M22 Foundation in Good Clinical Practice (GCP)

5th July 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.

ICR Training

M22 Foundation in Good Clinical Practice (GCP)

10 CPD POINTS

5th July 2023

M22

Venue -

Course Information

The Course

This course provides an in-depth look at the regulatory systems currently in operation in the EU and their impact, together with UK legislation, on the conduct of clinical research. Starting with a refresher on the history of medicinal product regulations and the need for ethics, the course explains in more detail the practical applications of GCP and outlines recent major developments in GCP. It also explores the impact of EU data protection laws on clinical research and summarises other current issues that affect clinical trials.

Delegates will receive a complimentary copy of the ICH GCP guidelines and a workbook

Learning Objectives

- Describe the purpose of Good Clinical Practice (GCP)
- Outline the significant milestones in the history of GCP development
- Review the respective responsibilities of Sponsors, Investigators and Ethics Committees in the context of GCP
- State the purpose of the EU Clinical Trial & GCP Directives
- Outline the scope of the Directives
- Review implications of the Clinical Trial Regulation
- Discuss some of the implications of the Directives for clinical researchers
- Describe some practical applications of GCP

Course Outline

- The need for ethics & regulation
- Roles & responsibilities in Clinical Research
- EU Clinical Trials directive
- EudraCT database
- UK legislation
- The EU Regulation proposals
- Clinical trials authorisations
- Voluntary harmonisation procedure
- Substantial amendments
- IMPs & NIMPs
- HMA Strategies
- Informed consent
- GMP Annex 13
- Pharmacovigilance reporting
- Advanced therapy regulations
- Inspections
- Declaration of Helsinki 2013
- Risk based Monitoring

Who would benefit

The course is ideal for delegates with no prior experience of GCP who wish to understand and explore the wider application of GCP and gain knowledge of the regulatory aspects of clinical research.

Course Fees

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

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: M22 Foundation in Good Clinical Practice (GCP)

Date: 05 July 2023

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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Special 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.

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: M22 Foundation in Good Clinical Practice (GCP) **Course Date:** 05 July 2023

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:** .....