



## J02 Introduction to Medical Device Clinical Investigations and ISO 14155; 2020

28th March 2024



**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

J02 Introduction to Medical Device Clinical Investigations and ISO 14155; 2020

10 CPD  
POINTS



28th March 2024

J02

Venue - Online Course,

## Course Outline

### The Course

Guest - £550.00 - <https://buy.stripe.com/3cs4jcawUcl8ds4blQ>

ICR Member - £450.00 - <https://buy.stripe.com/dR63f8fRe6jK3Ru3cl>

ICR Academic £350.00 - <https://buy.stripe.com/28og1U48weQg4VyeV4>

This course will run ONLINE VIA ZOOM

Medical Devices have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease. There are over 300 000 types of medical devices on the EU market, examples of which include sticking plasters, contact lenses, X-ray machines, pacemakers, breast implants, software apps and hip replacements. The medical devices sector is essential to the provision of healthcare and is an important player in both the European and global economy.

Released in 2020 the updated ISO14155 standard, which addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices, has been significantly revised.

Approximately 1.5 million different medical devices are available globally; with thousands of new and innovative medical devices being introduced to the market every year. While there is legislation at the national and regional level ISO 14155 provides a global standard for clinical investigations on human subjects.

**Please note:** ISO 14155 is only applicable for Medical Devices including diagnostic/imaging devices BUT NOT In Vitro diagnostics (IVD).

### Learning Objectives

To gain a clear understanding of the responsibilities of each of the key stakeholders (Sponsor/Monitor/Investigator) and an appreciation of the impact of the revisions to the updated ISO document and its relationship to the Medical Device Directive (MDD) and Medical Device Regulation (MDR)

The day will be spent reviewing the updated ISO document and its relationship to the Medical Device Directive (MDD) and Medical Device Regulation (MDR). This will enable you to go away with a clear understanding of the responsibilities of each of the key stakeholders (Sponsor/Monitor/Investigator) and an appreciation of the impact of the revisions. The day is interactive, and there will be discussion of real life examples enabling you to immediately start implementing the revised Standard in a practical way.

### Who would benefit

Clinical, quality and regulatory personnel working at a medical device manufacturer, academic institution, study site, or independent consultants, who are involved in the preparation, execution or evaluation of clinical investigations with medical devices.

### Course Fees

**Course Fees not found for this course on this date**

Please contact ICR for more information.

## 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: J02 Introduction to Medical Device Clinical Investigations and ISO 14155; 2020

Date: 28 March 2024

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

.....  
.....  
.....

Special 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.



**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.

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:** J02 Introduction to Medical Device      **Course Date:** 28 March 2024  
Clinical Investigations and ISO 14155;  
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

.....

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:** .....

