Swiss Epidemiology Winter School 2023

UNIVERSITÄT BERN

Advanced Clinical Trial Design

19–21 January 2023

Faculty	**PD Dr. Sven Trelle** Clinical Trials Unit, University of Bern, Switzerland **Prof. James Wason** Newcastle University, United Kingdom
Venue	**CH – 3823 Wengen | SWITZERLAND** Hotel Sunstar (map)
Course 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, and estimands. The faculty reserves the right to change focus regarding some of the topics based on developments over the coming months.
Course 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 different estimands and the implications for trial planning

Contact:
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Course 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.
Course outline	The course runs over three days and consists of lectures, group work, and computer practical sessions. We start early in the morning by reviewing the previous day. During extended afternoon breaks, participants review course materials, catch up on email, or ski. We reconvene at 4:30 pm for computer practical sessions. ***Thursday, 19 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*** • Adaptive trials • Multi-arm, platform and precision medicine trials • Sequential multiple assignment randomized trials ***Friday, 20 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*** • Pragmatic trials • Sample size calculation (basics) • Cluster-randomized trials ***Saturday, 21 January 8:00 am – 12:00 pm | 1:00 pm – 3:00 pm*** • Non-inferiority trials • Sample size calculation (advanced) • Endpoints and estimands
Credits	1.0 ECTS
Course materials	Students should bring their own portable computers. A course license for Stata® will be available to install before arrival. Onsite University of Bern IT staff provides support upon e-mail (it@ispm.unibe.ch) request.
Course fee	PhD Bern Students: CHF 350 PhD Students: CHF 700 Academic: CHF 900 Industry: CHF 2000
Registration	Register on the Winter School website. Pre-Registration starts 29 August 2022 at 12:00 pm (CET).
Accomodation	Book your accommodation separately. Please see recommendations for special prices.

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