Clinical Trial Unit - Education

GCP Refresher

Monday, May 2, 2022

Room A2.08 Campus Est, Lugano
From 13h00 to 18h00

This course is designed for research personnel who have already obtained a GCP certificate but want to update their knowledge: Investigators, Sponsors-Investigator, Co-Sub Investigators, and non-medical research personnel.

➔The certificate obtained by passing the final test of this course does not replace the GCP Investigator or Sponsor-Investigator certificate

Duration: 5 hours ca

Modality:

In general GCP training can combine face-to-face (F2F), online, self-study or homework. Although online training is recognized at a national level, Swissethics strongly recommends completing the course (or part of the course) with F2F training. Online final test assessing knowledge within two weeks of completion of GCP course.

Objectives:

- At the end of the course, the participants are able to describe the different types of human research including the applicable law and regulations in Switzerland.
- At the end of the course, the participants are able to determine the study feasibility in terms of patient recruitment, resources and logistics needed, time and budget and regulatory obligations. They are able to list the roles and responsibilities of all those involved in the study and their working relations. They know the essential study documents and their “raison d’être”.
- At the end of the course, the participants know how to conduct a clinical trial. They know the roles and responsibilities of the investigator and site staff, the tools and documents needed and how to track and keep records during the course of the study. They know the informed consent process and the management of subjects’ safety and safety reporting, as well as how to handle, store and document the study medication and medical devices.
- The participants are up to date with some of the new developments in clinical research and some current burning themes (new regulations and standards, new modes of operation and tools, …).

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SCHEDULE	THEME	CONTENT	TEACHER
13h00-14h00	**1. Basic principles**	• Name and explain the different types of research, i.e. Clinical Trials, Human Research Projects, research involving the further use of biological material or health-related personal data • Name and describe the applicable laws, regulations and standards in Switzerland	B. Gai Ethical Committee Ticino
14h00 15h15	**2. Planning and preparation**	• Identify and describe the roles, responsibilities and working relations of all those involved in the clinical trial, e.g. Investigator(s), Sponsor(s), CRO, Monitor, Ethics Committee, competent authorities • Assess the feasibility of the clinical trial in terms of patient recruitment, logistics and resources • Assess the costs of the clinical trial, define funding and budgeting for the clinical trial • Ensure coherence and traceability of study procedures and documentation (e.g. Quality management system and SOPs) • Ensure tasks assignments in study team • Identify and describe the key study documents (e.g. Protocol, patient information, data source, contracts, …)	C. Sessa Scientific Consultant IOSI
15h15-15h30	**BREAK**		
15h30-16h30 **BREAK 15'** **16h45-17h45**	**3. Execution**	• Describe submission and reporting requirements towards competent authorities • Explain the informed consent process (e.g. with reference to vulnerable groups but not only) • Ensure protocol adherence throughout the study (from screening to patient randomization and treatment, implementation of significant protocol amendments, …) • Correctly handle and store the study medication or medical devices • Name the implemented measures to prevent or minimise risks and to ensure the safety of the participants • Identify, document and report safety events and safety documents • Implement proper measures for surveillance (e.g. monitoring, audits). Inspections • Handle study end procedures and reporting obligations	G. Dal Pra Quality Assurance Consultant
Additional Learning Contents *This part is only implemented when there are significant changes to regulations and/or relevant current specialistic topics*			
	4. Update on legal and ethical norms, advanced topics	• E.g. Name relevant changes to current laws, regulations and processes, including new and updates to ethical guidelines. identify and describe current pressing issues • E.g. Identify and describe cutting edge topics: e.g. Dynamic consent, vulnerable populations, adaptive study designs, data protection laws. BASEC, …	B. Gai C. Sessa G. Dal Pra