



**EUROCORES Programme**  
European Collaborative Research  
ECT Pan-European Clinical  
**E**UROPEAN  
**O**STEOSARCOMA  
**I**NTERGROUP



# EURAMOS-1 GROUP NEWSLETTER

## SUMMER 2011 EDITION

**Welcome to the Summer edition of the EURAMOS-1 Group Newsletter!  
We would like to again extend our gratitude to everyone working so hard on EURAMOS-1 for their continued efforts to make the trial a success.**

### Thank you for your contribution!

The target number of registrations in EURAMOS-1 has been reached! We would like to thank all of you for your participation and your great contribution to the trial. EURAMOS-1 is the largest osteosarcoma trial ever conducted and will identify interventions that aim to improve the outcome for all osteosarcoma patients.

### Closure to registration

EURAMOS-1 closed to registration on 30 June 2011. In the whole trial, 2260 patients have been registered and 1278 patients randomised to date. Randomisations will remain possible for all registered patients until they have been randomised or it is confirmed that they will not be randomised. The target for EURAMOS-1 is to randomize a minimum of 1260 patients: 567 good responders and 693 poor responders.

### Treatment recommendation for future osteosarcoma patients treated outside of trial

Following the closure to accrual of EURAMOS-1, the Trial Management Group members consider MAP (high-dose methotrexate, doxorubicin, cisplatin), with no adjustment of post-operative treatment based on histological response, to be the standard of care for their patients with newly diagnosed, resectable osteosarcoma. All emerging data from the analyses of EURAMOS-1 will be disseminated to investigators when available. Plans for a further international trial, EURAMOS-2, are in development. MAP will again be the chosen standard treatment arm. In the meantime, inclusion of patients in well designed clinical trials when available is encouraged.

