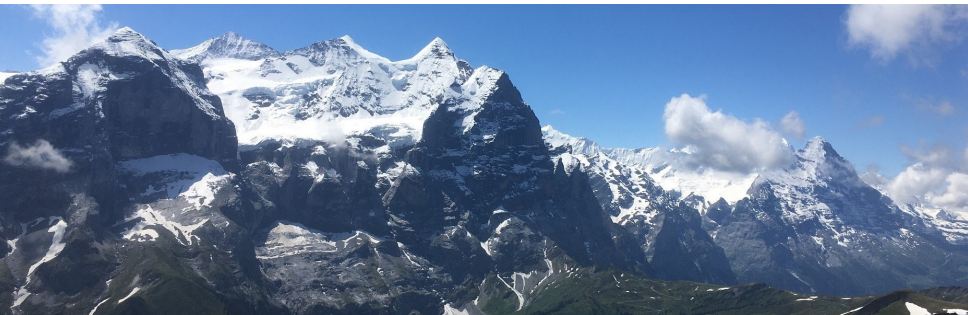

RCTs meeting causal inference: principal stratum strategy and beyond

BBS webinar

7th September 2020

Kaspar Rufibach, on behalf of BBS and the organizing committee



Supporting organizations

Basel Biometrics Section

<http://bbs.ceb-institute.org>

Industry working group “Estimands in Oncology”

www.oncoestimand.org

Organizing committee

Björn Bornkamp (Novartis)

Giusi Moffa (Uni Basel)

Kaspar Rufibach (Roche)

**Randomization may not be enough
to establish causality!**

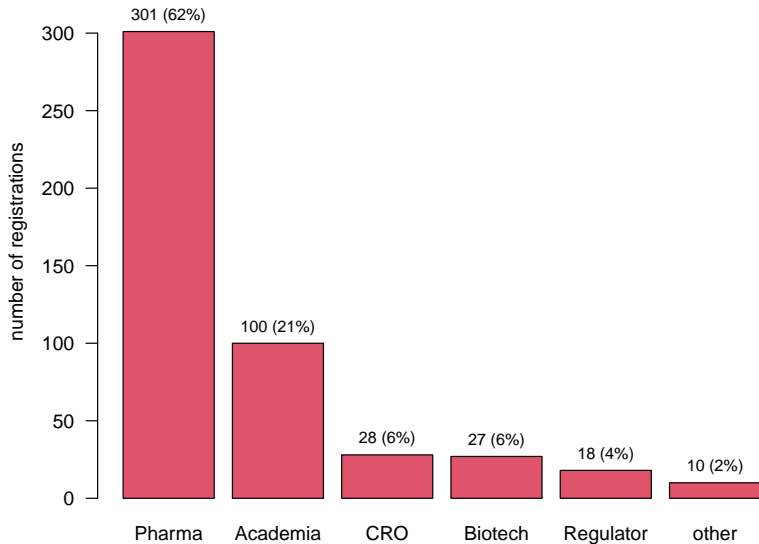
Goal today:

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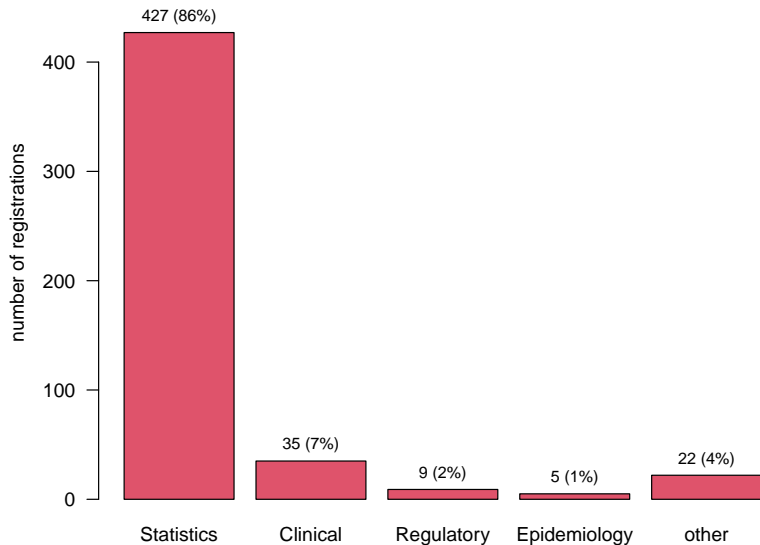
**Connect causal inference methodology and
clinical biostatistics in pharma**

- 14:00 – 14:10 **Kaspar Rufibach (member of BBS board and co-lead industry working group “estimands in oncology”)**
Welcome and scene setting
- 14:10 – 14:35 **Vanessa Didelez (Keynote speaker, Leibniz Institute for Prevention Research and Epidemiology - BIPS, Bremen)**
Time-Varying Treatments in Observational Studies: Lessons for Clinical Trial
- 14:35 – 14:50 **Jack Bowden (University of Exeter)**
Connecting Instrumental Variable methods for causal inference to the Estimand Framework
- 14:50 – 15:05 **Kelly van Lancker (Ghent University)**
Efficient, doubly robust estimation of the effect of dose switching for switchers in a randomised clinical trial
- 15:05 – 15:15 **Break**
- 15:15 – 15:30 **Björn Bornkamp (Novartis)**
Principal Stratum Strategy: Potential Role in Drug Development
- 15:30 – 15:45 **Dominik Heinzmann (Roche)**
Principal stratum strategy to investigate anti-drug antibody impact on cancer immunotherapy outcome
- 15:45 – 16:00 **Aiesha Zia (Novartis)**
Exploring estimation approaches for principal stratum estimands in Phase III randomized trials in CAR-T anti-cancer therapy
- 16:00 – 16:10 **Break**
- 16:10 – 16:25 **Fabrizia Mealli (University of Florence)**
The ICH E9 addendum from an academic causal inference perspective and feedback on the previous talks
- 16:25 – 16:40 **Andrew Thomson (EMA)**
Regulatory feedback on the previous talks
- 16:40 – 16:55 **All speakers**
Comments on talks
- 16:55 – 17:00 **Giusi Moffa (member of BBS board)**
Next webinars and closure

