

## INTENSIVE STUDY NURSE TRAINING



The study team at the clinical site has many actors: principal investigator, sub-investigators, study coordinators, study nurses etc.

The Clinical Research Nurse, under the guidance and supervision of the Principal Investigator (PI), ensures that the clinical trials are conducted following the study protocol. This position is primarily responsible for the accurate completion of visit procedures and collection of information from the patients participating in the study according to protocols to protect the health, safety and welfare of research participants. In some particular cases, the study nurse may act as the study coordinator.

30 March – 3 APRIL

### **5 DAYS COURSE**

**AIM:** to prepare properly study nurses for their participation in clinical trials developed in Romania

**COURSE PARTICIPANTS PROFILE:** nurses from hospitals, who are already active as study nurses or willing to be, with medical general or laboratory medicine background.

**COURSE DURATION:** Daily, from 14:00h to 18:30, 5 working days

**METHOD:** Different physicians, clinicians or laboratory specialists, playing the role of participating in CT as investigators and clinical research logistics coordinators are speakers for this project.

Nurses would have the possibility to put the knowledge in practice (1 day of practical exercise in a phase I unit and a lab).

### **BENEFITS FOR PARTICIPANTS:**

- diploma issued by partners;

- continuing medical education credits from the National Order for General Nurses, Midwives and Medical Nurses - OAMGMAMR Bucharest Branch
- enhance knowledge for future participation of the study nurse to CT
- add value to nurse CV for better employment or retention within hospitals

**FEES:** 500 Lei / 100 Euro (no VAT refund)

**Discounts:** 5% for over 3 participants and 10% for over 5 participants from the same institution.

**Locations:** Online

**Certificates of Attendance:** after the completion of the course, they will be available to be downloaded from the participants' accounts on [www.avantyo.com](http://www.avantyo.com).

**Attendance only by online reservation. Booking available after registering on this site. Check the red button under the price.**

For more information and assistance please contact us:

[info@avantyo.com](mailto:info@avantyo.com), [diana.lupu@avantyo.com](mailto:diana.lupu@avantyo.com), 0726 840 456.

Come back soon for more information about this course!

## PART I

### MODULE I - INTRODUCTION IN CLINICAL TRIALS

Day 1, Monday

**Location:** OAMGMAMR Bucharest Branch, 12 Avrig Str, 2nd District, Bucharest

14:00 – 16:00

- Generalities, scope, benefits, course program
- Definitions, type of study and classification, patient population, clinical trials participants

**Speakers:** *Dr Cristina Florescu Moraid (Avantyo); Carmen Mazilu (OAMGMAMR)*

16:00 – 16:30 Coffee break

16:30 – 18:30

- Introduction into principles of GCP (- Good Clinical Practice)
- Introduction into principles of GCLP (Good Clinical Laboratory Practice)

**Speaker:** *Dr Cristina Florescu Moraid (Avantyo)*

### MODULE II - TREATMENT OF ENROLLED SUBJECT AT SITE FOR LABORATORY TESTS

Day 2, Tuesday

**Location:** OAMGMAMR Bucharest Branch, 12 Avrig Str, 2nd District, Bucharest

14:00 – 16:00

- Specimen collection for laboratory tests (microbiology, parasitology, virology)

***Speaker:** Dr Mihaela Toderici ("Ana Aslan" National Institute of Gerontology and Geriatrics, Bucharest)*

16:00 – 16:30 Coffee break

16:30 – 18:00

- Blood drawing for laboratory tests (immunochemistry, haematology and coagulation)

***Speaker:** Dr Codruta Delia Popa (Fundeni Clinic Institute, Bucharest)*

### **MODULE III - TREATMENT OF ENROLLED SUBJECT AT SITE – INPATIENTS**

Day 3, Wednesday

**Location:** OAMGMAMR Bucharest Branch, 12 Avrig Str, 2nd District, Bucharest

14:00-16:00

- Roles and responsibilities of the clinical study team
- Study protocol: generalities, study flow-chart
- Screening and enrolling the subject in the study
- Adverse events: observation, monitoring and reporting

***Speaker:** Dr.Ileana Stoicescu ("Marius Nasta" Institute of Pneumophysiology, Bucharest)*

16:00 – 16:30 Coffee break

16:30 – 17:30

- Hospitalized patients - responsibilities of study nurses at the study site
- Study medical procedures (ECG, Rx etc.)
- Study medication-administration, monitoring

***Speaker:** Dr.Ileana Stoicescu ("Marius Nasta" Institute of Pneumophysiology)*

17:30 – 18:30

- Logistics coordination of clinical trials
- Shipment of CT samples and study medication

*Speaker: Cosmin Tincu - World Courier Romania*

## **PART II – Practical Exercise**

### **MODULE IV - TREATMENT OF ENROLLED SUBJECT AT SITE – Practical Exercises**

Day 4, Thursday

14:00-15:00 **PRACTICAL EXERCISE 1**

**Location:** Arensia Exploratory Medicine, Phase I Unit

- Practice at study site -patients and documentation flow (visit and training within a phase I unit)

16:00 – 17:00 Coffee break

16:30 – 18:30 **PRACTICAL EXERCISE 2**

**Location:** Bioclinica Laboratories, 161 Calea Calarasi, 3rd District, Bucharest

- Laboratory practice – patients, sample and documentation flow (visit and training within a laboratory conducting clinical trials)

*Speaker: Dr Mihaela Rotaru - Experienced head of Laboratory*

## **PART III – Evaluation**

### **MODULE V - FINAL EXAMINATION**

Day 5, Friday

**Location:** OAMGMAMR Bucharest Branch, 12 Avrig Str, 2nd District, Bucharest

14:00-16:00

- Written test, 2h

16:00-17:00

- Coffee break for participants and releasing of tests' results

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*If you would like to be placed on a waiting list for the next course or you need something else, please let us know at [info@avantyo.com](mailto:info@avantyo.com). Do not forget to mention your specific education needs in clinical trials.*

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