Programme Directors

- **Prof. Jules Desmeules**, Head of the Clinical Trial Unit, Clinical Research Center (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr François Curtin**, PD, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich (ETH Zürich) & Lecturer at Hospitals of Geneva (UNIGE)

Coordinators

- **Dr François Curtin**, PD, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich (ETH Zürich) & Lecturer at Hospitals of Geneva (UNIGE)
- **Dr Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Dr Françoise Lascombes**, External Consultant
- **Ms Camille Arni**, Administrative Assistant of the DAS, University Hospitals of Geneva, 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 (CRA), Clinical Research Scientists (CRS), Data Managers (DM), Clinical Research Coordinators (CRC), Clinical Trial Managers (CTM) and regulatory affairs specialists 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**, Head of Biopharmaceutics, Section of Pharmaceutical Sciences, 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
- **Dr Angèle Gayet-Ageron**, CC, Lecturer, Head of the Methodological Support Unit, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Prof. Arnaud Perrier**, Medical Director, University Hospitals of Geneva
- **Prof. Jérôme Pugin**, Vice-Dean of the Faculty of Medicine and President of the Clinical Research Center (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
Scientific Committee

- **Dr Emilie Alirol**, Project Leader, Global Antibiotics Research and Development Partnership (GARDP), Drugs for Neglected Diseases initiative (DNDi)
- **Dr Vanya Beltrami**, Vice-President, Head of Manufacturing, Anergis, Lausanne
- **Dr Jocelyne Chabert**, Clinical Research Associate, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr Francois Curtin**, PD, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich (ETH Zürich) & Lecturer at Hospitals of Geneva (UNIGE)
- **Dr Patricia Delaite**, Medical Director, Geneva
- **Dr Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Prof. Philippe Ducor**, Faculty of Law, University of Geneva
- **Prof. Marc Froissart**, Chief Medical Director of the Clinical Research Centre (CRC), CHUV-UNIL, Lausanne
- **Dr Angèle Gayet-Ageron**, CC, Lecturer, Head of the Methodological Support Unit, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medecine, University of Geneva
- **Dr Françoise Lascombes**, External Consultant
- **Prof. Hervé Porchet**, Pharmaceutical consultant
- **Dr Victoria Rollason**, PharmD, Division of Clinical Pharmacology and Toxicology, University Hospitals of Geneva and Faculty of Medicine, University of Geneva
- **Dr Gabriele Ackermann**, Chief Scientific Officer ad interim, Therapeutic Area Head Cardiovascular, Renal & Metabolism Therapeutic Area Head Respiratory, Novartis Pharma Switzerland
Target Audience
Medical doctors, biologists, pharmacists, 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

Skills and Competencies
- Understand and use in a relevant context the different Clinical Trial designs and methodologies
- Be familiar with drug development and marketing authorization processes
- Gain knowledge of GCP and of clinical research regulations in Switzerland, Europe and 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
8 modules over one year (average 24 hours of teaching per module)
8h00-12h00/13h00-17h00 | Teaching: 160 hours | Dissertation: 320 hours
| Number of ECTS credits: 33 | Each module is subjected to an evaluation in order to be accredited | Modules 2 to 10 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 (320 hours over 3-4 months)
- The development of a Clinical Trial protocol or a literature review and dissertation (320 hours)

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 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
September 28, 29, 30, 2020
Dr Angèle Gayet-Ageron, Dr 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
October 26, 27, 28, 2020
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

November 17, 2020
Prof. Gerrit Borchard, Prof. Youssef Daali, Dr Catherine Deloche, Dr Marie Besson
- Pharmacodynamics
- Pharmacokinetics
- Toxicology
- Drug metabolism
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)

Module 5 | Safety Management and Drug Development

November 23, 24, 2020
Dr Victoria Rollason, Dr 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 – Part 1
January 11, 12, 13, 2021
Dr Mariagrazia Di Marco, 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)

Module 8 | Clinical Trials Set-up and Conduct – Part 2
February 1, 2, 3, 2021
Ms Jennifer Kealy, Ms Virginie Vidal
- 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
- Documents and records
- Monitoring of clinical studies
- Root-cause analysis
Module 10 | Clinical Trials Close-out and Reporting
April 12, 13, 2021
Dr Mariagrazia Di Marco, Me Gabriel Avigdor
- Clinical trial close-out activities
- Data cleaning and database lock
- Statistical Analysis Plan and result reporting (SAP)
- Medical writing and clinical study report
- Safety reconciliation and MedDRA coding
- Medical devices and clinical requirements under MDR/IVDR
- Clinical investigation of medical devices and submissions to authorities
- Medical device vigilance
- Regulatory aspects of digital health and medical software

Module 11 | Audits and Inspections
May 10, 11, 12, 2021
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/cours/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 July 31, 2020 to the DAS secretariat (DAS.clinicaltrials@hcuge.ch). Candidates should mention in their cover letter if they want to realize a vocational training as DAS thesis.
- For individual modules, application should be sent at least one month prior to the beginning of the selected module (2 to 10). 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 7,500.– for the Diploma
- CHF 1,500.– for an individual module

**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
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/cours/clinical-trials