Study Plan for the CAS Clinical Research in Health Care Organisations

UNIVERSITÄT BERN

2 June 2026

The study program in Clinical Research in Health Care Organisations (CRHCO) is a continuing education program leading to the award of the Certificate of Advanced Studies in CRHCO, University Bern (CAS CRHCO UniBern).

The legal basis is the Regulations of the Faculty of Medicine for Continuing Education and the “Reglement für die Weiterbildungsstudiengänge in Leading Learning Health Care Organisations” from 16 December 2020.

1. Objectives, Scope and Structure of the Study Program

Objectives CAS CRHCO

The participants:

a are familiar with basic epidemiological concepts as well as the advantages and disadvantages of various study types in descriptive and analytical epidemiology,

b have a solid understanding of the design, conduct, and analysis of randomized clinical trials, diagnostic and prognostic studies, as well as systematic reviews and meta-analyses,

c learn about and apply the statistical methods and regression models (linear, logistic, Cox, Poisson, Weibull) commonly used in epidemiology,

d can analyze datasets from the aforementioned studies using statistical software (e.g. R), interpret the results, and discuss their relevance for clinical practice, healthcare, and public health,

e can draw conclusions about possible causal relationships based on epidemiological data,

f can locate relevant individual studies and reviews in relevant literature databases,

g can evaluate study designs and published studies in terms of quality of data collection, measurement methods, and analysis,

h can identify suitable funding sources for own clinical research,

i are familiar with the ethical principles of scientific publication,

k can communicate complex scientific content in an understandable way,

l can use appropriate tools to improve scientific communication.

Scope and Structure CAS CRHCO

The CAS Clinical Research in Health Care Organisations comprises 15 ECTS credits (approx. 375-450 working hours). It is made up of 8 compulsory modules and 2 elective modules totaling 15 ECTS credits.

The detailed description of the modules can be found in the appendix to the study plan. The Study Commission may extend and adapt the catalogue of modules.

Language

The course language in all modules is English. All performance assessments (module assessments, written assignments, presentations) are conducted in English.

Scope, objectives and content of the modules

The modules are described in detail in the module tables in the appendix to the study plan.

2. Performance Assessments

Performance Assessment

Each module includes an assessment in the form of multiple-choice questions. A course certificate with ECTS credits is issued only upon satisfactory completion of the assessment.

Performance assessment is governed by the study regulations. Unsatisfactory performance assessments can be repeated once. The repetition must take place no later than 3 months after the written notification of the participant.

At the end of the program, participants take a written examination and an oral examination. The written examination consists of an analysis of a clinical study with a report. The oral examination consists of a questions and answers-session with an examiner based on the written examination. In case of failure, an oral examination will be secondarily organized to assess the participant's understanding of core content and concepts. Both exams are evaluated based on a set of predefined criteria. The exams are graded as "pass" or "fail".

[3] The Study Commission decides based on the participant's attendance (minimum 80% per module), the assessment of the performance records (per module and general assessment) on the passing of the examination and the award of the CAS degree.

Implementing provisions

Further details are regulated in the guidelines of the program.

Bern, 2 June 2026 The Director,

Prof. Dr. Angèle Gayet-Ageron

Appendix to the CAS Clinical Research in Health Organisations Curriculum

List of Modules (Descriptions)

Compulsory-Module 1: General Principles of Clinical Research

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will: • Formulate clinically relevant research questions using PICO and PEO frameworks. • Compare common clinical research study designs and justify their appropriate use. • Explain key ethical principles and the role of patient and public involvement in clinical research. • Classify variable types and select appropriate descriptive statistical methods and visualizations. • Perform basic data cleaning, descriptive analyses, and visualizations in R. • Create reproducible analytical reports using R Markdown.		
Learning content	General principles of clinical research: • PICO and PEO (research question) • Study design: cross-sectional, case-control, cohort, randomized controlled trial, ecological study • Ethics principles: informed consent, risk assessment, equity in research • Patient and public involvement and engagement (PPIE): information, consultation, collaboration, co-construction, leadership Biostatistics: • Types of variables: continuous, binary, categorical, ordinal • Measures of central tendency, measures of dispersion: mean, median, standard deviation, interquartile range, percentiles • Frequency tables, contingency tables • Simple graphs: bar plots, histograms, box plots, violin plots, scatter plots, and extensions • Understand about possible caveats in graphs Programming in R: • Introduction to basic functionalities of R and RStudio • Setting up and cleaning data • Descriptive statistics and simple visualizations in R • Using projects in RStudio • R markdown		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Pre-lecture from the course book chapters 1,2,7 (Browner & Neuman) & chapters 1-8,10,11 (Petrie & Sabin).		
Language of instruction	English		

