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## Clinical Trials Epidemiology Course 14-25 September 2020

This course will give an introduction to the concepts and methods of randomized clinical trials. It will be given over a 2-week period at half pace, corresponding to 5 full days. Note that this course will be given as an online course and since the teacher is based in the US, all sessions will take place in the afternoon, most 3-6 pm and some 1-4 pm (Swedish time) on all course days (a final schedule will be distributed in the weeks before the course).

To the extent possible, the course will utilize students' own ongoing or planned clinical trials as examples and exercises. Please provide a brief project description in your application.

### Course content

The course covers three parts: a basic introduction/review of clinical trials, practical issues of clinical trials, and a more in-depth coverage of selected topics of clinical trials.

#### Basic Introduction:

- Observational Study of interventions
- Randomized clinical trial overview
- Trial Design: Questions, Subjects, Treatments, Endpoints
- Trial Design: Types of Trials
- Trial Conduct: Randomization
- Trial Analysis: Analysis Groups, ITT
- Trial Analysis: Adjustments, Subgroups

#### Practical Issues in Clinical Trials:

- Pilot Studies
- Protocol Development
- Use of biological measurements
- Questionnaire design

#### Selected Clinical Trial Topics

- Trial Monitoring and Stopping rules
- Adaptive randomization
- Equivalence and Non-inferiority trials
- Group randomized trials
- Generalizability of trials

**Course literature**

Dr. Baron will circulate a clinical trials monograph shortly before the course begins, as well as a list of recommended texts and articles.

**Teachers**

John A. Baron, MD, MS, MSc, Professor of Medicine and Epidemiology at the University of North Carolina, and Professor Emeritus of Medicine and of Epidemiology at the Geisel School of Medicine at Dartmouth, and Guest Professor at the Department of Surgical Sciences, Orthopedics, Uppsala University. He has long experience in both large-scale clinical trials and advanced epidemiology.

Georgina Warner, MA in psychology, PhD, researcher at the Department of Public Health and Caring Sciences, Uppsala University.

**Who should apply?**

The course is aimed at PhD students who have an interest in randomized clinical trials. Students involved in their own ongoing or planned clinical trials are particularly urged to take part. Students in Dr. Baron's previous course (Clinical Trials Epidemiology 2019) are welcome to attend the first part of the course as a review with suggestions for more in-depth reading or only the other parts of the course for novel material. Applicants from Uppsala and Lund Universities will be given priority.

**Application (deadline 31 July 2020):**

[http://www2.medfarm.uu.se/utbildning/forskarniva/for\\_doktorander/kurs713.html](http://www2.medfarm.uu.se/utbildning/forskarniva/for_doktorander/kurs713.html)

**Course dates:** 14-18 September and 21-25 September

**Time of day:** Due to the time difference between the US and Sweden, this course will be given as an afternoon course with lectures 3-6 pm (Swedish time) all days. Attendance online is mandatory.

**Course venue:** Online, via Zoom

**Language:** English.

**Number of students:** 25

**Higher education credits:** The full course will qualify for 1.5 higher education credits (högskolepoäng) and a certificate of attendance will be awarded. For returning students (who took the course in 2019 and who won't qualify for credits for the introductory part of this course), 1 higher education credit (högskolepoäng) will be awarded (corresponding to the amount of time spent on the novel content of the course).

**Course organisers:** Liisa Byberg, Department of Surgical Sciences, Uppsala University, and EpiHealth, a large-scale research collaboration network at Lund and Uppsala Universities.

**Contact:** Questions will be answered by Liisa Byberg, email: [liisa.byberg@surgsci.uu.se](mailto:liisa.byberg@surgsci.uu.se), phone: 070-167 9400