



SIOPE EUROPE

SIOPE's Community Newsletter

SIOPE News

May 2008 Issue 2

SIOPE News from the Office

Dear Readers,

We are really glad to report that since we published our very first newsletter in December 2007, our activities have steadily developed thanks to the support and guidance received from our members.

The second edition of SIOPE News introduces our newly appointed SIOPE President-Elect, announces the Call for Nominations for the SIOPE Board, features a special editorial on the current situation of clinical trials in Central and Eastern Europe as well as other reports on current SIOPE activities.

We hope you enjoy this second issue and warmly welcome any comments or suggestions for future content. Please do not hesitate in contacting the SIOPE Office directly at:

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We wish all our Members a very refreshing and energetic Spring.



Message from the President

Prof. Kathy Pritchard-Jones
SIOPE President



Welcome to the second Newsletter from SIOPE Europe with updates on the latest in childhood cancer. Cancer has been at the forefront of Europe-wide discussions promoted by the Slovenian Presidency of the EU. The final report of the Eurocan+ Plus Project was presented to the European Parliament on the same day they adopted the Cancer Resolution; both initiatives should have important outcomes for children with cancer. Momentum is building to have a real critical review of the EU Clinical Trials Directive with the needs of academic researchers and patient groups with rare diseases firmly in mind. The final report of the 'Conference on the Operation of the EU CTD and Perspectives for the Future' organised jointly by the EMEA and the European Commission has been published and we expect to see actions arising from it. Our Clinical Trials Helpdesk will provide access to all relevant information via our Gateway (see page 3).

New drugs to treat childhood cancer are on the horizon, and are already making waves in the adult cancer world. SIOPE Europe's Board was therefore delighted to see that seventeen applicants submitted a clinical trial proposal in childhood cancer for the 10th Joint ECCO/AACR/ASCO Workshop on "Methods in Clinical Cancer Research". Eight were selected and three projects propose to study novel therapeutics. The two highest ranking applicants were awarded SIOPE Europe FLIMS Scholarships. (see page 4)

I was pleased to be involved in two recently published papers about the challenges of clinical trials in childhood cancer. *The first was truly multidisciplinary with contributions from a clinical trial statistician, a medical sociologist and a parent, links that were fostered through SIOPE Europe. ** The second, arose from SIOPE Europe and the TEDDY Network highlighting the appalling lack of paediatric data on so many drugs we use to treat children with cancer. Two research consortia nurtured through SIOPE received EU Framework Programme 7 funding under the Call for Off-patent Medicines in Children. I am optimistic that access to new agents and clinical trials for children with cancer in Europe is set to improve.

Finally, I am delighted that Professor Ruth Ladenstein of the Children's Cancer Research Institute, Vienna has accepted the nomination as President-Elect of SIOPE Europe. She is already well known to many of you through her work in neuroblastoma. For SIOPE Europe she is already very active in improving support for clinical trials and I am sure will lead SIOPE Europe into the next decade with gusto (a quirky English term meaning vigorous and enthusiastic enjoyment!). Her election creates an opening on the SIOPE Board which I hope will attract an enthusiastic volunteer to what I can assure you is a very enjoyable role.

* Pritchard-Jones K, Dixon-Woods M, Naafs-Wilstra M, Valsecchi M. Invited Review: Improving recruitment to clinical trials for cancer in childhood. *Lancet Oncol.*, 9(4): 392-9,2008

** Paolucci P, Pritchard-Jones K, Garcinumo M, Catapao M, Iolascon I, Ceci A. Challenges in prescribing drugs for children with cancer. *Lancet Oncology*, 9:176-83, 2008.

SIOPE Europe's Community

SIOPE Europe's new President-Elect

We are delighted to announce that Professor Ruth Ladenstein has been appointed as SIOPE Europe's President-Elect to commence following the SIOPE Europe General Assembly in October, Berlin, Germany. Her term as President will commence in October 2009 for two years.

Call for Nominations

We actively encourage members who would be interested in serving on SIOPE Europe's Board to submit their application.

