

Clinical Trials for Study Coordinators

Online Training

Date: March 13-14, 2025

Hour: 10:00 GMT+2

Day 1 - 13th of March 2025

10:00	Registration
10:00 – 10:20	(Recent) History of Clinical Research <ul style="list-style-type: none"> • Historical events that shaped today's regulatory landscape of clinical research • Nuremberg Code (1947) • Declaration of Helsinki (1964) • The Belmont Report (1979) • ICH E6 (GCP) (1996) • ISO 14155 (2003)
10:20 – 11:20	ICH GCP and CFR 21 <ul style="list-style-type: none"> • International Council of Harmonisation Good Clinical Practice Guidelines (ICH E6 - GCP) • Principles of GCP
11:20-11:35	Coffee Break
11:35 – 12:05	Clinical Research Process and Study Design <ul style="list-style-type: none"> • Phases of clinical research • Clinical Study Designs
12:05-12:35	Understanding the Organization of Clinical Research <ul style="list-style-type: none"> • Investigational Sites • Pharmaceuticals/Biopharma Companies • Contract Research Organizations • Site Management Organizations • Vendors • Independent Ethics Committees (IEC)/Institutional Review Boards (IRB) • Health Authorities
12:35 -13:35	Lunch
13:35-13:55	Investigational Site Staff <ul style="list-style-type: none"> • Investigators

- Clinical Research/Study Coordinators
- Other research staffs
- Delegation Log

13:55-14:45 Study Protocol and Informed Consent Form (ICF) including practical exercise

- Clinical Study Protocol
- Informed Consent Form (ICF)
- Source Documents
- Medical Records
- Essential Documents (in accordance with ICH GCP)

Day 2 – 14th of March 2025

10:00 Registration

10:00-10:30 Safety Reporting in Clinical Trials

- Adverse Events
- Serious Adverse Events
- Adverse/Medical Events of Special Importance
- Concomitant Medication

10:30-11:10 The Study Coordinator

- Study Coordinator's Role
- Study start up
- Recruitment
- Preparing On-site and Remote Site Visits
- Relationship with site staff and communication lines
- Practical exercise

11:10-11:40 Investigational Medicinal Products (IMP)/Medical devices (MDev)

- Receipt and storage
- IVRS/IWRS
- Documentation
- Drug compliance

11:40-11:55 Coffee Break

11:55-12:25 Inspections and audits

- Preparing for an audit.

12:25-12:45 Wrap-up

Course Description

This comprehensive course is designed to equip study coordinators with the essential knowledge and skills needed to effectively manage and conduct clinical trials. Participants will gain a thorough understanding of the clinical trial process, including project management, research design, protocol development, and regulatory compliance.

Through a combination of lectures, practical exercises, and interactive discussions, participants will be well-prepared to contribute effectively to clinical trials. This holistic approach ensures not only the acquisition of theoretical knowledge but also the development of practical skills essential for real-world application. Participants will be able to navigate the complexities of clinical trials, manage various aspects of the study efficiently, and ensure strict adherence to protocols and regulatory standards. By the end of the course, participants will have the confidence and competence to play a pivotal role in advancing clinical research and contributing to the success of clinical trials.

Key topics covered include:

- Phases and Designs of Clinical Research: Understand the different phases and designs involved in clinical research.
- Roles and Responsibilities of Investigational Site Staff: Learn about the roles and duties of various staff members at investigational sites.
- 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.
- Development and Management of Study Protocols and Informed Consent Forms: Gain expertise in creating and managing study protocols and informed consent forms.
- Safety Reporting: Learn about adverse events, serious adverse events, and other safety reporting requirements.
- Role of the Study Coordinator: Understand the responsibilities of a study coordinator in study start-up, recruitment, and site visits.
- Management of Investigational Medicinal Products and Medical Devices: Learn how to manage investigational medicinal products and medical devices.

Why Attend Our Clinical Trials For Study Coordinators Course?

Comprehensive Understanding of Clinical Trials: Gain the ability to prepare sites for clinical trial start-up with an in-depth understanding of the entire clinical trial process, from project management to research design and protocol development.

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

Effective Clinical Trial Conduct: Learn to conduct clinical trials proficiently by mastering patient recruitment and retention strategies, data management, data monitoring, pharmacovigilance, safety reporting, and good financial practices.

Quality Systems and Compliance: Acquire the skills to design and maintain the quality system of a clinical trial by implementing Standard Operating Procedures (SOPs), handling audits and inspections, and ensuring other aspects of Quality Assurance (QA) and Quality Control (QC).

Research Site Management: Identify and address key challenges in managing research sites, including developing and maintaining site capacity, engaging with the community, and managing grants efficiently.

People Management and Collaboration: Develop essential people management skills and techniques that will enhance your ability to work effectively with internal colleagues and external partners. This offer provides an excellent opportunity for those eager to continue their professional development in the field of clinical research.

Participants Profile

A Clinical Research Coordinator (CRC) plays a crucial role in managing clinical research according to the protocol, International Council for Harmonisation (ICH) - Good Clinical Practice (GCP), and other regulatory requirements. The responsibilities of a CRC are diverse and encompass various aspects of clinical trial management, including but not limited to:

- **Questionnaire Administration:** Administering questionnaires to participants to gather relevant data for the study.
- **Participant Information:** Informing participants about the objectives, procedures, and expected outcomes of the study.
- **Data Collection:** Collecting, recording, and maintaining accurate data from participants throughout the trial.
- **Recruitment:** Actively participating in the recruitment and screening of subjects to ensure they meet the inclusion and exclusion criteria for the study.
- **Trial Management:** Overseeing the day-to-day activities of clinical trials, ensuring they adhere to the established protocols and regulatory standards.

Additionally, Clinical Research Coordinators have the critical task of explaining to subjects what to expect during the trial and addressing any concerns they may have. This interaction necessitates strong communication and interpersonal skills, as CRCs must build trust and ensure participants feel informed and comfortable throughout the trial process.

Key Skills and Competencies:

- **Effective Communication:** The ability to clearly and effectively communicate information to participants, study teams, and other stakeholders.
- **Interpersonal Skills:** Building rapport and maintaining positive relationships with participants and colleagues.
- **Organizational Skills:** Managing multiple tasks and maintaining detailed records to ensure trial adherence and accuracy.
- **Ethical Awareness:** Understanding and upholding ethical standards in clinical research, ensuring participant safety and confidentiality.
- **Problem-Solving:** Addressing issues that arise during the trial and finding effective solutions to ensure smooth trial progress.

Qualifications and Experience:

- **Educational Background:** A degree in a relevant field such as life sciences, nursing, pharmacy, or a related discipline.
- **Experience:** Previous experience in clinical research or a related field is highly desirable.
- **Certification:** Certification in Good Clinical Practice (GCP) and familiarity with ICH guidelines are essential.

By fulfilling these roles and responsibilities, Clinical Research Coordinators play a vital part in the success of clinical trials, contributing to the advancement of medical knowledge and the development of new treatments. Their dedication ensures that clinical research is conducted ethically, accurately, and efficiently, ultimately benefiting patient care and medical progress.

Online Instructor-Led Course

Organizers: Avantyo Institute of Clinical Research

Location: Online

Duration: 2-day sessions for 4 hours each day

Training days: March 13-14, 2025

Training time: From 10 AM GMT+2

Language: English

Trainer: Dr. Goran Vesov, MD

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