Summary of sessions (in random order)

Regulator updates. Representatives from various regulatory agencies will discuss what they currently perceive as hot topics.

Estimands – Celebrating the 5th anniversary of ICH E9(R1) – what have we learned and where do we need to go? This year, November 20, the ICH E9(R1) will turn 5 years. We will discuss what has been achieved by introducing the estimand framework and the estimand thinking, but also the challenges we face including what needs to be improved going forward.

Openstatsware. We will discuss how open source software can be used in relation to marketing authorisations and how regulators assess the appropriateness of it.

Fast to market vs. Robustness of the data. There is considerable pressure on industry statisticians to ensure earlier delivery of trial results by considering various aspects such as smaller sample sizes, seamless phases, trial design adaptions, early unblinding etc. There are also different regulatory pathways that can be considered, e.g., FDAs accelerated approval, 21st Century Cure Act; EMA: PRIME, conditional approvals. The session will discuss considerations for ensuring sufficient robustness of data.

Patient centricity. Patients should be in the centre of drug-development, but how do we ensure that? What are the regulatory steps taken to ensure the patient voice is heard? We will not only get input from regulatory agencies and industry, but also from a patient.

We will of course also host our popular **short topics session** and we invite all of you to submit a problem you want to present to and discuss with a panel of regulators. Proposals should be sent to Helle Lynggaard, hlyn@novonordisk.com no later than 15 August 2024.

You will also get the opportunity to discuss the work of some of the EFSPI Special Interest Groups (ESIGs) and EFSPI Working Groups during the poster session on day 1.

As something new this year, an extra half day is added to discuss HTA topics in greater details. Specifically, two topics will be discussed:

The role of innovative statistical methods in pan-European HTA and **How can statisticians navigate the interface between the EU Joint Clinical Assessment and national HTA?**