AVANTYO
INSTITUTE OF CLINICAL RESEARCH

INNOVATION IN EDUCATION

Clinical Research Associate Entry Level (CRA)

Online Training | September13th, 2024

AGENDA

8:30 – 9:30 REGISTRATION

9:30 – 10:30 GENERAL OVERVIEW OF CLINICAL TRIALS

- A short history of Good Clinical Practice (GCP) guidelines
- Drug development and various types of clinical trials
- The Principles of ICH GCP (International Council for Harmonization guidelines for Good Clinical Practice)
- Declaration of Helsinki
- Running a clinical trial - the steps

10:30 – 10:40 COFFEE BREAK

10:40 – 12:30 RESPONSIBILITIES

- Investigators' responsibilities
- Monitoring responsibilities and limits
- Sponsor's responsibilities

12:30 – 13:00 LUNCH

13:30 – 14:00 ESSENTIAL DOCUMENTS IN CLINICAL TRIALS

- The significance of various documents in clinical trials
- The patient file and other source documents in clinical trials (practical approach)
- Medical history and physical examination
- Concomitant medical conditions and related medication
- Non-clinical investigations in clinical trials
- ALCOAC principles in practice

14:00 – 14:30 INFORMED CONSENT

- The Informed Consent Procedure
- Legal representative, witness

14:30 – 15:30 SAFETY REPORTING IN CLINICAL TRIALS

- Investigators to sponsor
- Sponsor to authorities
- The unblinding procedure

15:30 – 16:00 AUDITS AND INSPECTIONS

- Audits and inspections including frequent audit findings
- FDA (U.S. Food and Drug Administration), EMA (European Medicines Agency), sponsor inspections

16:00 – 16:45 MISCELLANEOUS

- Data management, statistical analysis
- Archiving of clinical trials at the site (ISF) and sponsor (TMF)
- Site contracts and investigators/institutions payment
- Subcontracted vendors

16:45 – 17:45 TEST

- Test (multiple choices)