Design and Analysis of Clinical Trials (m62219p)

Instructor: –

Elective Course, 3rd or 4th semester, 5 ECTS units

Course level: Graduate (MSc)

Language: Greek (or English if foreign students attend)

Course Description
Principles of Clinical Trials (CT), trials types, CT protocol, blinding, randomization methods, sample size, ITT, PP, TR populations, covariate adjustment, cross-over trials, analysis of repeated measures data, linear mixed models, GEE models, introduction to meta-analysis.

Prerequisites
Students should have basic knowledge of mathematical calculus, probability theory and generalized linear models.

Target Learning Outcomes
After successfully completing the course, students will be able to:

- write the statistical parts of a CT protocol,
- find the appropriate size of a CT,
- randomize patients into experimental groups,
- analyze clinical trials data,
- perform a basic meta-analysis using statistical techniques.

Recommended Bibliography

- Everitt, B.S. and Pickles, A. (1999). Statistical Aspects of the Design and Analysis of Clinical Trials, Imperial College Press.
- Chow, S-C. and Liu, J-P. (2013). Design and Analysis of Clinical Trials, Wiley.
- Fitzmaurice, G.M., Laird, N. and Ware, J. (2004). Applied longitudinal data analysis, Wiley.
- Whitehead, A. (2002). Meta-Analysis of Controlled Clinical Trials. Wiley.

Teaching and Learning Activities
One three-hour lecture per week, study exercises as homework (some to be submitted).

Assessment and Grading Methods
The final grade is the weighted average of the final examination grade (60%) and the grade of the study exercises to be submitted (40%).