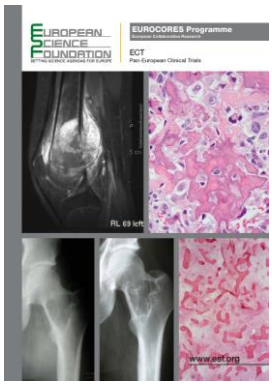
The Scientific Goal of the ECT (Pan-European Clinical Trials) Programme



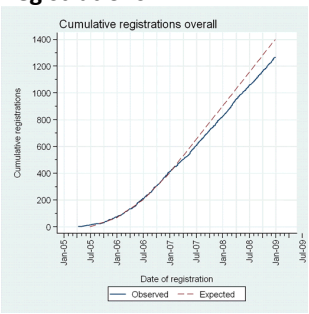
ECT is a unique EUROCORES Programme that was launched in February 2005 with the aim to coordinate funding for two pan-European investigator-driven clinical trials on rare diseases and pediatrics: **EURAMOS** (European and American Osteosarcoma Study Group) and **PROFIDYS**. This was done in parallel and somewhat slowed down by the EU Clinical Trials Directive 2001/20/EC. The **ECT** Programme should end in May 2011.

1. EURAMOS is 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 is still a rare disease with an annual incidence of 2-3 million cases per year. EURAMOS involves over 300 clinical centres in 15 European countries, the USA, Australia and Canada. EURAMOS is on course to recruit 2000 patients over the next few years (around 1300 patients of which over 1100 were recruited in Europe as of 31 March 2009).

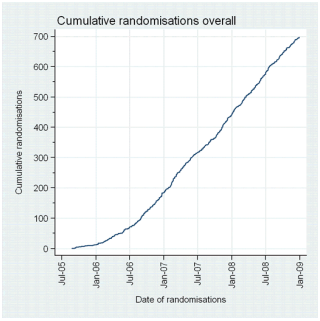
EURAMOS Project Leader: Professor Stefan Bielack, Olgahospital, Germany.

EURAMOS Accrual Information - December 2008

Registrations



Randomisations



2009 EURAMOS Highlights:

1. Recruitment to EURAMOS has been extended until around June 2010. The results of the primary outcome measure, i.e. event-free survival, should be known two to four years after the trial closes to accrual.
2. The 22nd Annual Meeting of the European Musculo-Skeletall Oncology Society (EMSOS) took place on 13-16 May 2009 in Stuttgart, Germany.

More information on EURAMOS: www.esf.org/ect
http://www.ctu.mrc.ac.uk/euramos

2. PROFIDYS is a randomised placebo-controlled trial assessing 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, 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 currently involves 4 active clinical centres in two European countries (France and Belgium), aiming at 11 centres in 5 countries. As this disease is so rare, approximately 156 patients are in the process of being recruited for the trial, of which about 35 are randomised as of May 2009.

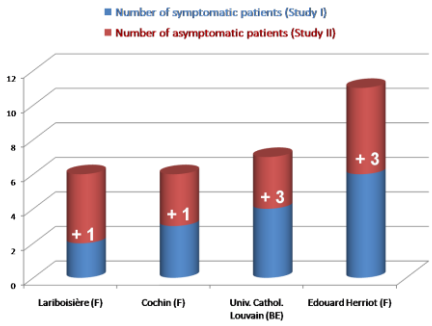
PROFIDYS Project Leader: Professor Philippe Orcel, Hôpital Lariboisière, France.

PROFIDYS Recruitment Information - January 2009

Number of European open centres as of 1 January 2009 (in green)

Future clinical centres in orange on map

Randomisation status as of 1 January 2009



The Assistance Publique des Hôpitaux de Paris (AP-HP) joined the founder group of the EUROCORES ECT programme, showing its willingness to develop its implication in Pan-European clinical trials.

2009 PROFIDYS Highlight:

More information on PROFIDYS: www.esf.org/ect;
http://www.dysplasie-fibreuse-des-os.info