# **Educational Courses** on Clinical Trials

# Εκπαιδευτικά Σεμινάρια

στις Κλινικές Δοκιμές

Scientific Committee Eпιστημονική Επιτροπή

#### **Angelos Hatzakis**

Professor of Epidemiology and Preventive Medicine, Head of the National Retrovirus Reference Center and Director of the Department of Hygiene, Epidemiology and Medical Statistics, Athens University Medical School



#### Klea Katsouyanni

Professor of Medical Statistics and Epidemiology, Department of Hygiene, Epidemiology and Medical Statistics of Athens University Medical School



#### Stephen Kelleher

Director of the Research and Development Department, Cambridge University Hospitals



#### Chris Palmer

Professor, Director of Centre for Applied Medical Statistics, School of Public Health, Post Graduate Medical Education Department, Cambridge University Hospitals



12-13 May

Program | Πρόγραμμα

Institute of Medical Education and Research (IMER)

2012

Organized by:

IN.I.E.EK

INETITOYTO

IATTIKHE EFENNAX

VOI EKTALISEVER

Διοργάνωση:

Ινστιτούτο Ιατρικής Έρευνας και Εκπαίδευσης (ΙΝΙΕΕΚ)

### Speakers Index

#### **Takis Kotis**

Takis Kotis graduated from the University of Minnesota, Minneapolis having acquired a B.A. in Health Management Administration, as well as, a MBA in Health Administration. His professional career started at the Mayo Clinic of Rochester, as Director of Management Operations (areas of involvement; quality control, finance, marketing, international research programs). Continuing his work in Minnesota, in 1987 he won the Best Innovation-Company Award and became president at Freshcheck, Inc. There he worked in the fields of overlooking entire operation, in microbiological laboratories, specialised in Food Contamination. Having completed his work in Minnesota, he goes to London where he stays for 19 years (1990 - 2009) working for The Royal Brompton & Harefield NHS Trust as Senior Management Consultant. His areas of involvement were strategic management - open system implementation (analysis, choice, implementation), defining health system goals and objectives, applying new public management, replacing hierarchical systems with managed networks, performance management evaluations, quality control measurements. He, also, conducted as director the European Research Program "Atopy and Asthma" in which 1,000 students (14-17 years old) participated in a European study, looking at eating habits and their affects in asthma. At the same time he acted as Director in the following European Funded Projects: TeleRemedy (Ten Telecom), Panaceia (IST), IREMMA (E-Ten), E-Openday (E-Ten), pEHR (e-Ten), PHARMAKOV (e-Ten), Until the resent day he continues his carieer in the UK as Senior Management Consultant at the Cambridge University Hospitals Foundation Trust and he, also, is the President of I.M.E.R. Finally, it is worth noting that Mr Takis Kotis is a member of the Int'l Board of Directors. Tokushukai Medical Group, Tokyo, Japan, Board of Directors and Tokushukai Sofia Corp., Board of Directors, Tokuda Hospital Sofia.

#### **Chris Palmer**

Dr Chris Palmer has spent over 20 years lecturing Medical Statistics to both future and current doctors at Cambridge University. Having first graduated in Mathematics from Oxford University, he went on to the US for his PhD in Statistics at University of North Carolina (with dissertation topic: an ethical design model for use in clinical trials) and then a post-doctoral Fellowship at Harvard University 's Department of Biostatistics. He returned to UK in 1989 and in 1996, he founded Cambridge 's Centre for Applied Medical Statistics (CAMS) where he continues to lead a small team of consulting medical statisticians collaborating with clinical researchers and giving short training courses in the UK and overseas. Chris has served on numerous academic and industry-sponsored Clinical Trial Steering, or Data Monitoring, Committees; spent five years as Deputy Editor of the journal Statistics in Medicine; regularly acts as statistical reviewer for several biomedical journals; authored or co-authored over 50 papers covering many medical fields and co-edited the reference book *Encyclopaedic Companion to Medical Statistics*" (2<sup>nd</sup> edition, Wiley, 2011).



# May | Mάϊος 2012

	<b>Saturday 12/5/2012</b>
	Clinical Trials 1. Background, Ethics and Design Issues
09:00-10:15	Background a. Introduction b. Randomisation c. History C. Palmer
10:15-11:30	Ethics a. Types of ethics b. Ethics committees c. Ethics & statistics C. Palmer
11:30-11:45	Break
11:45-13:00	Design a. Trial phases b. Trial types c. Trial protocols C. Palmer
13:00-14:00	Practical examples of working in European projects  T. Kotis
14:00-16:00	Lunch Break
16:00- 17:00	Adverse drug events (ADE) and their contribution towards escalation of healthcare costs. Drug Repositioning T. Kotis
17:00-17:30	Discussion
	Sunday 13/5/2012
	Clinical Trials 2. Trial Size, Analysis and Interpretation Issues
09:00-10:15	Trial Size a. Review of statistical tests b. Power and sample size c. Using a nomogram C. Palmer
10:15-10:30	Break
10:30-11:45	Analysis a. Types of analysis b. Methods of analysis c. Further methods C. Palmer
11:45-13:00	Interpretation a. Publication of trials b. CONSORT c. Regulatory agencies C. Palmer
13:00-15:00	Lunch Break
15:00-16:00	Funded programs for clinical trials, Clinical Trials in the elderly <b>T. Kotis</b>
16:00-16:30	Discussion

## Επόμενα Σεμινάρια

• 26-27 Majou 2012

**MAOHMA e-LEARNING** 

• 16-17 louvíou 2012

ΣΤΑΘΕΡΟ ΜΑΘΗΜΑ

#### Organized by:



#### Institute of Medical Education and Research

26 Marathonomachon Street GR 15124 Maroussi, Athens, Greece Tel.: +30 210 6827405, +30 210 6839690-1 Fax.: +30 210 68 27 409

E-mail: info@inieek.eu, Web site: www.inieek.eu

#### Διοργάνωση:



#### Ινστιτούτο Ιατρικής Έρευνας και Εκπαίδευσης

Μαραθωνομάχων 26, 151 24 Μαρούσι, Αττική Τηλ.: 210 6827405, 210 6839690-1 Fax: 210 6827409 E-mail: info@inieek.eu Web site: www.inieek.eu