

# MAS

Master of Advanced Studies  
Maîtrise universitaire d'études avancées

## Drug Discovery and Clinical Development

September 2018 > June 2019





## Programme Direction

- **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**, Chief Operating Officer, Geneuro, Geneva

## Coordination

- **Dr Victoria Rollason**, PharmD, PhD, Coordinator, Division of Clinical Pharmacology and Toxicology and Clinical Trial Unit, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Ms Sarah De Farias**, Administrative assistant of the DAS, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Ms Corinne Chaudet**, Assistant of the Clinical Trial Unit, Clinical Research Center, University Hospitals of Geneva, Faculty of Medicine, University of Geneva



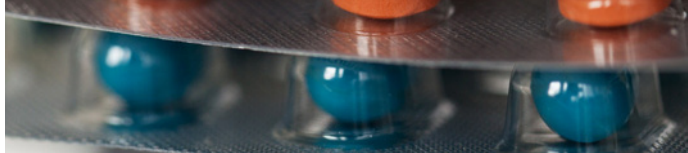
## A catalyst for career success in drug discovery and development

**T**he 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 medical devices research and development (R&D). 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. Henri Bounameaux**, 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. 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. Thomas Perneger**, Head of the Methodological Unit, Clinical Research Center (CRC), University Hospitals of Geneva, 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**, Senior Clinical Trial Manager, Global Antibiotic R&D Partnership (GARDP), DNDi
- **Dr Manica Balasegaram**, Director, Dynamic Portfolio, Global Antibiotic R&D Partnership (GARDP), 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, Chief Executive Officer, GeNeuro, Geneva
- **Dr Patricia Delaite**, Medical Director, Incyte, Geneva
- **Dr Catherine Deloche**, Chief Operating Officer, SOLID, Geneva
- **Prof. Philippe Ducor**, Faculty of Law, University of Geneva
- **Dr Corinne Merle**, Scientist, Intervention and Implementation research unit, Special Programme for research and training in tropical diseases (TDR), World Health Organization (WHO), Geneva
- **Dr Roch Ogier**, Chief Scientific Officer, Novartis Pharma, Rotkreuz
- **Prof. Hervé Porchet**, Chief Medical Officer, GeNeuro, Geneva
- **Dr Victoria Rollason**, PharmD, PhD, Coordinator, Division of Clinical Pharmacology and Toxicology and Clinical Trial Unit, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr Tra-Mi Phan**, Chief Scientific Officer, Novartis Pharma Schweiz, Head of the Medical Department, responsible for clinical research, overall medical strategy, medical education and external engagement with the scientific community for Novartis Pharma.



## Target

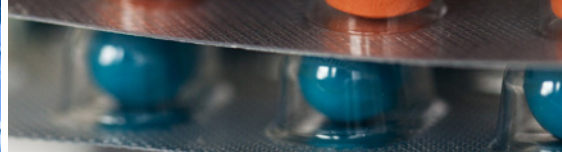
Medical doctors, biologists, pharmacists, nurses, biochemists and other professionals involved, or wishing to gain skills and knowledge, in the field of drug discovery and development.

## 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

- 12 modules over one year (average 24 hours of teaching per module)
- Teaching: 280 hours
- Dissertation: 540 hours
- Number of ECTS credits: 60
- Some modules may be attended individually

## Learning Methods

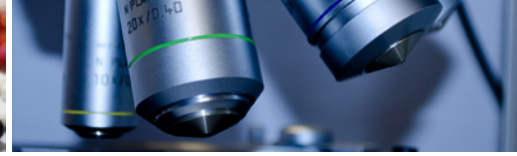
Lectures, interactive seminars, workshops, vocational training.  
Teachings in English or in French

## Dissertation

Students should select the dissertation subject from a list proposed at the beginning of the academic year.

## Diploma Awarded

Participants who successfully complete the programme will be awarded the Master of Advanced Studies in **Drug Discovery and Clinical Development** / *Maîtrise de Formation Continue 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

September 3, 4, 5, 2018

**Dr 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

September 24, 25, 26, 2018

**Prof. Thomas Perneger, Dr 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

October 17, 18, 19, 2018

**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 and authorship issues
- Ethical issues in biobanks

## Module 4A | Preclinical Pharmacology, Toxicology and Clinical Pharmacology

November 14, 15, 16, 2018

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

- Basics of Pharmacology
- safety assessment in pre-clinical research
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)



## Module 5 | **Safety Management and Drug Development**

November 22, 23, 2018

**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 Statistics and Trial Methodologies**

December 17, 18, 19, 20, 2018

**Dr 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**

January 14, 15, 16, 2019

**Dr Roch Ogier, Dr Manica Balasegaram**

- 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
- Case Report Forms (CRFs) development
- Standard Operation Procedures (SOP)
- Submission to Ethics Committee (EC) and notification to Regulatory Authorities (RA)

## Module 8 | **Clinical Trials Set-up and Conduct – Part 2**

February 11, 12, 13, 2019

**Ms Virginie Vidal, Ms Jennifer Kealy**

- 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**

March 11, 12, 13, 2019

**Dr Brigitte Happ, Ms Marion Laumonier**

- Role and responsibilities of regulatory agencies
- International regulatory environment
- EU and US legislation
- Early access to new therapeutic products
- Life-cycle management
- Special populations
- Medical devices
- Regulatory strategies and health agencies interactions

## Module 10 | **Clinical Trials Close-out and Reporting**

April 15, 16, 2019

**Dr Roch Ogier, Dr Mariagrazia Di Marco**

- Study close-out activities
- Data cleaning and database lock
- Preparation of Statistical Analysis Plan (SAP)
- Results review and interpretation
- Dissemination and publications of study results
- Clinical trials reporting
- Dossier preparation and submission for Marketing
- Authorization Applications (MAA)
- Regulatory specificities of Medical Devices, Orphan Drugs and Pediatric drugs



**M**<sub>odule</sub> 11 | **Audits and Inspections**

May 15, 16, 17, 2019

**Dr Isabelle Mercier, Dr Jocelyne Chabert**

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

**M**<sub>odule</sub> 12 | **New Perspectives, Personalized Medicine and New Therapeutics**

June 17, 18, 19, 2019

**Dr 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 in Oncology and Neurology



## 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:

[unige.ch/formcont/MASdrugdevelopment](http://unige.ch/formcont/MASdrugdevelopment)

- 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 June 15, 2018 to the MAS secretariat ([DAS.clinicaltrials@hcuge.ch](mailto: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 13,000.– for the Diploma
- CHF 1,500.– for individual module

### **Accreditation**

The course program 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**

- Module 1, september 3, 4 and 5, 2018  
Campus Biotech  
9 chemin des Mines-1202 Genève  
Bus 1 and 25 – direction Jardin Botanique, stop Mines  
Bus 11 – direction Jardin Botanique, stop Jardin Botanique
- Fondation Louis Jeantet  
77 route de Florissant-1208 Genève  
Bus 2 and 8 – direction Veyrier, stop Aubert

### **Contact**

[DAS.clinicaltrials@hcuge.ch](mailto:DAS.clinicaltrials@hcuge.ch)

[drugdevelopment.unige.ch](http://drugdevelopment.unige.ch)