Compulsory-Module 2: Cross-sectional Studies, Questionnaire Design, and REDCap Databases

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this course, participants will be able to: • Explain the strengths, limitations, and appropriate applications of cross-sectional and ecological study designs. • Identify potential sources of bias and confounding in observational studies. • Develop simple questionnaires considering clarity, feasibility, and basic validity principles. • Design and manage structured data collection instruments in REDCap. • Interpret confidence intervals, p-values, and common effect measures in clinical research. • Conduct basic statistical tests and sample size calculations in R.		
Learning content	Epidemiology: • Cross-sectional study • Ecological study • Biases and confounders Questionnaires: • Set up a basic questionnaire • Set up database in REDCap and export results Biostatistics: • Estimation • Uncertainty • Hypothesis testing • Effect measures: mean difference, risk difference, odds/risk ratio • Power / sample size calculations Programming in R: • Performing common tests • Estimating effects • Calculating power/ sample size		
Teaching/ Learning methods	Pre-lecture from the course book chapters 5, 6 (p116-119 till "Cohort studies") and 8 (Browner & Neuman) & chapters 9, 12, 17, 36 (Petrie & Sabin). Basic programming skills in R.		
Required prior knowledge	Basic programming skills in R		
Language of instruction	English		

Compulsory-Module 3: Cohort Studies

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will be able to: • Compare different types of cohort studies and justify their use in clinical research. • Critically assess potential sources of bias and confounding in cohort studies. • Use directed acyclic graphs (DAGs) to represent causal assumptions and identify appropriate covariates for statistical adjustment in observational studies. • Implement and interpret linear regression models in R. • Critically appraise published cohort studies regarding validity and causal interpretation.		
Learning content	Epidemiology: • Aspects of cohort study design: defining the population, measuring exposure, follow-up, measuring outcomes, types of cohorts • Differences of cohort studies from other study designs, advantages and disadvantages, relevant types of bias in the context of a cohort • Practical considerations related to cohort studies e.g. improving recruitment, reducing loss to follow-up, PPIE • Registry-nested cohorts, biobanks, record linkage to routinely available data Biostatistics: • Elements of causal inference: confounding, collider bias • DAGs • Use of DAGitty • Linear regression model • Multiple linear regression • Assumption of the linear regression model Programming in R: • Fitting linear regression		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Basic programming skills in R.		
Language of instruction	English		

Compulsory-Module 4: Case-control and Diagnostic Test Studies

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this course, participants will be able to: • Identify situations in which a case-control study design, including nested case-control studies, is appropriate, and define and select appropriate cases and controls. • Identify and critically assess major sources of bias in case-control studies and critically appraise published case-control studies with respect to the validity and applicability of their findings. • Explain and interpret key measures of diagnostic test accuracy, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), Receiver Operating Characteristic (ROC) curves, and Area Under the Curve (AUC) estimates. • Explain the basic elements of a logistic regression model and interpret results from logistic regression analyses. • Use R to estimate and visualize measures of diagnostic test accuracy and apply advanced visualization methods for the presentation of results. Fit and interpret logistic regression models in R.		
Learning content	Epidemiology: • Principles and applications of case-control studies • Historical examples of case-control studies in public health • Selection of cases and controls • Matching in case-control studies • Nested case-control studies • Sources of bias in case-control studies • Critical appraisal of case-control studies • Study design and interpretation of diagnostic test studies Biostatistics: • Logistic regression models • Multivariable logistic regression • Measures of diagnostic tests accuracy: sensitivity, specificity • ROC curves • Estimating AUC • The Bayes theorem • NPP, PPV Programming: • Fitting a logistic regression model in R • Estimating measures of diagnostic test accuracy in R • Creating ROC curves • Advanced visualization methods in R via the ggplot2 package		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Linear regression, basic programming skills in R and basic concepts in epidemiology		
Language of instruction	English		

