UNIVERSITY OF GOTHENBURG

INSTITUTE OF MEDICINE

MED563 Clinical Trials in Medicine, 7.5 credits

Klinisk prövning, 7,5 högskolepoäng

Second Cycle

Confirmation

This course syllabus was confirmed by Committee for Study Programmes in Medicine on 2011-03-17 and was last revised on 2019-11-11 by Institute of Medicine to be valid from 2019-11-11, spring semester of 2020.

Field of education: Medicine 100%
Department: Institute of Medicine

Position in the educational system

The course can be part of the following programme: 1) Master's Programme in Business Creation and Entrepreneurship in Biomedicine (M2BCE)

Main field of studies	*Specialization*
Business Creation and Entrepreneurship in Biomedicine	A1N, Second cycle, has only first-cycle course/s as entry requirements

Entry requirements

Admission to the course requires approved courses of at least 180 higher education credits.

In addition, language skills equivalent to English A / English 6 are required.

Learning outcomes

On successful completion of the course the student will be able to:

Knowledge and understanding

- describe overall quality principles (GCP) and regulations for clinical trials
- describe the different phases of a development program for a new drug
- explain the structure and content of the study protocol
- describe what is needed to plan, implement and complete a clinical trial

Explain and have an understanding of the different phases of a development program for a new drug

Describe and understand the overall quality principles (GCP) and regulatory framework for clinical trials

Describe and understand different types of study design related to the development phase

Describe and understand the study protocol structure and content

Describe and understand what it takes to plan, practically implement and complete a clinical trial

Competence and skills

- critically and systematically analyse, compare and discuss different forms of clinical trials
- understand the structure and content of a study protocol and be able to implement this in the clinical trial process
- apply current regulations and guidelines to be able to plan, practically execute and complete a clinical trial

Critically and systematically analyze, compare and discuss different types of clinical trials concerning design and statistical models.

Insight and knowledge of current regulations and guidelines to evaluate the various stages of planning, practical execution and completion of clinical trials.

Assimilate a study protocol and be able to implement this in the clinical trial process.

Able to write a study synopsis.

Judgement and approach

- identify, evaluate, formulate and discuss ethical issues in clinical trials
- relate to the regulations for the practical implementation of a clinical trial

Be able to identify, formulate, discuss and evaluate ethical issues in clinical trial activities.

Be able to evaluate various clinical trial designs

Be able to evaluate the impact of various study designs to verify a study result

Be able to evaluate the frameworks for practical implementation of a clinical trial.

Course content

The course contains the following parts:

- regulations and guidelines for clinical trials
- application to authorities for approval of the study
- study protocol, design and data management
- the clinical trial process; planning, implementation, completion and reporting

Regulations and guidelines for clinical trials

Application to authorities for approval of a clinical trial

Clinical trial protocol, design and data handling

The clinical trial process; planning, practical implementation, closing and reporting

Form of teaching

The course is web-based and the students meet and work with the course material on the University's learning platform. The course starts with all students attending a compulsory video conference, in small groups, where the course leader provides general information about the course content. The students carry out group work, study video lectures and interact through their group forums and through video conferencing. The students will also conduct an interview with a professional in clinical trials. The course can be completed remotely via internet connection.

Language: English

Language of instruction: English

Assessment

Students are examined on the basis of the following assessments;

- 1 oral final exam (individual),
- 1 written project plan (group assignment),
- 1 oral presentation of project plan (group assignment) as well as
- 8 compulsory elements in the form of;
  - 3 written multiple-choice tests (individual),

- 1 written assignment: GCP (group assignment),
- 3 written assignments: timeline of a clinical trial (group assignment) and
- 1 written report from an interview with a professional actor in clinical trials (group assignment).

For students who have not been passed a compulsory part, the possibility of a supplementary assignment is offered by the course coordinator.

Student is entitled to change examiner, if practically possible, after having failed twice on the same examination. Such a request is made to the institution and must be in writing.

Grades

The grading scale comprises: Pass (G) and Fail (U).

Course evaluation

The course is evaluated in writing by the course participants through a questionnaire.

A summary analysis of the course evaluations is compiled, which is communicated to the students.

The analysis will serve as a guide for the development of the course.

Additional information

The course is web-based and requires access to computer and internet connection.