AVANTYO
INSTITUTE OF CLINICAL RESEARCH

INNOVATION IN EDUCATION

Clinical Research Associate (CRA) Advanced Level

Online Training |January 26th, 2024

AGENDA

8:30 – 9:00 REGISTRATION

9:00 – 10:30

- Virtual Clinical Trials – Basic principles
- Guidelines for Computerized Systems in Clinical Investigations
- Electronic Medical Records
- Electronic Informed Consent
- Electronic Trial Master File
- Electronic Investigator File
- Electronic patient support and data collecting
- Electronic Data Capture (eCRF)
- The concept of Certified Copies

10:30 – 10:40 COFFEE BREAK

10:40– 11:45

- Remote monitoring visit
- Remote SDR / SDV

11:45 – 12:45

- Understanding Essential Documents and their management
- Cross-check of documents (Case scenarios)

12:45– 13:30

- Monitoring and safeguarding compliance to regulatory requirements, to protocol, manuals, systems.

- Aspects of patients' recruitment and retention (strategies on the various sites potential)
- Safety reporting

13:30 – 14:00 LUNCH

14:00 – 15:30

- Fraud in Clinical Research
- Investigators anti-bribery screening

15:30 – 16:30

- Screening and site-selection activities including QV (evaluating the enrolment potential)
- Essential points of a successful IV (initiation Visit)

16:30 – 17:30

- Audit preparation, participation, answers

17:30 – 18:00 TEST

- Communication with the site, the colleagues, the sponsor
- TEST (multiple choices)

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