



M35 Clinical Trial Administration - Beyond the Basics

22nd November 2023



**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.**



Venue -

Course Outline

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

- 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

Pre-Course Questionnaire - To be completed by all delegates

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

Course Title: M35 Clinical Trial Administration - Beyond the Basics

Date: 22 November 2023

Name:

Company / Hospital:

Position / Job Title:

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

.....
.....
.....

What are you hoping to get out of the day?

.....
.....
.....

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

.....
.....
.....

Dietary Requirements

.....
.....
.....

* 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.

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.

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: M35 Clinical Trial Administration - **Course Date:** 22 November 2023
Beyond the Basics

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 note 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:**