

## Online Training for Medical Device Professionals

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### Course Title:

## ISO 14155:2019 - Clinical Investigation Close Out

Product ID: N178

Duration: 25 mins

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First Released On: 06/06/2019

### Course Description:

This course explores the requirements for both premature terminations and temporary suspensions of clinical investigations. It provides in depth review of the risk management processes to be applied when a clinical investigation is to be suspended for un-anticipated risks that occur. It also reviews the process of resuming routine clinical investigation close outs and the requirements and content of the clinical investigation report

### Watch the Course Trailer:

### Learning Objectives:

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

- Close down or temporarily suspend a clinical investigation in a given site or throughout all sites involved and understand the necessary activities under risk management.
- Recognize that documenting all actions is mandatory
- Take into account that the essential documents referred to in Annex E of ISO 14155 must be kept in a traceable manner for a period of time determined by regulatory authorities
- Understand the contents of a clinical report
- Apply the necessary regulatory steps such as integrating the report in the technical file and update necessary related risk management documents.

### 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

The following material is required:

- A basic understanding of clinical investigations
- ISO 14155 - Scope (IDN158)
- ISO 14155 - Ethical Considerations (IDN175)
- ISO 14155 - Clinical Investigation Planning (IDN176)
- ISO 14155 - Clinical Investigation Conduct (IDN177)

### Price:

**Premium:** €57.00.- **Basic:** €76.00.-

### 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>).



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**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.