



**Karolinska
Institutet**

Course syllabus for

GCP and Clinical Pharmaceutical Trials, 3.5 credits

GCP och klinisk läkemedelsprövning, 3.5 hp

This course syllabus is valid from autumn 2024.

Please note that the course syllabus is available in the following versions:

Autumn2023 , Autumn2024

Course code	4FF011
Course name	GCP and Clinical Pharmaceutical Trials
Credits	3.5 credits
Form of Education	Higher Education, study regulation 2007
Main field of study	Translational Physiology and Pharmacology
Level	AV - Second cycle
Grading scale	Pass with distinction, Pass, Fail
Department	Department of Physiology and Pharmacology
Decided by	Education committee FyFa
Decision date	2023-02-02
Revised by	Education committee FyFa
Last revision	2024-03-05
Course syllabus valid from	Autumn 2024

Specific entry requirements

At least the grade Pass on the courses Integrated physiology and pharmacology (semester 1) and Physiological and pharmacological mechanisms and experimental methods (semester 2) on the Master programme in Translational Physiology and Pharmacology.

Objectives

The aim of the course is that the student should understand how a clinical assessment is carried out from the beginning of a study until the end, and how Good Clinical Practice (GCP) can be applied in the different parts of the study.

After completing the course, the student shall be able to:

- Give an account of how GCP regulates the different components of a clinical drug trials.
- Describe planning and implementation of a clinical drug trials.
- Explain clinical drug trials, the clinical experimental protocol and current regulatory frameworks

- for implementation of a clinical assessment
- Choose relevant statistical methods and analysis for a clinical drug trial
- Reflect how sustainability can affect GCP and clinical drug trials in the future

Content

Fields that are included are how a clinical trial is carried out, current regulatory frameworks including GCP, which documentation is required and which requirements are set on approvals to be able to carry out a clinical trials.

The education fulfils the requirements for TransCelerate GCP-education.

Teaching methods

The course has a mixture of learning activities as synchronous and asynchronous teaching with training in a web-based learning activity, which is combined with lectures, seminars and discussions.

Examination

Web-based part of the course. Graded Fail/Pass.

Individual oral presentation. Graded Fail/Pass.

Individual reflection regarding sustainability. Graded Fail/Pass.

Written examination. Graded Fail/Pass/Pass with distinction.

To pass the course (the grade Pass or higher), at least Pass on all examinations in the course is required.

Limitation of number of examinations

The students who have not passed the course according to the schedule are allowed to revise and hand in the report and/or do the oral presentation for at most five additional occasions. If the student has failed six times in total, no further examination or continued course participation is allowed. As submission, it is counted that the student submitted a revised version of the assignment and/or orally presented to examining teachers.

The students that have not passed the course after the regular examination session have the right to participate in five additional examination sessions. If the student has performed six failed examination sessions, no additional examination or new course admission is approved.

Each occasion the student participates in the same test counts as an examination. Submission of a blank examination is regarded as an examination. In case a student is registered for an examination but does not attend, this is not regarded as an examination.

In the event of special circumstances, or if a student with a disability is in need of certain adjustments, the examiner may decide to depart from the syllabus' regulations on examination form, number of examination opportunities, possibility of completion or exemption from compulsory educational elements, etc. Content and intended learning outcomes as well as the level of expected skills, knowledge and abilities must not be altered, removed or lowered.

Other directives

The course is offered in English. Course evaluation takes place according to the guidelines that are established by the Committee for education at basic level and second cycle.

Literature and other teaching aids

Recommended literature

Material available on the course website.

Supplementary study materials and reference articles will be provided during the course.