

GOOD CLINICAL PRACTICE (GCP) BASIC COURSE 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 Delegates, counsel Delegates, transport Delegates 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 comprehensive GCP course is adapted for the needs of non-clinical support staff. The course covers ICH and SA Good Clinical Practice guidelines and practical exercises applicable to this category, are included. Certificates of Completion are issued on the successful completion of an open book post-course assessment.

Course Content

- Drug Development Process
- Historical Review of GCP
- South African GCP
- Regulatory Process in SA
- Patient Recruitment and Retention
- Study Documents
- Informed Consent
- Investigational Product
- Safety Reporting

Accreditation and Registration

- The course is HPCSA accredited— 6 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

1 day

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

Course Fee

R 2,300.00 incl VAT (Non-WHC)

R 1,800.00 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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<http://www.academicadvance.co.za>