

MAS

Master of Advanced Studies
Maîtrise universitaire d'études avancées

Drug Discovery and Clinical Development

August 2022 > June 2023





Programme Directors

- **Prof. Jules Desmeules**, Head of the Division of Clinical Pharmacology and Toxicology, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Prof. François Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich (ETH Zürich) & Lecturer at Hospitals of Geneva, University of Geneva

Coordinators

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



A catalyst for career success in drug discovery and development

The Master of Advanced Studies (MAS) in Drug Discovery and Clinical Development is aimed at professionals from the academia, pharmaceutical industry, biotechnology sector, and international organizations who wish to gain an in-depth understanding of drugs and research and development. The program covers the entire medical product lifecycle – from molecule to the marketplace and addresses the scientific, regulatory, and market requirements of successful product development. By providing essential knowledge and understanding of this complex process, and by engaging in strong partnerships with industrials, regulatory experts and public stakeholders the program facilitates a smooth transition to an enduring and productive career within a biotechnology firm, pharmaceutical company, contract research or nonprofit organization or an academic institution.



Steering Committee

- **Prof. Cem Gabay**, Dean of the Faculty of Medicine, University of Geneva
- **Prof. Arnaud Perrier**, Medical Director, University Hospitals of Geneva
- **Prof. Gerrit Borchard**, Head of Biopharmaceutics, Section of Pharmaceutical Sciences, Faculty of Science, University of Geneva
- **Prof. 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. 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. 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**, Medicines for Malaria Venture, Associate Director, Access and Product Management
- **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
- **Dr Jocelyne Chabert**, Clinical Research Associate, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Prof. Francois Curtin**, Medical Director Personalised Health Programmes, Swiss Federal Institute of Technology in Zürich (ETH Zürich) & Lecturer at Hospitals of Geneva, University of Geneva
- **Prof. Youssef Daali**, Head of the laboratory of the Division of Clinical Pharmacology and Toxicology, University Hospitals of Geneva, 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. 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 Medicine, 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
- **Dr Angela Huttner**, Head of Clinical Investigation Unit (CRC), University Hospitals of Geneva, 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 drug discovery and development.

Objectives

- To provide essential business knowledge of drug and medical devices clinical research and development.
- To give health professionals the tools to comply with the highest scientific and ethical standards in clinical research.
- To empower physicians and health scientists to lead clinical trials within hospitals, pharmaceutical and biotechnology companies.
- To enable health professionals to gain a strategic vision of discovery and clinical development of drugs and navigate the complexities of bringing new medicinal products to the global market.

Skills and Competencies

- Understand the stakes, challenges and opportunities of drug discovery and development.
- Master the fundamental scientific and ethical principles of drug discovery and development.
- Gain knowledge of Good Clinical Practices (GCP) and of clinical research regulations in Switzerland, Europe and the United States.
- Learn how to navigate clinical trial authorization and marketing authorization processes.
- Master effective project planning and management for clinical trials.
- Successfully manage partnerships with pharmaceutical and biotechnology partners.
- Understand the issues related to research subject protection.
- Understand and take up the challenges of new technologies and personalized medicine.



Programme Structure

- 13 modules over one year (average 24 hours of teaching per module)
- Teaching: 280 hours
- Dissertation: 500 hours
- Number of ECTS credits: 60
- Some modules may be attended individually

Learning Methods

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

Dissertation

Students should propose their own dissertation subject of research.

Diploma Awarded

Participants who successfully complete the programme will be awarded the **Master of Advanced Studies in Drug Discovery and Clinical Development / Maîtrise d'études avancées en découverte et développement clinique de médicaments** delivered by the University of Geneva. It equates to 60 ECTS (European Credit Transfer and Accumulation System) credits.



Module 1 |

Introduction to Clinical Development: Challenges and Prospects

29, 30, 31 August 2022

Prof. François Curtin, Dr Emilie Alirol

- Definition of pharmaceutical development: purpose, players and phases
- Success and failure in drug discovery and development
- Fundamentals of health economics
- Intellectual property
- Marketing strategies in drug development
- Alternative models of drug development: Product development partnerships and not-for-profit entities

Module 2 |

Principles and Methods of Clinical Research

26, 27, 28 September 2022

Prof. François Curtin, Prof. Angèle Gayet-Ageron

- 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

17, 18, 19 October 2022

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 4B |

Preclinical Pharmacology, Toxicology and Clinical Pharmacology

14, 15, 16 November 2022

Prof. Gerrit Borchard, Prof. Youssef Daali, Dr Catherine Deloche, Prof. Marie Besson

- Basics 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 and Drug Development

28, 29 November 2022

**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 6 |

Medical Statisticals and Trial Methodologies

19, 20, 21, 22 December 2022

Prof. François Curtin, Dr David W Warne

- Statistical principles for drug development: ICH E9
- Distributions
- Parameters estimators
- Power calculations
- Clinical trials designs: parallel, cross-over, sequential, and adaptive designs
- Development of study protocols
- Pharmaco-epidemiology



Module 7 |

Clinical Trials Set-up and Conduct – Part 1

16, 17, 18 January 2023

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
- Standard Operation Procedures (SOP)
- Submission to Swiss Ethics Committee (EC) and Swiss Regulatory Authorities (RA)

Module 8 |

Clinical Trials Set-up and Conduct – Part 2

13, 14, 15 February 2023

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
- Documents and records
- Monitoring of clinical studies
- Root-cause analysis



Module 9 |

Regulatory Consideration in Drug Development

13, 14, 15 March 2023

Dr Brigitte Happ, Dr Enrica Alteri

- Role and responsibilities of regulatory agencies
- International regulatory environment
- EU, Swiss, US Legislation
- Early access to new therapeutic products
- Life-cycle management
- Special populations (orphan, paediatrics)
- Antibiotic development
- Advanced therapies
- In vitro companion diagnostics
- Regulatory strategies and health agencies interactions

Module 10 |

Clinical Trials Close-out and Reporting

20 March 2023

Dr Françoise Lascombes, Dr Catherine Deloche

- Clinical trial close-out activities
- Data cleaning and database lock
- Statistical Analysis Plan (SAP) and result reporting
- Medical writing and clinical study report
- Safety reconciliation and MedDRA coding



Module 11 |

Medical Devices

21, 22 March 2023

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
- Materiovigilance
- Conformity assessment and CE marking
- Digital health and medical software
- Combination products

Module 12 |

Audits and Inspections

9, 10, 11 May 2023

Dr Isabelle Mercier, Dr Isabelle Semac

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

Module 13 |

New Perspectives, Personalized Medicine and New Therapeutics

5, 6, 7 June 2023

Prof. Caroline Samer, Dr Patricia Delaite

- Personalized medicine scope and definition
- Omics and big data
- New requirements in drug development
- New tools and technologies enabling key patient benefit
- New therapeutic approaches being currently developed



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 Science plus a minimum of 1 year professional experience in clinical development.
- 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/drug-dvp

- 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 29, 2022 to the MAS secretariat (DAS.clinicaltrials@hcuge.ch).
- For individual modules, application should be sent at least one month prior to the beginning of the selected module. Priority will be given to candidates applying for the master.
- The MAS 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 MAS, 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 15,500.– for the MAS
- 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

77 route de Florissant-1208 Genève

Bus 21 and 8: direction Genève-Eaux-Vives-Gare, or Veyrier-Douane, stop Aubert

Contact

DAS.clinicaltrials@hcuge.ch

www.unige.ch/formcont/cours/drug-dvp



