University of Basel
Continuing Education

CONTINUING EDUCATION

STUDY HANDBOOK

DIPLOMA OF ADVANCED STUDIES

Clinical Trial Practice and Management

CERTIFICATE OF ADVANCED STUDIES

Clinical Research I

CERTIFICATE OF ADVANCED STUDIES

Clinical Research II

16.11.2023

INDEX

1. General Description

Successful clinical research requires clinical experience, but also extensive knowledge about all phases of the clinical research process, awareness of regulatory requirements as well as project management and leadership skills. The complex and highly competitive nature of clinical research results in a growing need for well-trained clinical research professionals, not least those working as study coordinators, study managers, clinical monitors or clinical research assistants.

Clinical research professionals usually start their careers with background knowledge from diverse graduate trainings often lacking structured training in clinical research. Still, they are facing highly demanding responsibilities in a complex, ever-evolving, interdisciplinary and often multinational environment. Fortunately, training at the postgraduate level is increasingly being recognised as essential to developing scientific, technical and interpersonal competences to ultimately enhance the quality of clinical research.

The Diploma of Advanced Studies (DAS) Clinical Trial Practice and Management program intends to prepare graduates for starting or successfully developing a professional career in different clinical research settings such as academia, pharmaceutical, medical device or biotech industry, clinical research organisations and regulatory agencies. It comprises two consecutive Certificate of Advanced Studies (CAS) programs (CAS Clinical Research I and CAS Clinical Research II) followed by a diploma thesis and a final examination. The two CAS programs can also be completed individually.

CAS Clinical Research I covers basic topics of clinical study planning and conduct and is particularly appropriate for people with no or limited work experience in operational clinical research. CAS Clinical Research II addresses advanced topics of clinical trial management and has been developed for participants with a solid understanding of clinical trial practices based on work experience and continuing education. Preparation of a diploma thesis provides candidates with the opportunity to demonstrate comprehensive theoretical and practical in-depth knowledge and understanding of a related professional topic.

2. Target Audience

The programs address people with educational backgrounds in life science, medical or nursing sciences working in any field related to clinical research or seeking a career change into an operational clinical research profession.

Admission criteria

- Science or medical degree (minimum Bachelor's degree) with or without professional work experience in any area of clinical research in either academia or industry (e.g. study coordinators, clinical research associates/assistants, study physicians, assistant physicians).
- Candidates without a university degree, but with a professional qualification („abgeschlossene Berufsausbildung" or similar) and at least two years of practical work experience in clinical research may be admitted on a „sur dossier" decision.

– Very good command of oral and written English.

Additional admission criteria for students attending CAS Clinical Research II without prior participation in CAS Clinical Research I
– Minimum of 5 years professional work experience in any area of clinical research.

Additional admission criteria for diploma thesis and final examination
– Successful completion of CAS Clinical Research I and CAS Clinical Research II or equivalent
– Approved thesis proposal including a confirmed thesis supervisor

3. Program Structure and Curriculum

a. Teaching and Learning Modes

Overall structure
DAS Clinical Trial Practice and Management

1. CAS Clinical Research I
    a. Module 1: Basics of Clinical Research
    b. Module 2: Clinical Study Planning
    c. Module 3: Clinical Study Conduct
    d. Work-shadowing 1
2. CAS Clinical Research II
    a. Module 1: Ethical and Legal Aspects of Clinical Trials
    b. Module 2: Clinical Study Project Management
    c. Module 3: Advanced Clinical Trial Management
    d. Module 4: Communication, Collaboration and Partnerships in Clinical Research
    e. Work-shadowing 2
3. Diploma thesis
4. Final examination

Modules
Each module comprises of an online training for self-study and individual completion and a classroom training (2-3 days with practical exercises, group discussions and homework assignments).

