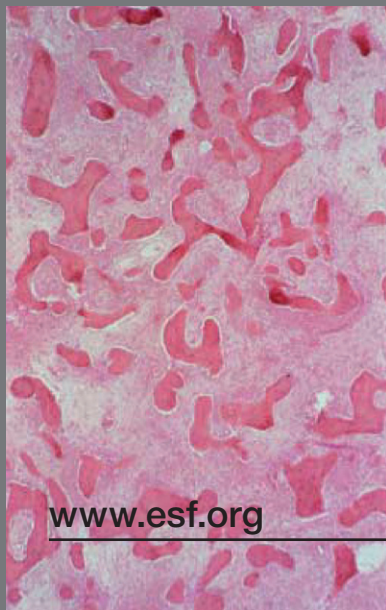
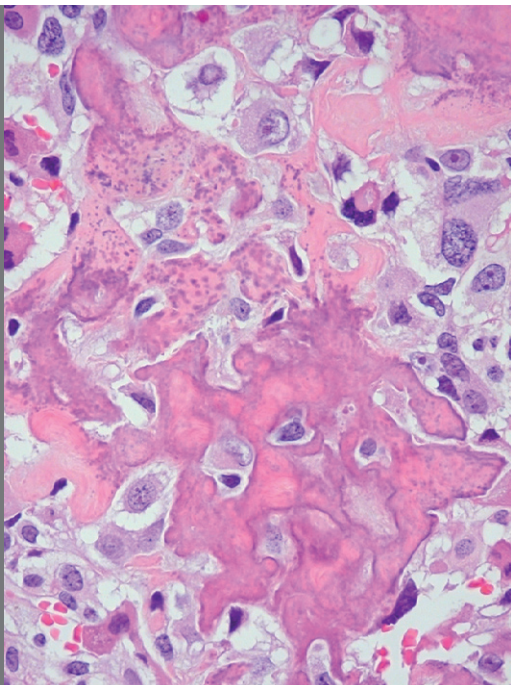


**ECT**

**Pan-European Clinical Trials**



# The Scientific Goal of the ECT (Pan-European Clinical Trials) Programme

ECT is a unique programme that coordinates funding for pan-European, non-commercial, investigator-driven clinical trials addressing questions that have a strong impact on the quality of life, morbidity and mortality of the European population. The ECT programme provides a framework for the implementation of pan-European clinical trials in compliance with Good Clinical Practice and current national legislation and European regulations.

By promoting and supporting networking, the ECT programme fosters synergy with other European and international initiatives.

**Training activities** have contributed to the development of the necessary expertise for the implementation and management of multi-centre, pan-European academic clinical trials, ensuring patient safety in compliance with the current National and European legislation.

**Dissemination activities** have brought together clinicians, ethicists, legal experts, policy makers, charities and funding bodies, representatives from regulatory agencies, professional associations and patient organisations to promote the best evidence-based approach for new treatments and also discuss current regulatory and ethical issues to ensure patient safety in the conduct of academic clinical trials. The impact of these activities is evidenced by the wide coverage in the media and specialised publications.

Two Collaborative Research Projects (CRPs), i.e., pan-European clinical trials aimed at rare diseases and the paediatric population are funded under this programme.

# Two Pan-European Clinical Trials are funded under the ECT EUROCORES Programme:

**EURAMOS** (European and American Osteosarcoma Study Group), a randomised trial designed to optimise treatment strategies for patients with resectable osteosarcoma based on histological response to pre-operative chemotherapy. Osteosarcoma is the most common bone cancer in children, adolescents and young adults but it is still a rare disease with an annual incidence of 2-3 million cases per year. EURAMOS involves over 200 clinical centres in 13 European countries, U.S. and Canada. EURAMOS is on course to recruit 1,400 patients over the next few years and has already recruited more patients than any previous osteosarcoma trial performed (792 patients of which 410 were recruited in Europe as of 30 November 2007). The trial is also funded in the UK by a grant from Cancer Research UK (CRUK).

