DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials

Good Clinical Practice Implementation and Quality Processes

September 2023 – May 2024

HUG Hôpitaux Universitaires Genève

CRC Centre de Recherche Clinique

UNIVERSITÉ DE GENÈVE

Programme Directors

- **Prof. Youssef Daali**, Head of the Pharmacological Investigation Unit, Geneva University Hospitals, Faculty of Medicine, Geneva University
- **Prof. François Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology Zürich & Lecturer at University Hospitals of Geneva, University of Geneva

Coordinators

- **Prof. François Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology Zürich & Lecturer at University Hospitals of Geneva, University of Geneva
- **Dr Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Dr Françoise Lascombes**, External Consultant
- **Ms Camille Arni**, Administrative Assistant of the DAS-MAS, Faculty of Medicine, University of Geneva

An essential step for transitioning your career to clinical research

In the past two decades, the number of Clinical Trials conducted in Switzerland and worldwide has virtually exploded. This tremendous increase went hand in hand with the development of codes, guidelines and regulations aimed at protecting human research subjects. Standardization and strengthening of clinical research regulations have led to the development of a rapidly growing economic sector in which Clinical Research Associates, Clinical Research Scientists, Data Managers, Clinical Research Coordinators, Clinical Trial Managers, Clinical Research Nurses and Investigators are key players.

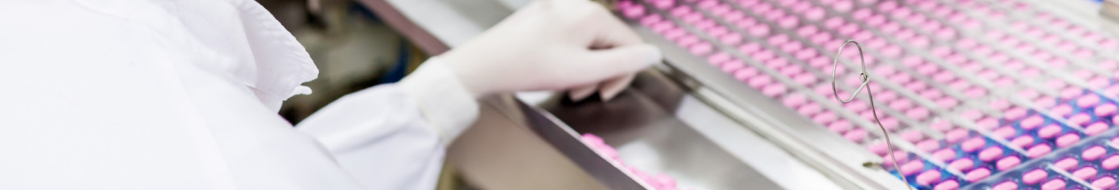
The Diploma of Advanced Studies (DAS) in Management of Clinical Trials – Good Clinical Practice Implementation and Quality Processes provides a theoretical and practical understanding of how Good Clinical Practice (GCP) principles are shaping each step of a Clinical Trial, including study design, trial management and conduct.

Steering Committee

- **Prof. Gerrit Borchard**, President of the Section of Pharmaceutical Sciences (ISPSO), Faculty of Science, University of Geneva
- **Prof. Cem Gabay**, Dean of the Faculty of Medicine, University of Geneva
- **Prof. Bernard Hirschel**, President, Cantonal Commission on Human Research Ethics, Canton of Geneva
- **Prof. Samia Hurst**, Director, Institute of Ethics, History and Humanities (iEH2), Faculty of Medicine, University of Geneva
- **Prof. Arnaud Perrier**, Medical Director, University Hospitals of Geneva
- **Prof. Jérôme Pugin**, President of the Clinical Research Center (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva

Scientific Committee

- **Dr Gabriele Ackermann**, Chief Scientific Officer ad interim, Therapeutic Area Head Cardiovascular, Renal & Metabolism Therapeutic Area Head Respiratory, Novartis Pharma Switzerland
- **Dr Emilie Alirol**, Senior Director Clinical Affairs, FIND
- **Dr Enrica Alteri**, Pharmaceutical consultant, former Head of Human Medicine R&D Support Division, EMA
- **Dr Vanya Beltrami**, CEO and founder at Beltrami Consulting, Geneva
- **Prof. Francois Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich & Lecturer at Hospitals of Geneva (UNIGE)
- **Prof. Youssef Daali**, Head of the Pharmacological Investigation Unit, Geneva University Hospitals, Faculty of Medicine, Geneva University
- **Dr Patricia Delaite**, Chief Medical Officer, Nouscom, Basel
- **Dr Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Prof. Philippe Ducor**, Faculty of Law, University of Geneva
- **Prof. Marc Froissart**, Medical Director of the Clinical Research Centre (CRC), CHUV-UNIL, Lausanne
- **Prof. Angèle Gayet-Ageron**, Head of the Methodological Support Unit, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medecine, University of Geneva
- **Dr Angela Huttner**, Head of Clinical Investigation Unit (CRC), University Hospitals of Geneva, Faculty of Medecine, University of Geneva
- **Dr Françoise Lascombes**, External Consultant
- **Prof. Hervé Porchet**, Pharmaceutical consultant
- **Dr Victoria Rollason**, Division of Clinical Pharmacology and Toxicology, University Hospitals of Geneva and Faculty of Medicine, University of Geneva



