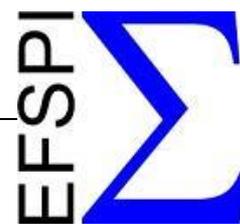


**Basel Biometrics Section seminar
Basel, 29th June 2020**



**Frist announcement, draft program
Final version of program expected end of March**



**Joint EFSPI / BBS Seminar:
Estimands addendum is final:
Anything new for oncology?**

Date: Monday, 29th June 2020, 08:30-16:45
Venue: Novartis Auditorium, Fabrikstrasse 15, Basel

After the publication of the final version of the ICH E9 addendum, the BBS jointly with EFSPI would like to offer a full-day seminar on the broad topic of estimands in oncology drug development. The event will feature talks from statisticians and clinicians in industry, regulatory agencies, and academia. It is the explicit intention of the event to extend the estimand discussion to those who partner with statisticians in drug development, i.e. clinicians, regulatory colleagues, etc. For this reason, many of the talks in the program are shared between a statistician and a clinician.

The intention is to make this the first of a series of events dedicated to estimands for specific therapeutic areas. We start with oncology and envisage further seminars on, e.g., neuroscience.

The organizing committee members are Evgeny Degtyarev, Kaspar Rufibach, Bibiana Blatna, Marie-Laure Casadebaig, Lynda Grinsted, Lorenzo Guizzaro, Wolfgang Kothny, Giusi Moffa, Hans-Jochen Weber. The event is supported by the *European special interest group "Estimands in oncology"*, sponsored by PSI and EFSPI, which is also an ASA scientific working group:
<http://tinyurl.com/oncoestimand>.

Registration: On or before 22 May 2020: Industry €100, Academic €50. After 22 May 2020: Industry €150.00, Academic: €75. To register please go to www.efspi.org. There you can also register at a reduced rate for the joint BBS / EFSPI meeting "HTA – 10th year anniversary of the EFSPI SIG", to be held the day after at the same venue. Students: a limited number of places is available free of charge, please contact giusi.moffa@unibas.ch.

Draft program (may be updated for the final announcement):

- 08:30 – 09:00 **All**
Registration
- 09:00 – 09:15 **Kaspar Rufibach (Roche, member of BBS board)**
Welcome and scene setting
- 09:15 – 09:45 **Regulator's view**
Experience with the estimand framework in oncology
- 09:45 – 10:15 **Hans-Jochen Weber (Novartis), Renaud Capdeville (Novartis), Tina Nielsen (Roche)**
Challenges and open questions in hematology: RATIFY and GALLIUM

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10:15 – 10:45 **Coffee break**

10:45 – 11:15 **Hannes Buchner (Staburo) + clinician**

Treatment switching: challenges, estimands, and estimators

11:15 – 11:25 **Chrissie Fletcher (GSK)**

Feedback from EFPIA/EFSPi estimand implementation working group

11:25 – 12:00 **Panel discussion (all speakers + Chrissie Fletcher, Michael Wenger + ...)**

Estimands – after first experiences anything new for oncology? If at all, what does it add?

12:00 – 13:00 Lunch

13:00 – 13:30 **Regina Stegherr (Uni Ulm, on behalf of the SAVVY working group)**

What are meaningful estimands for safety analyses?

13:30 – 14:00 **Anja Schiel (Norwegian Medicines Agency, chair of EMA Scientific Advice Working Party & Biostatistics Working Party)**

Treatment switching and safety analyses, the HTA perspective

14:00 – 14:30 **Evgeny Degtyarev (Novartis, moderator)**

Time to rethink additional analyses? Regulatory, industry and ICH E9 WG views on sensitivity and supplementary analyses in Oncology

14:30 – 15:00 **Coffee break**

15:00 – 15:20 **Björn Bornkamp (Novartis)**

Principal Stratum Estimand Strategy: Why, When and How?

15:20 – 15:40 **Aisha Zia (Novartis)**

A drug development application of the principal stratum estimand strategy

15:40 – 16:00 **Dominik Heinzmann (Roche)**

How the principal stratum estimands framework helped to analyze anti-drug antibody effect in immunotherapy

16:00 – 16:45 **Panel discussion (all speakers + Mouna Akacha)**

Time for statisticians to get out of their comfort zone and learn new methods? For example, causal inference?

16:45 – 16:50 **BBS or EFSPi representative**

Closure

We look forward to your participation!