



## J31 Introduction To Clinical Trials & Clinical Trials Practice

18th May 2021 - 20th May 2021



**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

J31 Introduction To Clinical Trials & Clinical Trials Practice

30 CPD  
POINTS



18th May 2021 - 20th May 2021

J31

Venue - Burnham Beeches Hotel , Burnham

[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.

## 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.



## 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

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

Course Title: J31 Introduction To Clinical Trials & Clinical Trials Practice

Date: 18 May 2021 - 20 May 2021

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?

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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.

# BURNHAM BEECHES HOTEL

**Address:** Burnham Beeches Hotel , Burnham Beeches Hotel Grove Road Burnham, SL1 8DP

## FROM M4

Exit J7 at next roundabout and turn left onto A4 (Bath Road). First right at traffic lights to mini-roundabout, turn right. Straight across traffic lights. Proceed until mini-roundabout. Turn left, take first right into Grove Road. Burnham Beeches Hotel is 200 metres on the right-hand side.

## FROM M40

Exit J2 on A355 Southbound to Slough. After Farnham Sommon, Turn right at the second of a pair of mini roundabouts onto Farnham Lane towards Burnham. Turn right at next mini-roundabout onto Britwell Road. Turn right after 100mt into Grove Road. Burnham Beeches Hotel is 200 metres on the right-hand side.

## Local Taxi Companies

LocalTaxi Companies

Dot to Dot +44 01628 200 999

Golden Executive + 44 1628 622955 Book

Airport Taxi Cabs +44 1494 372 003

## Accommodation

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

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:** J31 Introduction To Clinical Trials & Clinical Trials Practice **Course Date:** 18 May 2021 - 20 May 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

.....

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:** .....