Compulsory-Module 5: Randomized Controlled Trials

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will be available to: • Describe and develop key elements of a randomized controlled trial protocol, including the selection of control groups, randomization procedures, sample size estimation. • Compare and evaluate different randomized controlled trial designs and their methodological implications. • Calculate and interpret incidence rates, incidence rate differences, and incidence rate ratios. • Interpret results from survival data analyses including Poisson regression, Kaplan–Meier curves and, results from Cox proportional hazards regression models, taking underlying model assumptions into account. • Perform and interpret clinical trial and survival analyses in R, including randomization procedures, model diagnostics, data visualization, and communication of results.		
Learning content	Randomized controlled trial: • Principles: randomization, concealment of allocation, control group, blinding, analysis sets (intention to treat, per protocol) • Non-parallel controlled trial: cluster randomized controlled trial, stepped-wedge cluster-controlled trial, factorial trial, crossover-controlled trial, N-of-1 trial • Sample size calculation: power, type 1 error, effect size, ratio Biostatistics: basic elements of time-to-event (survival) analysis, including: • Definition of a time-to-event outcome • Censoring • Estimating incidence rate • Incidence rate difference • Incidence rate ratio • Poisson regression • Kaplan Meier curve • Log-rank test • Basics of Cox regression model • Checking model assumptions • Hazard ratios • Interpreting results from a Cox regression model Programming in R: • Conducting time-to-event analyses in R • Fitting Poisson regression models, interpreting results • Obtaining Kaplan-Meier plots • Fitting Cox regression models • Checking assumptions		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Linear regression, logistic regression, basic programming skills in R.		
Language of instruction	English		

Compulsory-Module 6: Systematic Reviews and Meta-analysis

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this course, participants will be able to: • Formulate focused research questions and define eligibility criteria for systematic reviews. • Develop and conduct structured literature searches using major biomedical databases. • Perform study selection and data extraction using transparent and reproducible methods. • Conduct and interpret basic meta-analyses using common-effect and random-effects models in R. • Assess heterogeneity and reporting bias in systematic reviews and meta-analyses. • Critically appraise published systematic reviews and meta-analyses regarding methodological quality and interpretation.		
Learning content	• Introduction to systematic reviews. Purpose and types of systematic reviews. Measures of association, which will be taught much earlier, in previous module. Formulating research questions and defining inclusion criteria. • Literature identification and study selection. Search strategies and database use (PubMed, Cochrane Library, ClinicalTrials.gov). Screening and selection of studies. • Meta-Analysis methods. Common-effect and random-effects models. Interpretation of summary estimates • Heterogeneity and its exploration. Sources of heterogeneity. Statistical assessment of heterogeneity. Practical exploration using R. • Reporting bias. Publication bias and selective reporting. Methods for identifying small-study effects and interpretation. • Critical appraisal. Assessing the quality of systematic reviews and meta-analyses. Application through case studies (including real-world examples). • Specialized and advanced types of systematic reviews. Systematic reviews of observational studies. Systematic reviews of animal studies. Network meta-analysis. • Practical application and integration. Hands-on R sessions for meta-analysis and advanced methods. Group exercises and quizzes to reinforce learning. Integration of concepts across the review process		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Randomized controlled trials, observational studies.		
Language of instruction	English		

