Clinical Research Coordinator

The role of a clinical research coordinator is important in facilitating the successful implementation of clinical research studies, ensuring participant safety and generating reliable and valid research findings.

Clinical research coordinators play a vital role in ensuring that all research activities comply with ethical guidelines, regulatory requirements and institutional policies, the protocol and SOP's.

Description

The course is designed to provide a practical context to help clinical research professionals learn more about conducting and coordinating clinical trials. Staff who are new to the research environment will also find the course beneficial, as it provides a comprehensive overview of the role of a clinical research coordinator and various site activities.

Available as classroom training

Content

Introduction.
Module 1: Introduction to Clinical Research.
Module 2: The Role of the Clinical Research Coordinator During the Pre-Study Phase.
Module 3: The Role of the Clinical Research Coordinator During the Study Conduct Phase.
Module 4: The Role of the Clinical Research Coordinator During the Study Termination Phase.
Final Assessment.

Cost

Classroom - R5,100 (VAT incl.)

For group discounts, please contact us at:
training@academicadvance.co.za

Duration

The classroom training is three full days (from 08h30 to 16h00).

Target Audience

Clinical Research Clinicians, Nurses and research professionals.

Certification

Delegates are required to complete a final assessment with at least 70% accuracy.

Upon successful completion of the course, the delegate will be given access to the Certificate of Completion.

CPD Points

CPD points will be issued with the certificate of completion.

In-House Training

In-house training will be considered, subject to viability.

https://www.academicadvance.co.za/
training@academicadvance.co.za
+27 11 274 9327/9263/9368
31 Princess of Wales Terrace, Parktown, 2193

Learning Outcomes

Module 1: Introduction to Clinical Research

- Understand clinical study design, Sponsor roles and ethical principles.
- Understand Good Clinical Practice (GCP).
- Understand Human Subjects Protection (HSP).
- Define essential documents:
  - Investigator File,
  - Protocol,
  - Manual of Procedures (MOP) and
  - Standard Operating Procedure (SOP).

Module 2: The Role of the Clinical Research Coordinator During The Pre-Study Phase

- Understand the CRC's responsibilities and required skills.
- Assess study suitability, manage budgets and engage stakeholders.
- Prepare study documentation, informed consent and research teams.
- Develop recruitment and retention strategies.

Module 3: The Role of the Clinical Research Coordinator During the Study Conduct Phase

- Recognise the importance of quality in clinical research and how to maintain high standards.
- Learn the procedures involved in a site initiation visit.
- Understand the recruitment and retention strategies for research participants.
- Familiarise with the process of informing and consenting participants.
- Understand the screening and randomisation processes in clinical trials.
- Learn clinic flow management and use of checklists and chart notes in research.
- Understand the role of Case Report Forms (CRFs) and their significance in data collection.
- Learn the requirements for safety reporting and handling adverse events.
- Understand the importance of data and safety monitoring plans.
- Learn quality management strategies and the role of monitoring, audits and inspections.
- Understand the principles of effective communication and staff management in clinical research.
- Learn how to coordinate and plan tasks, manage finances and ensure smooth trial operations.

Module 4: The Role of the Clinical Research Coordinator During the Study Termination Phase

- Understand the preparations required for study close-out.
- Learn the steps involved in completing a study close-out checklist and final site close-out procedures.
- Recognise the importance of handling premature study termination.
- Understand the Sponsor/Monitor's role in the close-out visit.
- Learn the process of archiving study documents and results.
- Understand the guidelines for disseminating study results.
- Familiarise with the structure and requirements of a clinical study report.

This course is administered by Academic Advance and authored by Chameleon Clinical Research Consultants.