

# GOOD CLINICAL PRACTICE (GCP) BASIC COURSE



Academic Advance is a division of Wits Health Consortium (Pty) Ltd



## Introduction

Robust Good Clinical Practice (GCP) standards are necessary in addition to the ethical guidelines because clinical trials may have complex trial designs that involve invasive interventions, as well as investigative products and procedures that pose more than minimal risk of harm for participants. Compliance with these guidelines are mandated.

The GCP Basic course is an introductory course that provides a detailed overview of clinical research, the current ICH and SAGCP Guidelines, Doh 2015 - Ethics in Health Research Guidelines, as well as the process of conducting successful clinical trials from start to finish.

## Content

- Module 1: Introduction to Clinical Trials.
- Module 2: Role-players in Clinical Trials.
- Module 3: The development of GCP.
- Module 4: SA GCP.
- Module 5: Informed Consent.
- Module 6: Ethics Guidelines (DoH 2015).
- General.
- Final Assessment.

## Final Assessment

At the end of this course, learners will be expected to complete a final assessment:

- There are 50 multiple choice questions.
- The pass mark is 70%.
- Learners have (2) attempts.
- A certificate will be issued on passing the assessment.

## Target Audience

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

## CPD Points

CPD points will be issued with the certificate of completion.

### Available Options

#### Classroom

Classroom based (2 days)

R 3,850 Incl Vat

R 2,650 Excl Vat (WHC divisions | projects)

#### Online

Online learning (self-paced)

R 2,640 Incl Vat

R 2,295 Excl Vat (WHC divisions | projects)

#### Hybrid

Zoom virtual training (4 hours) & Online learning (self-paced)

R 2,790 Incl Vat

R 2,425 Excl Vat (WHC divisions | projects)

● For group discounts, please contact us!

● Check our training calendar online.

● In-house training will be considered, subject to viability.