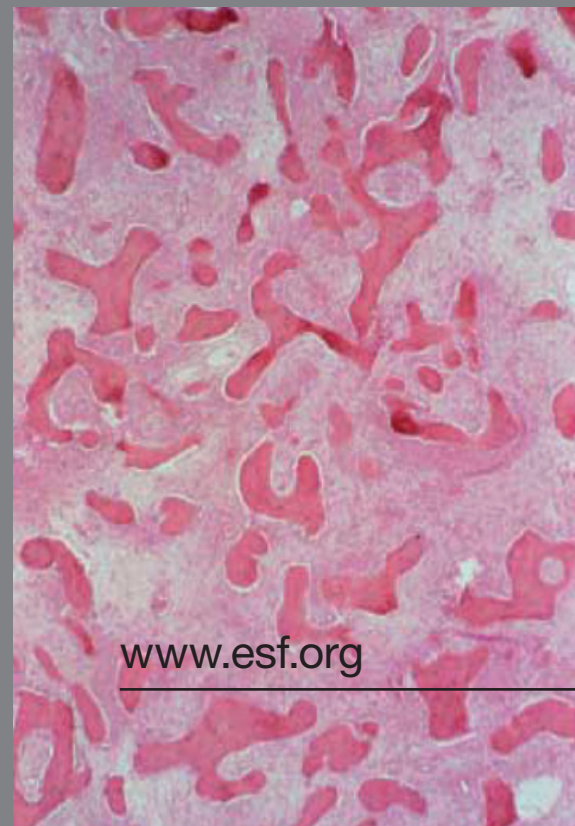
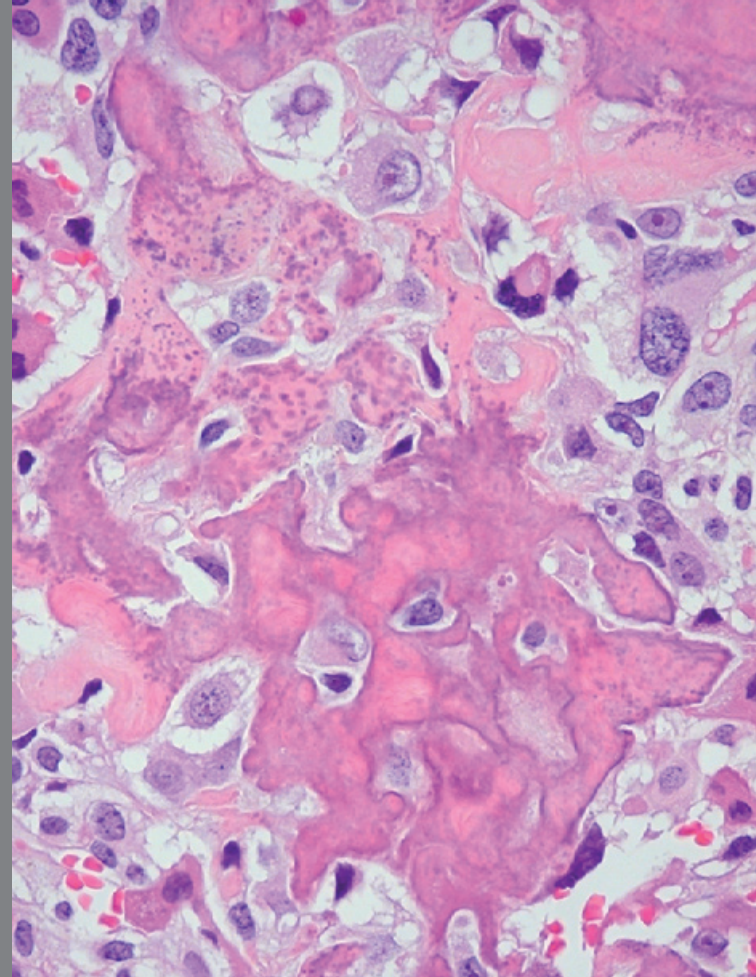


Pan European Clinical Trials under current EU regulations

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

24 - 25 January 2008, London, UK



Pan European Clinical Trials under current EU regulations

Selsdon Park Hotel, South Croydon, London, UK 24-25 January 2008

Initiated by:

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

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. A feedback session will follow each workshop to allow groups to share the group's discussion and learning points with the main combined group.

Registration

Registration deadline: 14 December 2007

Further information:

Sue Harrison
H2 Events
The Events Suite, Bryant House, 61-63 Wellington Road North, Stockport
Cheshire SK4 1HS
Tel: 0161 477 9877
Fax: 0161 477 8222
Email: sueharrison@h2-events.co.uk

Participation in the course, including hotel accommodation and assistance with travel costs is free of charge for participants of EURAMOS 1 and PROFIDYS trials. There are only 150 spaces available and so registrations will be accepted 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 within the **claim deadline of 3 March 2008**. Original train tickets/boarding passes must be retained and submitted with the expense claim form as proof of travel.
- Accommodation will be in the conference hotel, Selsdon Park Hotel (www.principal-hayley.com)
- **IMPORTANT:** Please do not finalise your travel arrangements until your participation on the course has been confirmed.

