

# CLINICAL RESEARCH MODULES



## Introduction

Academic Advance is proud to offer three practical clinical research modules aimed at individuals involved in the conduct of clinical trials, who would like a refresher on these key topics or who would like to expand on their existing knowledge.

Module 1



Module 2



Module 3

## Fees (Per Module)

R 600, incl VAT (Non-WHC)

R 450 ex VAT (WHC Divisions/Syndicates)

## Course times

Reading a Protocol	08h30 - 11h00
Essential Documents	11h00 - 16h00
Informed Consent	08h30 - 12h30

## Venue

BEESA Conference Centre,  
Unit 3, Sherborne Square,  
5 Sherborne Rd, Parktown, 2193

## Booking

Please contact us at;

+27 11 274 9256/ 274 9368 / 274 9200

[training@academicadvance.co.za](mailto:training@academicadvance.co.za)

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

## Reading a Protocol - Module 1

This module aims to assist delegates to understand the purpose of a protocol, to read, interpret and apply the research protocol as a clear blueprint for the conduct of a clinical trial. Knowing and applying the basics of a protocol reduces errors and leads to greater efficiencies.

At the end of this module the delegate will be able to:

- Understand the purpose of the protocol and the impact on the resulting data reliability and significance
- Distinguish between different meanings of the term 'protocol'
- Identify the characteristics of a high quality research protocol
- Apply the protocol as the blueprint in a clinical research setting
- Understand the consequences of non-compliance (protocol deviations)

## Essential Documents - Module 2

This module aims to highlight the importance of reliable trial data for compliance, audit and quality purposes, as well as for the successful management and validity of a clinical trial.

At the end of this module the delegate will be able to:

- Understand the purpose of keeping detailed records of every aspect of the clinical trial
- Distinguish between and compile the various types of essential documents which should be generated for each phase of the clinical trial
- Demonstrate compliance with the standards of Good Clinical Practice
- Avoid protocol deviations by creating accurate and compliant essential documentation

## Informed Consent - Module 3

This module aims to equip delegates with essential knowledge on how to provide a potential participant with information that is compliant and comprehensive, yet easy to understand, allowing the participant to make an informed decision. The informed consent process forms the cornerstone of ethical conduct within clinical trials.

At the end of this module the delegate will be able to:

- Prepare and review an informed consent document according to Good Clinical Practice guidelines and applicable governing bodies
- Apply knowledge about Regulations governing consent
- Execute a proper informed consent process
- Recognise and understand how to approach vulnerable groups and individuals