### Facts and Figures (to end of June 2011)

#### Total Patient Numbers

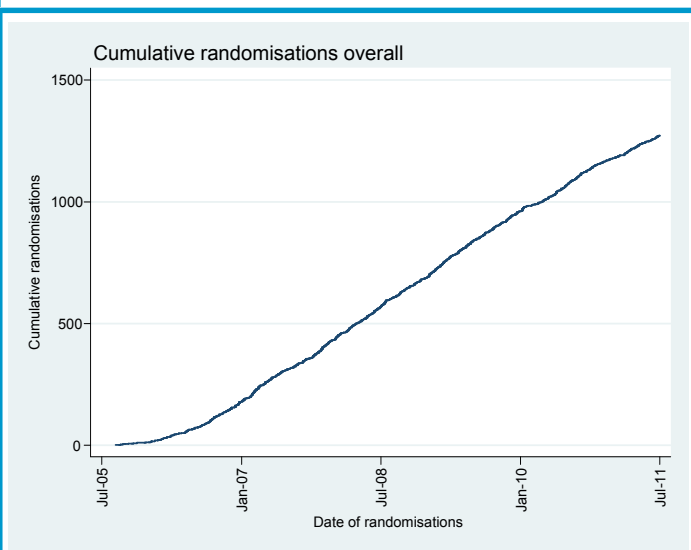
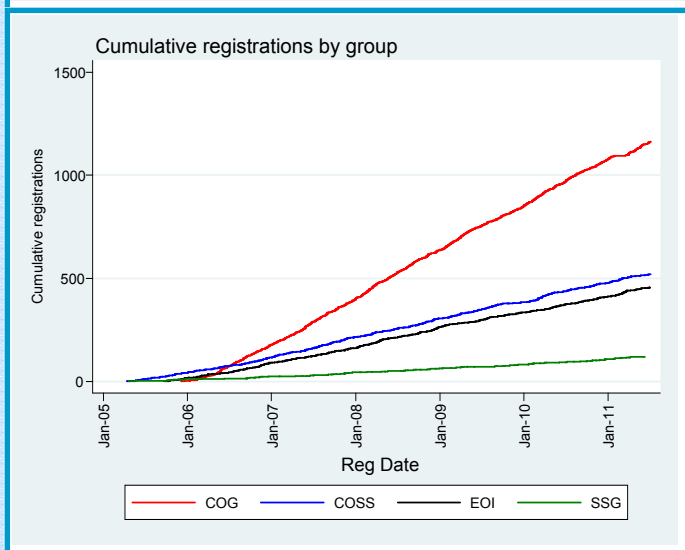
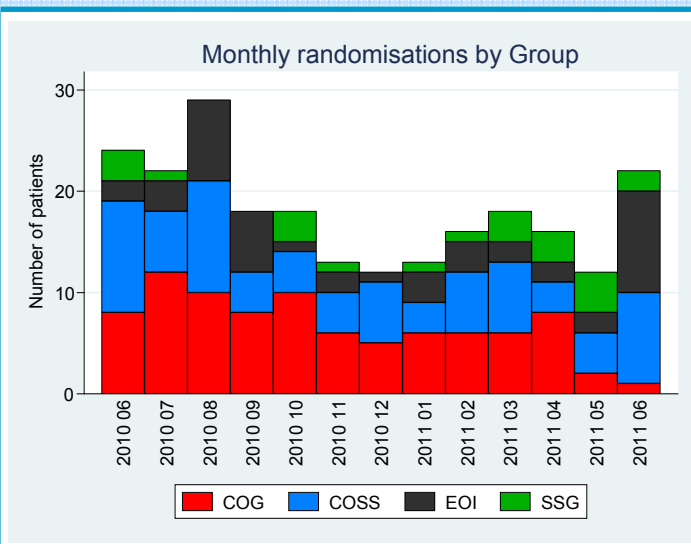
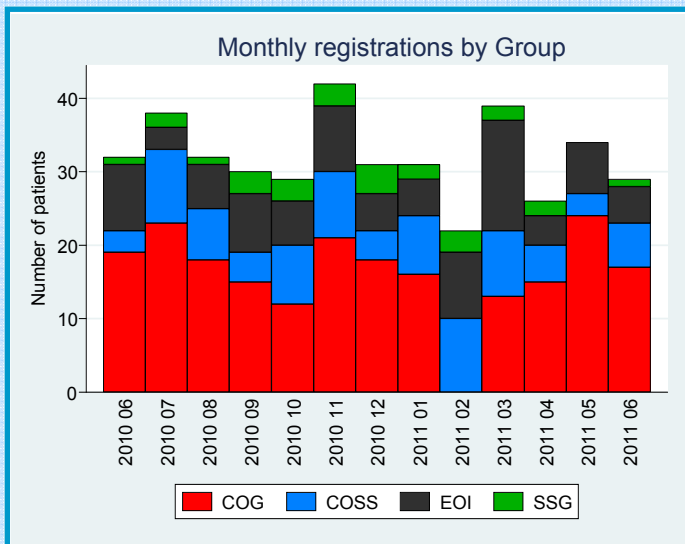
Registered: **2260**  
Randomised: **1278**

#### Top 11 Registering Centres

#### Total Centre Numbers

Recruiting Countries: 21  
Recruiting Centres: 330

Country	Hospital	Registered Patients
UK	University College Hospital	90
Netherlands	Leiden UMC	51
Germany	Univers. Kinderklinik, Münster	35
Norway	Oslo	30
USA	Children's Hospital of Philadelphia	26
USA	Children's Hospital and Regional Medical Centre	24
Germany	Kinderklinik & Poliklinik, München	23
USA	Doernbecher Childrens Hospital	23
USA	University of Minnesota Cancer Centre	23
Germany	Univers. Paediat. Oncology, Hamburg	22
Germany	Olgahospital, Stuttgart	22



**International Recruitment by Group (until end of June 2011)**

**COG**

	Nb sites	Registrations	Randomisations
Australia	6	28	13
Bahamas	2	2	0
Canada	15	82	44
Guatemala	1	1	1
New Zealand	3	14	5
Puerto Rico	1	5	1
Switzerland	3	12	5
USA	152	1020	515
<b>TOTAL</b>	<b>183</b>	<b>1164</b>	<b>584</b>

