	NATIONAL & KAPODISTRIAN UNIVERSITY OF ATHENS
	UNIVERSITY GENERAL HOSPITAL, 'ATTIKON'
	FOURTH DEPARTMENT OF SURGERY



Organize the 2nd introductory two-day Course on

'KEY THEMES IN MEDICAL EDUCATION'

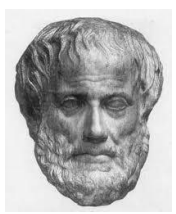
The Conduct of Clinical Trials in Conformity with the Rules of Good Clinical Practice (GCP)

Friday 30th & Saturday 31st, March 2012

UNIVERSITY GENERAL HOSPITAL, 'ATTIKON'

The crucial information of this course for medical doctors and medical study personnel is based upon the vocational training, as it is presented at the Department of Surgery (**Ludwig-Maximilians-University of Munich, Germany, Campus Grosshadern**) since several years. With this course the essentials about the conduct of clinical trials are taught in strict conformity with the rules of Good Clinical Practice (GCP). In many European countries as well as in North America, the verification of participants at such a continuing education represents the legal precondition for any eligible individual, to participate in any way in the conduct of a clinical study. To download the program click:

http://www.uoa.gr/fileadmin/user_upload/PDF-files/ekdilwseis/Hmerides-Seminaria/CLINICAL-TRIALS-GOOD-CLINICAL-PRACTICE-GCP.pdf

 Aristoteles (384-322 BC)	By the end of the course, Participants should be able to:
	<ul style="list-style-type: none"> • Understand the essentials of how to design, organize and conduct a clinical trial
	<ul style="list-style-type: none"> • Follow ethical and scientific research principles
	<ul style="list-style-type: none"> • Follow the Principles of Good Clinical Practice (GCP)
	<ul style="list-style-type: none"> • Evaluate, document and publish adequately the results of a clinical study

Program

The conduct of Clinical Trials & the rules of Good Clinical Practice (GCP)

March 30th 2012	Chair: Eugen Faist, Steffen Koerdt
Time	Title (Speaker)
07.30 – 08.15	Registration
08.15 – 08.30	Welcome (Iordanis Papadopoulos, E. S. Patsouris)
08.30 – 09.00	Introduction to the course (<i>E. Faist</i>), (30 min)
09.00 – 09.30	Trial design and biometrics (<i>H. Trentzsch</i>), (30 min)
09.30 – 10.15	Good Clinical Practice (GCP): Topics and guidelines, (<i>E. Faist</i>), (45 min)
10.15 – 10.45	Coffee time
10.45 – 11.45	Planning a clinical trial (<i>A. Baumgartner</i>), (60 min)
11.45 - 12.15	Ethics Committee: Need and benefit (<i>S. Koerdt</i>), (30 min)
12.15 – 12.45	Cooperation with a coordinating clinical study center (<i>E.Faist</i>), (30 min)
12.45 -13.15	Legal basis and pitfalls of clinical studies (<i>S. Koerdt</i>), (30 min)
13.15 – 14.15	Lunch
14.15 – 14.45	Quality management at the clinical study site: Monitoring (<i>A. Baumgartner</i>), (30 min)
14.45 – 15.15	Guidance and involvement of the study patient (<i>H. Trentzsch</i>), (30 min)
15.15 – 16.00	Teamwork Practice (<i>All Instructors</i>), (45 min)

March 31st, 2012	Chair: Anja Baumgartner, Heiko Trentzsch
08.30 – 09.00	The phases of clinical drug development (<i>P. Peristeris</i>), (30 min)
09.00 – 09.30	Clinical trials with medical devices (<i>S. Koerdt</i>), (30 min)
09.30 – 10.00	Adverse Events and Serious Adverse Events: What is it and how do we report it? (<i>A. Baumgartner</i>), (30 min)
10.00 – 10.30	Coffee time
10.30 – 11.15	Substantial preconditions for a successful investigator initiated clinical trial (IIT) (<i>A. Baumgartner</i>), (45 min)
11.15 - 12.45	Teamwork practice (<i>All Instructors</i>), (90 min)
12.45 – 13.15	The need of GCP audits and inspections (<i>A. Baumgartner</i>), (30 min)
13.15 – 14.15	Lunch
14.15 - 14.45	Clinical data management: The investigator MD's point of view (<i>H. Trentzsch</i>), (30 min)
14.45 – 15.30	Evaluation and adequate publication of study results (<i>H. Trentzsch</i>), (45 min)
15.30 – 16.00	Summary (<i>E. Faist</i>), (15 min), Planning the Next and Economic balance (<i>Iordanis Papadopoulos, E. S. Patsouris</i>), (15 min)

Sunday April, 1st, 2012	Time 09.00: Visit to The New Museum of Acropolis
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Tutors

Prof. Dr. Eugen **Faist**, MD, FACS, Ludwig-Maximilians University, Dept. of Surgery, Munich, Germany, eugen.faist@med.uni-muenchen.de

Dr. Anja **Baumgartner**, MD, Ludwig-Maximilians University, Study Center of the Medical Department III, Munich, Germany, anja.baumgartner@med.uni-muenchen.de

Dr. Steffen **Koerdt**, MD, Ludwig-Maximilians University, Dept. of Dentistry, Munich, Germany, steffen.koerdt@web.de

Dr. Platon **Peristeris**, PhD, Medical Director, MSD, Alimos, Athens, Greece, platon.peristeris@merck.com

Dr. Heiko **Trentzsch**, MD, Ludwig-Maximilians University, Institute for Emergency Medicine & Medical Management, Munich, Germany, heiko.trentzsch@med.uni-muenchen.de

Organizing committee:

Honorary Guest: Professor Dimitris Vasilopoulos

President / Coordinator: Iordanis Papadopoulos MD, FRCS, Associate Professor in Surgery, Medical School, Athens of University.

Vice president: Ioannis Dimoliatis MD, MPH, MMedEd, Assistant Professor of Hygiene & Epidemiology, Medical School, University of Ioannina

Scientific committee:

Working Group in Medical Education of The Medical School, University of Athens.

Under the Auspices of the Medical School of The National & Kapodistrian University of Athens.

Place: University General Hospital 'Attikon', 1-Rimini Street, 124 62, Haidari, Athens.

Language: English. **Certificate of Attendance** will be given to participants.

Fees: 230 Ευρώ. Κατάθεση στον Ειδικό Λογαριασμό (ΕΛΚΕ) του Πανεπιστημίου Αθηνών 81706531, μέσω της Εμπορικής Τράπεζας. Απαραίτητη η αναγραφή του Ονόματος και Επωνύμου σας. Παραδίδετε την Απόδειξη Κατάθεσης στη Γραμματεία του Σεμιναρίου και παίρνετε ειδική Απόδειξη του ΕΛΚΕ.

Προθεσμία: Θα τηρηθεί σειρά προτεραιότητας. *Ανώτατο όριο των 60 ατόμων.*

Information & Registration: Iordanis Papadopoulos MD, FRCS, Associate Professor in Surgery, Fourth Surgery Department, University General Hospital 'Attikon', 1-Rimini Street, 124 62, Athens. ++30 6944 661 484, ++30 210 583 1375, Fax: 210 532 6412, e-mail: ipapado@med.uoa.gr, inapapad@otenet.gr

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