



GOOD CLINICAL PRACTICE (GCP)

Basic Course for Support Staff

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 2,500 incl VAT(Non-WHC)

R 1,900 excl VAT(WHC Divisions)

COURSE DURATION

1 Day (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

In addition to the clinical personnel, a research team may include a number of support staff who recruit participants, take informed consents, counsel participants, transport participants, carry out laboratory procedures, capture data, etc. It is imperative that this category of staff understands the concept of research on human subjects, the guidelines that govern the conduct of this research, the roles of the study team and the importance of their role in the greater team.

COURSE OVERVIEW

This comprehensive GCP course is tailored for the needs of support staff. The course covers current ICH and SA Good Clinical Practice guidelines and practical exercises applicable to this category, are included. Certificates are issued on the successful completion of an open book post-course assessment.

COURSE CONTENT

- Drug Development Process
- Development of GCP
- South African GCP
- Regulatory Process in SA
- Study Documents
- Patient Recruitment and Retention
- Informed Consent
- Investigational Product
- Safety Reporting
- Responsibilities of the Study Team
- Data Privacy
- Standard Operating Procedures
- Monitoring and Auditing

ACCREDITATION AND REGISTRATION

- The course is HPCSA accredited— 6 CPD points
- This ICH E6 (R2) 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>