CTR 217 EDC Application Development

COURSE DESCRIPTION:

Prerequisites: CTR 215
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-study change administration, and application support. Upon completion, students should be able to design an EDC application, evaluate a study protocol and identify the critical data items to be collected via EDC, understand CDSIC standards and their application, develop and implement appropriate edit checks and standard reports, and implement testing plans to establish a quality application. Credit Hours: 3 Contact Hours 4.

LEARNING OUTCOMES:

Upon completion of this course, the student will demonstrate basic cognitive and practical knowledge and skills in each of the following areas:

1. Understanding of basic database design and how the design of the EDC application will mirror the flow of the study protocol activities
2. Upon reading a study protocol, identify/define which case report form modules are needed to meet the data needs of the clinical study protocol
3. Build/create case report form entry screens based upon CDISC standards
4. Develop and incorporate edit checks into the EDC application to help to ensure data integrity of data that are entered or captured from third party source
5. Perform administrative functions of the EDC application to develop user permissions, manage users, post or publish new studies and manage mid-study changes
6. Create and maintain basic standard reports to provide baseline information in a dashboard like presentation

OUTLINE OF INSTRUCTION:

I. Understanding of basic database design and how the design of the EDC application will mirror the flow of the study protocol activities
   A. Apply principles of Quality by Design (QbD) and Quality Risk Management (QRM) to EDC development planning, startup, conduct and close activities
   B. Relate principles of patient and site focused design to database design
   C. Outline the EDC development lifecycle including planning, startup, study conduct, mid-study changes, study close and archival
   D. Summarize regulatory and industry standard requirements for EDC functionality
   E. Develop essential documents required for design and documentation of EDC development

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
    F. Take part in peer review and user acceptance testing (UAT) activities to validate EDC design

IV. Develop and incorporate edit checks into the EDC application to help to ensure data integrity of data that are entered or captured from third party source
    A. Apply principles of Quality by Design (QbD) and Quality Risk Management (QRM) to development of data validation tools
    B. Apply principles of patient and site focused design to reduce patient and site data validation burden
    C. Summarize the process of integrating or reconciling EDC and third-party vendor data

V. Perform administrative functions of the EDC application to develop user permissions, manage users, post or publish new studies and manage mid-study changes
    A. Relate regulatory requirements for electronic and computerized systems to the user access management
    B. Categorize common EDC user roles and permissions-based study team roles
    C. Complete a mock periodic access user review to confirm user authorization status
    D. Summarize best practices for conducting mid-study changes
    E. Complete a mock impact analysis based on protocol amendment

VI. Create and maintain basic standard reports to provide baseline information in a dashboard like presentation
    A. Relate trend review and reporting to principles of QBD and QRM
    B. Recommend standard reports for mock protocol
    C. Build mock report based on report specifications

REQUIRED TEXTBOOK AND MATERIAL:

The textbook and other instructional material will be determined by the instructor.