MAS

Master of Advanced Studies
Maîtrise universitaire d'études avancées

Drug Discovery and Clinical Development

August 2016 > September 2017

HUG Hôpitaux Universitaires Genève

CRC Centre de Recherche Clinique

UNIVERSITÉ DE GENÈVE

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 Emilie Alirol**, Clinical Trial Manager, Clinical Trial Unit, Clinical Research Center (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Ms Isabelle Lagrange**, Administrative Assistant of the MAS, University Hospitals of Geneva, Faculty of Medicine, University of Geneva

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**, Vice-President, 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

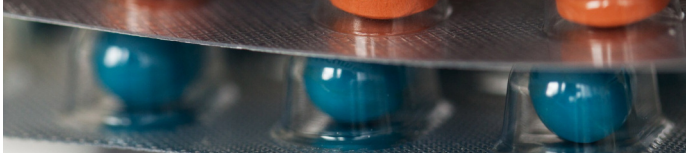
A catalyst for career success in drug discovery and development

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 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.



Scientific Committee

- **Dr Emilie Alirol**, Clinical Trial Manager, Clinical Research Centre (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr Manica Balasegaram**, Director, Access Campaign, Médecins Sans Frontières
- **Dr Vanya Beltrami,** Director Product Development, 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**, Chief Operating 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
- **Prof. Michel Lièvre**, Clinical Pharmacology Department, Faculty of Medicine Laennec, Lyon University Hospitals, France
- **Dr Christine Maure**, Technical Officer, Immunization, Vaccines and Biologicals, World Health Organization (WHO), 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



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

Target Audience

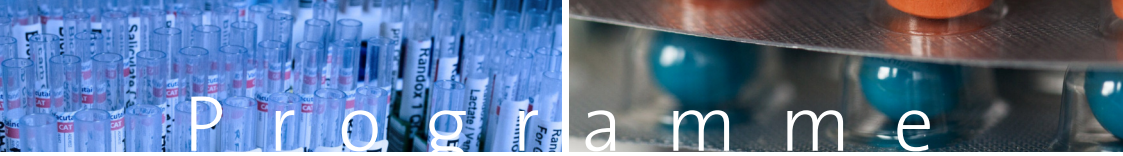
Medical doctors, biologists, pharmacists, nurses, biochemists and other professionals involved, or wishing to gain skills and knowledge, in the field of drug discovery and development.

Learning Methods

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

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
- Each module is subjected to an evaluation in order to be accredited
- Some modules may be attended individually



Programme

Module 1 | Introduction to Clinical Development: Challenges and Prospects

August 24, 25, 26, 2016

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 | Preclinical Pharmacology, Toxicology and Clinical Pharmacology

September 14,15, 16, 2016

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

- Fundamentals of pharmacology
- Safety assessment in pre-clinical research
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)
- Toxicology requirements
- Basics of clinical pharmacology
- Pharmacokinetics / Pharmacodynamics modelling
- Drug metabolism

Module 3 | Safety Management and Drug Development

September 19, 20, 2016

Prof. Jules Desmeules, Dr Victoria Rollason, Prof. Michel Lièvre

- 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 4 | Principles and Methods of Clinical Research

October 3, 4, 5, 2016

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 5 | Medical Statistics and Trial Methodologies

November 7, 8, 9, 10 2016

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
- Pharmaco-epidemiology

Module 6 | Ethical and Legal Aspects

December 5, 6, 7, 2016

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 7 | Planning of Clinical Trials

January 11, 12, 13, 2017

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 | Conduct and Management of Clinical Trials

February 6, 7, 8, 2017

Mrs Virginie Vidal, Mrs 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 8, 9, 10, 2017

Dr Brigitte Happ, Mrs 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 | Close-out and Reporting of Clinical Trials

April 5, 6, 2017

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)


Module 11 | Audits and Inspections

May 22, 23, 24, 2017

Dr Emilie Alirol, Dr Jocelyne Chabert

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

Module 12 | New Perspectives, Personalized Medicine and New Therapeutics

June 19, 20, 21, 2017

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

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.

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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:
drugdevelopment.unige.ch

- 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, 2016 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 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

Course Location

- 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
- Auditoire Jeantet
  77 route de Florissant-1208 Genève
  Bus 2 and 8 – direction Veyrier, stop Louis-Aubert

Contact

DAS.clinicaltrials@hcuge.ch

drugdevelopment.unige.ch

swissuniversities

University Centre for Continuing and Distance Education
www.unige.ch/formcont