Danish Society for Biopharmaceutical Statistics

DSBS Half-day Meeting on

Estimands

and their use in clinical trials

26 October 2017 9:00-13:00 at LEO Pharma A/S

The draft ICH E9 addendum on estimands and sensitivity analysis in clinical trials is now released for consultation. DSBS will host a meeting to discuss the definitions and their impact in our work.

Speakers

- **Prof. Dr. Frank Bretz, Statistical Methodology, Novartis Pharma AG**
- **Søren Andersen & Helle Lynggaard, Biostatistics, Novo Nordisk A/S**
- **Mette Krog Josiassen, Biostatistics, Lundbeck A/S**

Please come and join the discussion.

Detailed program on next page.

REGISTRATION

Venue: LEO Pharma A/S
Industriparken 55
2750 Ballerup

The meeting is free of charge, but please indicate whether you will

- ✓ only join the meeting
- ✓ stay for sandwiches after the meeting - to not waste food

Deadline:
20 October 2017 EOB

To register, please send a mail to Lea Helena Strother:

OLNDK@leo-pharma.com

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DSBS Half-day Meeting on Estimands and their use in clinical trials
26 October 2017 at LEO Pharma

Agenda

8:30 - 9:00	**Breakfast**
9:00 - 10:00	**How the ICH E9 addendum around estimands may impact our clinical trials.** *Frank Bretz, Statistical Methodology, Novartis Pharma AG* The way we think about clinical trial design, conduct and analysis is likely to undergo a step-change thanks to the much anticipated release of the draft ICH E9 addendum on estimands. Importantly, this topic is not only statistical. It is a multidisciplinary effort that requires a common understanding and buy-in beyond the statistics community. Soon after this release of this guidance document for public consultation in August, I will discuss where we currently stand and postulate on possible future directions.
10:00 - 10:45	**Implementation of estimands in Novo Nordisk.** *Søren Andersen & Helle Lynggaard, Biostatistics, Novo Nordisk A/S* Novo Nordisk has had a number of regulatory interactions with various agencies where the regulators have requested a precise description of the treatment effect to be estimated (the estimand) with emphasis on the method(s) for handling missing data. As a consequence, Novo Nordisk formed a cross-functional group to implement estimands in the clinical trials and align across projects. The presentation will focus on how this was done, the challenges and the implications this had on trial planning, conduct, analysis and reporting.
10:45 - 11:15	**Break**
11:15 - 12:00	**Applying estimand strategies in schizophrenia** *Mette Krog Josiassen, Biostatistics, Lundbeck A/S* The draft ICH E9 addendum suggests five strategies for addressing estimands in a study. The strategies are further elaborated on, by applying them to an example from schizophrenia, a disease with inherent high dropout rates. The advantages and disadvantages of the strategies are discussed in the setting of schizophrenia.
12:00 - 12:30	**Discussion**
12:30 - 13:00	**Sandwiches**