions and organizations on the road ahead in HTA - and how pharmaceutical statisticians can help pave it.

**Presentation 1**

**In the crystal ball: how the world might look for a pharmaceutical statistician when EU HTA is here**

*Anders Gorst-Rasmussen, Novo Nordisk*

Pan European Health Technology Assessment (EU HTA) is coming. Starting in 2025, manufacturers will be required to submit an HTA evidence dossier while EMA regulatory review is ongoing. The evidence dossier must simultaneously address all EU member states' questions on the relative effects of a new treatment, and will form the basis of the so-called Joint Clinical Assessment (JCA).

This may sound a lot like the EMA regulatory dossier and review but the scope of JCA will be very different: to support member state judgement of the added clinical and economic value of the new treatment within the context of their healthcare system. Accordingly, to ensure relevance within their health care system, a member state may ask questions involving different comparators, different populations, or different outcomes than those used in pivotal trials. And to address those questions with the available evidence, the HTA dossier may involve anything from subgroup analyses of pivotal trials, to observational studies, to network meta analyses.

 The concurrency with EMA regulatory review, the very short timelines, and the sheer scope of work needed for JCA is likely to have a major impact on how we operate as pharmaceutical statisticians. In this talk, I will reflect on how the world might look for a pharmaceutical statistician when EU HTA is here.

**Presentation 2**

**German requirements for direct and indirect comparisons in HTA dossiers**

*Ralf Bender, IQWiG, Germany*

According to the law on the reorganization of the pharmaceutical market, new approved drugs have to undergo an early benefit assessment in Germany since January 2011 with the aim of a structured price regulation. The basis of the early benefit assessment is given by dossiers prepared by the manufacturer submitted to the Federal Joint Committee (G-BA), which can commission the Institute for Quality and Efficiency in Health Care (IQWiG) with an assessment of the dossier. According to the Regulation on Health Technology Assessment (EU) 2021/2282, a European joint clinical assessment of HTA dossiers comes into application in January 2025 after a 3-year implementation period. The EUnetHTA 21 joint consortium was established to develop guidance documents to support the implementation of the EU HTA regulation. The first EUnetHTA 21 deliverables are already published, e.g., the methods and the practical guideline on direct and indirect comparisons. Although the joint clinical assessment has to be taken into account in the future, each EU member state remains responsible for drawing conclusions on the added value for their health system and taking decisions on pricing and reimbursement. In this talk, an overview of the German requirements for the HTA dossiers is given with a special focus on direct and indirect comparisons.

References

EUnetHTA 21 Methods Guideline D4.3.2: Direct and Indirect Comparisons, Version 1.0, 29.07.2022.<https://www.eunethta.eu/d4-3/>.

EUnetHTA 21 Practical Guideline D4.3.1: Direct and Indirect Comparisons, Version 1.0, 16.12.2022.<https://www.eunethta.eu/d4-3/>.

IQWiG: General Methods, Version 6.1. IQWiG, Cologne, Germany, 2022.<https://www.iqwig.de/en/about-us/methods/methods-paper/>.

**Presentation 3**

**Where can collaboration add value to HTA – A look at the UK, Australia and Canada**

*Zoe Garrett, NICE*

In May 2022 HTA agencies in the UK, Australia and Canada signed a collaboration arrangement to formalise a relationship that started during the COVID-19 pandemic. The collaboration arrangement identified 5 priority areas for collaboration including: (1) COVID19 related intelligence sharing, (2) futureproofing HTA systems, (3) collaborating with regulators, (4) work-sharing and efficiency gains, (5) digital and AI. This presentation will describe learnings from the first year of activity arising from the arrangement and where the group has chosen to focus their activities to provide most value to the agencies. It will cover activities described in the collaboration arrangement including development of science and methods and work sharing.

**Presentation 4**

**Statistical leadership: Do we hold the key to the future of HTA?**

*Justine Rochon, Boehringer Ingelheim*

No one holds the key to the future of HTA that is fast approaching.

Statisticians can, however, shape the future by treating data as a strategic asset they are responsible for throughout the entire lifecycle engagement.

Join this session with Justine Rochon, SVP Global Biostatistics and Data Sciences at Boehringer Ingelheim to learn why HTA is really a customer problem, and how statisticians can use their knowledge and creativity to solve it. Come for an informative session and leave it with some food for thought on why and how we should all learn to speak HTA statistics. The ultimate goal is to make your HTA initiatives successful and your HTA work more enjoyable in the future.