Work-shadowing
The work-shadowing comprises two one-week internships at a chosen host site where insights into the daily work life in a clinical research profession can be gained. The host may be involved in any field of clinical research such as on-site management, data management, clinical project management, regulatory affairs or methodological planning. The host's main field of activity should be different from the student's main expertise. It is the responsibility of the student to find a suitable host for the internship. Following institutions in Switzerland or abroad may serve

as work-shadowing hosts: academic clinical research sites (located mostly at university hospitals), pharmaceutical or biotech companies, consulting companies (clinical research organisations, regulatory affairs agencies, etc.) or regulatory agencies.

Language
The language of instruction is English in both the online and the classroom parts of the teaching modules. All course materials and module tests are in English. Homework assignments, work-shadowing reports and the diploma thesis may be submitted in English or German. The final examination may be held in English or German depending on the choice of the student.

b. CURRICULUM - PAGE 10
A detailed description of the Curriculum and Learning Outcomes can be found in the Attachment.

c. DEGREE
Completion of the DAS Clinical Trial Practice and Management program requires successful completion of the following components:
- CAS Clinical Research I (11 ECTS)
- CAS Clinical Research II (11 ECTS)
- Diploma thesis (7 ECTS)
- Final examination (2 ECTS)

The CAS Clinical Research I and CAS Clinical Research II programs can also be completed individually. Students will receive a certificate and supplement detailing the respective program.

4. ASSESSMENT FORMATS
- *Presence/active participation*
- *Module tests*
  At the end of each teaching module, a written examination covering all contents of the respective teaching module has to be passed.
- *Homework assignments*
  Students receive homework assignments after or before the classroom training.
- *Work-shadowing reports*
  After completion of a work-shadowing, a written report has to be submitted.
- *Diploma thesis*
  The diploma thesis has to be prepared independently by the student. The topic of a diploma thesis must be related to the student's personal work environment or of special interest within the scope of clinical research. Submission of a thesis proposal of sufficient quality is a pre-requisite for admission to the DAS program. A thesis supervisor with expert knowledge in

the chosen topic must be defined. The Directors of Studies can provide general advice to students regarding topics, methods and structuring of the thesis, but cannot act as supervisors for the thesis.

- *Final examination*
  All contents of the entire program will be subject to the final oral examination. An examination committee consisting of the reviewers of the student's thesis will hold the final oral examination.

Students may postpone their participation in the DAS program for one year after completion of the CAS Clinical Research II. Similarly, students who fail to meet the quality standards for the thesis proposal may re-attempt to enter the DAS program the following year.

5. Quality Assurance/Quality Development

Following quality assurance measures are in place:

- Standardised anonymous collection of feedback on content, quality of instructors, module structure etc.
- Individual feedback and discussion with instructors according to content of systematic course evaluation
- Debriefing and feedback round on homework assignments at the beginning of the following module
- Regular exchange with Program Board

6. Institutions

The program is operated by the CTU Basel, in partnership with the European Center of Pharmaceutical Medicine (ECPM) at the University of Basel. ECPM is responsible for development and operation of the module "Ethical and Legal Aspects of Clinical Trials".

7. Program Board

The program board consists of following experts:

Prof. Dr. med. Christiane Pauli-Magnus (Head of the Program Board), Director Department of Clinical Research, University of Basel, Department of Clinical Research, c/o University Hospital Basel

Prof. Dr. med. Matthias Briel, Department of Clinical Research and Leading Physician, Institute for Clinical Epidemiology and Biostatistics, University of Basel and University Hospital Basel

Annette Mollet, PhD, Head of Training and Education, European Center of Pharmaceutical Medicine, University of Basel

8. Director of Studies

Andrea Kiemen, PhD, Scientific Officer Training and Education, University of Basel, Department of Clinical Research, c/o University Hospital Basel
Daniel Hammes, PhD, Senior Scientific Officer Training and Education, University of Basel, Department of Clinical Research, c/o University Hospital Basel
Barbara Peters, PhD, Head of Training and Education and Head of Communication, University of Basel, Department of Clinical Research, c/o University Hospital Basel

9. Teaching Faculty

The multidisciplinary teaching faculty consists of national and international experts in clinical research ethics, regulatory sciences, and the different fields of operational clinical research.

