



J23 Introduction to Pharmacology and Phase 1 Clinical Trials

8th October 2020



**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

J23 Introduction to Pharmacology and Phase 1 Clinical Trials

10 CPD
POINTS



8th October 2020

J23

Venue - The Institute of Clinical Research Training Suite, White Waltham

Course Outline

The Course

The course will give an overview of clinical pharmacology, define phase 1 studies and describe how they fit into the clinical development programme. Delegates will be guided through the regulatory and clinical aspects of phase 1 studies and identify the key safety and ethical issues that need to be managed. The issues relating to design, set-up, choosing subjects and conduct of phase 1 studies will be discussed. The course will use trainer input, exercises, and delegate interaction.

Learning Objectives

- Give an overview of Clinical Pharmacology.
- Define Phase 1 studies and describe how they fit into the clinical development programme.
- The delegates will be guided through the regulatory and clinical aspects of Phase 1 studies and identify the key safety and ethical issues that need to be managed.
- The issues relating to design, set-up, choosing subjects and conduct of Phase 1 studies will be discussed.

- Clinical Pharmacology – terminology and definitions.
- Overview of Phase 1 Studies
- Patient populations.
- Phase 1 clinics.
- Ethical considerations.
- The EU Directive and legal requirements.
- Types of Phase I studies
- Considerations in Phase I study design.
- Adverse events/adverse drug reactions.
- Data collection and monitoring.

Who would benefit

This course is for those new to Phase 1 clinical research. Delegates should have a basic knowledge of clinical research and Good Clinical Practice.

Course Fees

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

Steve Dickinson

Dr Steve Dickinson is a scientist with over 30 years' experience in the pharmaceutical industry and over 25 years in clinical research, mainly early drug development and clinical pharmacology. Dr Dickinson's early career was in preclinical neuropharmacology, in academia at the Institute of Neurology and in industry with Reckitt & Colman Plc. Moving to Hoffmann La-Roche he transitioned to clinical development holding roles in Clinical Documentation; Clinical Pharmacology Operations, as a group leader and global functional head and Pharma Research Early Development, as the senior clinical operations leader with accountability for delivering all clinical trials up to Phase 3 in neuroscience, ophthalmology and rare diseases. He also spent a year as Head of Roche's clinical pharmacology research unit in Strasbourg. From January 2016, Dr Dickinson became an independent consultant, specialising in early drug development, organisational performance and change management and from June 2016 Dr Dickinson joined Heptares Therapeutics Limited as a Programme Director in Clinical Development.

Dr Dickinson has lectured on early drug development and the design of clinical pharmacology studies and as a committee member, represented the Association for Human Pharmacology in the Pharmaceutical Industry (AHPPI) on the MHRA's Phase 1 Accreditation Scheme Committee.



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: J23 Introduction to Pharmacology and Phase 1 Clinical Trials

Date: 08 October 2020

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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Special 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.



Address: The Institute of Clinical Research Training Suite, Suite 1, Cedar Court Grove Business Park White Waltham, Berkshire, SL6 3LW

The ICR's training suite is situated near the charming village of White Waltham. Located just off the A404, with connections by road or rail.

The Institute of Clinical Research Training Suite

Suite 1, Cedar Court

Grove Business Park

White Waltham

Maidenhead

SL6 3LW

By Car: Join the A404 either via at J5 of the M40, or J8/9 of the M4. Follow the A404 until you reach J9A signposted to Maidenhead/Reading. Turn right at the first roundabout, then continue on that road, going straight across any subsequent roundabouts. Take the second right past the airfield. If you reach the village, you've gone too far.

Once inside Grove Park, turn left at the first mini roundabout, then right at the T junction. Turn right at the red brick building, and we are in the one furthest from the road. Park in the large car park on your right. Please contact the Secretariat using the buzzer by the door - type in 12 and then press the small bell.

By Train: The nearest station is Maidenhead, located on the Paddington - Reading line. We recommend getting a taxi from the station, as bus routes are sporadic. It should take roughly 15 minutes.

Local Taxi Companies

Dot to Dot + 44 01628 200 999

Golden Executive + 44 1628 622955

Imperial +44 1628 771777

Accommodation

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

Hotel or Bed & Breakfast Name	Contact number	Website	Approximate Distance to The Institute of Clinical Research
Premier Inn Maidenhead	08715 279520	http://www.premierinn.com	4 miles 14 minutes
Taplow House Hotel	01628 670056	https://taplowhousehotel.com	6 miles 16 miles
Bel & The Dragon	01628 521263	https://belandthedragon-cookham.co.uk/	7 miles 18 minutes
CIM Moor Hall	+44 1628 427500	https://moorhall.cim.co.uk/	7 miles 18 minutes

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 or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: J23 Introduction to Pharmacology and Phase 1 Clinical Trials **Course Date:** 08 October 2020

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:**