SIOPE Europe Board Members are directly involved in:

- Representing the voice of Paediatric Oncology in Europe and liaison with the wider membership;
- Defining the annual work programme of the organisation;
- Setting priorities and targets;
- Reviewing financial management and scrutiny of annual accounts;
- Providing expertise in paediatric oncology, policy and management to support the activities of the SIOPE Office staff.

With the newly established office in Brussels, many of our activities are growing and flourishing. We firmly believe that these are exciting times to consider serving on our Board. It is thanks to the continued dedication of our Board Members that much can and will be done towards building an even brighter future for our Society.

For further information and to register your interest please contact Jocelyne Wang:

Email: Jocelyne.wang@ecco-org.eu

Tel: +32 2 775 2934.

Nominations, including a short CV (1 page) and a motivation letter must be received by **30 June 2008**.

Associate Membership of SIOPE

SIOPE Europe now has a new category of membership, Associate Membership, which is open to multinational clinical trial groups, national childhood cancer organisations and childhood cancer parents' organisations, regardless of whether they are a legally constituted. We strongly encourage all such groups to sign up to Associate Membership of SIOPE so that we can build a stronger European network for stakeholders in the field of childhood cancer.

Associate Members of SIOPE will have the opportunity to:

■ Actively participate in a Europe-wide network, with particular focus on clinical trial research.

Associate Members will have access to a membership database including contact details of the European Clinical Trials Groups and National Childhood Cancer Groups. Moreover, the recently established SIOPE Europe Clinical Trials Help Desk aims to be a 'one-stop-shop' disseminating the latest clinical trials information, as well as offering a common platform for trial design, best practice guidelines and Good Clinical Practice (GCP) workshops.

■ To stay abreast of and influence paediatric-oncology related policies within the EU.

SIOPE Europe will canvas all of its Associate Members for their views in order to provide a coordinated response from the childhood cancer community to the frequent public consultations for policy proposals and amendments initiated by the European Commission, European Medicines Executive Agency (EMA) or other relevant bodies that may affect care of children with cancer and/or research opportunities. SIOPE Europe aims to act as a unified and strong voice to represent the needs of children with cancer by informing policy makers



and experts during decision-making processes and 'forward thinking' at the European level.

Associate Members will be provided with regular updates on the latest policy-making issues within the sphere of paediatric oncology. All relevant documents will be made available on the SIOPE Europe Gateway.

■ Access support and information services from SIOPE Europe's Office.

We aim to launch the SIOPE Europe website - SIOPE Gateway within the next months. Among many other things, it will provide members with the latest information on research and training activities across Europe as well as consultations. The Gateway will serve as a platform to be developed in conjunction with the membership. Content will be devised and adapted to match the needs of our community. Members will also receive SIOPE news - our community newsletter by email three times a year.

■ Vote on issues relating to SIOPE Europe's internal affairs and long-term strategy.

Associate Members will be requested to appoint a representative to cast a vote on behalf of their organisation via e-ballot, postal ballot or at the Annual General Assembly. This will enable members to actively participate in internal decision-making processes.

In light of the recent EUROCAN+Plus project which identified the problem of impaired communication amongst different research groups, professional bodies and other stakeholders, we sincerely hope that by strengthening the SIOPE network, we will inspire all relevant parties in paediatric oncology to work together and make a difference. It is only through communication, connectivity and collaboration that we can hope to collectively bring about essential changes at the European level.

For further information or to send your application, please contact us directly:

Jocelyne.wang@ecco-org.eu

Tel: +32 2 775 29 34.

The SIOPE Gateway: Roadmaps and Resources in Childhood Cancer across Europe

We are delighted to inform you that the SIOPE Gateway will launch in the coming months. It aims to provide easy access to information and services provided by the SIOPE Office in Brussels as well as useful links to a variety of other childhood cancer information and resources.

Key features of the SIOPE website include:

Public Domain

- General information on the SIOPE Office and its activities;
- Up-to-date information on Paediatric Oncology events and training courses;
- Access to selected websites and information;
- Copies of consultation documents of relevance to Childhood Cancer, SIOPE's responses and relevant reports.

