

**Course Title:**

## ISO 14155:2019 - Clinical Investigation Conduct

Product ID: N177

Duration: 40 mins

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First Released On: 06/06/2019

**Course Description:**

This course describes the conduct and activities at the beginning and throughout the course of clinical investigations in accordance with ISO 14155.

This course covers the following topics:

- Initiation visits
- Site monitoring
- Adverse event and device deficiency reporting
- Documents, documentation, and data control
- Electronic system requirements
- Auditing requirements
- Training new site personnel
- Guaranteeing subjects' privacy and confidentiality
- Accounting for all subjects

### Watch the Course Trailer:

**Learning Objectives:**

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

- Comply with ISO 14155 on the following subjects:
- Site initiation and monitoring
- Adverse events and device deficiencies
- Documents, documentation, and data control
- Requirements of electronic systems
- Auditing requirements
- New site personnel
- Subject privacy and confidentiality
- Accounting of subjects

**Who Should Enroll:**

Clinical research associates (monitors), clinical study coordinators, assistant senior clinical 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

**Prerequisite Knowledge**

Knowledge of monitoring medical device clinical investigations is recommended.

**Price:**

**Premium:** €91.00.- **Basic:** €122.00.-

**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.



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## Online Training for Medical Device Professionals

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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.