

## Afternoon Meeting

# Statistical Oversight

### 22nd of October 2025

#### **Meeting Objective:**

Following the implementation of the revised ICH GCP E6(R3) Guideline, effective July 2025 (in EU), we invite the DSBS community to an afternoon meeting on statistical oversight.

The objective of the meeting is to foster knowledge sharing on statistical oversight from the perspective of individual statisticians, both at Sponsors and Service Providers.

The meeting will consist of an introduction to the revised ICH E6(R3) guideline and the impact on statistical oversight, followed by group discussions on key themes, including qualification process, oversight during trial conduct, and statistical programming and data analysis considerations. Themes for discussions will be shared in advance for participants to prepare. It is also recommended to familiarize yourself with the guideline in advance of the meeting.

#### Why Attend?

- Gain insights into the practical implications of ICH E6(R3) revision for statistical oversight.
- Exchange experiences and best practices with peers across the DSBS community.
- Contribute to shaping a shared understanding of statistical oversight practices.

Meeting material including themes for group discussion will be shared prior to the meeting.

 Date
 October 22<sup>nd</sup>

 Arrival
 14:30-15:00

 Meeting
 15:00-17:30

Venue Zealand Pharma Sydmarken 11 2860 Søborg

#### Registration:

Attendance is free of charge for DSBS members. Please register using this <u>link</u> or by scanning the QR code:



Deadline: Friday 10-Oct-2025

There is a limit to the number of attendees and the first come, first serve principle will be applied.