CTR 217 EDC Application Development

COURSE DESCRIPTION:
Prerequisites: CTR 125
Corequisites: None

This course is designed to provide students with the knowledge and understanding to use an electronic data capture (EDC) application development tool to build a functional and effective clinical study. Topics include data design structure based on the protocol, define basic application settings/permissions, building forms, incorporating edit checks in the application, data entry, data loading, coding, standard and ad hoc report development, testing processes, mid

II. Upon reading a study protocol, identify/define which case report form modules are needed to meet the data needs of the clinical study protocol
    A. Summarize the purpose and process of cross-functional, multi-disciplinary review of required CRFs
    B. Analyze mock protocol and system requirements to identify required CRFs
    C. Explain the purpose of CRF standards including CDASH and organization Global Library (GLIB)
    D. Complete a mock gap analysis between required CRFs and GLIB

III. Build/create case report form entry screens based upon CDISC standards
    A. Summarize regulatory and industry expectations for use of CDASH standards
    B. Make use of EDC development tools to create and edit forms and fields
    C. Develop EDC visit matrix to align with protocol
    D. Apply principles of patient and site focused design to reduce patient and site data entry burden
    E. Modify CDASH and GLIB CRF templates to match mock CRF specifications