

Online Training for Medical Device Professionals

Course Title:

Conducting studies using Electronic Data Capture

Product ID: 109

Level: CMDA

Duration: 30 mins

SME: Melody Lashlee

First Released On: 05/04/2010

Course Description:

This course introduces Electronic Data Capture (EDC), a method used to collect and deliver clinical trial data to sponsors in electronic form. Its objective is to reduce clinical data errors, increase the efficiency of communication between sponsors and investigators, and ultimately reduce the time needed to deliver regulatory submissions. This course provides comprehensive and expert recommendations to put EDC processes in place and to ensure ongoing effective management.

This course is based on the ISO 14155: 2011 and 21 CFR 11 requirements. It provides a detailed overview of the processes, roles, and responsibilities needed to implement EDC in clinical studies, as well as which pitfalls to avoid and what factors to consider when selecting an EDC vendor.

Watch the Course Trailer:

Learning Objectives:

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

- Define and demonstrate the basic principles and objectives of conducting studies using EDC
- Identify the roles, responsibilities, and processes involved in clinical studies using EDC
- Assess and select successful EDC vendors

Who Should Enroll:

Clinical project managers and directors, data managers, biostatisticians, and quality assurance managers involved in vendor selection and compliance with applicable laws and standards are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

The following courses are required:

- Clinical Project Management Complete Ten Course Suite (IDs 97–106)
- Overview of Data Management Plan and Query Process (ID 108)

Price:

Premium: €69.00.- **Basic:** €91.00.-

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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