

Final Announcement: "The application of estimands from a Neuroscience perspective"

November 3, 2020

Virtual seminar

13.00 am - 16.30 pm CET

This seminar covers the use of estimands in Neuroscience. Neuroscience is a heterogeneous therapeutic area in which development pathways and study analyses can substantially differ between different indications. Efficacy is usually based on longitudinal assessments which makes the application of the estimand framework specifically interesting and rich with many specific aspects from which we all can learn a lot.

A European scientific interest group (SIG) sponsored by EFSPi and PSI is working out in some typical Neuroscience indications how to best apply the estimand framework. This work is in progress and the seminar will provide an overview on the status of the working group including an opportunity to discuss issues and provide feedback. Finally, since the SIG also worked on the impact of Covid-19 pandemic in Neuroscience this topic will also be covered in the seminar. The seminar is not an introduction into the estimand framework. For more information see https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e9-r1-addendum-estimands-sensitivity-analysis-clinical-trials-guideline-statistical-principles_en.pdf.

Organizing committee:

Hans Ulrich Burger, Khadija Rantell, Nikolaos Sfikas, Peter Quarg on behalf of the European working group on Estimands in Neuroscience.

Final Agenda

13:00-13:10	Welcome Introduction to the estimand framework Hans Ulrich Burger, BBS president
13:10-13:30	Outline of an estimand strategy in MS Nikolaos Sfikas, Novartis
13:30-13:50	Outline of an estimand proposal in migraine prevention and neuropathic pain Mette Krog Josiassen, Lundbeck and Peter Quarg, Novartis
13:50-14:10	Using the Estimand Framework to address challenges in AD clinical trial with a closer look at the hypothetical strategy Paul Delmar, Hoffmann-La Roche AG
14:10-14:30	Estimands in Huntington's disease Carrie Li, Hoffmann-La Roche AG
14:30-14:45	Break
14:45-15:05	Impact of Covid-19 on studies in Neuroscience Andrew Hartley, PPD
15:05-15:45	Regulatory aspects of the estimand framework: Clinical and statistical perspectives Joel Raffel, MHRA and Khadija Rantell, MHRA
15:45-16:30	Panel discussion including all speakers and Anja Schiel, Norwegian agency and CHMP member
16:30	End of the meeting



Venue

Virtual seminar.
The event is for free.

Registration

Please register via the following link

[BBS Seminar - "Estimands in Neuroscience"](#)

Questions for Q&A

Please send questions for the panel discussion to
Hans Ulrich Burger
hans_ulrich.burger@roche.com
or use the chat room during the meeting.