DEPARTMENT OF LABORATORY MEDICINE

H5F6083, Quality Assurance Applied to Clinical Research, 1.5 credits (hec)

Kvalitetssäkring inom klinisk forskning, 1,5 högskolepoäng

Third-cycle level / Forskarnivå

Approval

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

Responsible department

Department of Laboratory Medicine, Faculty of Medicine

Contributing department/s

Department of Laboratory Medicine

Prerequisite courses, or equivalent

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

Purpose & Intended learning outcomes

The purpose of the course is that the students acquire essential knowledge and skills in quality assurance principles that ensure research integrity, participant safety, and regulatory compliance in clinical research. Whether conducting interventional studies, observational research, or registry-based studies, participants will gain practical understanding of how to design, conduct, and manage clinical research that meets international standards and regulatory requirements while maintaining the highest ethical standards.

At the end of the course the course participant is supposed to be able to:

Knowledge and understanding

Explain the regulatory framework governing clinical research, including GCP principles, ethical guidelines, and data protection requirements.

Identify the roles and responsibilities of investigators and other key stakeholders in clinical research.

Account for ethical considerations and informed consent procedures in clinical research involving human participants.

Competence and skills

Apply good clinical practice (GCP) principles to clinical research scenarios.

Evaluate appropriate data management strategies that ensure data integrity and compliance with GDPR.

Implement informed consent procedures and participant information materials.

Judgement and approach

Critically assess clinical research proposals for quality assurance and ethical compliance.

Integrate quality assurance principles into personal research practice.

Course content

This course covers essential quality assurance aspects of clinical research through four key areas:

Good Clinical Practice (GCP) Fundamentals

- International guidelines and regulatory requirements
- Investigator responsibilities and documentation requirements
- Protocol compliance and deviation management

Ethical Framework for Clinical Research

- Declaration of Helsinki and international ethical guidelines
- Informed consent processes and vulnerable populations
- Ethics committee review and approval procedures

Regulatory Compliance

- Swedish and European legislation affecting clinical research
- GDPR and data protection in clinical research
- Adverse event reporting requirements

Research Data Management

- Data integrity principles (ALCOA+)
- Electronic data capture and validation
- Data security, backup, and archiving requirements

Forms of teaching and learning

This course is delivered entirely online through the Canvas learning management system over a two-week period at 50% study pace (equivalent to one full-time week). The course includes:

- Self-paced video lectures covering core theoretical concepts
- Online discussion forums for peer interaction and faculty guidance
- Assessment quizzes after each module
- Peer review assignments facilitated through Canvas

Students are expected to have basic familiarity with Canvas as the primary learning platform. Faculty support is available throughout the study period via the discussion forum and Canvas messaging system.

Language of instruction

The course is given in English

Grading scale

Pass (G) /Fail (U)

Compulsory components & forms of assessment

Compulsory components

All components must be passed to receive course credit. Students who do not pass on the first attempt will be offered re-assessment during the next course offering.

Forms of assessment

Assessment is based on:

1. **Module Quizzes**: Assessment quizzes after each learning module that must be passed to proceed
2. **Written Assignment with Peer Review**: Analysis of a clinical research scenario applying quality assurance principles, followed by structured peer review of another student's work using Canvas peer review tool

The written assignment involves applying course concepts to evaluate a clinical research protocol or case study. Students submit their analysis and then review a peer's work using provided assessment criteria. The examiner provides final assessment based on both the original assignment and quality of peer review feedback.

Course literature

The recommended literature includes:

- ICH Guideline for Good Clinical Practice E6(R3) - International Council for Harmonisation. Available at: https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline
- Declaration of Helsinki - World Medical Association. Latest version available at: https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

- EU Clinical Trials Regulation (CTR) 536/2014 - European Medicines Agency guidance documents. https://health.ec.europa.eu/medicinal-products/clinical-trials/clinical-trials-regulation-eu-no-5362014_en
- General Data Protection Regulation (GDPR) - EUR-Lex. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj
- Good Research Practice - Swedish Research Council (Vetenskapsrådet). Available at: https://www.vr.se/english/analysis/reports/our-reports/2025-07-03-good-research-practice-2024.html
- Quality Risk Management ICH Q9 - International Council for Harmonisation. https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-ich-guideline-q9-quality-risk-management-step-5-first-version_en.pdf
- The European Code of Conduct for Research Integrity: https://allea.org/code-of-conduct
- Services and support for clinical research at KI:https://staff.ki.se/research-support/clinical-research

The course library in Canvas contains selected articles, regulatory guidance documents, case studies, and links to relevant websites. All materials will be accessible throughout the course period and after course completion for reference.