Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut
Institut Tropical et de Santé Publique Suisse

Associated Institute of the University of Basel

Department of Medicine

Good Clinical Practice (GCP) Training for Investigators and Study Teams

Location: **virtual via ZOOM**

Date/Time: Day 1: 18 August 2020, 08:45 – 17:00
Day 2: 19 August 2020, 09:00 – 16:00

Language: English

Day 1

Module	Time	Agenda Item
Introduction	08:45 – 09:00	**Welcome** Introduction of participants, course program and structure
Lecture 1	09:00 – 10:15	**Introduction to Good Clinical Practice** Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities
	10:15 – 10:30	***Coffee break***
Lecture 1 (cont.)	10:30 – 11:00	**Introduction to Good Clinical Practice** Historical Background, Research Ethics, Drug Regulations, Introduction to ICH E6 (R2) GCP Guideline, Investigators responsibilities
Lecture 2	11:00 – 12:00	**Basic Statistical Concepts and Study Design** Defining the research question
	12:00 – 13:00	***Lunch break***
Exercise 1	13:00 – 13:45	**Protocol Optimization** How would you improve the example protocols?
Lecture 3	13:45 – 14:45	**Source Records and Data Management** From Case Report Forms to Final Analysis
	14:45 – 15:00	***Coffee break***
Exercise 2	15:00 – 16:00	**Critical review of Source Documents and CRF Design** Principles of ALCOAC; Improving Data Quality from the Start
Lecture 4	16:00 – 17:00	**Study Documents and Archiving** Essential Documents, Trial Master File, Retention

Day 2

Module	Time	Agenda Item
Lecture 5	09:00 – 10:15	**Focus on Informed Consent and Safety Reporting** Investigator Responsibilities
	10:15 – 10:30	***Coffee break***
Exercise 3	10:30 – 11:30	**Critical Review of an Informed Consent Form** Analyze and discuss potential problems and ethical issues with the example informed consents
Lecture 6	11:30 – 12:30	**Quality Management** SOPs, Training, Monitoring, Auditing; Common Audit and Inspection Findings
	12:30 – 13:30	***Lunch break***
Lecture 7	13:30 – 14:15	**Research Misconduct and Fraud** Definition and Consequences; Case Examples
Lecture 8	14:15 – 15:30	**Legal Background, Ethics Committees & Submission processes** Introduction to HFG, ethics landscape Switzerland, BASEC, Swissmedic
Summary	15:30 – 16:00	**Summary** 13 Key Principles of ICH GCP; A look at addendum to ICH E6 (R2)

Additional time:

Prior to the course, participants will be expected to have read the "**ICH Harmonised Guideline – Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)**" and the **"Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects"** (*Version October 2013, Fortaleza*) (appr. 3 hours).

After the course, participants will need to pass a competency assessment (multiple choice consisting of 20 questions) with a minimum passing score of 70%. Following successful completion, a Certificate of Training will be provided.