Introduction to Clinical Research

Course Coordinator: Prof. Matitiahu Berkovitch MD

Course Description

This course will focus on the elementary aspects of clinical research. It is designed to familiarize the student with the basics of clinical research, types of clinical research, study design and methodology, basic statistics, basic aspects of pre-clinical and clinical studies, rules and regulations that need to be followed, ethics, and follow up of trial participants.

Course Objectives

1. To understand why and how clinical research is performed
2. To know the differences between pre-clinical and clinical research
3. To define a research question
4. To understand the steps involved in conducting clinical research
5. To review and evaluate the main study designs used in clinical research: case-control, cohort, clinical trials, cross-sectional, and meta-analyses
6. To understand the basis of statistical analyses of clinical research studies
7. To understand the methodological basis of diagnostic and prognostic testing

Credit – 2 credits

Topics

1. Who/what/why/where of clinical research
2. Developing clinical research questions/hypotheses
3. Types of clinical research designs
4. Ethics of clinical research
5. Designing a clinical research protocol
6. Outcomes, co-variants, sample size, analytic plans
7. Writing a clinical research paper and submitting to a journal
8. Effective data presentation: platforms & posters

Course Requirements and Grading System:

1. Mandatory participation in at least 80% of classes: 10%
2. Each participant should present up-to-date (from the last ~5 years) clinical research : 40%
3. An exam (multiple-choice questions), based on lectures and presentations, at the end of the course : 60% of the final grade

Required Reading

Ezekiel J. Emanuel, MD, PhD; David Wendler, PhD, and Christine Grady, PhD. "What Makes Clinical Research Ethical "Journal of the American Medical Association, Vol. 283, No. 20, May 24, 2000, pp. 2701-2711.

International conference on harmonization of technical requirements for registration of pharmaceuticals for human use, ich harmonized tripartite guideline structure and content of clinical study reports e3 current step 4, version dated 30 November 1995

ICH Topic E 9Statistical Principles for Clinical Trials STRUCTURE AND CONTENT OF CLINICAL STUDY REPORTS, E3 NOTE FOR GUIDANCE ON STATISTICAL PRINCIPLES FOR CLINICAL TRIALS

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm

http://www.hma.eu/

http://www.regsource.com/

http://www.ich.org/home.html