The following list provides an overview of currently established lecturers and may be subject to changes:
Claudia Becherer; University Hospital Basel, Switzerland
Christian Burri, PhD; SwissTPH, Switzerland
Stefanie Deuster, DPharm; University Hospital Basel, Switzerland
Thomas Fabbro, PhD; Switzerland
Sergio Fracchia, PhD; Novartis Pharma AG, Switzerland
Julian Gray, MD, PhD, MBA, FFPM; Gray's Academy, UK
Anya Hammann-Hänni, PhD; University Hospital Basel, Switzerland
David Haerry; Treatment writer and conference reporter, Switzerland
Lars Hemkens, MD (?), University Hospital Basel, Switzerland
Roland John; University Hospital Basel, Switzerland
Nienke Jones, MSc; EKNZ, Switzerland
Sandra Kohlmaier, PhD, University Hospital Basel, Switzerland
Ingrid Klingmann, MD, PhD, FFPM, FBCPM; Pharmaplex BVBA, Belgium
Birka Lehmann, MD; University Bonn, Germany
Julia Manzetti, PhD, University Hospital Basel, Switzerland
Nikki Rommers; PhD; University Hospital Basel, Switzerland
Matthias Schwenkglenks, ECPM, University Basel, Switzerland
Tamas Shisha, PhD; Novartis Pharma Switzerland
Constantin Sluka, PhD; University Hospital Basel, Switzerland
Thomas Szucs, MD, MBA, MPH, LLM, JSD; University Basel, Switzerland
Christopher Tränka, MD; University Hospital Basel, Switzerland
Madeleine Vollmer, PhD; University Hospital Basel, Switzerland
Florian von Raison, MD; Novartis Pharma S.A.S., France
Chantal Vroom, BA; Communication Training & Consulting, Netherlands
Andrea Wiencierz, PhD; University Hospital Basel, Switzerland
Tamara Zeschky, PhD, University Hospital Basel, Switzerland

10. Deregistraton and Finances

Course fees

The course fee for the DAS Clinical Trial Practice and Management program is CHF 13,500. The course fee will be collected in 5 tranches approximately every 6 months. Course fees for the CAS Clinical Research I and II programs are CHF 6,000 each.

Grants are available for members of research groups at the Department of Clinical Research at the University of Basel. If applicable, please provide the name of your research group leader in the application form to be considered for a grant.

Participants need to inform the Directors of Studies of any change of contact information or employment after course registration and/or during the course.

Cancellation

Cancellations made prior to the closing date for enrolment will not be subject to any charge. Where a cancellation is made after the closing date for enrolment, the full applicable fee will be charged. Course fees already paid will not be refunded.

Withdrawal

Should participants withdraw from the program or discontinue participation, no discount from the course fee will be granted nor will any share of the course fee will be refunded.
For individual parts, the Directors of Studies can define a minimum number of participants.

11. Organization

The DKF Basel holds all responsibilities related to organization, administration and student support. To learn more about the DKF Basel please visit the website: dkf.unibas.ch

12. Contact

Andrea Kiemen, PhD, Scientific Officer Training and Education
University of Basel, Department of Clinical Research
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13. Attachments

- Guideline “Assessment Formats”
- Guideline “Work-Shadowing”
- Guideline “Diploma Thesis and Final Examination”

