WMDO
WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

ISO 14155:2011 - Clinical Investigation Planning

Product ID: 63
Level: CMDA
Duration: 30 mins
SME: Danielle Giroud
First Released On: 10/29/2009

Course Description:
Let's now proceed with section 5 of the standard on the clinical investigation planning
Section 5 of the ISO 14155 latest revision describes all activities needed during the investigation planning phase including the risk assessment, justification of the investigation design, CIP, Investigator brochure and CRF requirements, the monitoring plan, site selection, investigation agreements, labeling requirements and setup of data monitoring committee.

Learning Objectives:
After taking this course, the trainee will be able to describe all activities needed during the investigation planning phase; know that a risk assessment and clinical evaluation are always needed prior to starting a clinical investigation ; lookup carefully the content requirements of the essential documents such as the CIP, investigator brochure and CRF. Further make sure you establish a justification for the extend of monitoring you will apply during the clinical investigation and make sure you perform a thorough evaluation of your investigation sites before you commit to work with a given investigator. Apply the specific labeling requirements that are for most parts of this world specific for clinical investigations but may be different from one region to another and last but not least, to consider carefully whether a DMC needs to be involved.

Who Should Enroll:
Any party involved in a clinical investigation, primarily Sponsors, monitors, investigators, ethics committees, regulatory authorities and 3rd party reviewers.

Related Resources: Yes

Prerequsite Knowledge
The learner should be familiar with the different activities and types of documents involved in a clinical investigation. These are explained in the different courses of the effective monitoring course.

Price:

Premium: €46.00.- **Basic:** €61.00.-

Course Format:
All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: http://www.adobe.com/products/flashplayer).

Premium Account Holders:
Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.

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