L30 Clinical Trial Administration - Beyond the Basics

30th November 2022

The day will start at 08:45 with registration and coffee for a prompt start at 09:15. We aim to finish by 17:30.

ICR Training

L30 Clinical Trial Administration - Beyond the Basics

10 CPD POINTS

30th November 2022

L30

Venue - Online Course,

Course Information

The Course

Clinical Trial Administrators are at the heart of any project team and play an essential role in the clinical trial process. This course gives an in-depth look into some of the aspects of clinical trials. It aims to give an understanding of the history and evolution of clinical research.

Delegates will be guided through the essential documents required at each stage of the clinical trial process and their respective functions, an outline of the key roles and functions, and explores how the role of the CTA fits into the clinical trial process.

The course also gives further insight into the EU legislation governing trials, ethics committees, audits and inspections, using and creating SOPs, auditing and archiving.

The course will utilise trainer input, exercises, and delegate interaction.

Learning Objectives

- Summarise the impact of the EU Directives on clinical research working practices
- Outline the ethics committee submission process
- Describe the function of SOPs and outline the process for creating one
- Identify essential documents and their respective functions
- Describe the key issues in preparing for and participating in an audit/regulatory inspection

Course Outline

- Review of ICH GCP
- EU Clinical Trials Directive & UK Legislation
- The EU Data Protection Act
- Ethics Committees & Submissions
- Standard Operating Procedures - Their management & writing them
- The wider role of the CTA
- CTA Key customers & interactions
- Essential Documents
- Regulatory aspects of Archiving
- Key Documents & Version Control
- Tracking systems
- Data management, data flow & audit trails
- Audits & Inspections

Who would benefit

Those new to the CTA role and those with experience who would like a more in depth look at clinical trials process

Course Fees

Guest	**£550.00**
ICR Member	**£450.00**
ICR Member Academic	**£350.00**

Your Trainer

Hanna Preus

Dr Hanna Preus is a Global Quality & Compliance and Business Strategies expert with more than 15 years of versatile quality and operational excellence experience in clinical trials – including creating and overseeing quality and business processes across multidisciplinary business units (project management, clinical operations, quality assurance etc.)

An expert in internal external and systems audits/controls, Dr Preus has a strong knowledge and wide practical experience in GxP requirements, Standard Operating Procedures (SOPs), global and local regulatory requirements.

Dr Preus is the author of research on socio-economic determinants of clinical trial systems (the doctoral dissertation), engaging pharmaceutical companies, CROs, sites (hospitals) – Principle Investigators and Sub Investigators, Study, Nurses, and patients.

Pre-Course Questionnaire - To be completed by all delegates

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Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: L30 Clinical Trial Administration - Beyond the Basics

Date: 30 November 2022

Name: .....

Company / Hospital: .....

Position / Job Title: .....

How much experience of clinical trials do you have? (Years)

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What are you hoping to get out of the day?

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State one issue/problem you would like discussed at the meeting

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Dietary Requirements

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* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

Training Location

Address: Online Course,

This course/forum will run online via Zoom

Local Taxi Companies

N/A

Accommodation

The ICR does not specifically recommend any accommodation - however the following are within easy travelling distance of the training venue

There are also a number of travel websites which may allow you to identify local accommodation and special offers - e.g. expedia

The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free – however it is not possible to cover all possible requests for dietary preferences.

Registration Form

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: L30 Clinical Trial Administration - Beyond the Basics **Course Date:** 30 November 2022

Membership No.: ..... **Title(Dr,Mr,Mrs,etc):** ..... **First Name:** .....

Surname: ..... **Job Title:** .....

Company Name: .....

Email Address: .....

Confirmation of booking will be sent by email, unless you request here that it is sent by post ☐

Correspondence Address

Address: .....

Postcode: ..... **Country:** ..... **Telephone Number:** .....

Special Dietary Requirements

.....

Declaration

I agree to the terms and conditions of booking **Signature:** .....

Method of Payment

Please not that your place will only be confirmed when payment has been received (please tick as required)

I wish to pay the fee of .....

☐ I enclose a cheque payable to "The Institute of Clinical Research"

OR

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Start Date ☐☐ ☐☐ **Expiry Date** ☐☐ ☐☐

Name (as it appears on the card) .....

Signature of card holder .....

OR

☐ Please invoice my company using Purchase Order Number ☐☐☐☐☐☐☐☐ Invoices can only be raised when a PO no. is provided

Correspondence Address

Address: .....

Postcode: ..... **Country:** .....