Medical Device Studies: Clinical Evidence

Description: This course has been designed specifically for those who are involved in gathering clinical evidence required for medical devices and in-vitro diagnostic products. Clinical data is required for all medical devices and the emphasis on high quality, appropriate clinical evidence has grown substantially in the last few years. 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 of a device is pivotal to CE marking a medical device. The collection of post market data is a key aspect of continued safety and performance considerations once the device is on the market.

This course will cover the full range of activities that should be applied during the collection of clinical evidence for both pre and post market studies. It will 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 should benefit from the advice and tips on the practicalities of conducting studies within Europe as well as the types of clinical data to collect in order to be compliant.

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

* Please note, events may be cancelled due to commercial or organisational reasons. In this case Research and Markets will refund all registration fees which have already been paid. Research and Markets will not refund any charges arising from the participant having to cancel or re-book transportation or accommodation which he or she has arranged.

Ordering:

Order Online - http://www.researchandmarkets.com/reports/3642613/

Order by Fax - using the form below

Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct.

Product Name: Medical Device Studies: Clinical Evidence
Web Address: http://www.researchandmarkets.com/reports/3642613/
Office Code: SCPLRO7T

Product Format
Please select the product format and quantity you require:

| Quantity       | Data 1 + Day 2 - Single User: | USD 2198 |

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: Mr ☐ Mrs ☐ Dr ☐ Miss ☐ Ms ☐ Prof ☐
First Name: ___________________________ Last Name: ___________________________
Email Address: * ___________________________
Job Title: ___________________________
Organisation: ___________________________
Address: ___________________________
City: ___________________________
Postal / Zip Code: ___________________________
Country: ___________________________
Phone Number: ___________________________
Fax Number: ___________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:

Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:

<table>
<thead>
<tr>
<th>Account number</th>
<th>833 130 83</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sort code</td>
<td>98-53-30</td>
</tr>
<tr>
<td>Swift code</td>
<td>ULSBIE2D</td>
</tr>
<tr>
<td>IBAN number</td>
<td>IE78ULSB98533083313083</td>
</tr>
<tr>
<td>Bank Address</td>
<td>Ulster Bank, 27-35 Main Street, Blackrock, Co. Dublin, Ireland.</td>
</tr>
</tbody>
</table>

If you have a Marketing Code please enter it below:

Marketing Code: __________________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp

Please fax this form to:

(646) 607-1907 or (646) 964-6609 - From USA
+353-1-481-1716 or +353-1-653-1571 - From Rest of World