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WORLD MEDICAL DEVICE ORGANIZATION

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Course Title:

ISO 14155:2011 - Clinical Investigation Close Out

Product ID: 65
Level: CMDA
Duration: 20 mins
SME: Danielle Giroud
First Released On: 10/29/2009

Course Description:
In chapter 7 of the revised ISO 14155, we will find elaborated requirements for either a premature termination of the clinical investigation or a temporary suspension and resuming a clinical investigation as well as for a routine close out.

Learning Objectives:
After taking this course the trainee will have reviewed all requirements on closing down or temporary suspend a clinical investigation either in a given site or throughout all sites involved; will know it is important to remember that documenting all actions is mandatory and that all essential documents as referred to in annex E of the standard needs to be kept in a traceable manner for a period that is defined by the regulatory authorities.

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
A basic understanding of what is a clinical investigation as well as knowledge of the previous ISO 14155 course contents will enable learners to apply the content of this 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.