Members-Only

- Access to the latest SIOPE internal news such as meeting minutes from different working groups;
- Contact details of professionals engaged in the field of paediatric oncology and clinical trials across Europe;
- Summaries about current trials throughout Europe;
- The latest information on SIOPE's activities at European level.

The SIOPE Gateway has been facilitated through the hard work and dedication of SIOPE Board Members (in particular Dr. Kjeld Schmiegelow, former SIOPE Board Member) and the Brussels Office Staff.

Should you have any ideas or suggestions for future Gateway content, we kindly invite you to email Jocelyne Wang at: Jocelyne.wang@ecco-org.eu



Highlights: SIOPE / FLIMS Grants

SIOPE received a number of applications in response to their Call for Proposals for the FLIMS workshop 'Methods in Clinical Cancer Research', 21 - 27 June 2008, Flims, Switzerland.

We are pleased to announce that eight applicants were selected to participate in the workshop, two of whom have been awarded a SIOPE / FLIMS Scholarship: Dr. Lucas Retortillo Moreno Martin from Spain and Dr. Shaun Wilson from the UK.



Dr. Lucas Moreno Martin Retortillo
Children's Hospital "La Fe"
Department of Paediatric Oncology

Project title:

A randomised phase II trial of TVD +/- bevacizumab for refractory metastatic neuroblastoma



Dr. Shaun Wilson
Birmingham Children's Hospital
Department of Paediatric Oncology

Project title:

A phase I study of PXD101 in childhood acute leukaemias

We would like to congratulate them both and hope that all workshop participants benefit from the prestigious FLIMS workshop, this coming June.



Committee Reports and Roundups

SIOPE Clinical Trials Group

Current Clinical Trials: Challenges in Central and Eastern Europe

Special Editorial

Entry into a clinical trial is viewed as the "best standard of care" for the treatment of the majority of childhood cancers. National Paediatric Oncology Groups from several countries in Central and Eastern Europe have been involved in international clinical trials many years before joining the EU. The majority of these front line therapies involved 'off-label' use of long established medicines that were out of patent. This situation was generally accepted by regulatory authorities and such trials were regarded as the obligatory standard for treatment of children with cancer. Agreement from the National or Local Bioethical Committee was the only necessary condition before trials were initiated. Since then, Central and Eastern European Countries have been obliged to implement the Directives 2001/20/EC and 2005/28/EC further to joining the EU.

The EU Clinical Trials Directive made conducting non-commercial cancer clinical trials more difficult due to increased documentation and difficulties relating to the identification and confirmation of the trial Sponsor. Several new protocols should also be initiated in such countries in 2007 and 2008: EuroNet-PHL-C1 for Hodgkin disease, SIOPE for neuroblastoma, EURAMOS, and ALL IC 2008. To-date no paediatric oncology centres in Poland have been able to open a new trial because of national interpretation of the EU Clinical Trials Directive. The main problem relates to a lack of regulation on what constitutes a National Sponsor of a trial. Universities do not want to take this responsibility since they have no resources for indemnity for clinical trials and 'no fault' compensation. Hospitals already facing a lack of funds for diagnosis and treatment cannot commit to additional spending to cover insurance of trials.

In the Czech Republic paediatric oncologists have persuaded the Motol University Hospital to serve as a National Sponsor for the Hodgkin Lymphoma Study and EURAMOS Trial. They have to pay, however, the no-fault insurance for patients from funds raised by parent organisations or through

charitable sources focused on childhood cancer which are generally limited.

In the Czech Republic and Hungary, approval from ethics committees is more straightforward. However, in Poland the procedure is still causing additional bureaucracy and delays – the clinical trial national chairperson submits the application to the relevant local ethics committee. If the decision of the EC is positive, this evaluation is a basis for other local ethics committees appropriate for participating centres, and the review is generally confined to local resource evaluation by each institution.

All the clinical trials we plan to run apply to the EU Clinical Trials Directive, at least according to regulatory authorities in Poland. Fortunately, there is no requirement to provide free drugs for the purpose of clinical trials.

Faced with such challenges, we are concerned that enrolment in clinical trials in Eastern/Central Europe countries will decrease due to the increased pressure on resources to initiate them. This may have a negative impact on the access to new treatment options for children with cancer in these parts of Europe.

