

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:

Simply put, Electronic Data Capture (EDC) is a method for collecting clinical trial data in such a way that they are delivered to the sponsor in electronic form as opposed to using paper Case Report Forms. With the objective to reduce clinical data errors, increase efficiency of communication between sponsor and investigator, and ultimately reduce time to regulatory submission, EDC has come a long way throughout recent years.

The course 'Conducting studies using Electronic Data Capture' will provide you with a comprehensive and expert recommendations to put these processes in place and ensure efficient ongoing management. The course takes into account the requirements of ISO 14155:2011 and 21 CFR part 11 and provides a detailed overview of processes and roles and responsibilities, how to effectively implement EDC in clinical studies as well as identifying pitfalls to avoid and considerations to make when selecting an EDC vendor.

Learning Objectives:

Upon completion of this course, trainees will be able to correctly and successfully:

- Define and demonstrate the basic principles and objectives of conducting studies using Electronic Data Capture (EDC)
- Identify the roles, responsibilities and process involved within a clinical study using Electronic Data Capture
- Successfully assess and select EDC vendors.

Who Should Enroll:

Clinical Project Managers, Clinical Directors, Data managers, biostatisticians, quality assurance manager involved in vendor selection and compliance with the applicable standards and laws.

Related Resources: Yes

Prerequisite Knowledge

General understanding of the clinical operations as per Clinical Project Management suite (ID 95) and data management activities/responsibilities (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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