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

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