



## M9 Foundation in Good Clinical Practice (GCP)

15th March 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.**

### The Course

Online payments currently temporarily suspended. To make a payment please contact [office@icr-global.org](mailto:office@icr-global.org)

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

- 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

Please complete and sent to [training@icr-global.org](mailto:training@icr-global.org) or fax to +44 01628 501 709

Course Title: M9 Foundation in Good Clinical Practice (GCP)

Date: 15 March 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

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

Special 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.



**Address:** The Institute of Clinical Research Training Suite, Suite 1, Cedar Court Grove Business Park White Waltham, Berkshire, SL6 3LW

The ICR's training suite is situated near the charming village of White Waltham. Located just off the A404, with connections by road or rail.

The Institute of Clinical Research Training Suite

Suite 1, Cedar Court

Grove Business Park

White Waltham

Maidenhead

SL6 3LW

**By Car:** Join the A404 either via at J5 of the M40, or J8/9 of the M4. Follow the A404 until you reach J9A signposted to Maidenhead/Reading. Turn right at the first roundabout, then continue on that road, going straight across any subsequent roundabouts. Take the second right past the airfield. If you reach the village, you've gone too far.

Once inside Grove Park, turn left at the first mini roundabout, then right at the T junction. Turn right at the red brick building, and we are in the one furthest from the road. Park in the large car park on your right. Please contact the Secretariat using the buzzer by the door - type in 12 and then press the small bell.

**By Train:** The nearest station is Maidenhead, located on the Paddington - Reading line. We recommend getting a taxi from the station, as bus routes are sporadic. It should take roughly 15 minutes.

## Local Taxi Companies

Dot to Dot + 44 01628 200 999

Golden Executive + 44 1628 622955

Imperial +44 1628 771777

## Accommodation

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

Hotel or Bed & Breakfast Name	Contact number	Website	Approximate Distance to The Institute of Clinical Research
Premier Inn Maidenhead	08715 279520	<a href="http://www.premierinn.com">http://www.premierinn.com</a>	4 miles 14 minutes
Taplow House Hotel	01628 670056	<a href="https://taplowhousehotel.com">https://taplowhousehotel.com</a>	6 miles 16 miles
Bel & The Dragon	01628 521263	<a href="https://belandthedragon-cookham.co.uk/">https://belandthedragon-cookham.co.uk/</a>	7 miles 18 minutes
CIM Moor Hall	+44 1628 427500	<a href="https://moorhall.cim.co.uk/">https://moorhall.cim.co.uk/</a>	7 miles 18 minutes

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.

Please complete and sent to [training@icr-global.org](mailto:training@icr-global.org) or fax to +44 01628 501 709

## Registration Form

Please photocopy this form for further registrations

**Course Title:** M9 Foundation in Good Clinical Practice (GCP)

**Course Date:** 15 March 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 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:** .....