CLINICAL RESEARCH

STUDY COORDINATOR COURSE (3 days)

Target Audience:

This course is recommended for anyone who is involved in the coordination of a clinical trial, including study coordinators, project heads and managers.

Staff who are new to the research environment will also find the course beneficial, as it provides a comprehensive overview of the role of a study coordinator and various site activities.

Prerequisite Learning:

A working knowledge of the principles of GCP

Course Fee:

R 4,500 VAT Incl. per delegate
R 3,950 VAT Excl. WHC divisions

Course Outcomes:

At the end of the course delegates will have a good understanding of;

- the multifaceted workings of a clinical trial in a research environment
- the responsibilities as clinical trial study coordinator in accordance with GCP
- dealing with the practicalities of conducting a trial in compliance with GCP guidelines
- the importance of the role of the study coordinator

Course Outline:

Module 1

Introduction to clinical research, including study design, sponsors, GCP, HSP, essential documents, MOP's, SOP's, protocol and investigator file.

Module 2

The role of the study coordinator during the pre-study phase, including pre-study phase overview, application for approval, suitability of study, budgets and funding, important stakeholders and their roles, informed consent form, set up of research team, participant recruitment and retention, study documentation and study files.

Module 3

The role of the study coordinator during the study conduct phase, including site initiation visit, recruitment and retention, informing and consenting participants, screening, randomisation and clinic flow, checklists, quality management, monitoring, audits, staff management and financial management.

Module 4

The role of the study coordinator during the study termination phase, including preparation for study termination, study close-out checklist, close-out visit from sponsor/monitor, close-out letter and document, archiving, dissemination of results and the clinical study report.

What do our delegates say about the course?

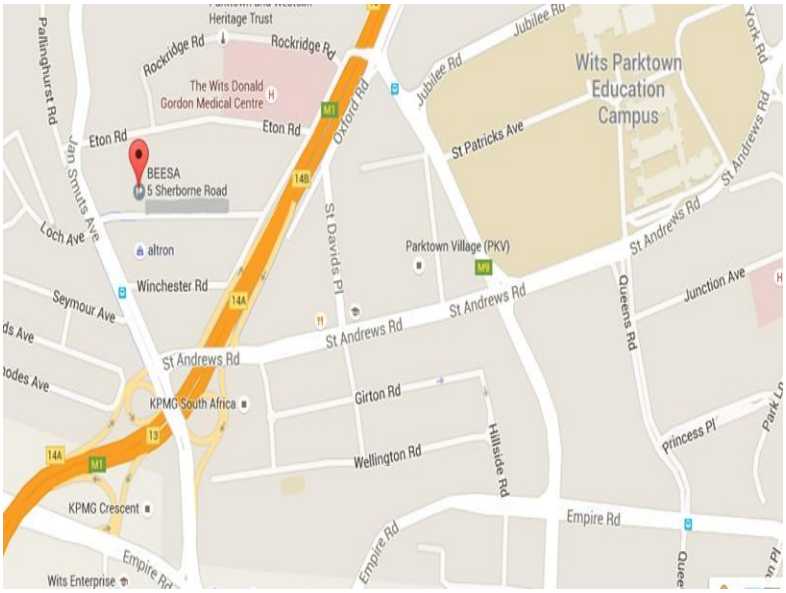
- The course was very informative and detailed. Material was well presented and relevant.
- Notes provided very useful. I definitely benefited from attending the course.
- I have learnt a lot, our facilitator is competent, experienced and equipped us with more information that will be good to our studies/research.
- Was an eye opener, small things we tend to take for granted.
- Checklist experience just clarified on how to do a QC and also minimise findings on a SDU report.
- Thank you for the opportunity and information shared.
- Training was generally informative and beneficial.

About the Facilitator

Wilma Pelser has extensive experience in the clinical research environment. She has been employed as study coordinator, study manager, project manager, project head, as well as consultant for various projects since 2002.

She holds a B.A. Cur. Degree (1983 – 1986) from UNISA, as well as B. Soc. Sc. Hons Degree (1978 – 1982) from the University of the Free State.

In addition to in-house training, Wilma has also completed various courses through Johns Hopkins University, Bloomberg School of Public Health, Wits Medical School and NIH as part of her personal development.



Course Times:

08h30-16h00 3 Full Days

Venue:

BEESA Conference Centre,

Unit 3, Sherborne Square,

5 Sherborne Rd, Parktown, 2193

Courses are also offered in Durban and in Cape Town subject to a minimum number of attendees.

Registration:

Please contact Melody Maddocks or Janine Roper.

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