K8 Clinical Investigations for Medical Devices - Foundation

31st March 2021

The Institute of Clinical Research

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

K8 Clinical Investigations for Medical Devices - Foundation

10 CPD POINTS

31st March 2021

K8

Venue - Online Course,

Course Information

The Course

In this one day course we explore clinical investigations for medical devices. We will review the latest legislation and its impact on determining whether a clinical trial is required. Our experienced trainer will guide you through the key stages in designing and executing your clinical investigation. Through practical exercises delegates will tackle common challenges and develop strategies to overcome them.

Learning Objectives

- Understand how to determine whether or not a clinical investigation is required
- Describe the key points of the MDR and their impact on clinical investigations

- Discuss common challenges in project managing and monitoring clinical investigations and how to overcome them

Course Outline

- Overview of MD classifications EU and US
- When do you need to do a clinical trial?
- Update on the MDR and the impact it will have on clinical investigations
- Review of other relevant directives and guidance including ISO 14155
- Designing your clinical investigation
- Key Points for Project Managing a clinical investigation
- Key Points for Monitoring a clinical investigation
- Medical Devices and Safety Monitoring in Clinical Investigations
- What about drug device combinations?

Who would benefit

Anyone looking for an overview of conductive clinical investigations with medical devices.

Course Fees

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

Your Trainer

Victoria Cavendish

A highly skilled clinical affairs specialist who has worked in clinical research for over 15 years, including 11 years in the medical device arena. Her experience includes work within academic, manufacturing, consulting and CRO environments. Dr. Cavendish has extensive knowledge of medical device development and clinical affairs in regulatory, post-market surveillance, marketing and registry environments within Europe. She has proven ability in the set-up, study document preparation, in-country submissions, vendor negotiations and leadership of global and European projects to ensure they are conducted in accordance with the highest ethical, clinical and scientific standards. Victoria has held increasingly senior positions at various medical device companies including DePuy Synthes, Novartis, and Reckitt Benckiser.

Her therapeutic areas of expertise include orthopedics, software, sexual health, Over The Counter (OTC) and combination products. For the last 18months, Dr. Cavendish has owned a medical device consultancy, Orca Solutions Ltd, providing strategic direction and management of the global clinical development portfolio for a UK based medical device software manufacturer, alongside providing training courses for medical device professionals.Victoria also has experience of the implementation and management of a quality system to obtain ISO13485 certification and is able to conduct internal and site audits. Dr. Cavendish obtained a BSc(Hons) in Immunology at theUniversity of Glasgow, an MSc in Diabetes at theUniversity of Manchester, a PhD in Respiratory Medicine at the University of Bristol, and holds a Post-graduate Diploma in Public Health.

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: K8 Clinical Investigations for Medical Devices - Foundation

Date: 31 March 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.

Training Location

Address: Online Course,

This course/forum will run online via Zoom

Local Taxi Companies

N/A

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.

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: K8 Clinical Investigations for Medical Devices - Foundation **Course Date:** 31 March 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 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:** .....