Compulsory-Module 7: Prognostic Research

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this course, participants will be able to: • Explain the principles and applications of prognostic and prediction research in healthcare. • Develop and interpret basic prognostic models using appropriate statistical approaches. • Apply strategies to address overfitting, missing data, and non-linear relationships in prediction modelling. • Evaluate prognostic models using measures of discrimination, calibration, and validation. • Conduct basic prognostic modelling analyses in R and interpret model outputs. • Critically appraise published prognostic studies regarding methodological quality, reporting, and clinical usefulness.		
Learning content	The course covers the following core topics: • Foundations of prognostic research. Frameworks for prognostic research. Key concepts and definitions. Types and purposes of prognostic models. • Statistical methods for prediction modelling. Introduction to prediction modelling techniques. Overfitting and optimism in model development. Handling missing data. Modelling non-linear associations. • Practical implementation. R-based practical sessions for model development and evaluation. • Reporting and critical appraisal. Reporting standards for prognostic models. Assessing the quality and transparency of published models. Group-based critical appraisal exercises • Model development and selection. Model selection strategies. Modern estimation methods. • Model evaluation and validation. Performance measures (e.g., discrimination, calibration). Internal and external validation techniques. • Advanced prediction modelling. Advanced statistical approaches in prognostic modelling. Step-by-step guide to building prediction models. • Evidence synthesis in prognostic research. Systematic reviews of prognostic studies. Interpretation and synthesis of prognostic evidence. • Application and knowledge integration. Development and presentation of participant projects (optional). Integration of concepts into real-world research contexts.		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Linear and logistic regression models, basics in R.		
Language of instruction	English		

Compulsory-Module 8: Funding Research and Science Communication

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will be able to: • Identify and evaluate major sources of research funding in Bern, Switzerland, and internationally, and select appropriate funding opportunities for a research project. • Apply authorship requirements and ethical principles in research dissemination, including the responsible use of artificial intelligence in research. • Prepare and revise scientific manuscripts by applying principles of efficient scientific writing and responding effectively to reviewers' comments. • Communicate research findings effectively through oral presentations and the use of graphics, visualizations, and other communication tools. • Develop a dissemination strategy for research findings and identify and critically assess predatory journals and other inappropriate dissemination channels.		
Learning content	Research funding: • Swiss National Science Foundation (SNSF) funding programmes • European competitive research fundings Research protocol: • Structure of a research protocol following appropriate guidelines • Identify the appropriate sources of funding • Establish a research budget • Present the project plan (gantt chart) in an informative way Scientific communication: • Know the International Committee of Medical Journal Editors (ICJME) recommendations • Structure of an original research paper • Learn how to write a research abstract • Become familiar about the peer-reviewing process • Adapt oral communication to different audiences		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	Pre-lecture from the course book chapter 20 (Browner & Neuman) & chapter 37 (Petrie & Sabin). Prepare a research abstract (based on documents providing the research protocol and main results).		
Language of instruction	English		

Elective-Module 9: Introduction to Qualitative Health Research

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will be able to: • Critically assess the relevance of qualitative research for addressing questions in health care organizations. • Identify and explain fundamental principles of qualitative research, including its epistemological and methodological assumptions. • Identify, compare, and appraise key approaches to data generation in qualitative research. • Identify, compare, and appraise key approaches to data analysis in qualitative research. • Critically assess the quality, rigor, and trustworthiness of qualitative research studies.		
Learning content	• How to think differently for qualitative health research: ontology, epistemology, and big Q vs. small q approaches • Integration of qualitative research across different phases of the public health action cycle, for different purposes, and within different study designs • Data generation approaches. • Data analysis approaches (focus: reflexive thematic analysis) • Specificities of qualitative research in health (ethics, reporting, and publishing)		
Teaching/ Learning methods	• Asynchronous preparation for class (preparatory readings, podcasts, videos) • Introductory lectures and interactive sessions during class-time • Group discussion and workshop formats to practise the application of qualitative approaches and transfer insights to own research		
Required prior knowledge	None		
Language of instruction	English		

Elective-Module 10: Patient Partnership in Clinical Care, Research and Guidelines development

ECTS credits	1.5	**Scope**	3 days
Assessment type	Multiple choice questions	**Attendance requirement**	≥80%
Learning objectives	By the end of this module, participants will be able to: • Explain and apply the principles of public and patient involvement and engagement (PPIE) in clinical research. • Develop, establish, and maintain patient partnerships in clinical research. • Assess the advantages and added value of patient partnerships across different types of clinical research. • Implement PPIE approaches in their own research projects. • Explain the process of clinical guideline development and the role of patient and public involvement within this process.		
Learning content	• Levels of involvement in PPIE • Benefits of PPIE in clinical research • Stages of patient engagement in clinical research • Identification and selection of patient partners • Practical considerations related to PPIE in clinical research • Basics of clinical guideline development		
Teaching/ Learning methods	The course uses a practice-oriented teaching approach combining lectures, hands-on work, and interactive learning.		
Required prior knowledge	None		
Language of instruction	English		