National Cancer Institute
Center for Cancer Research
Fellowship Clinical Trial Education Series for 2013-2014

Lecture 1: November 19, 2013

Clinical Trial Design

Clinical research is research conducted on human beings (or on material of human origin such as tissues, specimens, and cognitive phenomena) with the goal of generating useful knowledge about human health and illness. A clinical trial is one type of clinical research that seeks to answer a scientific or medical question about the safety or potential benefit of an intervention such as a medication, device, teaching concept, training method or behavioral change. This session will provide an overview of clinical trial design focusing on the types of clinical trials and standard design for Phase I-III clinical trials.

Lecture 2: November 26, 2013

U. S. Drug Development and Regulatory Oversight of IND Clinical Trials

The drug development process is a highly regulated process between manufacturers and the FDA. This session provides an overview of the Investigational New Drug Application (IND) process including historical basis for drug regulations.

Role of the Sponsor

Funding for clinical research comes from the federal government or the private sector. In addition to providing financial resources, some funding groups also provide the investigational agent. They are referred to as the Sponsor and are responsible for the initiation and management of a new agent under the FDA's Investigation New Drug (IND) Application (Title 21 Part 312). This session will review the role of the IND sponsor.

Lecture 3: December 3, 2013

Protocol Development, Review and Approval Process

The clinical trial protocol is the heart of any research project. It is a "recipe" for ensuring that the procedures outlined in the research study are carried out in a consistent, reproducible manner. All members of the research team ensure that protocols are adhered to which requires an in-depth knowledge of all components included in the protocol document and the various review and approvals required. This session will review how to plan a protocol, describe the essential elements of a protocol and measurement tools specific to oncology clinical trials, provide resources for protocol development, and discuss the review and approval process.

Lecture 4: December 10, 2013

Statistical Considerations in Trial Design and Data Analysis

This session will provide an overview of the statistical principals for designing and analyzing clinical trials including statistical concepts and tests, selecting optimal study design, statistical issues with Phase I – III designs, sample size calculation and interpretation of study results.

Lecture 5: December 17, 2013

Roles of the Research Team

All staff involved in clinical research must adhere to the regulations and understand the guidelines that govern clinical research. The Principal Investigator is ultimately accountable for the overall conduct of the clinical trial. This session will provide an overview of the roles and responsibilities of the research team and support staff including those roles seen in the Center for Cancer Research: Investigator, including the role in FDA regulated research and FDA Guidance on the Supervisory Role of the Investigator; Research Nurse Coordinator; and Data Manager.

Informed Consent

The cornerstone of clinical research today is that of the informed consent process. History has taught both investigators and research participants many valuable lessons. Informed consent is more than just a document. This session will define informed consent, its guiding principles, the document, and the process for obtaining consent for both English speaking and non-English speaking participants.

Lecture 6: January 8, 2014

Documentation in Clinical Research

Documentation in clinical practice is essential for communication among healthcare providers. This is also true for clinical research that involves patient volunteers. It is from this documentation that protocol-specific data are abstracted from and transferred to case report forms (CRFs). This session will outline appropriate clinical research practice documentation. In addition to clinical documentation, documentation of the regulatory process of protocol review and implementation is required. A regulatory binder or file contains all study-specific information and regulatory documentation. It organizes essential documents, provides easy access to essential documents by the trial monitor, auditor, IRB, or regulatory authorities

Clinical Data Management

Clinical data management (CDM) is a variety of activities involving the handling of data or information that is outlined in the protocol to be collected/analyzed. CDM is a multidisciplinary activity. This session will provide an overview of clinical data management including case report form design and clinical trial management systems.

Lecture 7: January 14, 2014

Documenting, Recording, and Reporting of Adverse Events (AE) and Unanticipated Problems (UP)

Monitoring of adverse events and unanticipated problems are critical to participant safety and data integrity. This session will provide an overview of AE and UP, including assessment, documentation, recording, and reporting.

Lecture 8: January 21, 2014

Clinical Trial Monitoring

Monitoring of clinical trials is necessary to assure that the rights and safety of participants are and that clinical trial data are accurate, complete, and verifiable from source documents. This session will review the purposes and regulations related to monitoring, discuss various types of monitoring plans, and discuss how to prepare for monitoring visits.