GOOD CLINICAL PRACTICE (GCP)

Basic

VENUE

Ground Floor Training Room
31 Princess of Wales Terrace
Parktown, Johannesburg, 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.

COURSE FEE

R 3,230 incl VAT(Non-WHC)
R 2,280 excl VAT(WHC Divisions)

COURSE DURATION

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

BOOKING

Please contact us at:
+27 11 274 9256/9327/9200
training@academicadvance.co.za
http://www.academicadvance.co.za

INTRODUCTION

Medical research involving human subjects is strictly controlled by the South African Health Products Regulatory Authority (SAHPRA) 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 1.5 day course that will give a detailed overview of clinical research,the current ICH and SAGCP guidelines and the process of conducting successful clinical trials from start to finish.Certificates are issued on the successful completion of an openbook post-course assessment.

COURSE CONTENT

- Drug Development
- Process
- Development of GCP
- South African GCP
- Regulatory Process in South Africa
- Study Documents
- Patient Recruitment and Retention
- Informed Consent
- Investigational Product
- Safety Reporting
- Responsibilities of the Study Team
- Data Privacy
- Standard Operating
- Procedures
- Laboratory Issues
- Sponsors and Audits

ACCREDITATION AND REGISTRATION

- The course is HPCSA accredited— 9 CPD and 2 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

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

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