Target Audience

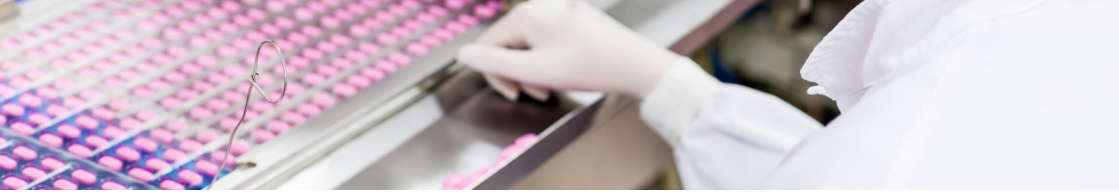
Medical doctors, biologists, pharmacists, veterinarians, nurses, biochemists and other professionals involved, or wishing to gain skills and knowledge, in the field of clinical research.

Topics

- Methodology of clinical trials, data management and analysis.
- Ethical principles of clinical research, regulations applicable to clinical research in Switzerland, Europe and United States.
- Project management and coordination in clinical research.
- Quality systems in clinical research.
- Safety aspects of drug development, pharmaco-vigilance and pharmaco-epidemiology.
- Drug development and marketing authorization process.
- Medical Devices development.

Skills and Competencies

- Understand and use in a relevant context the different Clinical Trial designs and methodologies.
- Be familiar with drug development and medical device development and marketing authorization processes.
- Gain knowledge of GCP and of clinical research regulations in Switzerland, Europe and the The United States.
- Become skilled at developing Case Report Form (CRF).
- Coordinate the development of clinical trial protocols.
- Master effective project planning and management.
- Know how to manage applications for Ethics Committee (EC) and Regulatory Authority (RA).
- Understand and implement Quality Systems used in Clinical Trials.
- Understand the issues related to research subject protection .



Programme Structure

9 modules over one year (average 24 hours of teaching per module) 8h00-12h00/13h00-17h00 | Number of ECTS credits: 33 | Each module is subjected to an evaluation in order to be accredited | Modules 2 to 12 may be attended individually.

Learning Methods

Lectures, interactive seminars, workshops, vocational training. Teaching is in English or in French.

Dissertation

Students may choose between:

- A vocational training in a pharmaceutical company, a Clinical Research Organization (CRO) or a Clinical Trial Unit in a University Hospital (3-4 months) followed by a report.
- The development of a Clinical Trial protocol or a literature review and dissertation.

Diploma Awarded

Participants who successfully complete the programme will be awarded the Diploma of Advanced Studies (DAS) in Management of Clinical Trials – Good Clinical Practice Implementation and Quality Processes / *Diplôme de formation continue (DAS) en Gestion des essais cliniques – Mise en application des bonnes pratiques cliniques et processus qualité* delivered by the University of Geneva. It equates to 33 ECTS (European Credit Transfer and Accumulation System) credits.

Module 2 | Principles and Methods of Clinical Research

18, 19, 20 September 2023

Prof. Angèle Gayet-Ageron, Prof. François Curtin

- Development of research questions and choice of endpoints
- Study designs
- Statistical methods used in clinical research
- Principles of Randomized Controlled Trials (RCT)
- Critical review of publications
- Development of study protocols
- Choice of endpoints
- Sample size calculation
- Interim analysis planning

Module 3 | Ethical and Legal Aspects

16, 17, 18 October 2023

Prof. Samia Hurst, Prof. Philippe Ducor, Dr Brigitte Happ

- Clinical research ethics
- Informed consent process
- Data protection and confidentiality
- Purpose and function of research Ethics Committees (EC)
- Assessing risks and benefits to research participants
- Vulnerable populations
- Good clinical practices
- Legal framework applicable in Switzerland, Europe and the United States for drugs, medical device and non-interventional trials
- Clinical Trial Agreements (CTA) and authorship issues
- Ethical issues in biobanks

Module 4A | Preclinical Pharmacology, Toxicology and Clinical Pharmacology

13 November 2023

Dr Valérie Nicolas, Prof. Youssef Daali, Dr Catherine Deloche, Dr Marie-Paule Simonin

- Pharmacodynamics
- Pharmacokinetics
- Toxicology
- Drug metabolism
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)

Module 5 | Safety Management in Drug Development

4, 5 December 2023

Dr Victoria Rollason, Prof. François Curtin, Prof. Jules Desmeules

- Risk management and safety monitoring during drug development
- Safety assessment, documentation and reporting during clinical trials
- Pre-and post-marketing pharmacovigilance
- Role of Data and Safety Monitoring Boards (DSMB)

Module 7 | Clinical Trials Set-up and Conduct

15, 16, 17 January 2024

Dr Shelly Bustion, Dr Sandrine Charvat

- Scientific, strategic and safety considerations in clinical trial design
- Budget development and resource planning
- Investigator sites selection
- Role of CROs and external providers
- Clinical trial documents
- Submission to Swiss Ethics Committee (EC) and Swiss Regulatory Authorities (RA)
- Risk Management

