M11 Introduction To Clinical Trials & Clinical Trials Practice

28th March 2023 - 30th March 2023

The Institute of Clinical Research

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

M11 Introduction To Clinical Trials & Clinical Trials Practice

30 CPD POINTS

28th March 2023 - 30th March 2023

M11

Venue - CIM Moor Hall Conference Centre, The Moor, Cookham SL6 9QH, Cookham

Course Outline

Course Information

The Course

Online payments currently temporarily suspended. To make a payment please contact office@icr-global.org

An Introduction to Clinical Trials and Clinical Trial Practice, the ICR's flagship training course, is accredited by Cranfield University. This highly practical course explores the relevance of clinical research in drug development and summarises the ethical and regulatory requirements for clinical trials. It covers clinical trial methodology and summarises the principles of Good Clinical Practice. The course gives an overview of the various aspects of clinical research and will be of interest to all members of the clinical study team. It uses a combination of lectures, tutorials and group workshops. Delegates receive a comprehensive workbook and a copy of ICH GCP guidelines. The content of the course will equip delegates to sit the ICR Certificate examination.

Learning Objectives

- Relate the relevance of clinical trials to the drug development process
- Design a simple protocol and draft appropriate case record forms
- Demonstrate the basic principles behind the statistical sections of a protocol
- Summarise the ethical and regulatory requirements that must be met before a clinical trial commences
- Describe the requirements for conducting monitoring visits
- Determine the difference between an adverse event and an adverse drug reaction
- Outline the audit process and how it fits into the quality system
- Compare the differences between drug and device trials

- Introduction to GCP
- Drug development process
- EU Directives
- Basic principles of statistics for CRA's
- Clinical trial & design workshop
- Phase 1 studies
- Designing simple protocols
- Case Report Form (CRF) design
- Pre trial organisation
- Ethics Committees approval
- Clinical trial applications
- Patient information sheets & informed consent
- Clinical trial monitoring visits
- Source data verification
- Pharmacovigilance, AEs & ADRs
- Quality assurance
- Marketing authorisation

Who would benefit

Anyone looking for a comprehensive overview of clinical research whether new to the field or currently working in a related profession. [e.g. Academic Researchers wanting to move into clinical research; CTAs or CRAs; those returning from a career break; clinical trial supplies; drug safety etc.] It covers a wide range of topics and is designed for those who need to understand the detail of clinical trials.

Course Fees

Guest	**£1360.00**
ICR Member	**£1125.00**
ICR Member Academic	**£915.00**

Your Trainers

Tina Barton

Dr Tina Barton is an experienced Board member and Chair, and a drug development specialist with a broad knowledge within health care. With a BSc, PhD in cancer research and a MBA, she has held Senior Management roles in large global through mid-size to small emerging drug development organisations, working in partnership to lead for success, as a customer-focused clinical research professional. Tina provides demonstrated strategic business acumen, change management and process enhancement expertise with a proven track record in driving growth, managing teams and training for the future. As past Chair and Board member for The Institute of Clinical Research she has a passion for sharing knowledge, raising standards and developing professionals which she has carried forward into her current Board roles and as a mentor for the Cherie Blair Foundation. With excellent negotiation and leadership talents, Tina is a reliable individual with commitment to achieving results and exceeding customer expectations via education, process and delivery, as part of a team or under her own initiative.

Your Trainers

Joy Dummer

Joy Dummer is a Clinical Research professional with extensive industry experience gained over 34 years working with several leading CROs in senior management roles as Senior Director of Project Management. Starting her career as a Project Manager and Global Project Director, she has a proven track record of delivering key global programmes in all study phases across EU, North America and Asia Pacific, working with a broad range of Clients from major Pharma to niche start up companies as well as smaller Biotechs. Responsibilities included providing Senior management governance and oversight of key Client Portfolios as a member of the Executive Oversight committee. Therapeutic experience includes Oncology, CNS, Women's Health, Immunology, Infectious Diseases, Cardio vascular disease and general medicine, in both adult and paediatric indications.

Joy is also a Registered General Nurse and State Registered midwife. She has been a member of the ICR Project Management Special Interest Group (SIG) for over ten years and is an active member of the SIG committee.

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: M11 Introduction To Clinical Trials & Clinical Trials Practice

Date: 28 March 2023 - 30 March 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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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: CIM Moor Hall Conference Centre, The Moor, Cookham SL6 9QH, CIM Moor Hall Conference Centre, The Moor, Cookham, Berkshire, United Kingdom, SL6 9QH

Local Taxi Companies

Accommodation

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

contact Lydia.Macdonald@cim.co.uk

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: M11 Introduction To Clinical Trials & Clinical Trials Practice **Course Date:** 28 March 2023 - 30 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

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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:** .....