3B Curriculum

DAS in Clinical Trial Practice and Management						
Modules	Content - Lecturer	Learning objectives	Duration	contact Hours	Work-load	ECTS
CAS Clinical Research I						
Module 1 Basics of clinical research	• The drug development process (online/J. Gray) • Drug discovery (online/J. Gray) • Manufacturing issues (online) • Pre-clinical studies (online) • Phases of clinical development (online/J. Gray) • Specificities of Investigator-initiated trials (C. Traenka) • Biologics and Advanced Therapies (S. Fracchia) • Study types and designs (T. Fabbro) • Basic statistic concepts (T. Fabbro)	• Outline and critically appraise the different phases and landmarks in drug development from target identification to market license. • Explain the general purpose and concept of each phase in clinical development. • Describe the specificities of investigator-initiated trials, of studies with medical devices and the development of advanced therapies. • Critically appraise different types of study designs and assess their pros and cons. • Describe the process of (random) sampling and sample size estimation and apply basic principles of the probability theory and hypothesis testing. • Explain the differences between non-inferiority, superiority and equivalence testing.	2 days classroom training + online training + home assignments	16 H	90 H	3
Module 2 Clinical study planning	• The evolution of regulatory guidelines (online) • ICH guideline E6 on Good Clinical Practice (online/I. Klingmann) • Swiss legal framework (online)	• Outline the structure and contents of the ICH-GCP E6 guideline and explain its influence on the national legislation. • Critically appraise the guiding principles of ICH-GCP E6 and the roles and responsibilities	3 days classroom training + online training + home assignments	24 H	90 H	3

	• Ethics committees (EC) – principles and roles (online/N. Jones) • Submission dossiers (Online/N. Jones) • The informed consent process (online/I. Klingmann) • Special patient populations (online/I. Klingmann) • Elements of a Quality Management System (QMS) in clinical research (online/R. John) • Standard Operating Procedures (SOPs): Purpose, structure & content, training (R. John) • Study protocol: purpose and content (online) • Feasibility assessments (I. Klingmann) • Time and resource management (I. Klingmann) • Investigator site file and Trial master file (online) • Studies with medical devices (C.Becherer)	of different parties involved in the planning and conduct of clinical studies. • Assess and compare the obligations and timelines in the clinical trial application process. • Demonstrate competence in the compilation of submission dossiers and relate essential documents according to the definitions of ICH-GCP E6. • Appraise and compare the principles of the informed consent process in regular and special populations. • Outline the essential elements of a quality management system in clinical research and explain the concepts of quality assurance and quality control. • Assess and compare Standard Operating Procedures (SOPs), standard forms and work instructions. • Explain the purpose and structure of a study protocol and critically evaluate its contents for feasibility. • Apply time and resource management to the overall planning and preparation of a clinical study. • Demonstrate competency in planning necessary study infrastructure and resources. • Efficiently set-up collaboration standards and communication tools with all necessary partners. • Prepare necessary trial documentation and filing systems.				

Module 3 Clinical study conduct	• Basics of data management (online/C. Sluka) • Source data (online/C. Sluka) • Case report forms (online) • Queries and data validation (M. Vollmer) • Databases (online) • Data protection issues (C.Sluka) • Purpose and process of monitoring (online/J. Manzetti) • Risk-adapted monitoring (online/R. John) • Audits and inspections (online/R. John) • Types of study reports (online/A. Hammann-Hänni) • Archiving of study data and documents (online/C.Burri) • Patient safety management (A. Hammann-Hänni) • Reporting requirements to EC and regulatory bodies (online/A.Hammann-Hänni)	• Outline and critically appraise all aspects of data management. • Explain technical terms like source documents, essential documents and case report forms. • Demonstrate competency in query management. • Critically review and interpret the ethical issues involved in data protection. • Outline the purpose of monitoring and critically interpret the contents of a monitoring plan. • Interpret monitoring reports. • Critically review and compare methods of risk-adapted monitoring. • Prepare for an audit or inspection and demonstrate competency in handling audit/inspection findings. • Review all documentation and reporting obligations according to Good Clinical Practice during and after running a clinical study. • Arrange for proper archiving of study documents. • Understand the responsibilities for patient safety and manage and report adverse events.	2 days class-room training + online course + home assignments	16 H	90 H	3
Work-shadowing I	• One-week internship, organised individually		5 days + report	42 H	60 H	2
			subtotal		**330 H**	**11**

