UNIVERSITY OF GOTHENBURG

INSTITUTE OF MEDICINE

MKB800 Methodology in clinical drug development and biostatistics, 7.5 credits

Metodik inom klinisk läkemedelsprövning och biostatistik, 7,5 högskolepoäng

Second Cycle

Confirmation

This course syllabus was confirmed by Institute of Medicine on 2017-01-02 and was last revised on 2020-09-03 to be valid from 2021-01-19, spring semester of 2021.

Field of education: Pharmacy 50% and Medicine 50%
Department: Institute of Medicine

Other participating department
Institute of Neuroscience and Physiology

Position in the educational system

The course is an elective course in the Pharmacy Programme and is given during semester 8.

The course can be part of the following programmes: 1) Programme in Pharmacy (F2APP) and 2) Programme in Pharmacy (F2APO)

Main field of studies	*Specialization*
Pharmaceutical Science	A1N, Second cycle, has only first-cycle course/s as entry requirements

Entry requirements

Admission to the course requires passed courses semester 1-5 and completed semesters 6-7 and passed course in Biostatistics (MED615 or an equivalent discipline).

Learning outcomes

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

Knowledge and understanding
- account for the fundamental features for how clinical drug development continues as well as which approvals that are required

- show understanding of the assumptions of different statistical methods' and show an ability to choose an adequate statistical method for a given hypothesis

Competence and skills
- discuss pros and cons different study design of clinical drug trials

- procure drafts to a clinical development plan (study protocol) as well as design proposal to patient information (informed consent)

- plan the fundamental features of a clinical development plan

- formulate a hypothesis and choose statistical method

- interpret results as well as test the theoretical preconditions for completed analyses

- interpret relevant post-hoc tests

Judgement and approach
- evaluate the ability of different statistical methods to handle repeated measurements in an efficient way

- reflect on alternative ways to test a given hypothesis and its effect on how the result can be interpreted

- evaluate the clinical relevance of different possible study design, how different hypotheses and analytical methods influence the assessment of the benefit of a drug intervention for an individual patient

Course content
This course is appropriate for pharmacists that seek a professional role in the industry, authorities, pharmaceutical or in the academic world where there is a need to have an advanced understanding of the problems around repeated measurements, post-hoc tests

as well as clinical trial methodology The students obtain an advanced understanding of how the statistical methods (the importance of how you define the hypothesis choice of analytical method etc) interact with the interpretation of how a drug influences the patients

Course content;
Parametric or non-parametric methods to handle two or several random samples
The principles around post-hoc tests (problems with multiplicity testing)
Linear regression (both bi and multivariate)

Logistic regression and survival analysis
Introduction to repeated measurements
Design, planning and implementation of explorative and confirming studies
How studies are reviewed by public authority and ethical committee the meaning of Good Clinical Practice and other international guidelines for clinical assessments
During the course different design issues are treated, e.g. how the response variable, as well as study population, influence the design and generalisability of the study

Form of teaching

The teaching is conducted in the form of lectures (with elements of discussion exercises), computer exercises and group work. Study visits may also be undertaken.

The students are expected to solve computer assignments independently without too detailed instructions.

Language of instruction: Swedish
The course may be given completely or partly in English

Assessment

Examination takes place through written examination, written advanced assignment and mandatory computer sessions.

If a student has failed the same examined component twice, and wishes to change examiner before the next examination, a written application should be sent to the department responsible for the course and should be approved unless there are special reasons to the contrary (Chapter 6, Section 22 of the Higher Education Ordinance). When a course has been discontinued or has undergone major changes, the student should normally be offered at least three examination sessions (including the regular ones examination) over a period of at least one year, based on the course's former structure.

If a student has received a recommendation from the University of Gothenburg for special support in learning when compatible with the learning outcomes of the course

and provided that unreasonable resources are not required, the examiner may decide to allow the student adjusted conditions for exam or alternative form of assessment

Grades

The grading scale comprises: Pass with Distinction (VG), Pass (G) and Fail (U).
In order to pass the course PASS (G), a student has to pass the written examination (at least 60% of maximum score) and pass all the other examinations and mandatory excercises. To pass with distinction (Pass with distinction) a student has to earn VG on the written examination (at least 80% of the maximum score) and pass (G) all the other examinations and mandatory excercises.

Course evaluation

The course evaluation takes the form of an anonymous written questionnaire that is made available on the course's page in the University of Gothenburg's virtual learning environment. A compilation of the questionnaire is done by the course coordinator and the results are to be discussed between course administration and student representatives at a Course Board, where proposals for development of the course are discussed. Notes from the Course Board meeting should be taken and submitted to the course administration for archiving, and to the management as well as the Pharmacy Education Council, AUR, for information. The result and potential changes should be shared to both the students who carried out the evaluation and the student that are about to start the course.

Additional information

Study visits can take place outside the Gothenburg area, which can entail costs for the student.