M4 The Essentials of Trial Master File (TMF) Management

27th April 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

M4 The Essentials of Trial Master File (TMF) Management

10 CPD POINTS

27th April 2023

M4

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

Course Information

The Course

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

The MHRA GCP Inspectorate has updated their definition of critical to include, 'where provision of the Trial Master File (TMF) does not comply with Regulation 31A 1-3, as the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations.'
This follows numerous issues with inspector access to TMFs and incomplete TMFs. The TMF provides the basis for inspection by the competent authority (2005/28/EC). The UK Clinical Trial Regulations (2004/1031, Regulation 31A) require that the sponsor must keep a TMF and it must be readily available and shall at all times contain the essential documents relating to the trial.
This course demonstrates how to set up, maintain and manage a document system that meets the required regulatory standards. It gives an overview of the specific requirements in document management and explains the need for an audit trail of documents that is transparent and robust. Delegates are guided through the process of archiving documentation and the preparation for, and participating successfully in, a quality assurance audit or regulatory inspection.

Learning Objectives

- Summarise the regulatory framework of Good Clinical Practice and the relevant European Directives
- Review the GCP requirements for essential documents
- Describe the significance of document management in clinical research
- Develop a systematic approach for preparing documents for archive
- Identify the requirements for participating successfully in a quality assurance audit or regulatory authority inspection

Course Outline

- Review of the regulatory framework of Good Clinical Practice
- EU Clinical Trials Directive
- GCP requirements for essential documents
- Electronic Records Management
- Audits & inspections
- Investigator archiving
- GCP & RA compliant archiving and retention
- Preparation & tracking of documents for archiving
- Requirements for long term storage of archived documents
- What the inspectors are waiting to see
- How to select a suitable of site company
- Alternative long-term storage media

Who would benefit

Anyone involved in the management of clinical trial documentation, for example Clinical Research Associates, Clinical Trial Administrators, and those involved in the archiving and long term storage of documentation.

Course Fees

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

Your Trainer

Russell Joyce

Russell Joyce is an independent Information Governance Consultant with over 25 years' experience in life sciences and healthcare, the legal sector, NHS, banking, and professional services. He is Director of the Health Sciences Records and Archives Association, for whom he has co-authored numerous publications including: "eTMF Evaluation and Selection Template", "Guidance on the Scanning and Destruction of Original TMF Documents"; "An Assessment of the Impact of EU536/2014 on Clinical Records Management"; "Evaluation and Selection of Commercial Archive Contractors", "Guide to the Use of Digital Signatures"; and "Guide to the Archiving of Digital Records". An active member of the TMF Reference Model Steering Committee, Russell has co-authored the "TMF Reference Model Implementation Guidance", the "Guidance for the Management of e-Mail Communications in Clinical Studies", and with an expert working team, recently lead the development and publication of the "Real World Evidence Study Master File Index". In his free time Russell is a passionate tuba player, dedicated hill-walker, and tennis player.

Pre-Course Questionnaire - To be completed by all delegates

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: M4 The Essentials of Trial Master File (TMF) Management

Date: 27 April 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

.....

.....

.....

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.

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: M4 The Essentials of Trial Master File (TMF) Management **Course Date:** 27 April 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:** .....