**Stefan Bielack** (Project Leader)  
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MOTOL Hospital, Prague, Czech Republic

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**Smeland Sigbjørn**  
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**Maija Tarkkanen**  
University of Helsinki, Helsinki, Finland

**Jeremy Whelan**  
University College London Hospitals, London, UK

**Andreas Zoubek**  
St. Anna Kinderspital, Vienna, Austria

**PROFIDYS**, a randomised placebo controlled trial designed to assess the safety, tolerability and efficacy of an oral bisphosphonate in the reduction of bone pain and osteolytic lesions in patients with fibrous dysplasia of the bone. Fibrous dysplasia of the bone is a rare congenital bone disease characterised by replacement of normal bone by fibrous tissue; this disease accounts for about 2.5% of bone disorders and 7% of benign bone tumours or "pseudo-tumours". PROFIDYS involves 11 clinical centres in five European countries. The trial is funded in France through a dedicated programme called PHRC (Programme Hospitalier de Recherche Clinique). As this disease is so rare, approximately 160 patients are being recruited for this trial among of which about 22 are randomised as of 30 November 2007.

**Philippe Orcel** (Project Leader)  
Assistance Publique des Hôpitaux de Paris, Paris, France

**Roland Chapurlat**  
Institut National de la Santé et de la Recherche Médicale (Inserm), Lyon, France

**Jean-Pierre Devogelaer**  
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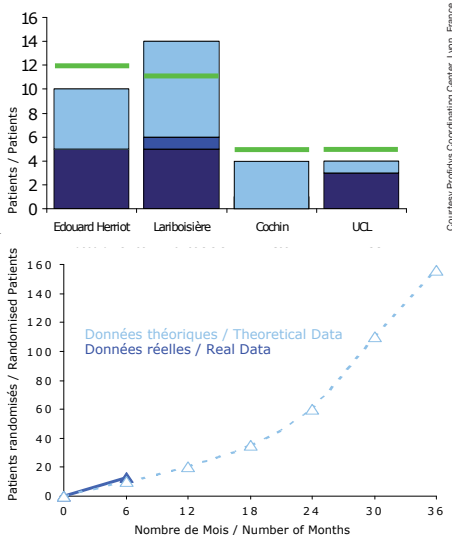
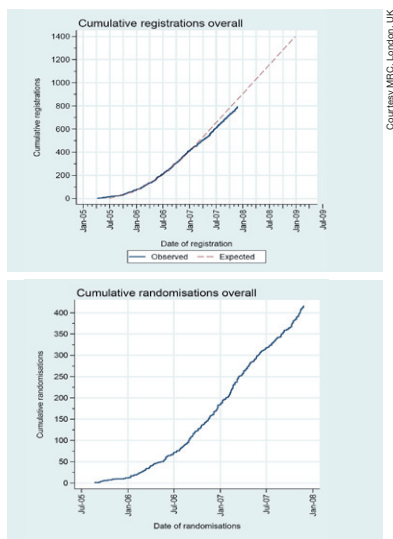
**Dieter Felsenberg**  
Universitätsklinikum Benjamin Franklin, Berlin, Germany

**Socrates E. Papapoulos**  
Leiden University Medical Centre, Leiden, The Netherlands

**David Reid**  
University of Aberdeen, Aberdeen, UK

# Activities developed within the frame of the ECT Programme in 2008

## • Recruitment status (as November 2007)

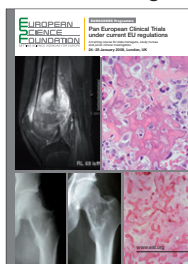


EURAMOS

PROFIDYS

## • Global PROFIDYS Conference Tuesday 22 January 2008, Lyon, France

## • Pan-European Clinical Trials under current EU regulations



A training course for data managers, study nurses, and junior clinical investigators. Thursday 24 and Friday 25 January 2008, London, UK

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](http://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)**

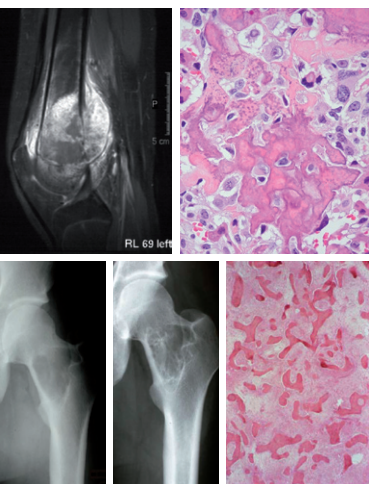
*Research Council of Norway, Norway*

**ZonMw**

*The Netherlands Organisation for Health Research and Development, The Netherlands*

**Medical Research Council (MRC)**

*United Kingdom*



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

## CONTACT DETAILS

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