DEPARTMENT OF ONCOLOGY-PATHOLOGY

K7F5274, Introductory Course in Clinical Studies: From Idea to Archiving, 1.5 credits (hec)

Introduktionskurs i kliniska studier: från idé till arkivering, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

This syllabus was approved by the The Committee for Doctoral Education on 2023-12-07, and was last revised on 2024-09-16. The revised course syllabus is valid from autumn semester 2024.

Responsible department

Department of Oncology-Pathology, Faculty of Medicine

Prerequisite courses, or equivalent

No prerequisite courses, or equivalent, demanded for this course.

Purpose & Intended learning outcomes

Purpose

The purpose of the course is to give the participants a practical understanding and insight into the process, principles and rules within the start-up, implementation and completion of clinical studies.

Intended learning outcomes

After the course, the doctoral student is expected to:
- be able to plan and develop a study protocol including a thorough methodical evaluation and selection of an appropriate study design.
- be familiar with the various regulations surrounding a clinical study (Declaration of Helsinki, Ethical Review Act, EU Regulation 536/2014 CTR, Data Protection Regulation GDPR, etc.) and based on these be able to plan, carry out and end a clinical study in the right way.
- know the various agreements required at start-up, of a clinical study.
- be able to reflect critically on other students' research projects in a scientifically constructive way.

Course content

- Review of the study process /study planning
- Writing study protocols
- Statistics and method review

Study implementation (data collection, journal entries, safety reporting, etc.)

- Review of different concepts and actors in clinical studies (incl. medical technology and IVDR)
- Lectures on Good Clinical Practice (GCP), Declaration of Helsinki and other regulations
- Applications (Ethical Review Authority, Medical Products Agency, Biobank)
- Ethics in research based on regulations (Declaration of Helsinki, Ethical Review Act, CTR, etc.); to weigh risk against benefit, to write a patient information consent, the consent process, etc.,
- Agreement/cost calculation
- Closing/Archiving/Reporting

Forms of teaching and learning

Lectures from authorities and people specialised in their respective fields, group exercises, seminars and oral and written presentations. The course focuses on practical learning by translating knowledge in a practical sense and critical reflection of ability.

Language of instruction

The course is given alternately in Swedish and English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

Compulsory attendance at lectures, group exercises and presentations. Absences are made up for at a later course after consultation with the course coordinator.

Forms of assessment

To pass the course, the student must demonstrate that the intended learning outcomes have been achieved. This is assessed through active participation in seminars and approved oral and written presentation.

Participants will be divided into smaller groups. The aim is to review the study protocols within each group, critically analyse the content, and give feedback to each other. Participants will complete several assignments throughout the course, which will aid their ability to write a study protocol.

Certificates in GCP are included for those who pass.

Course literature

Recommended course literature:
- Declaration of Helsinki
- ICH GCP, The International Council for Harmonization, Guideline for Good Clinical Practice (E6),R2
- Act on ethical review of research (2003:460)
- Clinical Trials Regulation EU, 536/2014
- Biobank Act
- Clinical Studies Sweden

During the lectures will also be referred to other applicable laws and regulations.