

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

Date: Monday, 29th June 2020, 09:00-11:45

Webinar: dial-in details will be communicated to registered participants

After the publication of the final version of the ICH E9 addendum, the BBS jointly with EFSPI would like to offer a half-day webinar 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 or webinars 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://www.oncoestimand.org>.

Initially, this event was planned as a full-day seminar on the Novartis campus. Given the current COVID-19 situation we turn this event into a series of webinars. If you'd like to attend please fill out the [registration form](#). After registration you will receive a calendar invite with a webex link. Slides and recordings of some of the talks will be made available after the event on the [BBS webpage](#), both pending speaker approval.

The webinar is free of charge.

Basel Biometrics Section webinar

Basel, 29th June 2020

Program:

- 09:00 – 09:10 **Kaspar Rufibach (Roche, member of BBS board)**
Welcome and scene setting
- 09:10 – 09:40 **Regulator's view (Anja Schiel, Norwegian Medicines Agency)**
Experience with the estimand framework in oncology
- 09:45 – 10:10 **Renaud Capdeville (Novartis), Tina Nielsen (Roche)**
Challenges and open questions in hematology: RATIFY and GALLIUM
- 10:10 – 10:20 **Break**
- 10:20 – 10:50 **Hannes Buchner (Staburo) & Ingolf Griebisch (Boehringer Ingelheim)**
Treatment switching: challenges, estimands, and estimators
- 10:50 – 11:10 **Stefan Englert (AbbVie)**
Commentary on previous talks taking COVID-19 into account
- 11:10– 11:15 **Break**
- 11:15 – 11:45 **Panel discussion**
(all speakers + Rob Hemmings from Consilium, Michael Wenger from Novartis)
Estimands – after first experiences anything new for oncology? If at all, what does it add?
- 11:45 – 11:50 **BBS or EFSPI representative**
Next webinars and closure

We look forward to your participation!