Speakers

- Stefan Bielack, Stuttgart, Germany
- Lizzie Burns, London, UK
- Trude Butterfass-Bahloul, Münster, Germany
- Gaby Calaminus, Münster, Germany
- Dorothe Carle, Stuttgart, Germany
- Lesley Fallowfield, Brighton, UK
- Lars Hjort, Lund, Sweden
- Carole Moquin-Pathey, Strasbourg, France
- Raj Nagarajan, Cincinnati, USA
- Martha Perisoglou, London, UK
- Roy Sinclair, London, UK
- Matthew Sydes, London, UK
- Sue Tebbs, London, UK
- Andreas Weiner, Münster, Germany
- Jeremy Whelan, London, UK

This training course has been made possible thanks to the support from the European Science Foundation (ESF) under the EUROCORES Programme European Clinical Trials (ECT), through contract No. ERAS-CT-2003-980409 of the European Commission, DG Research, FP6.

Cover images:

Top: Osteosarcoma of the left knee visualized by Magnetic Resonance Imaging (MRI), and histological section. Courtesy Prof. S. Bielack

Bottom: Fibrous dysplasia of the femur before and after a 4-years bisphosphonates treatment, and histological section. Courtesy Prof. P. Orcel and Dr. A. Quillard

Programme

Thursday 24 January 2008

12:30 - 13:30

Lunch

Restaurant

13:30 - 13:40

Welcome and Introduction

Jeremy Whelan

Main room (Terrace)

13:40 - 14:30

Obtaining Consent: a demonstration of the consent process with discussion

Lesley Fallowfield and Jeremy Whelan

Main room (Terrace)

14:30 - 15:00

Improving Randomisation Rates: Practical steps

Dorothe Carrle

Main room (Terrace)

15:00 - 15:20

Refreshment Break

Solarium (next to reception)

15:20 - 15:50

SAE Reporting

Trude Butterfass-Bahloul

Main room (Terrace)

15:50 - 16:20

Toxicity Reporting: Guide to CTCAE

Martha Perisoglou

Main room (Terrace)

16:20 - 16:40

Refreshment Break

Solarium (next to reception)

16:40 - 17:50

Workshop: Safety Reporting

Trude Butterfass-Bahloul, Stefan Bielack (COSS group)

Martha Perisoglou (SSG & EOI group)

COSS group: remain in main room (Terrace)

SSG & EOI group: move to Kent suite

17:50 - 18:40

Workshop: Toxicity Reporting

Matthias Kevric (COSS group)

Martha Perisoglou (SSG & EOI group)

COSS group: remain in main room (Terrace)

SSG & EOI group: move to Kent suite

18:40 - 18:50

Feedback from workshops and Close

Stefan Bielack, Trude Butterfass-Bahloul, Jeremy Whelan

Main room (Terrace)

20:00 - 20:30

Pre-Dinner drinks

Solarium (next to reception)

20:30

Dinner

Main room (Terrace)

Friday 25 January 2008

08:30 - 09:00

Role of the clinical trials pharmacist

Roy Sinclair

Main room (Terrace)

09:00 - 09:20

Art in medicine

Lizzie Burns

Main room (Terrace)

09:20 - 09:50

Quality of life

Gaby Calaminus

Main room (Terrace)

09:50 - 10:15

Group Photograph and Refreshment Break

Solarium (next to reception)

10:15 - 11:00

Workshop: Improving Quality of Life compliance

Andreas Wiener, Gaby Calaminus, Lars Hjort &

Raj Nagarajan, Meriel Jenney

COSS group: remain in main room (Terrace)

SSG & EOI group: move to Kent suite

11:00 - 11:10

Feedback from workshop

Main room (Terrace)

11:10 - 11:20

The importance of multi-national trials for rare diseases – the EURAMOS model

Matthew Sydes

Main room (Terrace)

11:20 - 11:30

Funding pan-European trials: Role of ESF

Carole Moquin-Pathey

Main room (Terrace)

11:30 - 11:40

European Clinical Research Infrastructures Network (ECRIN)

Christine Kubiak

Main room (Terrace)

11:40 - 11:50

Refreshment Break

Solarium (next to reception)

11:50 - 12:20

GCP: Investigator responsibilities

Nicola Kaganson

Main room (Terrace)

12:20 - 12:30

Summary and Close

Jeremy Whelan

Main room (Terrace)

12:30 - 13:30

Lunch

Restaurant

13:00 - 14:00

QoL Panel Meeting

Main room (Terrace)

14:00 - 18:00

TMG Meeting

Main room (Terrace)

Refreshments will be provided during the meeting

The aim of the European Collaborative Research (EUROCORES) Scheme is to enable researchers in different European countries to develop collaboration and scientific synergy in areas where European scale and scope are required to reach the critical mass necessary for top class science in a global context.

The scheme provides a flexible framework which allows national basic research funding and performing organisations to join forces to support excellent European research in and across all scientific areas.

The European Science Foundation (ESF) provides scientific coordination and support for networking activities of funded scientists currently through the EC FP6 Programme, under contract no. ERAS-CT-2003-980409. Research funding is provided by participating national organisations. The ECT programme is managed by the EMRC (European Medical Research Councils) Unit at the ESF.

www.esf.org/eurocores

The following national funding organisations support the ECT Programme:

Fonds National de la Recherche Scientifique (FNRS)

National Fund for Scientific Research, Belgium

Fonds voor Wetenschappelijk Onderzoek (FWO)

Research Foundation Flanders, Belgium

Forskningsstyrelsen

Danish Research Agency, Denmark

Suomen Akatemia

Research Council for Health at the Academy of Finland, Finland

Institut National de la Santé et de la Recherche Médicale (Inserm)

National Institute for Health and Medical Research, France

Deutsche Forschungsgemeinschaft (DFG)

German Research Foundation, Germany

Norges forskningsråd (NFR)

Research Council of Norway, Norway

ZonMw

The Netherlands Organisation for Health Research and Development, The Netherlands

Medical Research Council (MRC)

United Kingdom