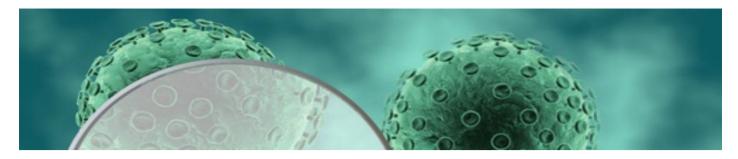
### CAS in Clinical Research



# Fundamentals of randomized controlled clinical trials

#### Description

This basic and intermediate level course covers design, conduct and analysis issues of clinical trials with a focus on randomized-controlled trials. We will only briefly discuss clinical studies without randomization. We will cover design issues such as the identification of the target population, choice and definition of the interventions and comparators, of study outcomes and assumptions needed to determine the size of the trial. Regarding the conduct and implementation of clinical trials we will cover the choice of randomization strategies and procedures, the role of blinding, issues on prevention and handling of missing data, (safety and efficacy) monitoring of the study, and the standards for the reporting of the trial results. For all topics, focus is on fundamentals and principles rather than practical/implementation aspects. The course is based on lectures and small group works with an emphasis on the critical appraisal of published trials.

Participants should have knowledge of epidemiological study designs

## **Objectives**

By the end of this 3 day course, students will be able to:

- critically assess the design, conduct, and analysis and reporting of a (randomized) clinical trial
- identify and design the fundamental characteristics of a clinical trial to address a clearly specified clinical question
- understand the challenges related to selected aspects of the implementation and conduct of a clinical trial.

#### **Dates**

20-22 September 2021 (Monday – Wednesday)

#### Contact:

Address

Course coordination:

Ann Walser

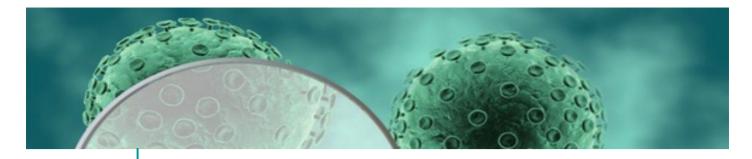
ISPM Bern

Mittelstrasse 43, CH-3012 Bern

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## **CAS in Clinical Research**



**Equipment** 

Participants must bring their own laptops or handheld devices.

Course Structure Lectures, practical exercises, and group work.

**Assessment** 

Attendance and completion of practicals and group work. Critical appraisal of a published trial.

**Credits** 

1 ECTS

Preparation work: 4h, Contact: 21h (1 ECTS corresponds to appr. 25-30 hours' workload)

**Facilitator** 

PD Dr. Sven Trelle, CTU Bern & Prof. Dr. Marcel Zwahlen, Institute of Social and Preventive Medicine (ISPM) Bern

Location

ISPM, University of Bern, Mittelstrasse 43, room 216 (2<sup>nd</sup> floor)

Contact:

Address

Course coordination:

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