7th

Good Clinical Practice (GCP) Course

21-22 November, 2011
Szeged, Hungary

PRELIMINARY PROGRAM

Dear Colleagues,

We are pleased to welcome you to Szeged to take part in the 7th Good Clinical Practice Course organized by the Department of Obstetrics and Gynecology at the University of Szeged, and the Hungarian Clinical Trial Management Society, with the support of the World Health Organization.

Doctors, researchers and clinical investigators are welcome mainly from our Euroregion. The first day of the Course will be dedicated to the basic knowledge of the GCP, mainly for those who are interested in Clinical Trials and are in need of a Certificate. A Valedictory lecture which will be held on behalf of the WHO, entitled ***"The involvement of the transitional countries in Clinical Trials. (Awareness of good clinical practice or implementation of the guidelines of WHO)"***, to share the experience and knowledge of the WHO accumulated in the field of GCP. The course ends with a test.

For the first time in Szeged/Hungary, on the second day a **Biosimilar Symposium** will be held as a hot topic of research on ***„Bioequivalence, Bioavailibility and Biosimilarity"*** by internationally acknowledged clinicians

The 7th GCP Course will take place in Szeged. We would like to introduce you the host city, for those who will attend the first time: Szeged is an exciting University city with a rich cultural life. It is also famous for exhibitions, ballet and opera performances, and many of beautiful buildings in secessionist style. Besides, the Hungarian traditional food, such as fish-soup and Pick salami, is worth trying.

We are certain that everyone will enjoy the 7th Good Clinical Practice Course to be held in Szeged,

On behalf of the organizers,

Professor György Bártfai MD ***Judit Tarnai MD***

Organizers
Department of Obstetrics and Gynecology, University of Szeged, Hungary
Director: Professor Attila Pál MD
and
Hungarian Clinical Trial Management Society, Hungary
President: Judit Tarnai MD
with the support of the
World Health Organization

Venue of the Course
Residence of the Chamber of Commerce and Industry – Conference Hall
Address: H-6721 Szeged, Párizsi krt. 8-12., Hungary

Official language
The official language of the course is English.

Organizing committee
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URL: http://www.standartkonferencia.hu

Accreditation
The CME accreditation is in process.

Accommodation
Accommodation in Szeged should be booked and paid by the participants themselves.
You can find information about hotels and pensions here:
http://en.standartkonferencia.hu/Szegedhotel/szallas

Taxi
Rádió Taxi: +36 62 480 480

Parking
Please be advised that in downtown of Szeged there are three different designated parking zones (green, yellow and blue). To park in these zones (indicated on the traffic signs) you will have to obtain a pre-paid parking ticket. This has to be displayed in a well-visible place, possibly behind the windscreen (from Monday to Friday, 8.00-18.00). A daily parking ticket is available for 1.475,- HUF. **PLEASE NOTE that your car may be towed if you do not have a valid ticket!** Parking tickets can be bought at grocery stores, tobacconists and newsagents. The congress venue is in the **blue** zone.

21 November, 2011 – Monday

PRELIMINARY PROGRAM

08.00 – 08.45
Registration

08.45 – 09.00
Opening ceremony

09.00 – 09.15
Introduction of the Hungarian Clinical Trial Management Society (15')
Speaker: *Judit Tarnai, Country Manager, Pharm-Olam (Hungary) Medical Research Ltd.*

09.15 – 09.35
ICH-GCP – history and current position (20')
Speaker: *Szabolcs Barótfi, Quintiles Ltd., Budapest, Hungary*

09.35 – 09.55
Role of the regulatory authority (20')
Speaker: *Csilla Pozsgay, National Institute for Quality and Organizational Development in Healthcare and Medicine*

09.55 – 10.10
Declaration of Helsinki and the Ethics Committees (15')
Speaker: *Dorottya Mogyorósi, Ministry of National Resources*

10.10 – 10.30
Human Drug Development: Phases and Methods (20')
Speaker: *Gábor Renczes, GXP Ltd.*

10.30 – 10.40
Panel I discussion (10')

10.40 – 11.00
Coffee break

11.00 – 11.20
ICH guidelines and the Non-interventional trials (20')
Speaker: *László Veres, Covance Ltd., Budapest, Hungary*

11.20 – 11.40
Main Operational Issues of Clinical Trials I.: Site Selection and Site Initiation Process (20')
Speaker: *Krisztina Köböl, Pharm-Olam (Hungary) Medical Research Ltd.*