Professor Jerzy R.Kowalczyk, Lublin, Poland
SIOPE Europe Board Member

Note from the SIOPE Office

We would like to inform you that the SIOPE Gateway will have a dedicated members-only area where information on clinical trials will be posted and regularly updated. We would like to encourage you to send us information should you start a new (paediatric oncology) trial or have articles / reports that you would like to share.

For further information, please contact Samira Essiaf at: samira.essiaf@ecco-org.eu

SIOPE Educational & Training Committee

Paediatric Oncology is a complex and rapidly evolving medical speciality. It involves the care of children with leukemia, tumours of the central nervous system and other solid tumours as well as the care of children with bone marrow transplants or other stem cell rescue procedures.



Prof. Riccardo Riccardi
Chair of SIOPE Education &
Training Committee.

The Educational and Training Committee (ETC) was founded in 2000 in collaboration with the European Society for Paediatric Haematology and Immunology (ESPHI). One of the goals of the ETC was to harmonise training programmes and assessment throughout Europe. A syllabus describing the minimum requirements for training in Tertiary Care paediatric Haematology and Oncology was prepared. This training programme was submitted and approved by the European Board of Paediatrics (EBP), by the Committee of European Specialists in Paediatrics / European Academy of Paediatrics (CESP/EAP) and by the

European Union of Medical Specialties (UEMS). In 2001 Paediatric Haematology and Oncology were recognised as paediatric subspecialties in Europe. Through this training, European specialists in Paediatric Haematology and Oncology will acquire an understanding of children with blood disorders or cancer and will acquire clinical competence in diagnosis and management.

The Training Programme Syllabus has been made available for Paediatric Societies in each country. National authorities and training bodies are aiming towards the implementation of local paediatric subspecialty. However identifying centres accredited for adequate training in Paediatric Haematology and Oncology is a complex process that requires additional time and resources at European level. In addition the ETC will play a crucial role for European Paediatric Oncologists by offering them the opportunity to update their skills in the management of paediatric oncology patients. Despite funding difficulties related to the rarity of cancer in children the ETC has been active in

proposing training and promoting already existing courses. Thanks to an outstanding partnership with the European School of Oncology (ESO), the first ESO / SIOPE Paediatric Oncology Masterclass was organised in Orta in 2006 with fifty young Paediatric Oncologists participating from twenty different countries.

Following the success of this event, ESO and SIOPE Europe are planning the second Masterclass in Paediatric Oncology that will be held in Ascona, Switzerland, 7-13 November 2008 (www.cancerworld.org/eso) focusing mainly on solid tumours.

Previously, Paediatric Oncology Masterclasses have taken place every other year alternating with the ESH-EHA-SIOP Conference that focuses mainly on Leukemia and Paediatric Haematology. The last conference was held in October 2007, Spain, organised by A. Biondi, A. Baruchel, I. Roberts, and K. Welte. This clinically orientated meeting was highly successful as were the previous ones held in 2003 and 2005. Another edition is foreseen for 2009.

SIOP Europe's ETC also offers its support to other important meetings. A notable example is the forthcoming FLIMS workshop 'Methods on Clinical Cancer Research', 21 - 27 June 2008, Flims, Switzerland. This Workshop represents an excellent opportunity for young investigators to be in direct contact with experts in clinical trials and learn how to develop a proposed clinical project.

The ETC will continue to plan increased activities for 2009 including SIOP Europe courses to support the harmonisation and improvement of standard care for children with cancer in Europe.

Professor Riccardo Riccardi
Chairman of the Education & Training Committee
of SIOP Europe and ESPHI

Note from the SIOPE Office

We are delighted to inform you that the first 2008 meeting of the SIOPE Education and Training Committee was held on the 31 March 2008. Thanks to the dynamic and motivated participants, interactive discussions on various topics and positive conclusions were drawn. We firmly believe that our highly driven Education and Training Committee will keep working as a strong force and lead more initiatives to improve education and training activities in the field of childhood cancer in the future.

