DAS

Diploma of Advanced Studies
Diplôme de formation continue

Management of Clinical Trials

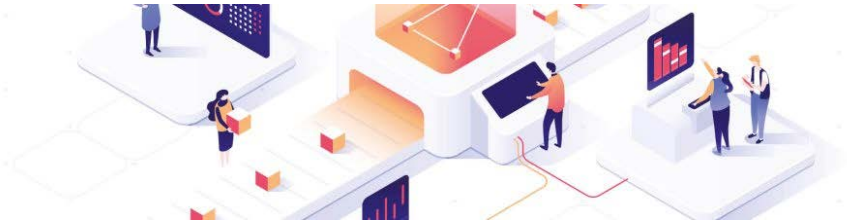
Good Clinical Practice Implementation and Quality Processes

September 2024 – May 2025

HUG Hôpitaux Universitaires Genève

CENTRE DE RECHERCHE CLINIQUE

UNIVERSITÉ DE GENÈVE



Course Programme on Medical Devices
(18th – 19th March 2025)

Module 11: Medical Devices

Coordinators: Dr Mariagrazia Di Marco, Me Gabriel Avigdor

Dates of the module: *18th – 19th March 2025. To register for this module only, please contact:* das-mas-clinical@unige.ch *or* register online*.*

Aim / Goal: *The aim of this module is to introduce learners to the fundamentals of medical device regulations and clinical investigations.*

Learning objectives: *Participants will gain insights into the newly implemented European Medical Device Regulations and the legislative changes in the Swiss Medical Device Ordinance. They will acquire both knowledge and practical experience in risk management and the clinical evaluation of medical devices.*

Download the full DAS Brochure for 2024/2025.

Key topics:

- Medical devices (MD), new EU regulations (MDR, IVDR, CDx)
- Qualification and classification
- Clinical investigation and clinical trial application to authorities
- Market access strategy
- Conformity assessment and CE marking
- Materiovigilance
- Digital health and medical software
- Combination products (drug devices)

Learning method: *Lectures and workshops*

Evaluation method: *Multiple-Choice Questions (MCQs)*

Supporting documents: *Refer to list of study programme refs on Moodle.*

Number of speakers: 9

Number of ECTS: *1*

DAY 1			
08h30-08h45	Introduction: Modules and speakers.	Intro	MDM
08h45-09h30	**Topic 1** - Medical Devices: Definition, product-life cycle overview classification & registration in EU.	Lecture	MG
09h30-10h15	**Topic 2** - Pre-clinical development of medical devices	Lecture	CL
	Break		
10h30-11h30	**Topic 3** - MD registration: Clinical Development	Lecture	MG
11h30-12h30	**Topic 4**: Market Access, incl. Feasibility analysis – etc.	Lecture	CL
	Lunch Break		
13h30- 14h15	**Topic 5**: MDR - Regulation (EU) 2017/745 – annex XV and new Swiss regulations	Lecture	MDM
14h15-15h15	**Topic 6**: ISO 14971:2019 and Medical Device Risk Management	Lecture	MA
	Break		
15h30-16h30	**Workshop 1**: Risk management - Interactive simulation	Workshop	MA
16h30-17h30	**Topic 7**: Safety reporting in clinical investigations and guidance documents: MDCG 2020-10/1 and MDCG 2020-10/2	Lecture	FT

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Day 2			
08h15-09h30	**Topic 8**: Medical Software and Digital Health Regulation: Qualification and Classification.	Lecture	GA
09h30-10h15	**Workshop 2**: Case law and study	Workshop	GA
	Break		
10h30-12h15	**Topic 9**: Regulatory Nuances and Clinical Study Approaches for Combination Products: Pathways to Clinical Development and Market Authorization	Lecture	RP
	Lunch Break		
13h15-15h15	**Workshop 3**: Clinical Evaluation – interactive simulation	Workshop	AL
	Break		
15h30-16h15	**Topic 10**: IVDR overview regulation and Companion Diagnostics (CDx).	Lecture	DF
16h15-17h00	**Case studies**: Real life examples developing and using IVD & Companion diagnostics devices	Discussion	DF

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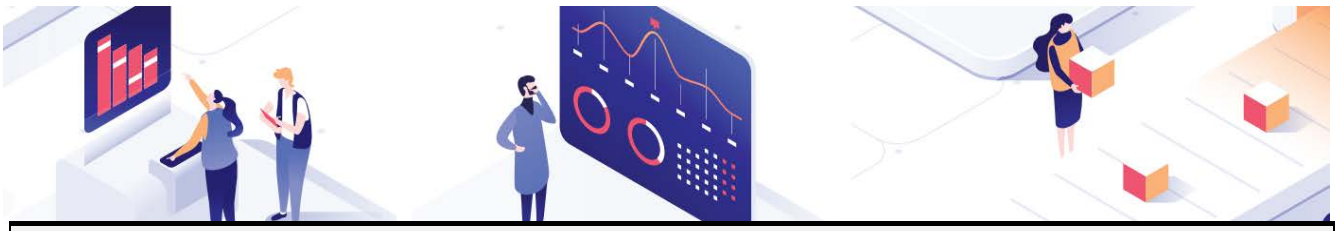
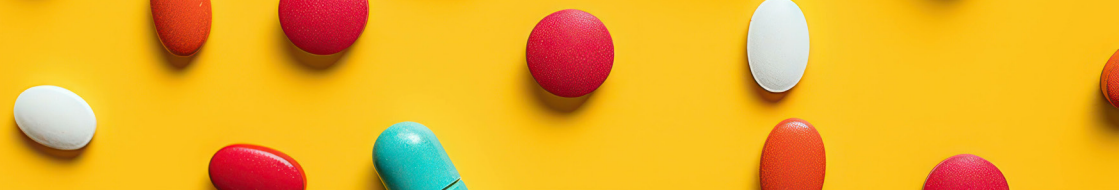


DAS Management of Clinical Trials 2024-25 Module 11 Speakers	
AL	**Andrea Lopes**, Confinis AG
CL	**Corinne Lebourgeois**, MedC. Partners
FT	**Fabiana Tirone**, Clinical Trial Materio/Phamacovigilance Vigilance, HUG
DF	**Didier Falconnet**, Medical Devices & IVD Product Development expert
GA	**Gabriel Avigdor**, Attorney-at-law & Legal Director
MA	**Markus Angst**, Regulatory and tech consultant, ISS AG
MDM	**Mariagrazia Di Marco**, Regulatory affairs specialist, CTU, HUG
MG	**Marie Gaumet**, Managing Director, SwAPP
RP	**Rima Padovani**, Director, Quality & Regulatory Affairs



Contact

das-mas-clinical@unige.ch

www.unige.ch/formcont/en/courses/clinical-trials