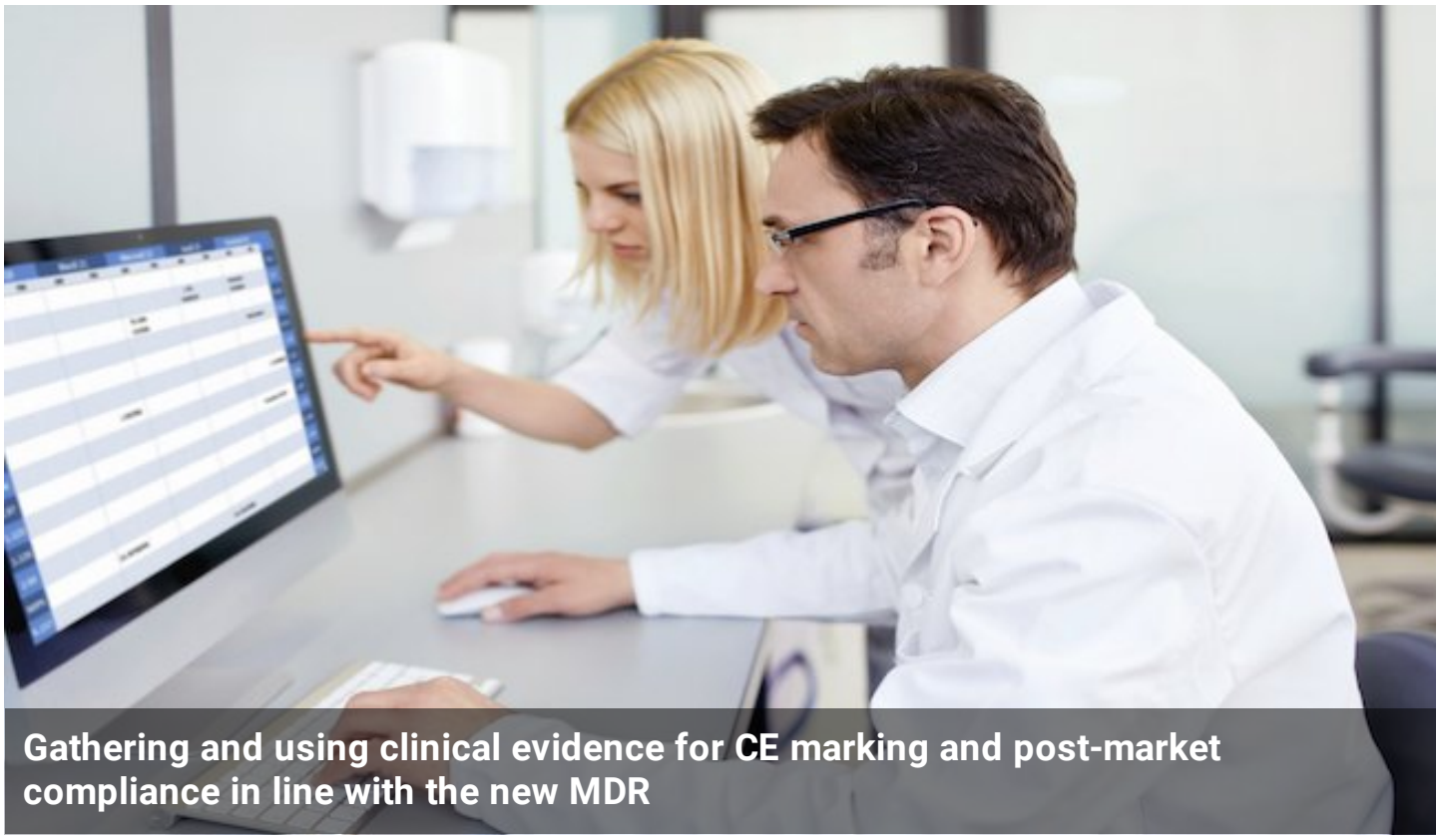
Medical Device Studies: Clinical Evidence

9-10 Nov 2020, Live webinar
+ 4 more dates - see back page for full schedule



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

Programme at a glance:

- The regulatory aspects of gathering clinical evidence for devices
- Conducting a pre-market clinical evaluation and the literature review
- Conducting a pre-market (regulatory) clinical investigation
- Documentation for pre-market (regulatory) clinical investigation
- How to obtain the necessary approvals for pre-market studies
- Study management and monitoring of regulatory clinical investigation
- How to write a final study report for a regulatory clinical investigation pre-market study
- PMCF
- Current key issues affecting clinical evidence for medical devices
- The differences between drugs and devices

Full programme inside

NEW FOR 2020: LIVE WEBINAR DATES ADDED

★★★★ *"A very interesting course, good for networking. Speakers were very prepared and good in enhancing discussions."*

Barbara Acca, CRA Lead/ CTM, Cepheid

★★★★ *"I appreciated the interactive way of presenting and the incorporation of questions and examples. I learned a lot."*

Sandra Tobisch, Clinical Trial Manager, BSN medical GmbH / Essity

★★★★★ *"This course was extremely helpful and relevant. The trainers were very knowledgeable and experienced."*

Jessica Allen, Regulatory Affairs Specialist, JRI

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Course overview

Clinical evidence is crucial to bringing a device to market and is a very important aspect of post-market compliance to meet the requirements of current 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 practical and intensive two-day 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. Participants 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.

