

GOOD CLINICAL PRACTICE (GCP) REFRESHER FOR NON-CLINICAL SUPPORT STAFF



Introduction

In addition to the clinical personnel, a clinical research team may include a number of non-clinical support staff for example, those who may deal only with documents, recruit/follow up Participants, counsel Participants, transport Participants to/from appointments. It is imperative that this category of staff understand the concept of clinical trials, the guidelines that govern the conduct and roles of the study team and the importance of their role in the greater team.

Course Overview

This course is a revision of Good Clinical Practice principles and processes for all non-clinical support staff who have previously attended GCP training. The course is interactive and discussion around current issues is encouraged.

Course Content

- Good Clinical Practice Overview
- GCP Audits and Inspections
- Research Involving Genetic Studies
- Litigation in Clinical Trials
- Informed Consent Deficiencies
- Conflict of Interest
- Breach of Contract
- Compensation
- Class Action
- Topical Issues in Clinical Research
- Risk Based Monitoring

Accreditation and Registration

- The course is HPCSA accredited— 2 CPD and 4 Ethics points
- This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors. <http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/>



Target Audience

Non-clinical support staff, such as counselors, fieldworkers, recruiters, data capturers, study administrators, drivers, etc.

Course Duration

4 hours

(Start and end times may vary slightly, confirmation will be provided on registration)

Course Fee

R 1,250.00 incl VAT (Non-WHC)

R 850.00 ex VAT (WHC Divisions/Syndicates)

Venue

BEESA Conference Centre,
Unit 3, Sherborne Square,
5 Sherborne Rd, Parktown, 2193

Courses are also offered in Durban on a regular basis and in Cape Town subject to a minimum number of attendees.

On-site training for groups of 20 or more will be considered, subject to viability.

Booking

Please contact Melody Maddocks or Janine Roper.

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