

# Swiss Epidemiology Winter School 2025



## Advanced Clinical Trial Design

Thu 23 – Sat 25 January 2025

<b>Faculty</b>	<p><b>PD Dr. Sven Trelle</b> Clinical Trials Unit, University of Bern, Switzerland</p> <p><b>Prof. James Wason</b> Newcastle University, United Kingdom</p>
<b>Venue</b>	<p><b>CH – 3823 Wengen   SWITZERLAND</b> Bühlstube (<a href="#">map</a>)</p>
<b>Course description</b>	<p>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, multi-arm, sequential multiple assignment randomized trials, cluster-randomized trials, non-inferiority (combined with superiority) study questions, Bayesian trials, adaptive designs, trials for precision medicine, and estimands. The faculty reserves the right to change focus regarding some of the topics based on developments over the coming months.</p>
<b>Course objectives</b>	<p>By the end of this course participants will have:</p> <ul style="list-style-type: none"><li>• Understanding of the concept of platform trials</li><li>• Understanding of the principles of adaptive trial designs</li><li>• Understanding of the specifics of non-inferiority and cluster-randomized trials</li><li>• Understanding of trial designs that aim to test multiple hypotheses</li><li>• Understanding of the implications of these design choices on sample-size calculation and how to perform them in practice</li><li>• Understanding of different estimands and the implications for trial planning</li></ul>
<b>Course audience</b>	<p>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.</p>

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**Course outline** The course runs over three days and consists of lectures, group work, and computer practical sessions. We will also have the opportunity to discuss projects of participants. 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, 23 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*

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

*Friday, 24 January 8:00 am – 12:00 pm | 4:30 pm – 6:30 pm*

- Sample size calculation (basics)
- Non-inferiority trials
- Multiple testing

*Saturday, 25 January 8:00 am – 12:00 pm | 1:00 pm – 3:00 pm*

- Cluster-randomized trials
- Bayesian trials
- Sample size calculation (advanced)
- Clinical trials for precision medicine

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**Credits** 1.0 ECTS

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**Course materials** Students should bring their own portable computers. Prior to the course, we will provide instructions regarding the installation of the software packages to be used in the course. All practicals will be supported in R (<http://www.r-project.org/>) and Shiny Apps web-interfaces. Some practicals will additionally be supported in Stata. A course license for Stata® will be available to install before arrival if required.

Onsite University of Bern IT staff provides support upon e-mail ([it.ispm@unibe.ch](mailto:it.ispm@unibe.ch)) request.

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**Course fee**

PhD Bern Students:	CHF	600
PhD Students:	CHF	800
Academic:	CHF	1000
Industry:	CHF	2000

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**Registration** Register on the [Winter School website](#). Pre-Registration starts 26 August 2024 at 12:00 pm (CET) until 1 September 2024.

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**Accommodation** Book your accommodation separately. Please see [recommendations for special prices](#).

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