

General information

How to register

If at all possible, please register on-line on the website of the GCP course:
<http://prof-congress.hu/2007/gcp> If you do not have Internet access, please complete the Registration Form enclosed to this announcement and return it by fax to the Organizing office.



Travel information

Planes arrive at Ferihegy Airport, Budapest (25 km from the centre). There is a service for minibuses to the city centre (Erzsébet tér=Elisabeth Square or Deák tér=Deak Square), to the Western Railway Station (Nyugati Pályaudvar) for HUF 2.100 (about EUR 8). Trains to Szeged leave from the Nyugati Pályaudvar (Western Railway Station). The railway station is easily accessible by metro (underground/blue line, #3). If you wish to come **by train** to Szeged we recommend you to use an InterCity (IC) train. One way IC train ticket costs HUF 3.800 (EUR 15). The travelling time is about 2.5 hours. Please check the timetable carefully; in general there are no trains to Szeged later than 18.38h. Szeged can be reached easily **by car** from Budapest via Kecskemét using the M5/E75 road (approximately 170 km on the motorway, toll HUF 1.400 / EUR 6).



Accommodation

At the 4-stars Hotel Novotel single and double rooms are available for the participants. Please submit your hotel reservation as soon as possible.

Organizers

Department of Obstetrics and Gynecology
WHO Collaborating Centre for Research in Human
Reproduction, University of Szeged, Hungary
Director: Attila Pál MD.

and

Hungarian Clinical Trial Management Society,
Hungary

President: Zoltán Hosszú MD.

with the support of the

Department of Reproductive Health and Research
World Health Organization



Venue of the course

Hotel Novotel****

Address: Maros utca 1. H-6721 Szeged, Hungary

Phone: +36 62 562 200 Fax: +36 62 562 221

<http://www.novotel-szeged.hu>



Official language

The course will be held in English.



Organizing committee

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Organizing office

CONGRESS & HOBBY SERVICE

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Website of the 3rd GCP Course

(registration, hotel room booking)

<http://prof-congress.hu/2007/gcp>



3rd

Good Clinical Practice (GCP) Course

**16-18 September, 2007
Szeged, Hungary**



Announcement

Dear Colleagues,

You are cordially invited to participate in the 3rd Good Clinical Practice Course (GCP) which will be held in the Hotel Novotel Szeged, Hungary from 16th to 18th September 2007, organized by the Department of Obstetrics and Gynecology, University of Szeged, and the Hungarian Clinical trial Management Society, under the auspices of the World Health Organization.

Through the GCP Course we aim at engaging colleagues mainly from the Danube-Koros-Maros-Tisza (DKMT) Euro Region in a fruitful and productive dialogue. The Organizing and Scientific Committee is hoping to continue the success of the meetings in 2005 and 2006. Our goal is to disseminate experience and knowledge on the field of GCP that has accumulated in the WHO and to focus on the similarities and the differences in the practice on the different countries of this region.

On this instance the special issue emphasized by the Course will be; Reproductive Health in the lime light of good clinical practice, followed by the basic knowledge of GCP on the second day and finally there will be two workshops a) Using placebo in clinical trials and, b) Pediatric trials: perspectives and regulations, on the last day. The course will end with written test.

We are pleased to host the 3rd GCP Course in Szeged the cultural and economical center of Southern Hungary with many interesting places and beauties in the surrounding area. We hope that this meeting will be a good occasion to discover the historical remains and enjoy the atmosphere of the well-preserved architecture of the city. You can taste the specialties of 'fish soup a la Szeged' and 'Pick salami' and various Hungarian wines and enjoy the thermal water in the famous Anna curative spa.

We look forward to welcome you in Szeged, Hungary.

On behalf of the organizers,



Professor György Bártfai MD.

Chairman of the Organizing and Scientific Committee

New Topics

(with internationally acknowledged speakers)

- Reproductive Health - Good Clinical Practice
- Pediatric trials: regulations and perspectives
- Using Placebo in Clinical Trials

Additional topics/lectures

- ICH GCP History, Elements and Definitions
- ICH GCP Guidelines, Current Issues
- Human Drug Development Phase and Methods
- The Clinical Research Site: Requirements and Approvals
- The Investigator (Role and Responsibilities)
- Effective Site Selection
- Clinical Research Site: Requirements
- The Sponsor (Role and Responsibilities)
- Regulatory Authorities (NIP, EMEA and FDA)
- Pharmacovigilance
- Contract Research Organizations
- Operational Issues of Clinical Trials
- Ethical Committees (Role and Responsibilities)
- Documents of a Clinical Trial (protocol / CRF, IB, IC, etc.)
- Quality Issues of Clinical Trials: Audit, Inspection
- Phase I and Bioequivalence Studies
- Laws, Regulations. The EU Clinical Trials Directive and Hungarian Regulations
- The Informed Consent

Preliminary program overview

16 September, 2007 (Sunday)

12:00-14:30 Registration
14:30-15:00 Opening Ceremony
15:00-18:00 New topics – Plenary lectures
19:00- Get together party

17 September, 2007 (Monday)

08:00-13:00 Scientific program I.
Lunch
14:00-18:00 Scientific program II.
19:00- Social program, dinner

18 September, 2007 (Tuesday)

08:30-12:00 Scientific program III.
12:00-12:30 Written test
Lunch



Registration fee: EUR 250

Registration deadline: 1 September, 2007

Please note, that the number of participants is limited (maximum 120 persons)

Registration fee includes:

- Access to scientific sessions
- Symposium material
- Welcome reception (16 September)
- Two lunches (17 and 18 September)
- Social program incl. dinner (17 September)