Current Members of the SIOPE Education and Training Committee

Chair: Professor Riccardo Riccardi (*IT*)

Past-Chair: Professor Willem Kamps (*NL*)

Ordinary Members:

Professor François Doz (*FR*)

Professor Monika Fuherer (*DE*)

Professor Helen Komidis (*GR*)

Professor Finn Wesenberg (*NO*)

Professor Jan Stary (*CZ*)

Report on the SIOP Europe/EONS/ECCO Special Project



Pairing Nurses and Doctors in Paediatric Oncology

This research project funded by SIOP Europe and ECCO, was initiated as a two year project in 2006. Pairing doctors and nurses from across eastern and western Europe to collaborate in improving patient care in their respective centres, the Project adopts Appreciative Inquiry - a technique which seeks to develop the positive aspects of existing practices and further develop them.

Organised across three weekend seminars held in Europe (over a period of two years), ongoing support between meetings is provided by a designated mentor. The main goals of the seminars are to promote the implementation of theoretical content, facilitate discussion and receive feedback on methodologies to manage change, analyse issues encountered in clinical practice, as well as discuss implementation in the real world using learned models of analysis and planning.

To-date there have been two residential weekends (November 2006 and June 2007) and each team – comprising one nurse and one doctor from a paediatric oncology centre in each represented country - is now working

on respective developmental work in their own centres. They have been asked to plan and implement projects aimed at promoting the integration/collaboration of doctors and nurses drawing on the theory presented in the seminars.

The project has recruited 10 pairs with the following countries currently participating: Estonia, Switzerland, Greece, Belgium, Poland, Lithuania, Serbia, France, Germany, UK, and The Netherlands.

The project will end in November 2008. The results will be submitted to future SIOPE and ECCO Congresses.

Dr. Faith Gibson (UK)
Project Coordinator



SIOPE outreach and awareness building throughout Europe

SIOPE Europe responds to the EU Commission's public consultation on 'Rare Diseases: Europe's Challenge'*

The European Commission plans to publish a Communication on a European Action in the field of Rare Diseases in November 2008. According to the European Commission, the communication will be the result of a process starting with a public consultation aiming at gathering expertise across all EU Member States.

The consultation paper identifies all types of childhood cancer as Rare Diseases (RDs).

The SIOPE response to this EU public consultation was compiled by Professor Kathy Pritchard-Jones (UK) in consultation with Board and other SIOPE members.

Key points:

- There is a need to improve coding and classification in the RD area, particularly in cancers in the adolescents aged 15 years and upwards - who often have paediatric type cancers yet may be subject to adult type anatomical coding. There is also an urgent need to improve registration of cancers in adolescent age group. Some European countries still need assistance and resources to establish population-based childhood registries.
- A coordinated approach to facilitate data collection (such as web-based international registries) should be considered.
- Regarding the question of offering or improving specialised social and educational services for RD patients and their families, the views of childhood cancer parent's organisations should be considered at both national and European levels.
- SIOPE Europe supports the idea of establishing a new European Agency of RD and launching a feasibility study in 2009. Since research into rare diseases is lengthy, long term investment to allow research to conclude is required.

* For further information, please [CLICK HERE](#).

SIOPE Europe's comment on the draft guidance on the information concerning paediatric clinical trials to be entered into the EU database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMA), in accordance with Article 41 of Regulation no. (EC) 1901/2006*

The SIOPE response to this EU public consultation was compiled by Dr. Bruce Morland (UK) in consultation with Board and other SIOPE members.

Key points:

- In relation to timelines of the results-related information, internally a period of six months from the closure of the study to the time when result-related information needs to be provided is too short. In many phase III trials in paediatric oncology the main outcome measurables often relate to survival. Therefore it is necessary for the data to mature for a period of time (at least for one year and often from entry of the last patient) before the final outcomes are known.
- It would be helpful to understand why there is pressure to have results made public at such an early stage. If it is related to the fact that a lot of trials with negative outcomes are not published in peer-review journals, perhaps a solution would be to provide the published reference for the study. This would therefore allow the data to be analysed within an appropriate time scale. If there is no intention to publish the data, then a mandate to publish it on EudraCT database within a specified period should be implemented. Similarly, if no peer-review publication has been forthcoming (within two years) then an EudraCT update should be released.
- Suggestion of varying times for different studies. Since Phase I and some Phase II trials tend to have shorter endpoints, the data may be available within 6 months.

