Module 3 Data Collection, Management and Basic Statistical Concepts

Goal and Learning Objectives

The goal of this module is to learn about the basic principles of data collection, management and some basic statistical concepts in clinical research.

Specific Objectives:

1. Describe and understand what data should be collected.
   - Data collected depends on question being asked and hypothesis of study
   - Demographic data
   - Independent and dependent variable data
   - Possible confounders

2. Describe and understand standardization of data collection.
   - Data forms
   - Data code book
   - Methods of data collection
   - Testing data collection
   - Training and calibration of personnel who collect data
   - Quality control of data collection
   - Data storage and transmission

3. Describe an understand some basic statistical concepts in clinical research.
   - Convenience and probability /random sampling
   - Statistical Power
   - Type I error
   - Type II error
   - Sample size
   - Random allocation of interventions in clinical trials
   - Common randomization methods
   - Clinical versus statistical significance
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Key Concepts

The following are the key concepts to be focused on in this module. Trainers of this module are expected to have full understanding of these key concepts and to be able to explain them to the trainees using the materials provided.

1. To begin a clinical research study, it is essential that new investigators appreciate and understand some basic aspects of data collection, data management and basic statistical concepts that are important in clinical research.

2. An essential element of data collection and management is understanding what data should be collected. The data that should be collected depends on the:
   - Question being asked in the study
   - Testable research hypothesis of the study
   - Type of study being planned (observational, clinical trial)

3. It is important to understand that data collection in a clinical study must be standardized. This involves:
   - Deciding who collects data and enters it in the study data base
   - Assuring quality control of data
   - Training and calibrating personnel who will record and enter study data
   - Deciding how data will be stored and transmitted

4. It is essential that clinical researchers understand some basic statistical concepts involved in clinical research. These include:
   - Convenience and probability (random) sampling
   - Statistical power
   - Determining Sample
   - Type I and type II error
   - Statistical significance
   - Clinical significance
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References

Clinical Research


Data Management


Statistical Concepts and Sample Size


 Examiner Calibration

Randomization


Statistical and Clinical Significance