TFS Trial Form Support - Global Trainee Program

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Objective

The objective of the trainee program is to provide participants with a basic understanding of the clinical development of pharmaceutical products with focus on clinical studies. After completion of the program, the trainees will have a clear understanding of GCP, applicable regulatory regulations, guidelines for conducting clinical research and the monitoring process. After the completed course trainees should have the basic skills and knowledge to work as a Clinical Research Associates (at a junior level), Clinical Research Administrators or Data Entry Associates.

Requirements

Trainees should have at least 2 years full-time university studies in life science, medicine, or similar field. Furthermore, trainees should have a good working knowledge of the English language and MS Office package.

Previous knowledge/experience from the pharmaceutical industry and/or clinical research is a merit but not mandatory.

Trainee Program

The program consists of twelve modules which will be conducted as a combination of lectures, practical exercises and self studies. In addition, four visits to external sites will be offered. The sites that will be visited are: preclinical laboratory, clinical phase I unit, clinical laboratory and clinical research unit at pharmacy. The total duration of the program is planned to be 3 months.
Candidates are required to pass both a written and an oral examination at the end of the course. In order to receive certification candidates are required to have at least 70% correct in the examination. Additionally candidates should have been present for at least 90% of the time.

Lectures and practical moments will be performed in Stockholm, Sweden.

Tuition fees

The cost for the trainee program is 2200 Euros including VAT. Costs for travel and accommodation will be covered by the trainee.

Scholarship

A scholarship will be awarded to the two candidates who are judged by the trainers to have achieved the best results in the program. The trainers' decision cannot be questioned and will not be based on examination results alone but will be based on the trainers overall perception of the candidates suitability for a role in clinical research. The scholarship will consist of reimbursement of the tuition fees 2200 Euros including VAT.

Registration

Registration is performed by completing the registration form at the end of this document. Applications should be received not later than 10 August 2007.

Candidates who fulfil application criteria will be offered a place on the course on a first come first served basis. However, a limited number of places are reserved for internal candidates. If all these places are not filled they will be offered to applicants who fulfil application criteria in the order in which we received them after the internal process has been finalised in August.

Block I

Module 1: Introduction

Introduction to clinical research:

- From identification of substance to marketing of the product
- Terminology
- Phase I to phase IV
- Study design
- Investigational Products

Module 2: Regulations and Guidelines

The main focus of this module is Good Clinical Practice GCP as defined by ICH E6 guideline and the declaration of Helsinki. The module will also address the EU Directive and its implementation in different countries. Other regulations and guidelines relevant for clinical studies will also be presented and discussed, such as Data Protection Act, Annex 13.

Module 3: Regulatory Environment

This module will focus on application to regulatory authorities and ethics committees and Guidance documents for application to competent authority/ethics committee.

Block II

Module 4: Data Management

The aim is to provide trainees with an understanding of what data management is and how data in clinical studies are collected and entered into a database. Various data management documents, such as Data Management Plan, Data Entry Manual and Data Validation Plan will be discussed.
Case Report Form design, data entry, data clarification procedures and clean file procedures will also be presented.
The practical session will involve entry of data into a study database.

Module 5: Monitoring

Monitoring according to ICH/GCP: site selection, site initiation, site monitoring and site closure. The module will also include how to write a monitoring report and study file management.
A large part of this module will be devoted to simulated monitoring visits and in house monitoring as well as study files.

Module 6: Drug safety

This module will focus on drug safety. What is an adverse event? What is the difference between an SAE and a SUSAR? Coding of adverse events, diseases and medications according to MedDRA.

This module will include a practical session, which mainly consists of coding of adverse events and medication.

Block III

Module 7: Statistics

A short introduction to basic statistics, according to ICH E9 guideline, in order to provide trainees with a basic understanding of statistics as related to clinical trials. The introduction will provide participants with information regarding for example the role of statistics in clinical studies, sample size determination and study design.

Module 8: Essential Documents

In this module, focus is on the essential documents as defined by ICH-GCP guidelines, i.e. what to archive at investigator site and at sponsor.
The study protocol and subject information/informed consent form, will be presented in more detail combined with a practical session.

Module 9: Clinical Study Report

This module will focus on clinical study report as defined in the ICH E3 guideline.

Block IV

Module 10: Quality Assurance

This module will focus on quality assurance. What is quality assurance? What is quality control? What is the difference between an audit and an inspection? Why do we need Standard Operating Procedures?

Module 11: Investigational Medicinal Products

This module will present how investigational medicinal products should be manufactured according to GMP (Annex 13) and how to label the product to be used in a clinical study. Furthermore, the shipment, dispensing and drug accountability will be discussed.

Module 12: Medical Device – 2 days

This module will give an introduction to clinical trials with medical devices and explain the main differences when performing a clinical study on a medical device as compared to a clinical study on a pharmaceutical product.

Registration Form

I am interested to participate in the Trainee Program and to receive more information about the Program.

Name: _____

Address: _____

_____

_____

_____

E-mail: _____

Phone: _____

Please fax or e-mail the form with attn. Siw Anehus
(fax no. +46 (0)46 31 32 50;
e-mail siw.anehus@trialformsupport.com)

If you have any questions about the trainee program you are welcome to contact Siw Anehus