

# Educational Courses on Clinical Trials

Εκπαιδευτικά Σεμινάρια  
στις Κλινικές Δοκιμές

Scientific Committee  
Επιστημονική Επιτροπή

## Angelos Hatzakis

Professor of Epidemiology and Preventive Medicine,  
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## Toni Staykova

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## Nick Wareham

Professor of the MRC Epidemiology Unit,  
Institute of Metabolic Science,  
Addenbrooke's Hospital, Cambridge, UK

29-30 June  
Ιουνίου

Program | Πρόγραμμα

2013

Athens | Αθήνα - Thessaloniki | Θεσσαλονίκη

Organized by | Διοργάνωση



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



Scientific Society of Epidemiology,  
Biostatistics and Preventive Medicine

Cambridge University Hospitals **NHS**  
NHS Foundation Trust



Institute of Medical Education and Research

# Experts' Index

## **Stephen Kelleher**

Stephen Kelleher is the Research and Development Manager at both Cambridge University Hospitals and Cambridge and Peterborough NHS Trust. Both institutions are world leading academic centers of research excellence. Stephen also is the NIHR Biomedical Research Centre Manager and is responsible for the legal, financial and administrative aspects of those institutions research and clinical trial activity. Stephen is the lead on Intellectual Property exploitation and innovations for Cambridge University Hospitals and sits on a number of national research committees. CUH has at any one time approximately 1000 research studies active and circa 200 studies in set up, at any one time. CUH also acts as Sponsor to large portfolio of CTIMPS including multisite and multinational trials. Prior to his current role Stephen ran a number of research departments within the university sector both in the UK and abroad. Stephen also led on the FP6 implementation for the University of Cambridge and the FP7 implementation for University of Essex.

## **Nick Wareham**

Nick Wareham is the Director of the MRC Epidemiology Unit and co-Director of the Institute of Metabolic Science. His principal research interests are the aetiology and prevention of obesity and diabetes. He also leads the Aetiology of Diabetes Programme.

Nick qualified from St Thomas' Hospital Medical School, London, and trained in epidemiology at the London School of Hygiene and Tropical Medicine, London. He then worked at Harvard University, Boston, USA before joining the University of Cambridge where he became a Wellcome Trust Senior Fellow in Clinical Science. Now he is a Professor and an Honorary Consultant at Addenbrooke's Hospital, Cambridge. He is also the Clinical Lead for the Eastern England Diabetes Local Research Network.

## **George Kolios**

George Kolios is Professor of Pharmacology and Head of the Laboratory of Pharmacology in the Medical School at Democritus University of Thrace. He obtained his first degree in Medicine in 1980 and his PhD degree in 1992 from the Medical School of the University of Athens. In 1998, he obtained his PhD degree in Pharmacology from the University of Bath, UK. In 1990 he finished his Specialization in Gastroenterology and he first worked as Registrar in Gastroenterology at the Royal United Hospital, Bath, UK and then as Senior Registrar in Gastroenterology at the Hippokraton General Hospital of Athens. From 1998 till 2001, he worked as Consultant Gastroenterologist at the Royal United Hospital, Bath, UK and as Senior Research Fellow in the Department of Pharmacology at the University of Bath. In 2001 he was appointed Assistant Professor of Gastroenterology in the School of Medicine at the University of Crete and Visiting Professor in Pharmacology at the University of Bath, UK. From 2008 he is Head of the Laboratory of Pharmacology in the Medical School at Democritus University of Thrace. Professor George Kolios is Director of the Master's Degree Program "Clinical Pharmacology and Therapeutics" that is organized by the Medical School of the Democritus University of Thrace in collaboration with the Medical School of the University of Crete. From 2008, he is Member of the Scientific Board of Approvals of the Greek National Organization for Medicines. His research interests cover immunopharmacology, and mucosal immunology and fibrosis, mainly focused on the inflammatory bowel diseases. He has more than 65 publications in peer reviewed journals which have been cited more than 1500 times.

## **Anna Tavidou**

Anna Tavidou graduated from the School of Pharmacy of the Aristotle University of Thessaloniki. She received her MSc and PhD degrees from The Medical School of Newcastle University (UK), where she also worked as a postdoctoral researcher. Subsequently, she worked as a senior researcher in the Laboratory of Pharmacology of ELPEN Pharmaceuticals, focusing on the preclinical and clinical development of drugs targeting the cardiovascular system. In 2004, she was appointed as a Lecturer in the Laboratory of Pharmacology of the Medical School of Democritus University of Thrace, where, since 2009, she is an Assistant Professor. Her research interests, focusing on pharmacogenetics with emphasis on the cardiovascular system and diabetes, as well as on the study of the mode of action of antiatherosclerotic compounds in preclinical and clinical level, are funded by national and European research grants. She acts as a reviewer for several international peer-reviewed journals, while she has been invited as an evaluator of grant proposals by the General Secretariat for Research & Technology, as well as by the European Commission under the FP7 call. She has published over 40 papers in international peer-reviewed journals which received more than 900 citations.

June | Ιούλιος 2013

Live streaming Athens - Thessaloniki

### Saturday 29/6/2013

**Coordinators in Thessaloniki: Kolios G., Tavridou A.**

- 09:00 - 10:00 Ethics. Types of ethics. Ethics committees and examples of problems encountered. Ethics and statistics, **N. Wareham**
- 10:00 - 11:00 How to write a scientific paper? Trial participation leading to publication in a reputable journal, **N. Wareham**
- 11:00 - 11:20 **Coffee Break**
- 11:20 - 12:20 Interpretation of study and trial results - Reading published literature exercise, **N. Wareham**
- 12:20 - 12:30 **Short Break**
- 12:30 - 13:00 Clinical Trial Basics, **S. Kelleher**
- 13:00 - 13:30 Research Landscape, **S. Kelleher**
- 13:30 - 14:30 ICH Good Clinical Practise - part I, **S. Kelleher**
- 14:30 - 15:15 **Lunch Break**
- 15:15 - 17:15 ICH Good Clinical Practise - part I, **S. Kelleher**
- 17:15 - 18:00 Discussion

### Sunday 30/6/2013

**Coordinators in Thessaloniki: Kolios G., Tavridou A.**

- 09:00 - 10:00 Cost - effectiveness, cost - utility and cost - benefits, **N. Wareham**
- 10:00 - 11:00 Practical examples and lessons learnt from diabetes trials, **N. Wareham**
- 11:00 - 11:30 Comparison between running an industry funded trial vs. an EU funded trial - Experience from FP6, FP7 trials, Do's and Don'ts, **N. Wareham**
- 11:30 - 12:00 **Coffee Break**
- 12:00 - 12:30 Horizon 2020 - what to expect for clinical trials, **S. Kelleher**
- 12:30 - 12:40 **Short Break**
- 12:40 - 14:20 ICH Good Clinical Practise - part II, **S. Kelleher**
- 14:20 - 14:30 Conclusion: What do pharma companies value to commission a hospital / site to run a trial, **S. Kelleher**

Organized by:



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