Good Clinical Practice (GCP) Entry Level

Online Training

Date: August 1-2, 2025

Hour: 13:30 GMT+2

Day 1 – 1st of August 2025

13:30 – 14:00	Registration
14:00 – 15:30	General Overview Of Clinical Trials
	• A short history of Good Clinical Practice (GCP) guidelines • Drug development and various types of clinical trials • The Principles of ICH GCP (International Council for Harmonization guidelines for Good Clinical Practice) • Declaration of Helsinki • Running a clinical trial - the steps
15:30 – 16:30	Responsibilities
	• Investigators' responsibilities • Monitoring responsibilities and limits • Sponsor's responsibilities
16:30 – 16:45	Coffee Break
16:45 – 17:15	Essential Documents In Clinical Trials
	• The significance of various documents in clinical trials • The patient file and other source documents in clinical trials (practical approach) • Medical history and physical examination • Concomitant medical conditions and related medication • Non-clinical investigations in clinical trials • ALCOAC principles in practice
17:15 – 18:00	Informed Consent
	• The Informed Consent Procedure • Legal representative, witness

Day 2 – 2nd of August 2025

13:30 – 14:00	Registration
14:00 – 15:00	Safety Reporting In Clinical Trials
	• Investigators to sponsor • Sponsor to authorities • The unblinding procedure
15:00 – 15:15	Coffee Break
15:15 – 16:20	Audits and Inspections
	• Audits and inspections including frequent audit findings • FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), sponsor inspections
16:20 – 17:30	Computerized system
	• Computerized system requirements • Electronic medical records • Electronic investigator site file • Electronic informed consent
17:30 – 18:00	Questions and answers
18:00	Test
	• Test (multiple choices) Note: Due to the interactive nature of the Agenda, the timing may change.

Course Description

ICH Good Clinical Practice (GCP) training is all about ensuring that clinical trials involving human participants are conducted ethically and to a high standard of quality. The training is based on the ICH E6 (R2) guidelines, which provide an international framework for the design, conduct, recording, and reporting of clinical trials.

The training covers various aspects of clinical trials, including the roles and responsibilities of sponsors, investigators, and other stakeholders, as well as the ethical and regulatory requirements that must be followed. It also provides practical guidance on how to apply GCP principles in real-world research settings.

The main objectives of ICH GCP training include:

- Protecting the rights, safety, and well-being of trial participants: Ensuring that participants are treated ethically, and their rights are respected throughout the trial.
- Ensuring the integrity and credibility of clinical trial data: Making sure that the data collected is accurate, reliable, and can be trusted for regulatory and scientific purposes.
- Facilitating mutual acceptance of clinical trial results: Harmonising standards across different regions to support global collaboration in drug development.
- Promoting transparency and accountability: Encouraging the registration of clinical trials and the reporting of results to maintain public trust.

Why Attend Our GCP Entry Level Course?

Comprehensive Curriculum: Our course covers all aspects of GCP, including regulatory requirements, ethical considerations, and practical implementation.

Expert Trainers: Learn from experienced professionals like Catalina Sarbu, who bring real-world insights and expertise to the training.

Interactive Learning: Engage in interactive sessions, case studies, and discussions to enhance your understanding and application of GCP principles.

Flexible Learning Options: Attend the course online via Zoom, making it accessible to professionals worldwide.

Certification: Upon completion, receive an internationally recognised certification from TransCelerate, demonstrating your competence in GCP. Participants will be able to download their Participation Certificates directly from their accounts on www.avantyo.com

Discount: Participants in Module 1 – GCP Training for Entry Level will enjoy a 15% discount on Module 2 – GCP Training for Advanced Level. This offer provides an excellent opportunity for those eager to continue their professional development in the field of clinical research.

Participants Profile

This training offers the opportunity to acquire basic Good Clinical Practice (GCP) knowledge for professionals willing to enter the clinical trials field. It is designed for a wide range of participants, including:

- Investigators and Clinical Study Teams: Individuals involved in the planning, conduct, and oversight of clinical trials.
- Clinical Referrals: Such as clinicians, general practitioners (GPs), and other healthcare providers who refer patients for clinical trials.
- Study Coordinators and Study Nurses: Professionals responsible for the day-to-day management of clinical trials, ensuring adherence to protocols and regulatory requirements.

- Physicians and Pharmacists: Medical professionals who play a crucial role in the administration and monitoring of clinical trials, ensuring patient safety and data integrity.
- Life Science Graduates: Individuals with a background in life sciences who are looking to transition into the clinical research field.
- Clinical Trials Assistants (CTAs): Professionals who provide administrative support to clinical research teams, helping to ensure the smooth conduct of trials.
- Clinical Research Coordinators (CRCs): Key personnel who manage the logistics and documentation of clinical trials, playing a vital role in the coordination between the clinical site and the research sponsor.
- Other Medical-Related Professionals: Including those in allied health fields, who aspire to build a career in the clinical research scientific domain.

This comprehensive training program aims to equip participants with the foundational knowledge of GCP principles, enhancing their ability to contribute effectively to the clinical trials process. It fosters the development of essential skills needed to navigate the complexities of clinical research, from ethical considerations to regulatory compliance and data management.

By participating in this training, professionals will be better prepared to embark on a rewarding career in clinical research, playing a crucial role in the advancement of medical science and patient care.

Online Instructor-Led Course

Organizers: Avantyo Institute of Clinical Research

Location: Online

Duration: 2-day sessions for 4 hours each day

Training days: August 1-2, 2025

Training time: From 2 PM GMT+2

Language: English / Romanian

Trainer: Dr. Catalina Sarbu

Attendance only by online reservation. Booking available after registering on this site.