Draft program as of 30 May 2024 – subject to change

Sessions will include 3-4 talks followed by a panel discussion.

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.

- How much it matters to be first in class and how can you catch up? Speaker: Jenny Devenport (Roche)

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.

- What has improved and what new issues did we uncover and what issues are we still ignoring? Speakers: Frank Bretz, Novartis and Rob Hemmings, Consilium
- Implementation of the estimand framework in the regulatory assessment. How are clinicians and industry involved? Speaker: Laura Rodwell, EMA

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.

- ICH E22 General Considerations for Patient Preference Studies. Speaker: Dr Francesco Pignatti, Rapporteur (EC)
- Industry case study. How a patient preference trial impacted the approval/SmPC. Speaker: Brett Hauber, Pfizer
- Selecting the treatment – my patient and statistician perspectives. Speaker: Anna Wiksten

Openstatsware.

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

- General GCP principles with focus on software. Speaker: Sarianne Päivike, (fimea)

Regulatory updates.

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

- EMA Speaker: Kit Roes Radboud University, Netherlands, EMA

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 allow for more **HTA** discussions. Specifically, there will be two sessions:

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