Module 8 | Clinical Trials Conduct and Close out

26, 27, 28 February 2024

Dr Françoise Lascombes, Ms Virginie Lemeaux

- Project management applied to clinical trials
- Recruitment and retention of study subjects
- Management of randomization and blinding systems
- Data collection and data management
- Management of investigational medicinal product
- Monitoring of clinical studies
- Clinical trial close out activities
- Statistical analysis plan
- Data cleaning and data base lock
- Clinical study report
- Safety reconcilation

Module 10A | Chemistry, Manufacturing and Controls

Optional

18 March 2024

Dr Lucie Bouchoud, Dr Farshid Sadeghipour, Dr Laurent Carrez

- Explanation of the GMP (good manufacturing practice)
- Quality Assurance of the drug
- Qualification and Validation (premice, equipment)
- Raw material for drug manufacturing
- What can be manufactured by a hospital pharmacy for clinical trials?

Module 10B | Clinical Development of anti-cancer and anti infective vaccines

Optional

18 March 2024

Dr Angela Huttner, Prof. Carole Bourquin

- Preclinical vaccine development and prerequisites for clinical trials
- Vaccine-relevant immunology: pathways to immunogenicity against infectious antigens and neoplastic cells
- Good Manufacturing Practice (GMP) in vaccine production
- Quality Assurance in vaccine production and testing
- Phases of clinical testing of anti-infective and anti-cancer vaccines

Module 11 | Medical Devices

19, 20 March 2024

Dr Mariagrazia Di Marco, Me Gabriel Avigdor

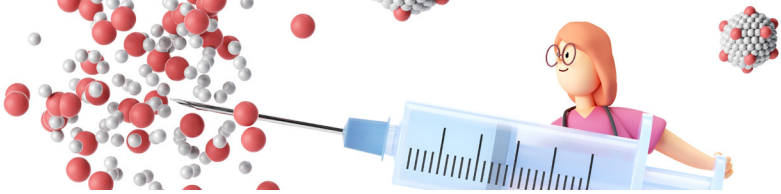
- Medical devices (MD) and new EU regulations (MDR, IVDR)
- Qualification and classification
- Clinical investigation and clinical trial application to authorities
- Market access strategy
- Conformity assessment and CE marking
- Materiovigilance
- Digital health and medical software
- Combination products

Module 12 | Audits and Inspections

13, 14, 15 May 2024

Dr Isabelle Mercier, Dr Isabelle Semac

- Quality management systems
- Audit
- Purpose and conduct of regulatory inspections
- Site preparation to inspections



General Information

Admission Criteria

- Title of physician
- Or Master's or Bachelor's degree in Life Science or title deemed equivalent
- Or Bachelor's degree from a Swiss University of Applied Sciences plus a minimum of 1 year professional experience in the field of the DAS
- Good understanding of both French (knowledge equivalent to B2 Level) and English (knowledge equivalent to the Cambridge First Certificate)

The candidates who follow the programme during their working time must provide written authorization from their employer.

Application and Deadline

Online application may be submitted via the course website at:
www.unige.ch/formcont/en/courses/clinical-trials

- Candidates should send copies of relevant university degrees, a Curriculum Vitae, a covering letter, two reference letters and a written authorization from their employer by June 30, 2022 to the DAS secretariat (DAS.clinicaltrials@hcuge.ch). Candidates should mention in their cover letter if they want to realize a vocational training at the end of the DAS.
- For individual modules, application should be sent at least one month prior to the beginning of the selected module (2 to 12). Priority will be given to candidates applying for the Diploma.
- The DAS is entirely paperless and students are encouraged to bring their laptop during classes.

Important Note

Candidates are warned that a significant amount of self-study is required to complete the DAS, and that they are expected to go through preparatory work before each module. Students should thus allow sufficient time to study at home, in addition to attending the classroom lectures.

Tuition Fee

- CHF 9,000.– for the Diploma
- 1-day-module: CHF 1,000.–
- 2-day-module: CHF 1,400.–
- 3-day-module: CHF 1,800.–

Accreditation

The course programme is accredited by:

- Swissethics
- Swiss Association of Pharmaceutical Professionals (SwAPP)
- Swiss Society of Clinical Pharmacology and Toxicology (SGKPT-SSPTC)
- Swiss Institute for Postgraduate and Continuous Medical Education (SWIF-ISFM)

Course Location

- Fondation Louis Jeantet or CMU
  77 route de Florissant – 1208 Genève
  Bus 21 and 8 – Genève-Eaux-Vives-Gare, or Veyrier-Douane, stop Aubert

Contact

DAS.clinicaltrials@hcuge.ch

www.unige.ch/formcont/en/courses/clinical-trials

swissuniversities

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