**COSS**

	Nb sites	Registrations	Randomisations
Austria	5	28	17
Czech Rep.	2	9	6
Germany	85	432	291
Hungary	2	24	19
Switzerland	5	27	20
<b>TOTAL</b>	<b>99</b>	<b>520</b>	<b>353</b>

**EOI**

	Nb sites	Registrations	Randomisations
Belgium	6	52	39
Ireland	1	6	1
Netherlands	4	101	61
UK	24	298	160
<b>TOTAL</b>	<b>35</b>	<b>457</b>	<b>261</b>

**SSG**

	Nb sites	Registrations	Randomisations
Denmark	2	27	12
Finland	1	3	3
Norway	3	41	33
Sweden	6	48	32
<b>TOTAL</b>	<b>12</b>	<b>119</b>	<b>80</b>

### When will we see the EURAMOS-1 results?

Analysis of the primary end-point Event-Free Survival (EFS) is planned to take place around 2013 and analysis of the secondary end-point Overall Survival (OS) is planned to take place around 2015.

The final analysis depends entirely on data return from sites, in order to see all of your hard work rewarded with a publication, we urge you to return the CRFs to your data center in a timely manner, in particular the follow-up forms.

### EURAMOS-1 at EMSOS

A presentation about EURAMOS-1 was given by Prof. Stefan Bielack at the 24<sup>th</sup> European Musculo-Skeletal Oncology Society (EMSOS) Annual meeting in Belgium in May 2011: *'Osteosarcoma treatment in Europe and elsewhere is far from being centralised: lessons from EURAMOS-1'*. Slides of this presentation are available on the EURAMOS website.

### EURAMOS-2 – Follow-on trial

There will be a follow-on trial to EURAMOS-1. The design and collaboration model have been discussed at the ASCO meeting held in Chicago beginning of June 2011. The design is likely to be MAP regimen versus MAP + zoledronic acid and the study is likely to open around 2012/2013.

### Staff changes and MRC relocation

We would like to welcome Miriam Wilhelm (physician) and Claudia Wurster (secretary) as new members of the COSS team and Karen Sanders (Clinical Project Manager) and Aurélie Faysse (Trial Manager) as new members of the EOI team. Hans Gelderblom is the new National Coordinator in the Netherlands. Please note that the MRC CTU has moved offices on 1<sup>st</sup> July 2011 to: [MRC CTU, Aviation House, 125 Kingsway, London, WC2B 6NH](#).

### EURAMOS-1 A Message from our Chair, Mark Bernstein

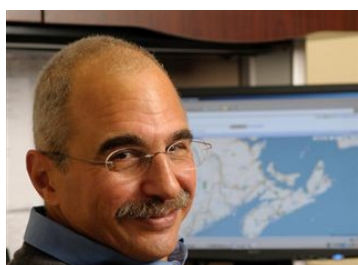
On behalf of the Trial Management Group, I would like to thank all investigators, patients and families for their participation in the Euramos-1 study, the largest clinical trial to date in osteosarcoma. We are confident that the results will contribute to the understanding of the management of patients with osteosarcoma, and that the collaboration among the cooperative groups that has been established will speed the completion of other large studies in this patient population. Thanks again!

**Mark Bernstein**

**TMG Chair, EURAMOS-1**

**With best wishes on behalf of the EURAMOS-1 Trial Management Team**

**Mark Bernstein, Jeremy Whelan, Stefan Bielack, Sigbjørn Smeland and Neyssa Marina**



**Mark Bernstein**  
TMG Chair



**Jeremy Whelan**  
EOI Chief Investigator



**Stefan Bielack**  
COSS Chief Investigator



**Sigbjørn Smeland**  
SSG Chief Investigator



**Neyssa Marina**  
COG Chief Investigator