



## DEPARTMENT OF MEDICINE, SOLNA

### **K2F5580, Quality Assurance of Clinical Research, 1.5 credits (hec)**

Kvalitetssäkring av klinisk forskning, 1,5 högskolepoäng

*Third-cycle level / Forskarnivå*

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#### **Approval**

This syllabus was approved by The Committee for Doctoral Education on 2023-12-12, and was last revised on 2025-09-01. The revised course syllabus is valid from spring semester 2026.

#### ***Responsible department***

Department of Medicine, Solna, Faculty of Medicine

#### **Prerequisite courses, or equivalent**

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

#### **Purpose & Intended learning outcomes**

##### **Purpose**

This course is suitable for any kind of clinical researcher at KI. The purpose of the course is to carry insights to the participant how to create trustful data, and how to become a trusted researcher. The course brings information of what is required to act safely and in accordance with local rules, national legislation and international treaty's when involved in clinical research. Whether your research is interventional or non-interventional, using quantitative or qualitative methodology, you will after this course know how to act to secure your research persons, your data and your professional career.

##### **Intended learning outcomes**

Knowledge and understanding:

Conclude which legislations affects clinical research and how they do it.

Deduce how clinical research integrity is affected by fabrication, falsification and plagiarism.

Account for common problems that may arise in clinical research.

**Competence and skills:**

Differentiate the responsibilities between the investigator, the study team members, and the sponsor in a clinical study.

Analyse the validity of a research project proposal or publication with a risk-benefit analysis.

Translate general research quality systems into own research area.

**Judgement and approach:**

Critically identify good clinical scientific practices and deviations from it in clinical research.

Judge data validity and their reproducibility.

Handling bias, sponsorship, and scientific authorship in a paper.

**Course content**

This course presents different quality systems in clinical research including good clinical practice (GCP). In more detail the course also discusses:

How and when the informed consent shall be asked for in relation to the research.

Why you can't substitute research persons.

What to consider when constructing a study protocol.

How to handle violations to the protocol.

Why you need to screen for unwanted effects.

What is the responsibility on your shoulders as an investigator?

What you can do to safeguard your research and career.

**Forms of teaching and learning**

You should have some basic experience using Canvas as this software is our learning management system. **NB! The course is provided in a digital format with video lectures, readings, discussion postings and self-tests. It corresponds to one-week full time course distributed over four weeks.** Digital lectures are provided on different aspects on research quality. There are self-tests after each lecture. The first phase includes the GCP course. The second phase lets the student pick an article from a selection of different research areas for an in-depth critical analysis using the analysing tools provided. Finally, the student must present how quality is applied to, or how it could be incorporated, into the students' own research area. The faculty is available and on stand-by during the study period (office hours). The study path of each student is monitored digitally.

***Language of instruction***

The course is given in English

**Grading scale**

Pass (G) /Fail (U)

**Compulsory components & forms of assessment**

### **Compulsory components**

There will be a mandatory attendance check upon study start. If no-show, the seat will be cancelled and referred to another student on the waiting list for the course. Each self-test, task and discussion must be passed to be able to take the final exam.

### **Forms of assessment**

Having cleared all preceding moments an individual final examination is taken. This start with multiple answer questions. Following this is a short essay. The theme for the two tests is implementation of the quality standards in the students own research field. If the final exam is not cleared a new final exam will be offered at next course occasion.

### **Course literature**

Recommended literature:

1. Guideline for Good Clinical Practice ICH E6(R2) ICH Consensus Guideline. <https://ichgcp.net/>. Version E6(3).
2. Good Clinical Practice: Pharmaceutical, Biologics, and Medical Device Regulations and Guidance Documents; Volume 2 by Mindy J. Allport-Settle. PharmaLogika ISBN 978-0-98-2147689.
3. The European Code of Conduct for Research Integrity. <https://allea.org/code-of-conduct/>
4. God forskningsset 2024 (Svenska) - Vetenskapsrådet. <https://www.vr.se/analys/rapporter/vara-rapporter/2024-10-02-god-forskningsset-2024.html>
5. Good research practice 2024 (English) - Swedish Research Council. <https://www.vr.se/english/analysis/reports/our-reports/2025-07-03-good-research-practice-2024.html>.
6. Science fictions. Stuart Ritchie. Bodley Head, London. ISBN 9781847925657.

The course library in the learning management platform Canvas contains several articles and links to relevant sites and will be open during the course for download.