DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials

Good Clinical Practice Implementation and Quality Processes

September 2016 > September 2017

HUG
Hôpitaux Universitaires Genève

CRC Centre de Recherche Clinique

UNIVERSITÉ DE GENÈVE


Programme Director

Prof. Jules Desmeules, Head of the Clinical Trial Unit, Clinical Research Center (CRC), University Hospitals of Geneva, Faculty of Medicine, University of Geneva

Coordination

- **Dr Emilie Alirol**, Clinical Trial Manager, Clinical Trial Unit, Clinical Research Center, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Ms Isabelle Lagrange**, 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

An essential step for transitioning your career to clinical research

In the past two decades, the number of Clinical Trials conducted in Switzerland and worldwide has virtually exploded. This tremendous increase went hand in hand with the development of codes, guidelines and regulations aimed at protecting human research subjects. Standardization and strengthening of clinical research regulations have led to the development of a rapidly growing economic sector in which Clinical Research Associates (CRA), Clinical Research Scientists (CRS), Data Managers (DM), Clinical Research Coordinators (CRC), Clinical Trial Managers (CTM) and regulatory affairs specialists are key players.

The Diploma of Advanced Studies (DAS) in **Management of Clinical Trials – Good Clinical Practice Implementation and Quality Processes** provides a theoretical and practical understanding of how Good Clinical Practice (GCP) principles are shaping each step of a Clinical Trial, including study design, trial management and conduct.


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


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, Dynamic Portfolio, GARD Partnership Operations, 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**, 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


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 authorization process

Skills and Competencies

- Understand and use in a relevant context the different Clinical Trial designs and methodologies
- Be familiar with drug development and marketing authorization processes
- Gain knowledge of GCP and of clinical research regulations in Switzerland, Europe and the United States
- Become skilled at developing Case Report Form (CRF)
- Coordinate the development of clinical trial protocols
- Master effective project planning and management
- Know how to manage applications for Ethics Committee (EC) and Regulatory Authority (RA)
- Understand and implement Quality Systems used in Clinical Trials
- Understand the issues related to research subject protection

Target Audience

Medical doctors, biologists, pharmacists, nurses, biochemists and other professionals involved, or wishing to gain skills and knowledge, in the field of clinical research

Learning Methods

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

Dissertation

Students may choose between:

- A vocational training in a pharmaceutical company, a Clinical Research Organization (CRO) or a Clinical Trial Unit in a University Hospital (320 hours over 3-4 months)
- The development of a Clinical Trial protocol or a literature review and dissertation (320 hours)

Diploma Awarded

Participants who successfully complete the programme will be awarded the Diploma of Advanced Studies in Management of Clinical Trials – Good Clinical Practice Implementation and Quality Processes / *Diplôme de formation continue en Gestion des Essais Cliniques – Mise en application des bonnes pratiques et processus qualité* delivered by the University of Geneva. It equates to 33 ECTS (European Credit Transfer and Accumulation System) credits

Programme Structure

- 8 modules over one year (average 24 hours of teaching per module)
- Teaching: 160 hours
- Dissertation: 320 hours
- Number of ECTS credits: 33
- Each module is subjected to an evaluation in order to be accredited
- Modules 1 to 7 may be attended individually

Module 2A | Preclinical Pharmacology, Toxicology and Clinical Pharmacology

September 14, 2016

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 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 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 (CTA) 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 ,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 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)
- Regulatory specificities of medical devices, orphan drugs and pediatric drugs

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

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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 Sciences plus a minimum of 1 year professional experience in the field of the DAS
- 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 DAS secretariat (DAS.clinicaltrials@hcuge.ch). Candidates should mention in their cover letter if they want to realize a vocational training as DAS thesis.
- For individual modules, application should be sent at least one month prior to the beginning of the selected module (1 to 7). Priority will be given to candidates applying for the Diploma.
- The DAS 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 DAS, 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 7,500.- 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
- Fondation Louis 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