BOSTON
EVENTS LIST

Clinical Data Management

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Event URL : http://www.BostonEventsList.com/events/clinical-data-management-jul-2018

Organizer : GlobalCompliancePanel

Venue :

Location : Boston, MA,
Boston, MA, US, ZIP: 10001

Clinical Data Management

When new drugs or devices are tested in humans, the data generated by, and related to, these trials is known as clinical data. This data represents a huge investment by the biopharmaceutical or device company and is one of its greatest assets. It is this data that will eventually make a new product both useful as a treatment or therapy and marketable. The management of clinical data, from its collection during a trial to its extraction for analysis, has become a critical element in the steps to prepare a regulatory submission and to obtain approval to market a treatment. As its importance has grown, clinical data management (CDM) has changed from an essentially clerical task in the late 1970s and early 1980s to the highly computerized specialty it is today.

This seminar is based on the current state of regulations and will cover the essential parts of the data management plan, study startup, study conduct, study closeout and study monitoring.

A data management plan or DMP is a formal document that outlines how data are to be handled both during a research project, and after the project is completed. The goal of a data management plan is to consider the many aspects of data management, metadata generation, data preservation, and analysis before the project begins; this ensures that data are well-managed in the present, and prepared for preservation in the future.

Study startup activities include designing case report forms (CRFs), paper or computer;

specifying cleaning rules (edit checks); building and testing the database; and releasing the study database to collect data.

Study conduct activities include collecting the data on CRFs and via electronic files, cleaning that data, managing adverse event and serious adverse event collection, and producing reports.

Study closeout focuses on ensuring the data is complete and of a quality to support final analysis.

Study monitoring is an in-person evaluation carried out by sponsor personnel or representatives at the sites at which the clinical investigation is being conducted. On-site monitoring can identify data entry errors (e.g., discrepancies between source records and case report forms (CRFs)) and missing data in source records or CRFs; and assess compliance with the protocol and investigational product

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At the end of this class attendees will be able to:

- Define best practices as they apply to CDM processes
- Describe CDM processes from study start-up to database lock
- Apply best practice rationale when assessing data collection requirements/instruments
- Evaluate the benefits of standardization in establishing CDM processes
- Discuss current technology/methods of data collection and associated documentation

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Who Will Benefit:

- New or aspiring Clinical Data Managers
- Clinical Data Managers
- Data Coordinators
- Clinical Research Associates
- Data Management Personnel
- Biostatisticians
- Regulators
- Doctors
- Nurses
- Project Managers
- Government employees at clinicaltrials.gov
- College Students and New Graduates in a Scientific Field
- This course is also ideal for "on-boarding" of individual new hires or entire teamJOA180521CEVs

Event Categories :