

GOOD CLINICAL PRACTICE (GCP)

Basic Course

2018

Introduction

Medical research involving human subjects is strictly controlled by the Medicines Control Council of South Africa and Ethics Committees. It is mandated that the research team be well versed with the International (ICH) and SA Good Clinical Practice guidelines. Each member of the team must be in possession of a valid, accredited GCP certificate.

Course Overview

The GCP Basic course is an introductory 1½ day course that will give a detailed overview of clinical research, the current ICH and SA GCP guidelines and the process of conducting successful clinical trials from start to finish. Certificates are issued on the successful completion of an open book post-course assessment.

Course Content

| Day 1 | Day 2 |
|---|--|
| <ul style="list-style-type: none">• Drug Development Process• Development of GCP• South African GCP• Regulatory Process in South Africa• Study Documents• Patient Recruitment and Retention• Informed Consent | <ul style="list-style-type: none">• Investigational Product• Safety Reporting• Responsibilities of the Study Team• Data Privacy• Standard Operating Procedures• Laboratory Issues• Sponsors• Audits |



Target Audience

Investigators, study coordinators, scientists and project or site managers new to clinical trials.

Course Duration

1 ½ days

Course Fee

R 3,000.00 incl VAT (Non-WHC)

R 2,150.00 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

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

Booking

Please contact us at:

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training@academicadvance.co.za

<http://www.academicadvance.co.za>

Accreditation and Registration

- The course is HPCSA accredited—11 CPD points plus 4 Ethics points .
- The certificate is recognised by Ethics Committees and Medicines Control Council of South Africa.
- 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/>