DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials

Good Clinical Practice Implementation and Quality Processes

September 2025 – April 2026

HUG Hôpitaux Universitaires Genève

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**, Head of the Centre for Clinical Research, Lucerne Cantonal Hospital (LUKS), Lecturer at Geneva University Hospitals, University of Geneva

Coordination Team

- **Prof François Curtin**, Head of the Centre for Clinical Research, Lucerne Cantonal Hospital (LUKS), Lecturer at Geneva University Hospitals, University of Geneva
- **Dr Catherine Suarez**, Coordinator of the DAS, Faculty of Medicine, University of Geneva
- **Ms Camille Arni**, Administrative Assistant of the DAS, Faculty of Medicine, University of Geneva

An essential step for transitioning your career to clinical research

Over the past two decades, the number of clinical trials conducted in Switzerland and globally has increased dramatically. This growth has occurred alongside the development of codes, guidelines, and regulations designed to protect human research participants. The standardisation and strengthening of clinical research regulations have given rise to a rapidly expanding economic sector in which Clinical Research Associates, Clinical Research Scientists, Data Managers, Clinical Research Coordinators, Clinical Trial Managers, Clinical Research Nurses, and Investigators play essential roles.

The Diploma of Advanced Studies (DAS) in Management of Clinical Trials – Good Clinical Practice Implementation and Quality Processes offers both theoretical and practical insight into how Good Clinical Practice (GCP) principles shape each stage of a clinical trial, from study design through to 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 Samia Hurst**, Director, Institute of Ethics, History and Humanities (iEH2), Faculty of Medicine, University of Geneva
- **Dr Pierre-Yves Martin**, President, Cantonal Commission on Human Research Ethics, Canton of Geneva
- **Prof Klara Posfay-Barbe**, 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**, Head of the Centre for Clinical Research, Lucerne Cantonal Hospital (LUKS), 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 Catherine Deloche**, Chief Operating Officer, Solid Drug Development, Geneva
- **Prof (emerit.) Jules Desmeules**, Faculty of Medicine, University of Geneva
- **Prof Marc Froissart**, Medical Director of the Clinical Research Centre (CRC), CHUV-UNIL, Lausanne
- **Prof Angèle Gayet-Ageron**, Full Professor in Epidemiology and Public Health & Director of the Institute of Social and Preventive Medicine (ISPM) at University of Bern
- **Dr Brigitte Happ**, External Consultant
- **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 authorisation process.
- Medical Devices development.

Skills and Competencies

- Understand and apply various clinical trial designs and methodologies in relevant contexts.
- Be familiar with the development and marketing authorisation processes for drugs and medical devices.
- Gain a solid understanding of Good Clinical Practice (GCP) and clinical research regulations in Switzerland, Europe, and the United States.
- Develop skills in designing Case Report Forms (CRFs).
- Coordinate the development of clinical trial protocols.
- Master effective project planning and management techniques.
- Manage submissions to Ethics Committees (ECs) and Regulatory Authorities (RAs).
- Understand and implement quality systems used in clinical trials.
- Understand the key issues related to the protection of research participants.

Programme Structure

- 9 modules over one year (8 to 24 hours of teaching per module)
- Teaching time: 168 hours
- Work placement/Internship: 320 hours
- Total number of ECTS credits: 33
- Each module is assessed for accreditation
- Modules can be attended individually

Learning Methods

Lectures, interactive seminars, and workshops.
All teaching is conducted 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

22, 23, 24 September 2025

Dr Maël Barthoulot, Dr Cyril Jaksic

- Development of research questions and choice of endpoints
- Overview of different study designs
- Fundamentals of statistical methods used in clinical research
- Principles of Randomized Controlled Trials (RCT)
- Critical review of publications
- Development of study protocols
- Sample size calculation
- Interim analysis planning
- Use of Real World Data and Real World Evidence in product development

