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Course Title:

ISO 14155:2019 - Clinical Investigation Planning

Product ID: N176
Duration: 50 mins
SME: Danielle Giroud
First Released On: 06/06/2019

Course Description:
This course describes all activities involved in the clinical investigation planning process.
It covers the following topics:
- Risk assessment
- Justification of the investigational design,
- Clinical Investigation Plan (CIP),
- Investigator Brochure (IB),
- Case Report Form (CRF) requirements
- Monitoring plan,
- Site selection,
- Investigation agreements,
- Labeling requirements,
- Set up of data monitoring committee.

Watch the Course Trailer:

Learning Objectives:
Upon successfully completing this course, learners will be able to:
- Understand all necessary activities for the investigation planning phase
- Know that risk assessments and clinical evaluations are mandatory prior to starting clinical investigations
- Look up the content requirements of CIPs, IBs, and CRFs
- Establish justification for the extension of monitoring during clinical investigations
- Perform a thorough evaluation of investigation sites before committing to working with a given investigator
- Apply specific clinical investigation labeling requirements and be aware that these may vary from one region to another
- Consider whether a Data Monitoring Committee should be involved

Who Should Enroll:
Clinical research associates (monitors), clinical study coordinators, assistantseniorclinical research associates, clinical project and data managers, data entry personnel, ethics committee and institutional review board members, regulators, and notified body personnel involved in auditing clinical evaluations are all welcome to participate in this course.

Related Resources: Yes

Prerequsite Knowledge
The following series is required:
- Effective Monitoring of Medical Device Clinical Investigations (IDs 41–48, 59, 56, 50–55, 108, 96)

Price:

Premium: €114.00.- **Basic:** €152.00.-

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

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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.