

How to become an investigator in clinical trials

Two days training

12th & 13th of October, 2023

Course description:

The course is dedicated to resident doctors, specialists, clinicians, or family doctors, beginners or already participants in clinical trials, who want to work (or are already working) in this field of clinical trials and need a set of consolidated knowledge adapted to the existing legislation in clinical research.

Course agenda

Day 1 – 12th of October, 2023

13:00-13:30 Registration

- **13:30 - 13:45** - A Short Introduction to the Subject and Purpose of the Course - Dr. Cristina Florescu Moraid (15 min)
- **13:45 - 14:30** - The role of the principal investigator in a clinical study - Conf. Dr. George Daniel Radavoi (45 min)
- **14:30 - 15:30** - The drug development cycle and good clinical practice - Dr. Catalina Sarbu (60 min)
- **15:30 - 16:30** - The responsibilities of the investigator required by the Good Clinical Practice Guide versus the responsibilities of the clinical study sponsor - Dr. Catalina Sarbu (60 min)

16:30- 17:00 Coffee Break

- **17:00 - 18:00** - Essential documents in clinical studies - Dr. Catalina Sarbu (60 min)
- **18:00 - 18:30** - *The* medical file and other documents used in clinical studies by the investigator-Dr. Catalina Sarbu (30 min)
- **18:30 - 19:00** - Questions and answers session (30 min)

Day 2 – 13th of October, 2023

13:00-13:30 Registration

- **13:30 - 14:30** - How do you organize and manage a successful clinical trial? - Prof. Dr. Michael Schenker (60 min)
- **14:30 - 15:00** - Informed consent - the investigator's approach - Dr. George Tanaseanu (30 min)
- **15:00 - 15:30** - Methods of selecting eligible patients - Dr. George Tanaseanu (30 min)

15:30 - 16:00 Coffee Break

- **16:00 - 16:30** - Safety reporting - Dr. Catalina Sarbu (30 min)
- **16:30 - 17:00** - Inspection and audit at the enrollment center - Dr. Catalina Sarbu (30 min)
- **17:00 - 17:30** - Questions and answers session (30 min)
- **17:30 - 18:00** - Final written test (30 min)