11.40 – 12.00
Main Operational Issues of Clinical Trials II.: Interim Monitoring Procedures + Informed consent development (20')
Speaker: *Norbert Szakolczai-Sándor, Theorem Clinical Research Ltd.*

12.00 – 12.20
Main Operational Issues of Clinical Trials III.: Close-down Procedures, The Trial Master File (20')
Speaker: *Gábor Szamosközi, Novartis Pharma Hungary*

12.20 – 12.30
Panel II discussion (10')

12.30 – 13.30
Lunch break

13.30 – 13.45
Informed Consent Process (15')
Speaker: *János Annus, University of Szeged*

13.45 – 14.00
Quality issues/How to prepare for a Successful Audit ? (15')
Speaker: *Éva Kállai, Quintiles Hungary Ltd.*

14.00 – 14.20
Pharmacovigilance and Reporting Procedures (20')
Speaker: *Gábor Koncsik, Servier ICTR Hungary*

14.20 – 14.40
The Sponsor's Role and Responsibilities (20')
Speaker: *Géza Szövérffy, MSD Hungary Ltd.*

14.40 – 14.55
The Investigator: Role and Responsibilities (15')
Speaker: *Tamás Bitó, University of Szeged*

14.55 – 15.05
Panel III discussion (10')

15.05 – 15.25
Coffee break

15.25 – 15.40
The Role of Study Nurse and Study Coordinator (15')
Speaker: *Andrea Tiszai, University of Szeged*

15.40 – 15.55
Project Management of Clinical Trials (15')
Speaker: *Gábor Keszthelyi, I3 Research Ltd.*

15.55 – 16.10
Device studies (15')
Speaker: *Eszter Fodor, Pharma Hungary Ltd.*

16.10 – 16.25
Emerging Countries (pros and cons) (15')
Speaker: *Zsuzsanna Pozsonyi, SynCon International*

16.25 – 16.40
Statistics in clinical trials - Essentials for non-statisticians (15')
Speaker: *Wouter Wijker, Auxiliis Pharma Ltd., Budapest*

16.40 – 16.50
Technical break

16.50 – 17.10
VALEDICTORY LECTURE
The involvement of the transitional countries in Clinical Trials. (Awareness of good clinical practice or implementation of the guidelines of WHO) (20')
Speaker: *Nguyen Thi My Huong, MD, PhD, Clinical Trial Manager, Department of Reproductive Health & Research (RHR), World Health Organization*

17.10 – 17.30
GCP test

22 November, 2011 – Tuesday

BIOSIMILAR SYMPOSIUM

By attending this workshop you will gain a comprehensive outlook on the key issues surrounding biosimilars including manufacturing, non-clinical and clinical development. The regulatory requirements for similars will be presented together with the already existing clinical and market experience in the EU.

Session 1 - Chair: Dr. Andras Ballagi

08.30 – 09.05
Dr. Ildiko Aradi: Biosimilars - General overview, regulatory (EU, US and WHO guides) (35')

09.05 – 09.40
Dr. Andras Ballagi: The development of similar biological medicines (35')

09.40 – 10.15
Dr. Arnold M. Kiss: Quality requirements - analytics (35')

Discussion (15')

10.30 – 10.40
Coffee break

Session 2 - Chair: Dr. Ildiko Aradi

10.40 – 11.15
Dr. Ivett Jelinek and Dr. Mark Barok - Non-clinical program of biosimilars - goals and regulations (35')

11.15 – 11.50
Dr. Alice Rokszin and Dr. Andras Illes: Medical consequences of immunogenicity (35')

11.50 – 12.25
Dr. Adam Kreiss: Adaptive design (35')

Discussion (15')

12.40 – 13.30
Lunch break

Session 3 - Chair: Dr. Andras Illes

13.30 – 14.05
Dr. Karoly Horvát-Karajz: Endpoints for clinical trials in oncology (35')

14.05 – 14.40
Dr. Zsuzsanna Kiss and Dr. Adam Kreiss: Endpoints for clinical trials in Rheumatoid arthritis (35')

14.40 – 14.50
Coffee break

14.50 – 15.25
Dr. Eniko Jokai and Dr. Andras Illés: Approved biosimilars in the EU - clinical requirements (35')

15.25 – 16.00
Zsuzsanna Molnar and Dr. Alice Rokszin: Biosimilars in the EU: medical and market experience (35')

Discussion (15’)

Closing remarks (10’)