



Basel Biometrics Section Seminar Basel, 15th July 2022

On market approval and market access: Breaking the linear thinking or how to innovate in a crowded space?

Date: Friday, 15th July 2022, 14:00-17:00

Hybrid: Auditorium Roche Building 71, Grenzacherstrasse, Basel
Dial-in details will be communicated to registered virtual participants

Encouraged by regulators, e.g. through the FDA complex innovative design (CID) initiative or last year's [EMA workshop on complex clinical trials](#), sponsors are increasingly utilizing these designs for registrational purposes. One example are single-arm trials which may or may not be contextualized using real-world data. While this may in some situations be fit-for-purpose for regulatory approval, challenges may arise in discussions with Health Technology Assessment (HTA) bodies. Questions that will be addressed include:

- 1) How to break the linear thinking for regulatory approval and market access?
- 2) How can we further innovate in a space crowded with many drugs?

The event will feature talks from statisticians in HTA bodies and industry. The organizing committee of this event are Frank Bretz (Novartis) and Kaspar Rufibach (Roche). Slides and recordings of the talks will be made available after the event on the [BBS webpage](#), both pending speaker approval. The webinar is free of charge.

If you'd like to attend please fill out the [registration form](#). If you register for virtual attendance you will receive a calendar invite with a link.

This discussion will be continued in a related session at the upcoming [EFSPi regulatory statistics workshop](#).

Program (find abstracts below), moderated by Kaspar Rufibach:

14:00 – 14:05 **Frank Bretz (Novartis, virtual)**

Welcome and scene setting

14:05 – 15:00 Anja Schiel (NoMA & EMA): Why everyone really needs to learn to “think HTA” early

15:00 – 15:20 Nigel Yateman (Novartis): Challenges in developing next generation CART

15:20 – 15:50 Coffee break

15:50 – 16:10 Iain Bennett (Roche): No comparator no problems? Experiences with Entrectinib

16:10 – 16:20 Karen Facey (Uni Edinburgh & self-employed): Comments to introduce panel discussion

16:20 – 16:55 Panel discussion with all speakers and Gorana Capkun (Novartis), Lilla di Scala (J&J, virtual), Andrew Thomson (EMA).

16:55 – 17:00 **Kaspar Rufibach (Roche, member of BBS board)**

Next webinars and closure

We look forward to your participation!