

## Workshop

# "Biostatistics Made Simple: Topics in Randomized Trials"

2-3 May 2008

Athens

### Hosting Institutes:

#### Frontier Science Foundation - Hellas

A non-profit company for the advancement of Clinical Research  
&

#### Laboratory of Biostatistics

University of Athens

### Abstract

#### Background

Biostatistics and Epidemiology are the two most fundamental scientific disciplines required for conducting research in the area of biomedical sciences. Knowledge in biostatistics is a sine qua non, not only for being involved in research activities but also for transferring into clinical practice the scientific findings from contemporary basic and clinical research projects reported in peer-reviewed journals.

#### Objectives

The current workshop will help participants build a strong and solid knowledge base on the fundamentals of biostatistics tailored for physicians and other health professionals involved in research activities. This workshop would also be a must for health professionals who use research findings through peer-reviewed scientific journals.

#### Participants

The workshop is strongly recommended for physicians and other health professionals involved either as researchers or users of research findings, and other scientists interested in securing a strong knowledge base on the fundamentals of biostatistics.

#### Language

English

**Workshop**  
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 Topics in Randomized Trials”**  
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**Program**

**First Day**

12:30 - 14:00	Registration
14:00 - 14:15	Welcoming Remarks
14:15 - 15:00	First Session - Introduction
14:15 - 15:00	<p><b>Non-inferiority and Superiority Trials</b>          Urania Dafni, Associate Professor          Director, Laboratory of Biostatistics          University of Athens, Athens, Greece</p>
15:00 - 17:30	Second Session - Endpoints and Monitoring
15:00 - 15:45	<p><b>Surrogate Endpoints and Composite Endpoints</b>          Stephen Lagakos, Professor          Department of Biostatistics          Harvard School of Public Health, Boston, MA USA</p>
15:45 - 16:00	Discussion
16:00 - 16:30	Coffee Break
16:30 - 17:15	<p><b>Interim Monitoring</b>          Stephen Lagakos, Professor          Department of Biostatistics          Harvard School of Public Health, Boston, MA USA</p>
17:15 - 17:30	Discussion
17:30 - 18:30	Third Session - Quality of Life
17:30 - 18:15	<p>Shari Gelber, IBCSG Statistician          Department of Biostatistics and Computational Biology          Dana Farber Cancer Institute, Boston, MA USA</p>
18:15 - 18:30	Discussion
20:30 - 23:30	Dinner

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### Second Day

08:30 - 09:00	Registration - Coffee break
09:00 - 11:00	First Session - Subgroup Analysis
09:00 - 10:30	Richard Gelber, Professor Department of Biostatistics Harvard School of Public Health, Boston, MA USA
10:30 - 11:00	Discussion
11:00 - 11:15	Coffee Break
11:15 - 13:15	Second Session - Meta - analysis
11:15 - 12:45	Michael Hughes, Professor Department of Biostatistics Harvard School of Public Health, Boston, MA USA
12:45 - 13:15	Discussion
13:15 - 14:30	Lunch break
14:30 - 16:00	Practice session - Evaluation of Clinical Trials' Publications
14:30 - 15:15	Shari Gelber, IBCSG Statistician Department of Biostatistics and Computational Biology Dana Farber Cancer Institute, Boston, MA USA
15:15 - 16:00	Urania Dafni, Associate Professor Director, Laboratory of Biostatistics University of Athens, Athens, Greece
16:00 - 16:30	Concluding Remarks
16:30	Course Certificates

## Course leaders

### Urania Dafni, ScD

Associate Professor

Director, Laboratory of Biostatistics, School of Nursing  
University of Athens, Athens, Greece

### Stephen Lagakos, PhD

Professor

Department of Biostatistics  
Harvard School of Public Health, Boston, MA, USA

## Invited Speakers

### Rich Gelber, PhD

Professor

Department of Biostatistics  
Harvard School of Public Health, Boston, MA, USA

### Shari Gelber, MS

IBCSG Statistician

Department of Biostatistics  
Dana Farber Cancer Institute, Boston, MA USA

### Michael Hughes, PhD

Professor

Department of Biostatistics and Computational Biology  
Harvard School of Public Health, Boston, MA, USA

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