Swiss Epidemiology Winter School 2020

Advanced Clinical Trial Design
23 – 25 January 2020

Faculty	**PD Dr. Sven Trelle** CTU Bern, University of Bern, Switzerland **Prof. Matthias Briel** Department of Clinical Research, University of Basel, Switzerland
Venue	**CH – 3823 Wengen | SWITZERLAND** Bühlstube (see map on http://www.epi-winterschool.org/hotels)
Description	This course will provide an introduction to advanced topics of clinical trial design. The focus will be on trial planning especially sample-size calculations within a hypothesis testing framework and implications for study design. Topics are selected based on practical experience of the faculty and relevance over recent years. In the course we will cover platform trials, pragmatic trials including routine-data supported or registry trials, cluster-randomized trials, non-inferiority (combined with superiority) study questions, multi-arm versus sequential multiple assignment randomized trials, studies within a trial (SWATs), and estimands. The faculty reserves the right to change focus regarding some of the topics based on developments over the coming months.
Objectives	By the end of this course participants will have: • An understanding of the concept of platform trials • An understanding of what constitutes a pragmatic trial and how it differs from an efficacy trial • An understanding of the potential and limitations of routinely-collected data for randomized trials • An understanding of the specifics of non-inferiority and cluster-randomized trials • An understanding of trial designs that aim to test multiple hypotheses • An understanding of the implications of these design choices on sample-size calculation and how to perform them in practice • An understanding of the concept and value of SWATs • An understanding of different estimands and the implications for trial planning

Target audience	Clinical researchers, (clinical) epidemiologists, medical statisticians, or any research stakeholder with an interest in trial methodology. Participants should have some experience with developing and conducting randomized clinical trials in their professional role.

Outline

The course will run over three days and consist of lectures, group work and computer practical sessions. We start early in the morning with a review of the previous day. During the extended break in the afternoon participants review course materials, catch up on emails or go skiing. We reconvene at 4:30 pm for the computer sessions.

Thursday, 23 January (8:00 – 12:00 | 16:30 – 18:30)
- Platform trials
- Multi-arm trials
- Sequential multiple assignment randomized trials

Friday, 24 January (8:00 – 12:00 | 16:30 – 18:30)
- Pragmatic trials
- Routine data-supported trials and registry trials
- Cluster-randomized trials

Saturday, 25 January (8:00 – 12:00 | 16:30 – 18:30)
- Studies within a trial (SWATs)
- Non-inferiority trials
- Estimands

Credits

1.0 ECTS

To bring along

Students should bring their own portable computers. A course license for Stata® will be available, to be installed before arrival. University of Bern IT staff onsite can provide help upon request per e-mail (it@ispm.unibe.ch)

Course fee

SSPH+ students:	CHF 700
Academic:	CHF 900
Industry:	CHF 2000

Registration

You can register on the Winter School website www.epi-winterschool.org.

Accomodation

Participants must book their accommodations themselves. Please see our recommendations on www.epi-winterschool.org/hotels for special prices.