Navigating the New European Clinical Trial Regulation (EUCT Regulation 536/2014)

Description: This course covers the newly proposed requirements for conducting Clinical Studies across the EU via the requirements of the EU Clinical Trial Regulation 536/2014 (for Drugs, Biologics & Combination Products). The course also covers recent updates on EU-GCP associated with the Directive, the highlights of the new EU Pharmacovigilance Directive, as it relates to studies and helpful tips into working with the European regulators. This NEW REGULATION will affect ALL Sponsors of Clinical Studies conducted in the EU. Changes against the current EU Clinical Trial Directive 2001/20/EC are highlighted. This new regulation is expected to go into Force in the EU no earlier than May 2016. Knowing what changes will be implemented now, will allow all Sponsors time to adjust their processes and responsibilities across the EU.

Course Objective:

Attendees will leave the Course clearly understanding the New Processes and Requirements for EU Sponsors of Clinical Trials as the New Regulation is published, rolled-out and implemented by the Member States, the European Medicines Agency and the European Commission. In addition, this Course has been updated to provide participants with competitive insight into:

- How to efficiently initiate trials, first patient, first visit.
- How to link the strategy of Country Selection to an ultimate EU Licensing Plan.
- Efficiently implementing studies via project teams and CROs at the National and multi-state level.
- How to stay compliant, What can make the difference in your data passing Regulatory scrutiny.
- Related area - GCP and PV-reporting updates
- New EUCT Regulation vs. FDA Regulations

Target Audience:

This 90-minute overview will be of value to clinical research professionals, project team members and associated disciplines conducting clinical studies across the European Union. The course will benefit the following stakeholders:

- Clinical Operations Staff
- Project Team Members
- Quality Assurance, Monitors, CRAs
- Regulatory Affairs
- Investigators & Site Study Staff
- Clinical Trial Supply
- CROs, Consultants, Insurers

Contents: Course Outline:

- Overview of the EU and the EU Regulatory Structure
- Marketing Authorization Options in the EU and Linkage to Conducting Clinical Studies
- Overview of the European Union Clinical Trial Regulation 536/2014
- Pertinent, Critical Articles of Regulation 536/2014
- Processes and Timelines
- The Ethics Committee
- Phases of a Clinical Trial
- Trial Protocol and Project Management
- Investigational Medicinal Product Dossier
- Standard Operating Procedures
- Clinical Trial Authorization Application
- Good Clinical Practice (GCP)
- Good Manufacturing Practice (GMP)
- Pharmacovigilance - New EU Requirements Overview
- End of a Clinical Trial
- Databases
- European Union vs. The United States
- Regulatory Process
- Questions

Ordering:

Order Online - [http://www.researchandmarkets.com/reports/3450906/](http://www.researchandmarkets.com/reports/3450906/)

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 and select the format(s) you require.

Product Name: Navigating the New European Clinical Trial Regulation (EUCT Regulation 536/2014)
Web Address: http://www.researchandmarkets.com/reports/3450906/
Office Code: SCPLJDV3

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Format</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Online Access (Recorded)</td>
<td>USD 249</td>
</tr>
<tr>
<td>Single User:</td>
<td></td>
</tr>
<tr>
<td>DVD - Enterprisewide</td>
<td>USD 499 + USD 57 Shipping/Handling</td>
</tr>
</tbody>
</table>

* Shipping/Handling is only charged once per order.

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:
Account number 833 130 83
Sort code 98-53-30
Swift code ULSBIE2D
IBAN number IE78ULSB98533083313083
Bank Address Ulster Bank,
27-35 Main Street,
Blackrock,
Co. Dublin,
Ireland.

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