Benefits of attending

- Understand the regulatory requirements and guidance applicable to clinical evidence
- Clarification on Clinical Evaluations (Literature Reviews)
- Understand 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 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 setup, management, monitoring and close down
- Discuss how to prepare a paper or presentation for publication and marketing
- Understand the differences between drugs and devices

Who should attend

- Personnel involved in setting up, managing and monitoring studies
- Setting up, managing and monitoring studies
- R&D
- Marketing
- Regulatory Affair
- Those who conduct clinical evaluations/investigations/post market follow up studies
- Those moving from Pharma to Medical Device studies

★★★★ *"For me the course content was pitched well for the time allowed. I thought the presenters did a great job of managing the participants expectations."*

Stephen Rowe, Managing Director, SGR Consulting Services Ltd

★★★★ *"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. The speakers were very open to interaction and there was enough time for discussion. The combination with hands-on tasks was also key to understand the content."*

Ricardo De Sa, Regulatory Affairs Manager, Definiens AG

★★★★★ *"Great course to give an overview of a very big topic"*

Louise Corcoran, Director of Quality and Regualtory Affairs, FIRE1

Expert trainers

Janette Benaddi

Janette Benaddi is a business mentor, international speaker/trainer and consultant to the medical device industry. Janette has over 25 years' experience of managing pre and post market clinical studies in both devices and pharmaceuticals. Janette has worked with several multinational organizations in various clinical, regulatory and marketing roles.

She has extensive experience of conducting clinical studies with medical device products as well as regulatory expertise for CE marking of devices. Specifically she has been involved in writing and reviewing hundreds of Clinical evaluation reports for the medical device industry, she has also provided training to Notified bodies in this subject.

Janette qualified as a registered nurse in 1984, she has a BSc in Management studies, a Diploma in Company Direction, and a Diploma in Management studies, holds a teaching certificate and is a Chartered Scientist and Chartered Director. Janette sits on several committees in the device community and industry and has been an instrumental advocate of improving and advancing medical device research in the UK. Janette has published several articles relating to medical device regulation and clinical studies.

Robin Stephens

Robin Stephens is CEO & Principal Consultant, Psephos Biomedica a clinical, regulatory & quality consultancy in client-partnerships and/or interim management relationships with entrepreneurial corporations and venture-backed companies since 2001. Robin has more than 30 years experience in clinical research and regulatory affairs for medical devices throughout the world, but principally in Europe.

Prior to his role with Psephos Biomedicca, Robin was the Director of QA/RA/CA for Apica Cardiovascular that is now part of the Thoratec Corporation. He was 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 medical technology publishing house as well as being an author on regulatory matters and editor for a series of books on biomaterials.

He holds a Masters Degree in Applied Theology from University of Wales, Bangor, a Bachelor of Science degree in Applied Chemistry from Northumbria University and is a member of the Royal Society of Chemistry.

New for 2020: Live webinars

Amid ongoing uncertainty with travel plans, this is one of our many courses which we are now delivering both in traditional face-to-face format, and as a live webinar.

Delegates attending the webinar format benefit from:

- Reduced prices - and no travel costs
- The same content and presenters
- Interactive virtual classroom environment

Visit our website for more information.

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 NBMED

Conducting a pre-market clinical evaluation and the literature review

- The Clinical Evaluation (Literature Review)
- What's involved and how it should be conducted
- What documents are required – 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

Documentation for pre-market (regulatory) clinical investigation

- What documentation is needed?
- How this should be produced and what detail is required
  This presentation will include template documentation for clinical investigation plans, investigator brochures, case report forms and consent forms

How to obtain the necessary approvals for pre-market studies

- How to obtain Researth Ethics approval
- How to obtain National competent authority approvals
- Other necessary approvals
- What to provide, timescales and practicalities

Study management and monitoring of regulatory clinical investigation

- Key aspects 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

The differences between drugs and devices

Medical Device Studies: Clinical Evidence

Schedule and prices

Three ways to book:

Online
management-forum.co.uk/2156

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
10774	**9-10 Nov 2020**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60		
10980	**10-11 May 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**29 Mar 21**
11318	**17-18 May 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**5 Apr 21**
10981	**8-9 Nov 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**27 Sep 21**
11427	**15-16 Nov 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**4 Oct 21**

Your choice of date & location

We can present this course on an in-house basis, tailored to your requirements, at your location and/or online. Contact us at inhouse@management-forum.co.uk or see inside the brochure for more details of how this can be a more cost-effective approach.

Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

FEE

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

PLEASE NOTE

Falconbury Ltd reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, Falconbury will refund the registration fee and disclaim any further liability.

TERMS AND CONDITIONS

The rest of the 'Small Print', the event cancellation policy and the terms and conditions are on our website, please visit management-forum.co.uk/content/terms-and-conditions