

# Swiss Epidemiology Winter School 2023



## Advanced Clinical Trial Design 19 – 21 January 2023

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### Faculty

**PD Dr. Sven Trelle**

CTU Bern, University of Bern, Switzerland

**Prof. James Wason**

Newcastle University, United Kingdom

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### Venue

**CH – 3823 Wengen | SWITZERLAND**

Hotel Sunstar (see map on <https://www.epi-winterschool.org/course-hotel-locations/>)

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### 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.

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### 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

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### Contact:

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**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.

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**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, 19 January 8:00 – 12:00 | 16:30 – 18:30*

- Adaptive trials
- Multi-arm, platform and precision medicine trials
- Sequential multiple assignment randomized trials

*Friday, 20 January 8:00 – 12:00 | 16:30 – 18:30*

- Pragmatic trials
- Sample size calculation (basics)
- Cluster-randomized trials

*Saturday, 21 January 8:00 – 12:00 | 13:00 – 15:00*

- Non-inferiority trials
  - Sample size calculation (advanced)
  - Endpoints and estimands
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**Credits** 1.0 ECTS

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**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)

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**Course fee** PhD Bern Students: CHF 700  
Academic: CHF 900  
Industry: CHF 2000

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**Registration** You can register on the Winter School website [www.epi-winterschool.org](http://www.epi-winterschool.org).

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**Accommodation** Participants must book their accommodations themselves. Please see our recommendations on <https://www.epi-winterschool.org/course-hotel-locations/> for special prices.

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