

Course Title:

Designing a Strategic Medical Device Clinical Investigation Plan/Protocol

Product ID: N141

Level: MMDP

Duration: 90 mins

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First Released On: 05/14/2012

Course Description:

This course focuses on designing thorough clinical investigation plans using a logical, step-by-step approach. It covers basic strategic claims, how to develop a design so that it translates valid and feasible endpoints, and guidance and regulatory documents and requirements to ensure that the final results are aligned with market needs.

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, learners will be able to:

- Define claims as starting points for study designs
- Interpret the information found in guidance and regulatory documents and plan an appropriate study design for a future medical device investigation
- Implement feasible methods for realistic endpoints
- Build clinical investigation plan designs that are acceptable to investigators, patients, and regulators

Who Should Enroll:

Clinical project directors, managers, and senior regulatory managers are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following courses are required:

- ISO 14155: In-Depth Review (series; IDs 61–67)
- The European Union Regulatory System for Medical Devices (ID 145)
- The Japanese Regulatory System for Medical Devices (ID 146)
- US FDA 510(k) Notification Process (ID 92)
- US FDA Investigational Device Exemption (IDE) Overview (ID 121)

Price:

Premium: €341.00.- **Basic:** €454.00.-

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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Online Training for Medical Device Professionals
