

DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials Good Clinical Practice Implementation and Quality Processes

September 2018 > May 2019





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 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



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**, 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 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
- **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**, Head of the Therapy Development Accelerator, University of Zurich
- **Prof. Hervé Porchet**, Chief Medical Officer, GeNeuro, Geneva
- **Dr Victoria Rollason**, PharmD, PhD, Coordinator of the DAS, 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 Audience

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

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



Programme Structure

8 modules over one year (average 24 hours of teaching per module)
8h00-12h00/13h00-17h00 | Teaching: 160 hours | Dissertation: 320 hours
| Number of ECTS credits: 33 | Each module is subjected to an evaluation
in order to be accredited | Modules 2 to 10 may be attended individually

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



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 (CTA) and authorship issues
- Ethical issues in biobanks



M_{odule} 4A | Preclinical Pharmacology, Toxicology and Clinical Pharmacology

November 14, 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)

M_{odule} 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 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 Jennifer Kealy, Ms Virginie Vidal

- 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 | **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

Module 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



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:

unige.ch/formcont/DASclinicaltrials

- 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 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 (2 to 10). 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 an 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

Fondation Louis Jeantet
77 route de Florissant – 1208 Genève
Bus 2 and 8 – Direction Veyrier, Stop Aubert

Contact

DAS.clinicaltrials@hcuge.ch

drugdevelopment.unige.ch

