



**Karolinska
Institutet**

Course syllabus for

Study design and analysis in medical research, 7.5 credits

Studiedesign och analys i medicinsk forskning, 7.5 hp

This course syllabus is valid from autumn 2025.

Course code	5BD003
Course name	Study design and analysis in medical research
Credits	7.5 credits
Form of Education	Higher Education, study regulation 2007
Main field of study	Biostatistics and Data Science
Level	AV - Second cycle
Grading scale	Pass with distinction, Pass, Fail
Department	Department of Medical Epidemiology and Biostatistics
Decided by	Programme committee for study programmes in biomedicine
Decision date	2023-10-11
Course syllabus valid from	Autumn 2025

Specific entry requirements

At least the grade G (Pass) for the courses "Biostatistics 1: Introduction to biostatistics" and "Survival analysis with applications in medicine".

Objectives

The course aims to extend the student's knowledge and skills related to statistical methods by equipping the student with additional knowledge, competence, and skills in study design and strengthening the student's knowledge about the link between study design and analysis. The course aims to equip the student with the knowledge, skills, and judgement to design studies in biomedical research as well as the knowledge, skills, and judgement to choose and conduct an appropriate statistical analysis for a given study design in biomedical research.

Upon completion of the course, the student should be able to:

Regarding knowledge and understanding

- Demonstrate an advanced understanding of statistical methods and their applications in the design and analysis of biomedical research studies.
- Demonstrate an understanding of the various phases of drug development, including regulatory aspects, and demonstrate an understanding of the role of the biostatistical scientist and statistical

methods in this process.

Regarding competence and skills

- Apply theoretical knowledge and practical skills to design biomedical research studies in three key areas: pre-clinical studies and animal research, clinical trials, and observational studies.
- Evaluate and select appropriate statistical designs for experiments, including but not limited to factorial designs and block designs, in the context of biomedical research.
- Demonstrate proficiency in designing efficient and optimal observational studies and controlled epidemiological studies, considering ethical and practical constraints.
- Conduct power calculations effectively to determine sample sizes necessary for statistically meaningful biomedical research studies.
- Apply methods for meta-analysis to synthesise and critically assess research findings in the biomedical field.

Regarding judgement and approach

- Establish a link between study design and statistical analysis, and make informed choices about appropriate statistical methods based on the research questions and design of the study.
- Exhibit critical thinking and judgment in assessing the quality and validity of biomedical research studies, including the ability to identify potential sources of bias.

Content

Both theoretical and practical (hands-on data analysis) components will be included. The course will build upon previous courses in the program by providing an overview of methods for the design and analysis of biomedical research studies in three areas:

- Pre-clinical studies and animal research
- Clinical trials
- Observational studies

The course covers the following specific topics: statistical design of experiments (e.g., factorial designs and block designs), introduction to drug development (including the various phases and regulatory aspects), power calculations, methods for meta analysis, efficient and optimal design of observational studies, and controlled epidemiological studies.

Teaching methods

The primary teaching methods will be lecture-based learning, technology-enhanced learning (primarily computer-based data analysis), individual learning, and group learning. The course focuses on active learning, i.e., putting knowledge into practice and critically reflecting upon the knowledge.

Examination

The examination consists of assignments (with written and/or oral presentation) and an individual written examination. The deliverable elements of the assignments (e.g., holding an oral presentation or submitting a written report) are to be completed before the end of the course according to the times specified in the schedule.

If there are special grounds, or a need for adaptation for a student with a disability, the examiner may decide to deviate from the syllabus' regulations on the examination form or the possibility of

supplementation or exemptions from compulsory sections of the course. Content and learning outcomes as well as the level of expected skills, knowledge and abilities may not be changed, removed, or reduced.

Compulsory participation

It is compulsory to attend the introduction to the course and the sessions in which the assignments are presented/discussed. The examiner assesses if and, in that case, how absence from compulsory components can be compensated. Before the student has participated in all compulsory parts or compensated absence in accordance with the examiner's instructions, the student's results will not be registered in LADOK. Absence from a compulsory activity may result in that the student cannot compensate the absence until the next time the course is given.

Limit to the number of examinations

A student who does not pass the first examination is entitled to participate in five more examinations. If the student does not pass after four examinations, he/she is recommended to retake the course at the next regular course date, and may, after that, participate in two more examinations. If the student has failed six examinations, no additional examination or new admission is provided.

The number of times that the student has participated in one and the same examination is regarded as an examination session. Submission of a blank examination is regarded as an examination. An examination, for which the student registered but not participated in, is not counted as an examination.

Other directives

The course language is English.

Literature and other teaching aids

Study material and reference articles will be provided during the course.