Clinical Research Coordinator Training Program

The Clinical Research Coordinator (CRC) Training Program was developed in collaboration with some of the top coordinators from North America, extending across all types of practices and therapeutic areas. The comprehensive nature of this course brings together the expertise of many disciplines in the industry.

The CRC training program was designed for both clinical research coordinators who are entering the industry and those who are looking to develop their skills further.

This course has been designed to provide comprehensive, performance based content blended with real world applications. After reviewing the comprehensive content, students will use scenario based learning to apply these skills and ensure retention of the content.

Certificates of completion and comprehension will be issued after the student has completed the module assessments and final course comprehension test. These should be retained and presented as evidence of training to Sponsors, CROs, ethics board, and regulatory authorities.

Module Content Breakdown

1. Introduction to Clinical Research
    a. Introduction
    b. Drug discovery and pre-clinical research
    c. Roles and responsibilities
    d. Investigational New Drug applications
    e. New Drug Application and post marketing
    f. Phases of clinical research
    g. Clinical study designs
2. The Clinical Research Coordinator
    a. Background and training
    b. Responsibilities
    c. Certification
3. Good Clinical Practice (Transcelerate recognized GCP training)
    a. What is GCP and why is it important
    b. Goals of GCP
    c. Foundations of GCP
    d. Principles of GCP

e. Applying the principles of GCP
f. Subject Safety
g. Roles and responsibilities
h. Documentation and record keeping
i. Research Misconduct

4. Informed Consent
    a. What is informed consent?
    b. Informed Consent Form
    c. Preparing an informed consent form
    d. Informed consent process & conducting the informed consent discussion
    e. Documentation of informed consent
    f. Identifying vulnerable populations
    g. Informed consent and assent in children and vulnerable populations
    h. Informed consent in emergency medical situations
5. Study Protocols
    a. Purpose
    b. Navigating protocol contents
    c. Protocol amendments
    d. Handling protocol deviations
6. Study Start up and Initiation
    a. Feasibility assessment & Site qualification
    b. Developing study budgets
    c. Ethics approval; application and maintenance
    d. Documentation requirements
    e. Site initiation Visit and opening to recruitment
7. Study Conduct
    a. Subject recruitment & screening
    b. Enrollment / randomization
    c. Baseline assessments and activities
    d. Ongoing protocol required assessments and study visits
    e. Subject compliance
    f. Subject retention, early termination
    g. End of study visit
    h. Investigational product accountability
8. Investigator Site File & Essential Documents
    a. Contents / required documentation
    b. Organization
    c. Maintenance

9. Data Management, Source Documentation & Case Report Forms
    a. Data management & process overview
    b. Source documentation
    c. Case report forms
    d. Queries and corrections
    e. Ensuring high quality data
10. Adverse Events, Safety Monitoring and Reporting
    a. Definitions
    b. Source of adverse events
    c. Documenting in source and case report forms
    d. Determining relatedness
    e. Coding- MeDRA & CTCAE
    f. Investigator and sponsor reporting requirements
    g. Data Safety Monitoring Boards
    h. Common errors in safety reporting
11. Study Monitoring
    a. Purpose
    b. Monitoring activities overview
    c. Monitor and site responsibilities
    d. Scheduling and preparing for monitoring visits
    e. What to except during monitoring visits
    f. Monitoring visit follow-up
12. Study Closure
    a. Early termination or completion of enrollment
    b. Closure procedures
    c. Investigator and sponsor responsibilities
    d. Record retention
13. Audits
    a. Audits vs ongoing monitoring
    b. Who can audit your site & audit target considerations
    c. Preparing for an audit
    d. During the audit
    e. Follow up and consequences
    f. Root cause analysis and CAPA (corrective action & preventative action)

For more information on the Clinical Research Coordinator Training Program and more course offerings please visit www.Advantage-Clinical.com or contact us at:

Email: info@advantage-clinical.com
Telephone: 1-800-674-8802

This course is part of our Organizational Subscriptions program.