

Do you, or somebody you know, wish to work on clinical trials but lack experience or training?

TFS - Global Trainee Program offers you the relevant training if you want to start a career within clinical research working as a Clinical Research Associate (CRA)/monitor, Data Management Associate, Clinical Research Administrator or in one of several related roles.

The program was recently run in the Copenhagen region, with participants from Sweden, Denmark and Italy. The program has previously been held in Stockholm in 2007.

The next opportunity to participate in TFS - Global Trainee Program will be during autumn 2008;

- Malmö, Sweden
- Madrid, Spain.

The program consists of 4 blocks of 1½-2 weeks each consisting of lectures, workshops, and practical exercises. Participants will be expected to do homework in between the blocks and there will be time for in-depth reading of course material. The program will finish with an internet based-GCP examination and a written exam.

For further information, or if you have specific queries or questions, please contact:

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TFS Trial Form Support - Global Trainee Program

Objective

The objective of the trainee program is to provide participants with a basic understanding of the clinical development of pharmaceutical products with a 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 completing the course, trainees should have the basic skills and knowledge to work as Clinical Research Associates (CRA)/monitors (at a junior level), Data Management Associate, Clinical Research Administrators or in one of several related roles.

Requirements

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

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

Trainee Program

The program consists of four blocks which will be conducted as a combination of lectures, practical exercises and self study. In addition, visits to external sites will be offered. The sites that will be visited may include a preclinical laboratory, a clinical phase I unit, a clinical laboratory and/or a clinical research unit at a pharmacy. The total planned duration of the program is three months.

Candidates are required to take both a web-based GCP exam and a written exam at the end of the course. In order to receive certification, candidates are required to have a pass-mark of 90 % in the GCP-exam and 70% in the written exam. Additionally, candidates should have been present for at least 90% of the time.

The Trainee Program will be held in two different locations during autumn 2008 – Denmark/Sweden and Spain.

Denmark/Sweden

Lectures and practical exercises will be held in Malmö, starting September 8th. The planned schedule is as follows:

- Block 1: 8 - 16 September
- Block 2: 29 September - 7 October
- Block 3: 20 - 31 October
- Block 4: 1 - 9 December

Spain

Lectures and practical exercises will be held in Madrid, Spain. Planned schedule is as follow:

Block 1: 3 - 12 November

Block 2: 18 – 27 November

Block 3: 8 – 19 December

Block 4: 13 – 21 January

Tuition fees

The cost for the Trainee Program is 2200 Euros including VAT. Costs for travel and accommodation will be covered by the trainee. Participants from pharmaceutical companies and CROs will be charged according to a separate tariff. Please contact TFS for details.

Registration

Registration is performed by completing the registration form at the end of this document. Applications (registration form and an up-to date curriculum vitae) should be received not later than:

Denmark/Sweden: **1st August 2008**

Spain: **29th September 2008**

Candidates who meet the 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 after the internal process has been finalized in August (Spain, middle of October), they will be offered to suitable external applicants in the order in which we received their application.

Block I “Candidate Drug to Application to Authorities”

Introduction

The aim is to provide the trainees with a basic understanding of how the pharmaceutical industry is organized, the process leading from a candidate drug to a marketed drug and finally an introduction to the guidelines, directives and laws regulating clinical trials:

- Introduction to the pharmaceutical industry
- Introduction to clinical research:
 - From identification of substance to marketing of the product
 - Terminology
 - Phase I to phase IV
 - Study design
 - Investigational Medicinal Products
- Introduction to Good Clinical Practice –GCP– as defined by ICH E6 guideline (ICH-GCP) and the Declaration of Helsinki. The module will also address the EU Directive and its implementation in different countries.

Essential Documents, part 1

We will focus on the study protocol and subject information/informed consent form as defined by ICH-GCP.

Block II “Application to Authorities to First Subject In”

Monitoring: Pre-Study Visit and Initiation Visit

Site selection procedures will be discussed including pre-study visit and site initiation according to ICH-GCP. This session will also discuss how to write pre-study visit and site initiation visit reports.

Essential Documents, part 2

We will focus on the essential documents needed for the conduct of a clinical trial such as Confidentiality-, Clinical- and Financial Agreements, CVs, and other documents as defined by ICH-GCP. The FDA 1572 form and financial disclosure regulations will be introduced.

Regulatory Environment

The application to regulatory authorities and ethics committees and associated guidance documents.

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 the Data Management Plan, Data Entry Manual and Data Validation Plan will be discussed.

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 session will include a practical exercise, which mainly consists of coding of adverse events and medications.

Investigational Medicinal Products

This session will introduce the manufacture of investigational medicinal products according to GMP (Annex 13) and how to label the product to be used in a clinical study.

Block III *“First Subject In to Last Subject Last Visit”*

Monitoring

Monitoring according to ICH-GCP will be introduced; the monitor's responsibilities will be discussed. A large part of this block will be devoted to simulated monitoring; furthermore, shipment, dispensing and drug accountability will be discussed

Data Management

Data entry and data clarification procedures will be presented. There will be a training exercise on entry of data into a study database, query handling and corrections to the database.

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?

Block IV *“Last Subject Last Visit to Report”*

Clean File

The procedures for Clean File and the monitor's role in progressing to Clean File will be presented.

Essential Documents, part 3:

The Clinical Study Report as defined in the ICH E3 guideline will be reviewed. The filing of essential documents as defined by ICH-GCP guidelines, i.e. what to archive at the investigator's site and what is retained by the sponsor, will be discussed.

Monitoring: Close Out Visit

The Close Out Visit, as described in the ICH-GCP guidelines, will be discussed. This session will also include a practical exercise: preparation for the visit and the documentation needed.

Statistics

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

Medical Devices

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



Registration Form

I am interested in participating in the Trainee Program and would like to receive more information.

Name: _____

Address: _____

E-mail: _____

Phone: _____

Please fax or e-mail the form:

For attn. Cristina Paz von Friesen

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If you have any questions about the trainee program you are welcome to contact Cristina.