DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials

Good Clinical Practice Implementation and Quality Processes

September 2024 – May 2025

HUG Hôpitaux Universitaires Genève

CENTRE DE RECHERCHE CLINIQUE

UNIVERSITÉ DE GENÈVE

Programme Directors

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

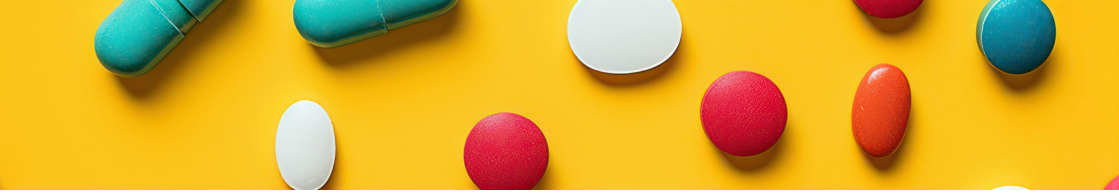
Coordinators

- **Prof François Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology Zürich & Lecturer at Geneva University Hospitals, University of Geneva
- **Dr Catherine Suarez**, Coordinator of the DAS-MAS, Faculty of medicine, University of Geneva
- **Ms Camille Arni**, Administrative Coordinator of the DAS-MAS, Faculty of Medicine, University of Geneva

An essential step for transitioning your career to clinical research

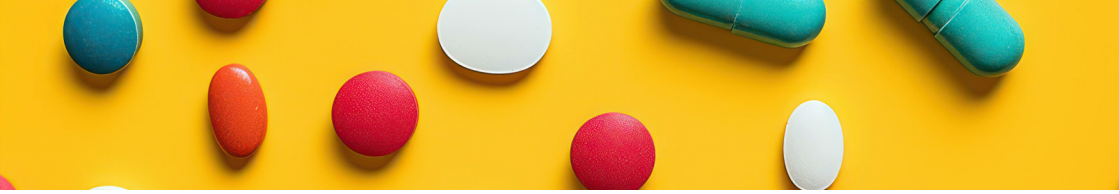
In the past two decades, the number of Clinical Trials conducted in Switzerland and worldwide has virtually exploded. This tremendous increase went hand in hand with the development of codes, guidelines and regulations aimed at protecting human research subjects. Standardisation and strengthening of 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 Alexandra Calmy**, Vice-Dean of clinical research, Director of the Clinical Research Centre (CRC), Head of HIV/AIDS Unit, Associate Physician, Department of Infectious Diseases, Geneva University Hospitals
- **Prof Youssef Daali**, Head of the Pharmacological Investigation Unit, Geneva University Hospitals, Faculty of Medicine, University of Geneva
- **Prof Antoine Geissbuhler**, Dean of the Faculty of Medicine, University of Geneva
- **Dr Olivier Huber**, 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, Geneva University Hospitals



Scientific Committee

- **Dr Emilie Alirol**, Senior Director Clinical Affairs, FIND
- **Dr Enrica Alteri**, Pharmaceutical consultant, former Head of Human Medicine R&D Support Division, EMA
- **Prof Francois Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich & Lecturer at Geneva University Hospitals, University of Geneva
- **Prof Youssef Daali**, Head of the Pharmacological Investigation Unit, Geneva University Hospitals, Faculty of Medicine, University of Geneva
- **Dr Patricia Delaite**, Chief Medical Officer, Nouscom, Basel
- **Dr Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Prof Jules Desmeules**, Faculty of Medicine, University of 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), Geneva University Hospitals, Faculty of Medecine, University of Geneva
- **Prof Angela Huttner**, Associate Professor, Department of Infectious Diseases, Geneva University Hospitals, Faculty of Medicine, University of Geneva
- **Dr Cyril Jaksic**, Statistician, Methodological Support Unit, Clinical Research Centre (CRC), Geneva University Hospitals
- **Dr Françoise Lascombes**, External Consultant
- **Dr Guillaume Perriard**, PhD, Lead patient Engagement, Novartis, Basel
- **Dr Victoria Rollason**, Division of Clinical Pharmacology and Toxicology, Geneva University Hospitals 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), approximate times: 8h00-12h00/13h00-17h00 | Number of ECTS credits: 33 | Each module is assessed for accreditation and can be attended individually

Learning Methods

Lectures, interactive seminars, workshops. Teaching is in English.