CAS Clinical Research II						
Module 1 Ethical and Legal Aspects of Clinical Trials	• Transparency (P. Kleist) • Equipoise (P. Kleist) • Inducement (I. Klingmann) • Misconduct and fraud (J. Barrett) • Data protection and intellectual properties (M. Wasem-Tréguer) • Vulnerable populations (J. Barrett, J. Bielicki) • Genetic testing (K. Vokinger)	• Enable and manage the appropriate ethical and legal environment for the performance of a clinical trial. • Identify and manage the ethical conflicts and issues in a particular clinical trial, including studies utilizing modern technologies. • Perform a comprehensive risk/benefit assessment of a clinical trial. • Define, prepare and supervise an informed consent process appropriate to the needs of the research participants in a specific biomedical research setting. • Identify and mitigate the risk of misconduct and fraud in biomedical research. • Assess the suitability of the environment for confidentiality and data protection in clinical trials. • Recognise and deal with vulnerable populations.	2 days classroom training + home assignments	16 H	60 H	2
Module 2 Clinical Study Project Management	• Sequencing and Scheduling (E. Reus, I. Klingmann) • Time management (E. Reus, I. Klingmann) • Resource management (E. Reus, I. Klingmann) • Budgeting (E. Reus, I. Klingmann) • Risk management (E. Reus, I. Klingmann)	• Apply basic principles of project management to the overall and detailed planning and preparation of a clinical study. • Demonstrate competency in planning necessary study infrastructures and resources. • Assess and select adequate study sites. • Successfully conduct stakeholder analyses. • Successfully conduct risk analyses and implement risk control strategies.	3 days classroom training + home assignments	24 H	60 H	2

	• Managing collaborations (E.Reus, I. Klingmann) • Stakeholder analysis (E. Reus, I. Klingmann)	• Develop and implement communication standards and effectively manage collaborations within your study team.				
Module 3 Advanced Clinical Trial Management	• Challenges of international, multicentre studies (online/E.Reus, I. Klingmann) • Feasibility assessment (E. Reus, I. Klingmann) • Risk-based quality management (online/I. Klingmann) • European legal framework (online/I. Klingmann) • European clinical trial authorization (CTA) process and documentation (online/TBA) • Digital tools (K. Langel)	• Explain and discuss issues and challenges of running international, multicentre studies. • Identify aspects critical for the feasibility of multicentre, international studies. • Demonstrate competencies in risk-based quality management. • Review all elements of the European legal framework for performing clinical research. • Appraise and compare different technology options developed for clinical research applications. • Explain the basic principles of health economics. • Critically appraise the contributions of registry-based studies in clinical research.	2.5 days classroom training + online training + home assignments	16 H	90 H	3
Module 4 Communication, Collaboration and Partnerships in Clinical Research	• Communication and conflict management (online/C. Vroom) • Key stakeholders in clinical research (online) • Patient involvement (online/D. Haerry, I. Klingmann) • PPI (S. Kohlmaier) • Transparency and data sharing (C. Sluca)	• Outline the challenges of teamwork with special focus on communication. • Assess your personal communication style and review communication tools. • Review and discuss strategies to handle conflicts in the working environment. • Discuss the key stakeholders in clinical research. • Involve patients as active partners in a clinical study	2 days classroom training + online training + home assignments	16 H	60 H	2

		• Appraise and compare different technology options for communication in a clinical study • Explain the responsibilities related to sharing study results with the medical community.				
Work-shadowing II	One-week internship, organised individually		5 days + report	**42 H**	**60 H**	**2**
			subtotal		**330 H**	**11**
			TOTAL	TOTAL	TOTAL	TOTAL
			26 DAYS	**212 H**	**660 H**	**22**

ECTS = *European Credit Transfer and Accumulation System*

ASSESSMENT FORMAT	WORKLOAD	ECTS
Diploma thesis	210 H	7
Final oral examination	60 H	2
	TOTAL	TOTAL
	270 H	**9**

DAS Clinical Trial Practice and Management	WORKLOAD	ECTS
TOTAL	**930 H**	**31**