Module 3 |

Ethical and Regulatory Aspects

13, 14, 15 October 2025

Prof Samia Hurst, Dr Emilie Alirol, Dr Brigitte Happ

- Fundamentals of clinical research ethics
- Informed consent process
- Purpose and function of research Ethics Committees (EC)
- Assessing risks and benefits to research participants
- Regulatory requirements of trials investigating drugs, medical devices, and *in vitro* diagnostics
- Good Clinical Practices
- Clinical trials authorisations
- Ethical issues in biobanks

Module 4A | Non-Clinical Development and Clinical Pharmacology

3 November 2025

Dr Valérie Nicolas, Dr Catherine Deloche, Dr Marie-Paule Simonin

- Fundamentals of pharmacology
- Safety assessment in pre-clinical research
- Drug metabolism
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)
- Preclinical development for specific indications and type of products
- Population physiologically-based pharmacokinetics
- Early phases of clinical development

Module 5 | Safety Management During Product Development

24, 25 November 2025

Dr Fabiana Tirone, Dr François Curtin

- Risk management and safety monitoring during product 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 Trial Planning and Set-up

19, 20, 21 January 2026

Dr Shelly Bustion, Dr Sandrine Charvat

- Essentials of Clinical Trial Management
- Budget development and resource planning
- Investigator sites selection
- Role of CROs and external providers
- Clinical trial documents
- Submission to Ethics Committee (EC) and Regulatory Authorities (RA)
- Logistics planning: Investigational Products and other Clinical Trial supplies

Module 8 |

Clinical Trial Conduct and Close-Out

9, 10, 11 February 2026

Dr Shelly Bustion, Dr Niloufar Marsousi

- Essentials of clinical trial monitoring
- Recruitment and retention of study subjects
- Data collection and data management
- Management of investigational product
- Documents and records
- Risk management
- Root-cause analysis
- Trial close-out activities
- Study report

Module 9 |

Audits and Inspections

9, 10, 11 March 2026

Dr Isabelle Mercier, Dr Isabelle Semac

- Fundamentals of Quality Assurance and Quality Control
- Quality management systems
- Purpose and conduct of clinical trial audits
- Purpose and Conduct of regulatory inspections
- Site preparation to inspections

Module 10A |
Optional

Chemistry, Manufacturing and Controls

24 March 2026

Dr Lucie Bouchoud, Dr Laurent Carrez

- Overview of drug product development and manufacturing for small molecules and biologics
- Quality by Design
- Good Manufacturing Practice
- Qualification and validation
- Stability studies

Module 10B |
Optional

Clinical Development of Anti-Cancer and Anti-Infective Vaccines

24 March 2026

Prof Carole Bourquin, Dr Valérie Dutoit-Vallotton

- Fundamentals of immunology and immunogenicity pathways
- Good manufacturing practice for vaccines
- Preclinical and clinical development of vaccines
- Use of vaccines in oncology and infectious diseases

Module 12 |

Medical Devices

11, 12 May 2026

Dr Mariagrazia Di Marco, Me Gabriel Avigdor

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

General Information

Admission Criteria

- Medical degree (physician title), or
- Master's or Bachelor's degree in Life Sciences or an equivalent qualification, or
- Bachelor's degree from a Swiss University of Applied Sciences plus at least one year of relevant professional experience
- Good command of English (level B2–C1)

Candidates attending the programme during working hours 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 15, 2025** 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. Priority will be given to candidates applying for the Diploma.
- The DAS is entirely paperless and students are encouraged to bring their laptops 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 online 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 whole DAS

For individual modules:

- 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 Geneva
  Bus 21 and 8 – stop Aubert
- CMU (Centre Médical Universitaire)
  1 rue Michel-Servet - 1206 Geneva
  Bus 1, 3 and 5 - stop Claparède
  Train: Genève-Champel Gare CFF

Contact

das-mas-clinical@unige.ch

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

swissuniversities

Centre for Continuing and Distance Education (CCDE)

University of Geneva | CH-1211 Geneva 4

Tel: +41 (0)22 379 78 33 | info-formcont@unige.ch

www.unige.ch/formcont