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 - R4,500 (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 Clinical Research Coordinator Certificate of Completion.

CPD Points

CPD points will be issued with the certificate of completion.

(20 CPD points).

In-house Training

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

academic advance

Http://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 study design.
- 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 DNA of a CRC.
- Explain the purpose of a CRC.
- Understand basic skills needed as a CRC.
- Understand knowledge and skills to develop/grow in the role of a CRC.
- Understand the role of a CRC during the:
  - Pre-study phase,
  - Study conduct, and
  - Study termination.

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

- Understand site initiation.
- Explain monitoring.
- Understand patient enrollment.
- Understand follow-up visits.
- Understand data management/statistical review.
- Implement leadership and professionalism.
- Implement communication and teamwork.

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

- Explain preparation for study end.
- Consider creating a checklist for exit visit of participants.
- Explain study close-out checklist.
- Explain site close-out.
- Understand premature termination.
- Understand close-out visit from sponsor/monitor.
- Understand close-out letter and document.
- Understand ICH Guidelines 8.4.
- Understand archiving.
- Understand dissemination of results.
- Understand clinical study report.

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