DAS

Diplôme de formation continue
Diploma of Advanced Studies

Management of Clinical Trials

Good Clinical Practice Implementation and Quality Processes

October 2015 – September 2016





HUG
Hôpitaux Universitaires de Genève

CRC Centre de Recherche Clinique

UNIVERSITÉ DE GENÈVE


Programme Director

Prof. Jules Desmeules, Head of the Clinical Trial Unit, Clinical Research Center, 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 ofMedicine, 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 in 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, Faculty of Medicine, University of Geneva
- **Prof. Gerrit Borchard**, Vice-president of Pharmaceutical sciences, Faculty of Science, University of Geneva
- **Prof. Bernard Hirschel**, President of the Human Research Ethics Commission, University Hospitals of Geneva
- **Prof. Samia Hurst**, Institute of Bioethics, Faculty of Medicine, University of Geneva
- **Prof. Thomas Perneger**, Methodological Unit, Clinical Research Center, 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, University Hospitals of Geneva, Faculty of Medicine, University of Geneva



Scientific Committee

- **Dr Emilie Alirol**, Clinical Trial Manager, CRC, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr Manica Balasegaram**, Director, Access Campaign, Médecins Sans Frontières
- **Dr Jocelyne Chabert**, Clinical Research Associate, CRC, University Hospitals of Geneva, Faculty of Medicine, University of Geneva
- **Dr Francois Curtin**, PD, Chief Executive Officer, GeNeuro, 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**, Lecturer, London School of Hygiene and Tropical Medicine, England
- **Dr Roch Ogier**, Chief Scientific Officer, Novartis Pharma, Rotkreuz
- **Prof. Hervé Porchet**, Chief Medical Officer, Eclosion SA, 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 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 writing clinical protocols and developing Case Report Form (CRF)
- Master effective project planning and management
- Know how to manage applications for Ethics Committee (EC) and Regulatory Authority (RA)
- Learn about 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, worshop, 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)

Programme Structure

- Seven modules (approximately 24 hours of teaching per module) over one year
- Teaching: 168 hours
- Dissertation: 320 hours
- Number of ECTS credits: 32
- Each module is subjected to an evaluation in order to be accredited. Some modules may be attended individually (1 to 6)

Programme

Module 1 | Principles and Methods of Clinical Research

September 28, 29, 30 2015

Prof. Thomas Perneger, Dr Angèle Gayet-Ageron

- Development of research questions and choice of endpoints
- Study designs
- Literature search strategies
- Statistical methods used in clinical research
- Principles of Randomized Controlled Trials (RCT)
- Meta-analyses
- Choice of endpoints
- Sample size calculation
- Interim analysis planning

Module 2 | Ethical and Regulatory Aspect

November 11, 12, 13 2015

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
- 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 3 | Safety Management and Drug Development

December 14, 15, 16 2015

Dr Victoria Rollason, Prof. Michel Lièvre, Dr Catherine Deloche, Dr François Curtin

- Basics of pharmacology
- Safety assessment in pre-clinical research
- Investigational Medicinal Product Dossier (IMPD) and Investigator Brochure (IB)
- Risk management and safety monitoring during drug development
- Safety assessment, documentation and reporting during clinical trials
- Pharmacovigilance and post- marketing studies
- Role of Data and Safety Monitoring Boards (DSMB)

Module 4 | Planning of Clinical Trials

January 18, 19, 20 2016

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

Module 5 | Conduct and Management of Clinical Trials

February 22, 23, 24 2016

Dr Christine Maure, Dr Corinne Merle, 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 product
- Documents and records
- Monitoring of clinical studies
- Root-cause analysis

Module 6 | Close-out and Reporting of Clinical Trials

March 14, 15, 16 2016

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 7 | Audits and Inspections

April 4, 5, 6 2016

Dr Emilie Alirol, Dr Jocelyne Chabert

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

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.

General Information

Admission Criteria

- Title of physician
- *Or* Master's degree in Life Science *or* a Master's degree deemed equivalent
- Level B2 and good understanding of both French and English (Knowledge of English 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/clinicaltrial

- Candidates should send copies of relevant university degrees, a curriculum Vitae, a covering letter and a written authorization from their employer by July 15, 2015 to the DAS secretariat (corinne.chaudet@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 6). 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 6'500.- for the certificate
- CHF 1'350.- for individual modules

Accreditation

The course program is accredited by:

- Swissethics
- Swiss Association of Pharmaceutical Professionals (SwAPP)
- Swiss Society of Clinical Pharmacology and Toxicology

Course Location

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

Contact

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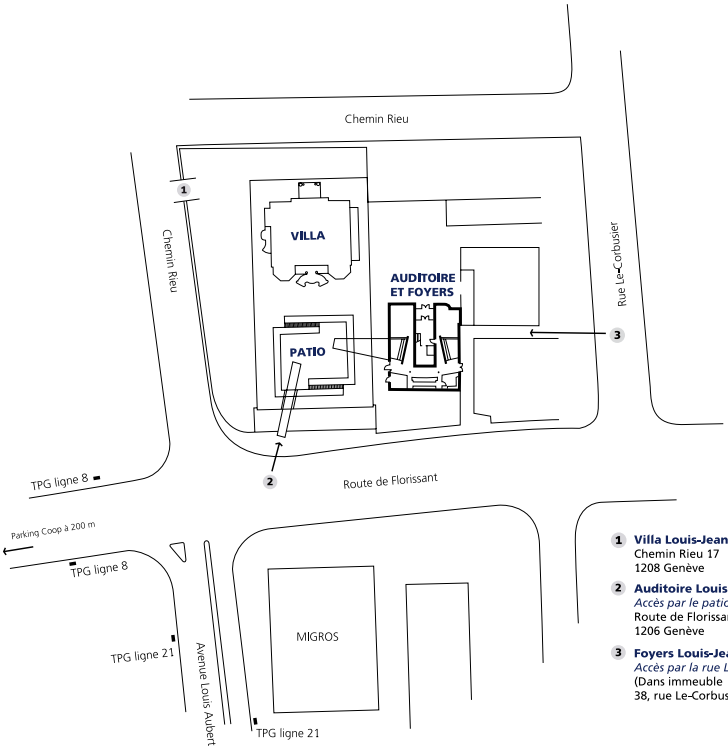
www.unige.ch/formcont/clinicaltrial

FONDATION
LOUIS-JEANTET

Plan de situation du Centre Louis-Jeantet



1 **Villa Louis-Jeantet**
Chemin Rieu 17
1208 Genève

2 **Auditoire Louis-Jeantet**
Accès par le patio
Route de Florissant 77
1206 Genève

3 **Foyers Louis-Jeantet**
Accès par la rue Le-Corbusier
(Dans immeuble
38, rue Le-Corbusier)

www.unige.ch/formcont/clinicaltrial

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