



“Alexandru Ioan Cuza”
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Faculty of Computer Science



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Faculty of Medicine

Statistical Methods for Clinical Trials

June 18th – 20th, 2012

Faculty of Computer Science

“Alexandru Ioan Cuza” University of Iasi

Romania

<http://thor.info.uaic.ro/~rng/>

Description

This short course will introduce statistical methods for design, conduct, monitoring and analysis of clinical trials. Topics include overview of clinical trials as a scientific method for clinical and experimental medicine; ethical issues; experimental designs; sample size estimation; randomization and masking; elementary survival analysis; group sequential methods for data monitoring in interim analysis; and issues in data analysis. Examples from the literature on a number of well-known randomized, controlled trials (RCTs) will be used to illustrate the concepts discussed.

Intended Audience

This short course is intended for biostatisticians and clinicians interested in clinical trials.

An introductory course on statistical methods is sufficient as a prerequisite for the short course.

Invited Professor

KyungMann Kim, Ph.D.

University of Wisconsin-Madison, Madison, Wisconsin, U.S.A.

Biographic Details

Professor Kim received B.S. in computer science and statistics and M.S. in statistics from Seoul National University, Seoul, Korea and Ph.D. in statistics from the University of Wisconsin - Madison. He is Professor of Biostatistics, Department of Biostatistics and Medical Informatics, Director of Biostatistics Shared Resource, Carbone Cancer Center, at the University of Wisconsin-

Madison. He is recognized for his contributions in group sequential methods for interim analysis of clinical trials and in clustered data analysis and for his extensive collaborative research in clinical oncology and other chronic diseases. He is an elected Fellow of the American Statistical Association. He served as Associate Editor for Biometrics during 2000-2008 and is serving as Associate Editor for Sankhya Series B. He serves on the National Advisory Dental and Craniofacial Research Council, a federal advisory council, of the U.S. National Institutes of Health.

Outline and Schedule

Day One: Monday, 18 June

- 09:00 - 10:30 **Introduction**
- 10:30 - 11:00 *Break*
- 11:00 - 12:30 **Designs**
- 12:30 - 13:30 *Lunch*
- 13:30 - 15:00 **Sample size estimation**
- 15:00 - 15:30 *Break*
- 15:30 - 17:00 **Randomization and masking**

Day Two: Tuesday, 19 June

- 09:00 - 10:30 **Conduct**
- 10:30 - 11:00 *Break*
- 11:00 - 12:30 **Survival analysis I**
- 12:30 - 13:30 *Lunch*
- 13:30 - 15:00 **Survival analysis II**
- 15:00 - 15:30 *Break*
- 15:30 - 17:00 **Data monitoring I**

Day Three: June 20th, 2012

- 09:00 - 10:30 **Data monitoring II**
- 10:30 - 11:00 *Break*
- 11:00 - 12:30 **Issues in data analysis**

Registration (the fees will be used to cover the course costs):

ISCB member/UMF member/UAIC member: 120 Euro

Non-ISCB member: 140 Euro

On-line version available

ISCB National Groups: 100 Euro

Deadline for registration: 20th May 2012

Interested participants can confirm the course attendance at the address: avitcu@yahoo.com

or avitcu@info.uaic.ro

Project Director

Anca Vitcu, Ph.D.

Assistant Professor

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