



K14 Introduction To Clinical Trials & Clinical Trials Practice

8th June 2021 - 10th June 2021



**The day will start at 09:45 with registration and coffee for a prompt start at 10:15.
We aim to finish by 18:30.**

ICR Training

K14 Introduction To Clinical Trials & Clinical Trials Practice

30 CPD
POINTS



8th June 2021 - 10th June 2021

K14

Venue -

Course Outline

The Course

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. We also run a one day course Clinical Research for Non Clinical Researchers [F9,F32 & F32] for individuals looking for a less detailed option.

Course Fees

Course Fees not found for this course on this date

Please contact ICR for more information.

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: K14 Introduction To Clinical Trials & Clinical Trials Practice

Date: 08 June 2021 - 10 June 2021

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.

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: K14 Introduction To Clinical Trials & Clinical Trials Practice **Course Date:** 08 June 2021 - 10 June 2021

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 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:**