AVANTYO
INSTITUTE OF CLINICAL RESEARCH

INNOVATION IN EDUCATION

General Pharmacovigilance Course and Applicability in Clinical Trials

27th September 2024

Online

Trainer: Prof. Dr. Viorel Robert Ancuceanu

AGENDA

9:00 – 9:30 REGISTRATION

9:30 – 10:25 Obligations of the pharmacovigilance department regarding adverse events received from clinical trials.

10:25 – 11:25 DSUR – legislative aspects, preparation, and submission to the authorities

11:25 – 11:40 Coffee break

11:40– 12:30 IMPD – legislative aspects, the obligations of the pharmacovigilance department for the preparation of the document

12:30 – 13:00 LUNCH

13:00 – 13:50 Management of "medical inquiries": registration, obligations of the departments involved in their management, reconciliation between departments.

13:50 – 14:45 Management of adverse events and reactions in bioequivalence and phase 1 clinical trials

14:45 – 15:35 Clarifications regarding the preparation of the "Reference Safety Information" from the Investigator's Brochure

15:35 – 16:05 QA

NOTE: Due to the interactive nature of the agenda, the timing may change.