

Pan European Clinical Trials under current EU regulations

A training course for data managers, study nurses
and junior clinical investigators



This course, as part of the European Science Foundation EUROCORES Programme ECT, is supported by funds from the EC Sixth Framework Programme, under Contract no. ERAS-CT-2003-980409

Holmenkollen Park Hotel Rica, Oslo, Norway
5. - 6. October 2006

Initiated by:

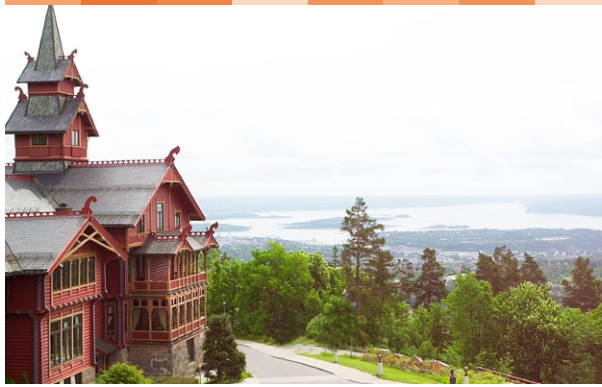
The Scandinavian Sarcoma Group (SSG)
The European and American Osteosarcoma Group (EURAMOS)
The Cooperative OsteoSarcoma Study Group (COSS)
The Koordinierungszentrum für Klinische Studien Münster (KKS Münster)
The Medical Research Council Clinical Trials Unit (MRC-CTU)

Course Content

This course, comprising panel lectures and workshops, provides a forum for people responsible for managing European clinical trials at the institutional level to discuss and work through the various challenges they face in their work in a supportive environment with peers and colleagues.

Particular emphasis will be placed on the practicalities of ensuring patient safety by adhering to Good Clinical Practice (GCP) whilst complying both with "local", national and European legislation.

Lectures will be held in English. Workshops will be coordinated by country groups and held in the common language of the group. After the workshops, a representative from each country group will be asked to share the group's discussion and learning points in a feedback session with the main combined group.



Registration

Registration online at www.ssg-org.net

Further information

Moya Berli
Director of Education
Rikshospitalet – Radiumhospitalet HF
Montebello 0310 Oslo
Tel: + 47 22 93 59 39
Fax: + 47 22 52 43 20
Email: moyab@klinmed.uio.no

**Registration deadline:
10. September 2006**

Participation in the course, including hotel accommodation and assistance with travel costs is free of charge for participants of the EURAMOS and PROFIDYS trials. As the number of participants is limited, registration will be dealt with on a first-come, first-served basis.

- Participants are requested to seek the most cost-effective travel arrangements and to book these in consultation with the organisers. Please note that only economy class train and airfares will be reimbursed and that local transport costs are at participants' own expense. Travel expenses will only be reimbursed when the sum has previously been agreed with the organisers, the claim is made on the official expense claim form and the claim deadline of 1. November 2006 has been met.
- Accommodation will be in the conference hotel, Holmenkollen Park Hotel Rica (www.holmenkollenparkhotel.no)
- Please do not finalise your travel arrangements until your participation on the course has been confirmed.

Speakers

- E. Ahlke, Münster, Germany
- T. Alvegaard, Lund, Sweden
- T. Beresford, London, UK
- S. Bielack, Stuttgart, Germany
- T. Butterfass-Bahloul, Münster, Germany
- D. Carrle, Stuttgart, Germany
- J. Ceberg, Lund, Sweden
- C. Danewid, Lund, Sweden
- M. Eriksson, Lund, Sweden
- A. Holliday, London, UK
- M. Kevric, Stuttgart, Germany
- R. Morgan, London, UK
- O. Myklebost, Oslo, Norway
- H. Oellers, Münster, Germany
- E.-M. Olofsson, Lund, Sweden
- M. Perisoglou, London, UK
- M. Resnicoff, Strasbourg, France
- S. Smeland, Oslo, Norway
- K. Sundby-Hall, Oslo, Norway
- M. Sydes, London, UK

Thursday 5. October 2006

- 12:00 - 13:00 **Registration and lunch**
- 13:00 - 13:15 **Welcome and introduction**
S. Smeland, Oslo, Norway
- 13:15 - 13:45 **Good clinical practice according to ICH-GCP E6**
M. Eriksson, Lund, Sweden
- 13:45 - 14:15 **Implementation of Pan-European clinical trials in compliance with current European Regulations**
M. Resnicoff, EUROCORES ECT Programme, Strasbourg, France
- 14:15 - 14:45 **Registering and randomizing patients into multi-center trials**
M. Sydes, London, UK
- 14:50 - 17:35 **Workshops**
- European regulations and their practical impact for centres participating in EURAMOS-1
 - Which rules do I need to be aware of?
 - Applications to ethics committees and competent authorities
 - Creating and maintaining an investigator site file
 - Registering patients - crucial points and helpful hints
- 15:50 - 16:20 **Coffee Break**
- Workshops**
- How to collect, code, store and transfer information relevant to a trial
 - Randomisation - challenges and pitfalls
- 17:20 - 17:35 **Preparation for feedback session**
- 17:40 - 18:30 **Feedback from workshops**
- 20:00 **Dinner**

Friday 6. October 2006

- 09:00 - 09:20 **How biological studies can complement clinical trials**
O. Myklebost, Oslo, Norway
- 09:20 - 09:40 **Grading toxicity according to CTCAE 3.0**
M. Perisoglou, London, UK
- 09:40 - 10:10 **Pharmacovigilance and safety evaluation in clinical trials/SAE**
T. Butterfass-Bahloul, Münster, Germany
- 10:10 - 10:30 **The background to source data verification/on-site monitoring**
H. Oellers, Münster, Germany
- 10:30 - 11:00 **Coffee Break**
- 11:00 - 12:30 **Workshops**
- PEG-Interferon – drug accountability illustrated
 - Pharmacovigilance and adverse event reporting
 - On-site monitoring: why it is done and how to prepare
- 12:30 - 12:45 **Preparation for feedback session**
- 12:50 - 13:00 **Feedback from workshops**
- 13:00 - 13:20 **Summary and closing remarks**
- 13:20 **Lunch**