Project Course: Clinical Trial

Projektkurs: Klinisk prövning
6.0 credits

Programme course

8BKG69

Valid from: 2022 Spring semester

Determined by	**Main field of study**	
Chairman of The Board for First and Second Cycle Programmes	Medical Biology	
Date determined	**Course level**	**Progressive specialisation**
2019-09-12	First cycle	G2X
Revised by	**Disciplinary domain**	
Chairman of The Board for First and Second Cycle Programmes	Medicine	
Revision date	**Subject group**	
2021-05-03	Medical Biology	
Offered first time	**Offered for the last time**	
Spring semester 2021		
Department	**Replaced by**	
Institutionen för biomedicinska och kliniska vetenskaper		

Course offered for

- Bachelor´s Programme in Experimental and Industrial Biomedicine

Entry requirements

To enter the course requires at least 90 credits from semester 1-4 in the Bachelor's Programme in Experimental and Industrial Biomedicine.

Intended learning outcomes

Knowledge and understanding

Having completed the course, the student is expected to be able to:

- Describe the different phases in development of new drugs
- Describe the principles for clinical studies of medical technology products
- Describe the overall quality control principles, Good Clinical Practice (CPL), and regulations for clinical trials
- Explain the principles of different type of design for comparing clinical trials; controlled, randomised and masking
- Describe the structure and content of a study protocol
- Describe what it takes to plan, perform and complete a clinical trial

Skills and abilities

On completion of the course, the student shall be able to:

- Critically analyse, compare and discuss different forms of clinical trials concerning design and statistical methods
- Make use of a study protocol and be able to implement it in a clinical trial process
- Write a study synopsis

Judgement ability and approach

On completion of the course, the student shall be able to:

- Identify, formulate and discuss ethical issues that may arise in clinical trials
- Assess advantages and disadvantages with different study design in different types of clinical trials
- Identify the various regulations that surround clinical trials

Course content

This is a basic course in clinical trials. Principles and regulations during the different phases in drug development are studied based on ethical, scientific and methodology aspects. The course also covers processes in drug development, including the role of the patient and other key roles necessary to complete a correct clinical trial. Practical assignments in clinical trial supported by theoretical studies prepare the students to their future professional role.

Teaching and working methods

At the Faculty of Medicine and Health Sciences student centred and problem-based learning make up the foundation of the teaching. The student takes responsibility for, studies and researches current content of the courses and study programme. The methods of the course work challenge the students to independently formulate questions for learning, to seek knowledge and in dialogue with others judge and evaluate achieved knowledge. Students in the Bachelor's programme in Experimental and Industrial Biomedicine work together in groups based on reality based and course related biomedical issues to apply their knowledges, develop their own learning, contribute to the fellow students' learning and to practice cooperation. Throughout the study programme theory is integrated with practical modules. The course methods and integration modules stimulate and support the student's ability to apply their knowledge and professional competence.

Work methods used on this course are lectures, seminars and work in project groups.

Examination

The form of examination is a written project report and an oral presentation carried out in groups but assessed individually. In addition, active participation in compulsory components is required to pass the course. Compulsory elements include project work, seminars and written assignments.

The written project report may be performed an unlimited of times by those students who have not achieved passing grade. The oral presentation is a resource-demanding form of examination and is limited to five times. Completion of the written report and the oral presentation are limited to two times.

Examination and teaching are normally done in English.

If special circumstances prevail, and if it is possible with consideration of the

nature of the compulsory component, the examiner may decide to replace the compulsory component with another equivalent component.

Application for examination

Instructions on how to apply for examinations are given prior to the beginning of each course.

Re-examination

The date for re-examination should normally be announced by the date of the regular examination at latest; in which case the scope must be the same as at the regular examination.

Examination for students with disabilities

If the LiU coordinator for students with disabilities has granted a student the right to an adapted examination for a written examination in an examination hall, the student has the right to it.

If the coordinator has recommended for the student an adapted examination or alternative form of examination, the examiner may grant this if the examiner assesses that it is possible, based on consideration of the course objectives.

An examiner may also decide that an adapted examination or alternative form of examination if the examiner assessed that special circumstances prevail, and the examiner assesses that it is possible while maintaining the objectives of the course.

Nomination of another examiner

A student who has taken two examinations in a course or a part of a course without obtaining a pass grade is entitled to the nomination of another examiner, unless there are special reasons to the contrary.

Grades

Two-grade scale, U, G

Course literature

A literature reference list must be set no later than two months before the course begins by the programme committee for the Bachelor's Programme in Experimental and Industrial Biomedicine. There is no compulsory course literature.

Other information

Planning and implementation of the course is to be based on the wordings in the course syllabus. A course evaluation is compulsory for each course and should include how the course is in agreement with the course syllabus. The course coordinator will analyse the course evaluation and propose appropriate development of the course. The analysis and proposal will be returned to the students, the Director of Studies, and as needed to the Education Board, if related to general development and improvement.

The course is conducted in such a way that there are equal opportunities with regard to sex, transgender identity or expression, ethnicity, religion or other belief, disability, sexual orientation and age.

If the course is cancelled or undergoes major changes, examination is normally offered under this course syllabus, at a total of three occasions, within/in connection to the two following semesters, of which one in close proximity to the first examination.

If special circumstances prevail, the vice-chancellor may in a special decision specify the preconditions for temporary deviations from this course syllabus, and delegate the right to take such decisions.