Clinical Research Associate (CRA) Entry Level

Online / Hybrid Training

Day 1

General Overview Of Clinical Trials

- 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

Responsibilities

- Investigators' responsibilities
- Monitoring responsibilities and limits
- Sponsor's responsibilities

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

Informed Consent

- The Informed Consent Procedure
- Legal representative, witness

Safety Reporting In Clinical Trials

- Investigators to sponsor
- Sponsor to authorities
- The unblinding procedure

Audits and Inspections	
	• Audits and inspections including frequent audit findings • FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), sponsor inspections
Miscellaneous	
	• Data management, statistical analysis • Archiving of clinical trials at the site (ISF) and sponsor (TMF) • Site contracts and investigators/institutions payment • Subcontracted vendors
Questions and answers	
Test	
	• Test (multiple choices) Note: Due to the interactive nature of the Agenda, the timing may change. Participants must achieve a minimum score of 80% in order to pass the assessment.

Course Description

A Clinical Research Associate (CRA) plays a central role in ensuring that clinical trials are conducted in full accordance with Good Clinical Practice (GCP) guidelines and all relevant legislation.

Our Clinical Research Associate (CRA) Training Programme has been carefully designed to develop your knowledge and practical abilities, helping you remain at the forefront of developments in the clinical research field as a fully qualified CRA.

This essential "how-to" and "why" course focuses on current professional practice. You will examine the CRA's responsibilities within the regulatory framework governing clinical trials and gain a realistic understanding of the role through an insight into a typical working day. You will also review mock protocols and study documents to reinforce and apply your learning.

Module 1 – CRA Training for Entry Level is specifically tailored for junior Clinical Research Associates (CRAs), Clinical Trial Assistants (CTAs), and individuals preparing to begin a career in clinical trial monitoring, including physicians, pharmacists, residents, students, biologists, and biochemists.

Why Attend Our CRA Beginner Course?

Comprehensive Curriculum. Our course provides thorough coverage of all key aspects of the CRA role, including regulatory requirements, ethical considerations, and practical implementation.

Expert Trainers. You will learn from experienced professionals, who bring real-world insight and extensive industry expertise to the training.

Interactive Learning. You will take part in interactive sessions, case studies, and guided discussions designed to strengthen your understanding and practical application of GCP principles.

Flexible Learning Options. The course is delivered online via Zoom, ensuring convenient access for participants across the world.

Recognised certification: On completion, participants receive an internationally recognised TransCelerate-aligned certificate. Certificates can be downloaded directly from each participant's account on www.avantyo.com..

Discount. Participants in Module 1 – CRA Training for Entry Level will receive a 15% discount on Module 2 – CRA Training for Advanced Level, offering an excellent opportunity to continue developing professionally in the field of clinical research.

Participants Profile

Module 1 – CRA Training for Entry Level is designed for individuals preparing to begin a career in clinical trial monitoring. It is suitable for a wide range of early-career professionals, including:

- Junior Clinical Research Associates (CRAs). Those who have recently entered the field and require a structured introduction to monitoring responsibilities.
- Clinical Trial Assistants (CTAs). Professionals supporting clinical research teams who wish to progress into a monitoring role.
- Life-science graduates. Individuals with backgrounds in biology, biochemistry, pharmacy, or related fields who are seeking a pathway into clinical research.
- Medical professionals. Physicians, pharmacists, residents, and other healthcare practitioners interested in transitioning into clinical trial oversight.
- Students and early-career researchers. Those aiming to build a foundation in clinical research and develop the skills needed for future CRA roles.
- Other science-related professionals. Individuals working in allied health or scientific environments who wish to enter the clinical research sector.

This module provides a solid grounding in the principles and practicalities of clinical trial monitoring. The programme equips you with the essential knowledge and skills required to perform effectively in an entry-level CRA role, ensuring you are well prepared to navigate the ethical, regulatory, and operational demands of the clinical research environment.

Training content covers a wide range of topics, including the ethical and regulatory framework governing clinical trials, the fundamentals of study design and protocol development, and the importance of participant safety and data integrity. You will also gain insight into the various phases of clinical trials, the responsibilities of key stakeholders, and best practice in managing and documenting trial activities.

The course is delivered through an engaging combination of lectures, practical exercises, and real-world case studies. This interactive approach ensures that you not only understand the theoretical concepts but can also apply them confidently in day-to-day practice.

Upon completing Module 1, you will be well equipped to take on the responsibilities of a Clinical Research Associate, contributing to the successful conduct of clinical trials and supporting the advancement of medical science.

Trainer Profile – Dr Catalina Sârbu

Dr Catalina Sârbu is a medical doctor with more than twenty years' experience in clinical research, clinical operations and the leadership of complex trial activities. Her career spans medical practice, specialist training and senior roles within the contract research sector, giving her a balanced understanding of both the clinical and operational realities of running trials.

She has worked extensively with investigators, sponsors, regulatory authorities and international project teams, and is known for her ability to translate regulatory requirements into practical, workable approaches at site level. Her background in haematology and general practice provides a strong clinical foundation, while her long tenure in CRO leadership has given her a clear view of industry expectations, operational constraints and the responsibilities carried by each party involved in a study.

In training settings, Dr Sârbu is valued for her clarity, her calm and structured delivery, and her ability to explain Good Clinical Practice in a way that is both accurate and directly applicable to day-to-day work. She brings real examples from her professional experience, helping participants understand not only what the regulations require, but why those requirements exist and how they can be met in practice.

Her professional background includes:

- Secretary General of the Romanian Association of CROs (ACCSCR), 2022–2025
- Director of the Romanian Representative Office of PAREXEL Nederland BV, 2000–2022
- Former President of the CRO Association in Romania (ACCSCR)
- General Practitioner – Centre of Haematology, Ploiești, Romania
- Haematology and Blood Transfusion, Saint Antoine University, Paris – one-year programme
- Medical Doctor degree, University of Medicine and Pharmacy, Bucharest