Medical Device Studies: Clinical Evidence

Gathering and using clinical evidence for CE marking and post-market compliance in line with the new MDR

14-15 November 2019 • 11-12 May 2020 London

Benefits of attending:

- Understand the regulatory requirements and guidance applicable to clinical evidence
- Get clarification of clinical evaluations and the role of literature reviews
- Learn what is required in terms of clinical data prior to CE marking and post-CE mark
- Know what documentation is needed for the pre- and post-market phases of clinical data collection
- Discover how to conduct a clinical investigation and post-market clinical follow-up (PMCF) study
- Plan how to prepare regulatory notifications to the Competent Authorities and obtain other necessary approvals
- Understand the key aspects of pre- and post-market study set-up, management, monitoring and close-down
- Find out the differences between drugs and devices

Earliest Booking Discount   Book BEFORE 4 October 2019
£1299.00 + VAT = £1558.80 • €1819.00 + VAT = €2128.80

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11-12 May 2020
The Rembrandt Hotel
11 Thurloe Place
London, SW7 2PS
Tel: +44 (0)20 7589 8100

Registration and refreshments: 09.00
Day one: 09.30-17.00
Day two: 09.00-16.30

Accommodation
We have arranged a preferential rate for accommodation at the venue. To take advantage of this, please state you are a Management Forum delegate.

There are limited rooms available at this rate so please book early to avoid disappointment.

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Web: www.sarova-rembrandthotel.com
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Fees and payment

Dates and venue
14-15 November 2019   Ref: 10515
11-12 May 2020         Ref: 10773
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Expert trainers:
Janette Benaddi, Independent Consultant
Robin Stephens, CEO, Psephos Biomedica

‘Great course to give an overview of a very big topic.’
Louise Corcoran, FIRE1

For event cancellation policy and T&Cs see our website
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Why you should attend
Clinical evidence is key to bringing a device to market and is a very important aspect of post-market evidence gathering to meet the legislation. The collection of clinical data to demonstrate safety and performance is pivotal to CE marking a medical device and the collection of post-market data is key to the continued safety and performance considerations once the device is on the market.

This course has been designed specifically for those who are involved in gathering clinical evidence required for medical devices. It will cover the full range of activities that should be applied during the collection of clinical evidence for both pre- and post-market studies and will also provide delegates with information on the European regulations for gathering clinical evidence and conducting medical device studies and help them to run studies in Europe and other countries. Delegates will benefit from advice and tips from industry experts on the practicalities of conducting studies within Europe as well as the types of clinical data to collect in order to be compliant with the new MDR.

Who should attend?
• Personnel involved in setting up, managing and monitoring studies
• R&D
• Marketing
• Regulatory affairs
• Clinical affairs
• Those who conduct clinical evaluations/investigations/post-market follow-up studies
• Anybody moving from pharma to the medical device sector

A certificate of attendance for professional development will be available to each participant who completes the course

Expert trainers

Janette Benaddi is an independent consultant and former director of Clinical & Consulting Europe for NAMSA, a global medical research organisation offering a breadth of services from pre-clinical to post-market throughout the medical device product development cycle. She has over 20 years’ experience of managing pre- and post-market clinical studies in both devices and pharmaceuticals and has worked with several multinational organisations in various clinical, regulatory and marketing roles. Janette has extensive experience of conducting clinical studies with medical device products as well as regulatory expertise for CE marking of devices. She is a registered nurse, has a BSc in Management Studies, a Diploma in Company Direction and a Diploma in Management Studies. She holds a teaching certificate and is a Chartered Scientist and Chartered Director. Janette sits on several committees in the device industry and has been an instrumental advocate of improving and advancing medical device research in the UK. She has published several articles relating to medical device regulation and clinical studies.

Robin Stephens is CEO and Principal Consultant of Psephos Biomedica – a clinical, regulatory and quality consultancy in client partnerships and/or interim management relationships with entrepreneurial corporations and venture-backed companies since 2001. Robin has more than 20 years experience in clinical research and regulatory affairs for medical devices throughout the world, but principally in Europe. Prior to his role with Psephos Biomedica, Robin was the director of QA/RA/CA for Apica Cardiovascular which is now part of the Thoratec Corporation. He held senior roles with Conor Medsystems as well as Medtronic Vascular (previously AVE) and before that held several positions with CR Bard. Robin has been scientific adviser to a series of books on biomaterials. An author on regulatory matters and editor for a series of books on biomaterials.

Programme

Day one

Welcome, introductions and course objectives

The regulatory aspects of gathering clinical evidence for devices

• An overview of the regulations governing the clinical evidence aspects of devices
• How the regulations impact on clinical data for regulatory studies and post-market studies
• Standards and guidelines applicable to medical device clinical evidence, ISO, GHTF (IMDRF), MEDDEV and NB MED

Conducting a pre-market clinical evaluation and the literature review

• Literature review
• The clinical evaluation
• What’s involved and how should it be conducted?
• What documents are required and how is clinical data used?

Example documents and templates will be provided to help delegates understand this process

Conducting a pre-market (regulatory) clinical investigation

• What types of studies and study designs are applicable to pre-market studies?
• What to consider in designing and implementing appropriate pre-market studies

Example documents and templates will be provided to help delegates understand this process

Day two

Study management and monitoring of regulatory clinical investigations

• Key aspects of study set-up
• Management, monitoring and close down
• Getting the best data

How to write a final study report for a regulatory clinical investigation pre-market study

• Practical considerations for final study reports; publications and presentations of study results
• Examples and templates will be provided to help delegates understand the processes
• How to prepare a paper or presentation for publication and marketing

PMCF

• Practical considerations for conducting PMCF studies
• The differences between PMCF and regulatory studies
• When to conduct PMCF studies and other PMC data requirements

Current key issues affecting clinical evidence for medical devices

• The effect of changes to the directives and current initiatives throughout Europe

Discussion session

• How to obtain the necessary approvals for pre-market studies
– The To obtain research ethics approval
– How to obtain national Competent Authority approvals
– Other necessary approvals
– What to provide, timescales and practicalities

• The differences between drugs and devices

‘Overall it was a great opportunity to get more awareness on clinical studies with medical devices. The documentation provided was very clear and provided valuable input for setting procedures in my company.’

Ricardo De Sa, Definiens AG

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Three easy ways to book

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