	<b>NATIONAL &amp; KAPODISTRIAN UNIVERSITY OF ATHENS</b>
	<b>UNIVERSITY GENERAL HOSPITAL, 'ATTIKON'</b>
	<b>FOURTH DEPARTMENT OF SURGERY</b>



**Organize the 2<sup>nd</sup> introductory two-day Course on**

**'KEY THEMES IN MEDICAL EDUCATION'**

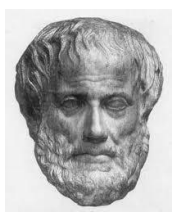
**The Conduct of Clinical Trials in Conformity with the  
Rules of Good Clinical Practice (GCP)**

**Friday 30<sup>th</sup> & Saturday 31<sup>st</sup>, 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 participation 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](http://www.uoa.gr/fileadmin/user_upload/PDF-files/ekdilwseis/Hmerides-Seminaria/CLINICAL-TRIALS-GOOD-CLINICAL-PRACTICE-GCP.pdf)

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

## Program

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

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

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

<b>Sunday April, 1<sup>st</sup>, 2012</b>	<b>Time 09.00: Visit to The New Museum of Acropolis</b>
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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](mailto: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](mailto:anja.baumgartner@med.uni-muenchen.de)

Dr. Steffen **Koerdt**, MD, Ludwig-Maximilians University, Dept. of Dentistry, Munich, Germany, [steffen.koerdt@web.de](mailto:steffen.koerdt@web.de)

Dr. Platon **Peristeris**, PhD, Medical Director, MSD, Alimos, Athens, Greece, [platon.peristeris@merck.com](mailto: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](mailto: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](mailto:ipapado@med.uoa.gr), [inapapad@otenet.gr](mailto:inapapad@otenet.gr)

**Secretariat:** Triaena Tours & Congress A.E, 206, Syngrou Ave, 17672 Athens-Greece, tel. ++30 210 7499337, ++30 210 7499300, fax ++30 210 7705752  
Έφη Παπασταυροπούλου, Email: [efip@triaenatours.gr](mailto:efip@triaenatours.gr)

