M16 Essentials of Clinical Trial Monitoring

17th May 2023

The Institute of Clinical Research

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

M16 Essentials of Clinical Trial Monitoring

10 CPD POINTS

17th May 2023

M16

Venue -

Course Information

The Course

This practical course defines the role of the clinical research monitor and explains the interaction with others in key roles as part of the clinical trial process as well as exploring the more complex aspects of clinical trial monitoring. Guidance will be given on best practices for selecting investigators, conducting monitoring visits and safety reporting. Delegates will explore strategies for dealing with common clinical trial management issues and how to adopt a preventative approach to handling monitoring issues. The course uses a blend of trainer input, exercises and delegate interaction.

Learning Objectives

- Define the roles and responsibilities of Monitors, Sponsors, Investigators and Ethics Committees
- Describe the key criteria for selecting investigators
- Summarise the preparation, conduct and follow-up of the major types of monitoring visit
- Define the requirements for safety reporting
- Prioritise tasks
- Apply risk based techniques to monitoring

Course Outline

- Refresher on the purpose of GCP
- Roles and responsibilities of monitors, investigators, & sponsors
- Investigator selection
- Preparing & conducting pre-study visits
- Preparing and conducting initiation visits
- Conducting monitoring visits
- SDV
- IMP
- Safety reporting
- Informed consent
- Monitoring visit reports
- Prioritising activities
- Preparing & planning close out visits
- Essential Documents

Who would benefit

This course is for all those involved in clinical research monitoring. It covers a wide range of topics and is designed for those who have been in the role for only a few months as well as the experienced CRA.

Course Fees

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

Your Trainer

Sarah Gill

Sarah Gill has worked in Clinical Research for over 16 years in Clinical Research Organisations and Pharmaceutical Companies. She began her career as a CTA, and developed into a CRA, Team Leader, and Line Manager in phases 1-4 in a multitude of therapeutic areas including Oncology, Rare Diseases, Paediatrics, and many other therapeutic areas.

As Director of Monitoring at dMed-Clinipace, Sarah is responsible for developing monitoring strategy, recruitment, line management, team training, project resourcing, and client management to ensure delivery, quality, and compliance.

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: M16 Essentials of Clinical Trial Monitoring

Date: 17 May 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.

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: M16 Essentials of Clinical Trial Monitoring **Course Date:** 17 May 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:** .....