Dissertation

Students may choose between:

- An internship/work placement in a pharmaceutical company, a Clinical Research Organisation (CRO) or a Clinical Trial Unit in a University Hospital (320 hours: two months full-time work or its equivalent on a part-time basis) followed by a report. It is the student's responsibility to find a work placement/internship. The DAS office regularly publishes vacancies, but students may find an offer elsewhere.
- 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 is equivalent to 33 ECTS (European Credit Transfer and Accumulation System) credits.

Module 2 | Principles and Methods of Clinical Research

23, 24, 25 September 2024

Prof Angèle Gayet-Ageron, Dr Cyril Jaksic

- 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

14, 15, 16 October 2024

Prof Samia Hurst, Dr Emilie Alirol, 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

11 November 2024

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

9, 10 December 2024

Prof François Curtin, Dr Fabiana Tirone

- 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

20, 21, 22 January 2025

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

17, 18, 19 February 2025

Dr Cécile Nicolas-Denizou, Dr Niloufar Marsousi

- 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

17 March 2025

Dr Lucie Bouchoud, Prof 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

17 March 2025

Prof Carole Bourquin, Dr Valérie Dutoit-Vallotton

- 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

18, 19 March 2025

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

12, 13, 14 May 2025

Dr Isabelle Mercier, Dr Isabelle Semac

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

General Information

Admission Criteria

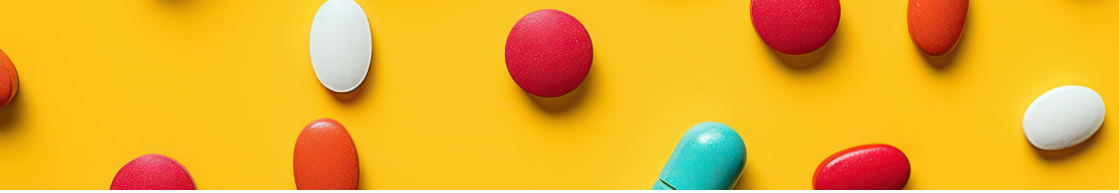
- Title of physician
- Or Master's or Bachelor's degree in Life Science or title deemed equivalent
- Or Bachelor's degree from a Swiss University of Applied Sciences plus a minimum of 1 year professional experience in the field of the DAS
- Good level of English (B2-C1)

The candidates who follow the programme during their working time must provide written authorisation 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 authorisation from their employer by June 30, 2024 to the DAS secretariat (das-mas-clinical@unige.ch).
- For individual modules, applications should be sent at least four weeks 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 advised that a significant amount of self-study is required to complete the DAS and that they are expected to carry out preparatory work before each module. Students should therefore allow sufficient time for home study in addition to attending lectures.

Examinations will take place at a specific date and time, usually a few days before the start of the next module. Candidates must ensure that they are available for these assessments.

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.–

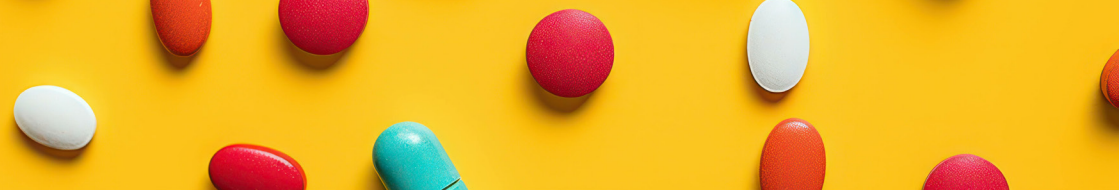
Accreditation

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 Locations

- Fondation Louis Jeantet
  77 route de Florissant – 1208 Genève
  Bus 21 and 8 – stop Aubert
- CMU (Centre Médical Universitaire)
  Rue Michel-Servet 1 - 1206 Genève
  Bus 1, 3 and 5 - stop Claparède



Contact

das-mas-clinical@unige.ch

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

swissuniversities

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