

MAS

Master of Advanced Studies
Maîtrise universitaire d'études avancées

Drug Discovery and Clinical Development

August 2025 > June 2026





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 MAS, Faculty of Medicine, University of Geneva
- **Ms Camille Arni**, Administrative Assistant of the MAS, 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 designed for professionals from academia, the pharmaceutical and Medtech industries, the biotechnology sector, and international organisations who seek a comprehensive understanding of health product research and development. The programme covers the entire product lifecycle—from molecule to market—and addresses the scientific, regulatory, and commercial requirements essential for successful product development. By providing critical knowledge of this complex process and fostering strong partnerships with industry leaders, regulatory experts, and public stakeholders, the programme supports a smooth transition to a successful and sustainable career in a biotechnology firm, pharmaceutical or Medtech company, contract research organisation, non-profit, or academic institution.



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**, PharmD, Division of Clinical Pharmacology and Toxicology, Geneva University Hospitals and Faculty of Medicine, University of Geneva



Target Audience

Medical doctors, biologists, pharmacists, nurses, biochemists and other life science professionals involved, or wishing to gain skills and knowledge, in the field of health products development.

Objectives

- To provide essential business knowledge related to the research and development of drugs and medical devices.
- To offer foundational training on the regulatory aspects of health product development.
- To equip health professionals with the tools to meet the highest scientific, ethical, and quality standards in clinical research.
- To empower physicians and health scientists to lead clinical trials and development programmes in hospitals, as well as within pharmaceutical, Medtech, and biotechnology companies.
- To enable health professionals to gain a strategic vision of product development and navigate the complexities involved in making health products accessible to patients.

Skills and Competencies

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



Programme Structure

- 13 modules over one year (average 24 hours of teaching per module)
- Teaching time: 280 hours
- Work placement / Internship: 500 hours
- Total number of ECTS credits: 60
- 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 are expected to propose their own research topic for the dissertation.

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 Product Development: Challenges and Prospects

25, 26, 27 August 2025

Prof François Curtin, Dr Emilie Alirol

- Definition of product development: purpose, stakeholders, duration, cost and phases
- Success and failure in product development
- Fundamentals of health economics and regulatory framework
- Intellectual property in the context of medicines and medical devices
- Marketing strategies
- Target Product Profiles and Clinical Development Plans

Module 2 |

Principles and Methods of Clinical Research

22, 23, 24 September 2025

Dr Cyril Jaksic, Dr Maël Barthoulot

- 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 Practice
- Clinical trials authorisations
- Ethical issues in biobanks

Module 4A 4B |

Non-Clinical Development and Clinical Pharmacology

3, 4, 5 November 2025

Prof Youssef Daali, Dr Catherine Deloche

- 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 6 |

Medical Statistical and Trial Methodologies

15, 16, 17, 18 December 2025

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 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 11 |

Regulatory Strategy in Product Development

20, 21, 22 April 2026

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
- Special populations (orphan, paediatrics)
- Advanced therapies
- Common Technical Document
- Generics and Biosimilars
- Regulatory strategies and health agencies interactions

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

Module 13 |

New Perspectives in Product Development

8, 9, 10 June 2026

Dr Enrica Alteri, Prof Youssef Daali, Dr Brigitte Happ

- Personalised medicine scope and definition
- Omics and big data
- Use of data, analytics and Artificial Intelligence in product development
- Advanced Therapeutic Medicinal Products
- New therapeutic approaches being currently developed



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/cours/drug-dvp

- 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 MAS secretariat (das-mas-clinical@unige.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 Diploma.
- The MAS 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 MAS 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 15,500.- for the whole MAS

For individual modules:

- 1-day module: CHF 1,000.-
- 2-day module: CHF 1,400.-
- 3-day module: CHF 1,800.-
- 4-day module: CHF 2,200.-

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

Centre Louis-Jeantet, Auditorium
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/cours/drug-dvp



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