



Emerging topics for statistical methodology in drug development: Estimands and advanced analytics

Date: September 11, 2017, Time: 9:00-15.30

Venue: Roche IT Training Center / Aeschentor, Aeschenvorstadt 56, 4051 Basel

The BBS would like to invite you for a seminar on estimands and advanced analytics in drug development. Since Stephen Ruberg, Head of the Advanced Analytics group at Eli Lilly, is visiting Basel we would like to use this opportunity to discuss a number of topics in which Stephen made important contributions. With the release of the draft ICH E9 addendum, the estimands concept will finally make it into the reality of drug development. Hence, the morning session will be dedicated to estimands and present examples of and new developments on this topic. Another topic of emerging importance is the use of advanced analytics by pharmaceutical industry. Inspired by companies like Google, Amazon, Apple and applications of advanced analytics for example to smartphone technology or digital medicine the second session offers presentations which allow us getting insights from different than clinical trial data analytics.

Please don't miss this easy access to presentations and discussions about rapidly emerging topics of relevance for people who analyse data.

Scientific committee: Stephen Ruberg, Frank Bretz and Uli Burger

The seminar is free of charge. For registration however please send an informal e-mail to Laurence Guillier (laurence.guillier@roche.com) or Barbora Martinec (barbora.martinec@roche.com).

Program:

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| 9:00-9:10 | Welcome, Uli Burger, BBS president |
| 9:10-12:00 | Morning session: Examples of and new developments on estimands
(chair: Heinz Schmidli, Novartis) |
| 9:10-9:55 | Stephen Ruberg (Eli Lilly) The patient perspective – the estimands they want |
| 9:55-10:40 | Stef van Buuren, (Netherlands Organisation for Applied Scientific Research TNO, Leiden and University of Utrecht, Utrecht): “Individual causal effect: What is it? Why we need it? How to estimate it?” |
| 10:40-11:05 | Baldur Magnusson (Novartis): “Using principal stratification to disentangle post-randomization outcomes in a randomized controlled phase 3 study” |
| 11:05-11:30 | Teresa Barata (Roche): “Estimands in early Parkinson disease” |
| 11:30-12:00 | Panel discussion |
| 12:00-13:00 | Lunch break |

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- 13:00-15:30** **Afternoon session: Advanced analytics in drug development**
(chair: Dominik Heinzmann, Roche)
- 13:00-13:40 Stephen Ruberg (Eli Lilly): “Making what’s advanced today routine tomorrow”
- 13:40-14:30 Jouni Kerman (Google): “Causal Measurement using Geo Experiments in a Time-Based Regression Framework”
- 14:30-14:50 Cornelia Dunger-Baldauf (Novartis): “A Smartphone-Based Study Capturing Longitudinal Vision Test Data, Movement Scores and User-reported Outcomes”
- 14:50-15:10 Fabio Pellegrini (Biogen): “Individualized medicine based on a treatment response continuous score”
- 15:10-15:30 Panel discussion
- 15:30** **Closure of the seminar**

We look forward to your participation!

Kind Regards,

Frank Bretz and Uli Burger (on behalf of the BBS)