

# Swiss Epidemiology Winter School 2024



## Advanced Clinical Trial Design

Thu 18 – Sat 20 January 2024

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<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> Hotel Sunstar (<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>• An understanding of the concept of platform trials</li><li>• An understanding of the principles of adaptive trial designs</li><li>• An understanding of the specifics of non-inferiority and cluster-randomized trials</li><li>• An understanding of trial designs that aim to test multiple hypotheses</li><li>• An understanding of the implications of these design choices on sample-size calculation and how to perform them in practice</li><li>• An 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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<b>Course outline</b>	<p>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.</p> <p><i>Thursday, 18 January 8:00 am – 12:00 pm   4:30 pm – 6:30 pm</i></p> <ul style="list-style-type: none"> <li>• Adaptive trials</li> <li>• Multi-arm, platform and precision medicine trials</li> <li>• Outcomes and estimands</li> <li>• Sequential multiple assignment randomized trials</li> </ul> <p><i>Friday, 19 January 8:00 am – 12:00 pm   4:30 pm – 6:30 pm</i></p> <ul style="list-style-type: none"> <li>• Sample size calculation (basics)</li> <li>• Non-inferiority trials</li> <li>• Multiple testing</li> </ul> <p><i>Saturday, 20 January 8:00 am – 12:00 pm   1:00 pm – 3:00 pm</i></p> <ul style="list-style-type: none"> <li>• Cluster-randomized trials</li> <li>• Bayesian trials</li> <li>• Sample size calculation (advanced)</li> <li>• Clinical trials for precision medicine</li> </ul>								
<b>Credits</b>	1.0 ECTS								
<b>Course materials</b>	<p>Students should bring their own portable computers. A course license for Stata® will be available to install before arrival.</p> <p>Onsite University of Bern IT staff provides support upon e-mail (<a href="mailto:it@ispm.unibe.ch">it@ispm.unibe.ch</a>) request.</p>								
<b>Course fee</b>	<table border="0"> <tr> <td>PhD Bern Students:</td> <td>CHF 350</td> </tr> <tr> <td>PhD Students:</td> <td>CHF 700</td> </tr> <tr> <td>Academic:</td> <td>CHF 900</td> </tr> <tr> <td>Industry:</td> <td>CHF 2000</td> </tr> </table>	PhD Bern Students:	CHF 350	PhD Students:	CHF 700	Academic:	CHF 900	Industry:	CHF 2000
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<b>Registration</b>	Register on the <a href="#">Winter School website</a> . Pre-Registration starts 29 August 2022 at 12:00 pm (CET).								
<b>Accommodation</b>	Book your accommodation separately. Please see <a href="#">recommendations for special prices</a> .								

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