



## INSTITUTE OF CLINICAL SCIENCES

### **SK00030 Clinical cancer research, 1.5 credits**

Klinisk cancerforskning, 1,5 högskolepoäng

*Third-cycle level / Forskarnivå*

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#### **Confirmation**

This syllabus was confirmed by the Council for PhD Education at Sahlgrenska Academy on 2021-11-25, and is valid from Spring semester 2022.

#### ***Responsible Department***

Institute of Clinical Sciences, Sahlgrenska Academy

#### **Entry requirements**

The course is open for PhD students accepted by a Swedish or international university.

#### **Learning outcomes**

After completing the course the student is expected to be able to:

##### ***Knowledge and understanding***

- define good-clinical practice, design, as well as ethical and regulatory requirements for clinical trials.
- describe the creation of study protocols, preparation, recruitment of patients and administration of clinical trials.
- show knowledge of data management, results and analysis of study data.
- ha knowledge of register-based randomized clinical trials and health economic analyzes.

##### ***Competence and skills***

- assess a clinical trial regarding Good clinical practice and ethical and regulatory requirements,
- show ability to design a basic clinical trial,
- apply strategies for data management and analysis of collected data.

##### ***Judgement and approach***

- assess the suitability of conducting different types of clinical studies,
- evaluate the usefulness of a clinical trial from a patient perspective.

## Course content

The course provides an understanding of the regulatory and quality principles that govern clinical trials for drugs, biomarkers and medical devices, including Good Clinical Practice (GCP), and different types of study design. The course also provides an understanding of ethical and statistical considerations, biobanking, study protocol structure and content as well as the requirements for planning, obtaining approvals and conducting a clinical trial.

## Types of instruction

The course is given digitally divided into chapters. Each chapter contains a recorded lecture as well as links to additional information including articles and web pages. The student reads each chapter separately, and at any pace. The course also includes a group discussion on clinical trials.

### *Language of instruction*

The course is given in English.

## Grades

The grade Pass (G) or Fail (U) is given in this course.

## Types of assessment

Each lecture ends with an examination consisting of digital multiple-choice questions where all correct answers are required. The course also includes a group discussion on clinical trials, and the final grade is based on approved digital examinations and active participation in group work.

If a doctoral student who has failed twice on the same examining part wishes to change examiner before the next examination, such a request should be submitted in writing to the department and must be approved if there are no special reasons to the contrary (HF Chapter 6, Section 22).

## Course evaluation

The course evaluation will be provided both as a written questionnaire (joint for Sahlgrenska Academy) and orally as a discussion between the students and the course leader(s). The course responsible teacher compiles analysis of the course evaluation and makes suggestions for further development of the course. The result and any changes in the set-up of the course shall be communicated both to the students that carried out the evaluation and to the students who are about to start the course.

## Other information

The course is given in digital format, requiring computer access and internet, since all content, communication and relevant documents, such as lectures, exercise and literature, will be posted at CANVAS.