

**Pan European Clinical Trials under current EU regulations:
A training course for data managers, study nurses and junior clinical investigators.**

The 3rd training course run by the EURAMOS group & funded by the European Science Foundation (ESF) under the EUROCORES Programme European Clinical Trials (ECT) was held in Surrey, UK on 24-25 January 2008.

Investigator-initiated Clinical Trials face a multitude of challenges, particularly if they are to be performed according to the guidelines of Good Clinical Practice (GCP) because the translation of GCP into national laws and regulations differs between countries. This is even more true if these trials are performed on an international, Pan-European scale, as is EURAMOS-1. In order to assure patient safety in a way that complies with European and national rules and regulations, personnel involved in clinical trials must be trained intensively.

The training course was open to study nurses, data managers and clinical (junior and senior) researchers who are involved in the day-to-day management of multi-centre clinical trials at the institutional level from any European institution participating in the *ECT EUROCORES* programme and also to those outside the programme. 123 delegates from 12 countries¹ attended the event which was held over two half-days and consisted of a combination of lectures and concurrent interactive group workshops.

Delegates learnt about why clinical trials on very rare diseases such as the EURAMOS 1 trial are important, the challenges and difficulties of international collaboration and why it is worth the effort. They learnt more about the role of the *European Science Foundation* (ESF) in funding pan-European trials and the activities of the *ECT-EUROCORES* programme. They were also introduced to the *European Clinical Research Infrastructures Network* (ECRIN) programme. This is an EU-funded initiative, which through the connection of national networks of clinical research centres and clinical trials units, aims to develop an integrated European Infrastructure of clinical research able to provide support to clinical research in any medical field, and for any type of clinical research.

Highlights of the event included a video demonstration of the informed consent process with which Prof. Lesley Fallowfield illustrated the importance of the involvement of the clinician and how best to present clinical trial to patients and the choices that patients have to make. Dr Lizzie Burns presented an inspiring collection of paintings and photographs taken from a unique art project called "*Bringing science to life*", which creates an awareness of the importance of clinical trials from the patients' perspectives. The exhibition, also part of the European Science Foundation EUROCORES Programme ECT, was supported by funds from the EC Sixth Framework Programme and involved patients with osteosarcoma taking part in EURAMOS-1 in the UK. The project provided an opportunity to help patients come to terms with their disease and communicate their experiences through art. The importance of collecting information on the patient's and the patient's family perspective on quality of life (QL) in randomised trials was emphasized to delegates. The EURAMOS-1 trial was used as an example to illustrate how QL may be measured and how information may be collected, interpreted and balanced with clinical outcome measures. Other topics covered were refresher training on how to be compliant with the Guidelines for Good Clinical Practice and EU-Directive 2001/20 and how to recognise, grade and report both routine toxicities and serious adverse events.

This training course provided an excellent forum for those involved in Europe-wide clinical trials to meet with peers and colleagues in a friendly and supportive environment, to discuss the various challenges in their work and to update their knowledge, review their working procedures and share best practice with each other. The feedback from the delegates was very positive and many hoped they could look forward to a similar event in the future.

¹ Austria, Belgium, Canada, Czech Republic, Germany, Hungary, Netherlands, Norway, Poland, Sweden, UK and USA.