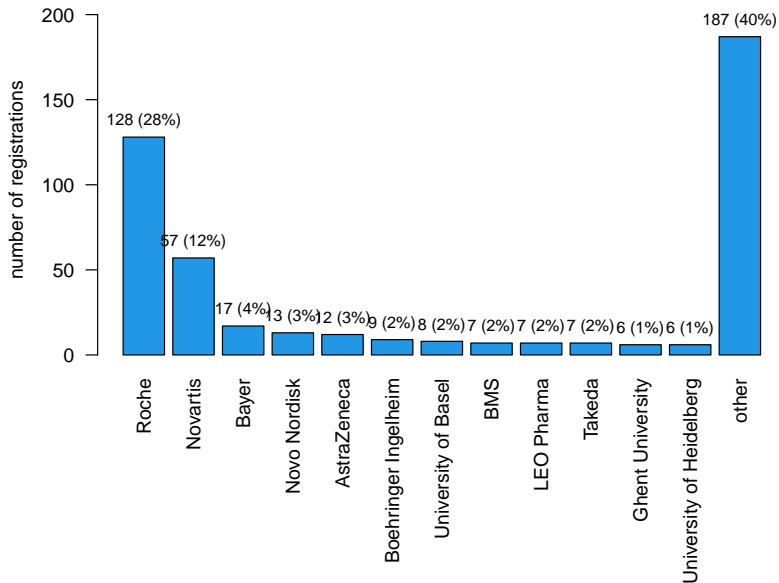
Total number of registrations: 465
type of institution (multiple mentions allowed)



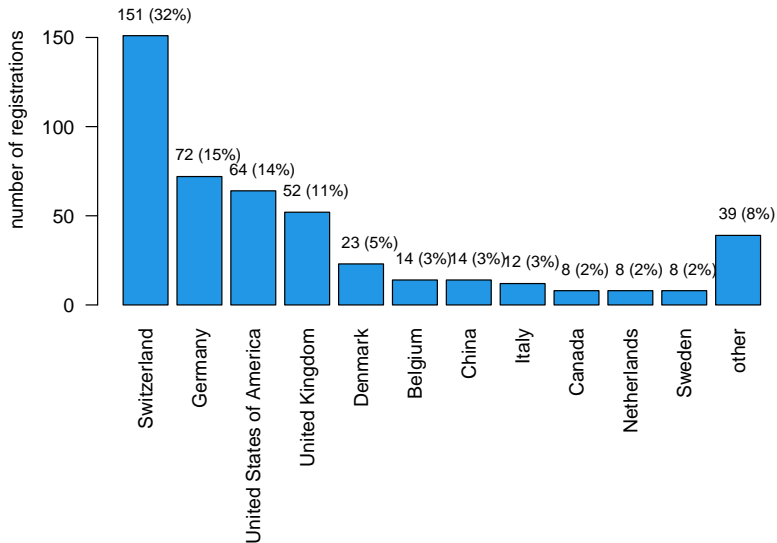
**Total number of registrations: 465
background (multiple mentions allowed)**



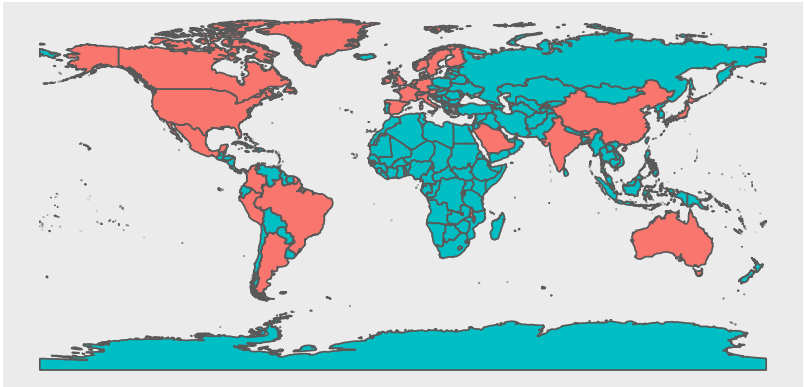
**Total number of registrations: 465
institution (multiple mentions allowed)**



Total number of registrations: 465
country (multiple mentions allowed)



Broad representation



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Ask questions in **chat**. We will reply in discussion or in writing.

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If presenter approved: **slidedecks** will be posted on BBS webpage.

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If presenter approved: **slidedecks** will be posted on BBS webpage.

If presenter approved: **Recording** will be posted on BBS webpage.

Thank you for your attention.

kaspar.rufibach@roche.com

<http://www.kasparrufibach.ch>

 [numbersman77](#)

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Doing now what patients need next

R version and packages used to generate these slides:

R version: R version 4.0.0 (2020-04-24)

Base packages: stats / graphics / grDevices / utils / datasets / methods / base

Other packages: PBSmodelling / RColorBrewer / ggplot2 / rnaturalearthdata / rnaturalearth / dplyr / readxl

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