- Clinical academics that run the risk of having the data made public in the EudraCT can face refusal to publish the definitive paper. Since peer-review publications are considered the lifeblood of clinical academics, this would lead to a negative result of undermining the future of investigator-led non-commercial trials.

* To access the document, please **CLICK HERE**.

Combating Cancer in an Enlarged EU: result of the vote on the draft Cancer Resolution*

The draft Cancer Resolution was adopted by a large majority of MEPs (621 votes in favour; 10 against) during the last EP Plenary on the 10th April 2008.

Key points included in this Resolution*:

- Asking for a review of the EU Clinical Trials Directive.
- Call for an inter-institutional EU Cancer Task Force. Initiatives taken by the Task Force will have a strong emphasis on children and adolescents.
- Better information on screening and cancer treatment is required.
The Commission should increase the information available to patients with cancer by encouraging initiatives which inform patients of their treatment and the ways to access such treatment.
- Support for more research and innovation
Point 29 in the Resolution - more funding from FP7 to stimulate research on paediatric cancers.

* For further information, please **CLICK HERE**.

* For further information on these points, please **CLICK HERE**.

* To view the latest version of this resolution, **CLICK HERE**. New added item: point 33 regarding the revision of an EU directive on the protection of workers.

EUROCAN+PLUS: Final Report*

After 2 years' investigation and consultation, the EUROCAN+PLUS Project final report was published on 14 April 2008.

The objective of this project was to define the best ways to improve cancer research in Europe through better coordination and connectivity of stakeholders. The project was funded under the 6th Research Framework Programme and concluded in December 2007. The International Research Centre on Cancer (IARC) was the coordinating centre for this project.

Key points which SIOPE addressed as Member of EUROCAN+PLUS General Assembly representative of the paediatric oncology community included:

- Lack of resources: particularly the stable long term funding necessary to carry out clinically relevant biomarker studies within clinical trials that take years to complete;
- Lack of Clinical MD/PhD training programmes for young professionals;
- SIOPE agreed on the need for harmonisation of tissue storage techniques and improved biological studies with epidemiological data;
- SIOPE expressed its interest in building up a 'one stop shop' for contact and exchange between academia and industry;
- SIOPE also stressed the need that Paediatrics must be recognised for future initiatives or collaboration at the European level since it has specific needs that are not necessarily common in adult cancers.

* To obtain more information on this project, please **CLICK HERE**.

* Reporting on the project, please read the summary published by ecancermedicalscience. **CLICK HERE**.

* To access the report directly, **CLICK HERE**.

Meeting with the International Confederation of Childhood Cancer Parents Organisations (ICCCPO)

SIOPE Europe and the International Confederation of Childhood Cancer Parents Organisations (ICCCPO) enjoyed a successful joint meeting on 19 March 2008.

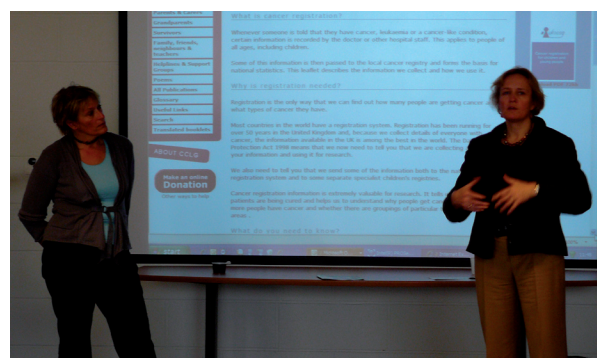
Together with the SIOPEurope President - Professor Kathy Pritchard-Jones and two SIOPE Europe staff – Samira and Jocelyne, 21 ICCCPPO delegates from 15 countries enthusiastically exchanged opinions on how to improve the communication between the patients (parents) groups and the paediatric oncology professionals; how to strengthen the joint input in relation to childhood cancer related policy at both national and European levels; and how to build on collaboration between ICCCPPO and SIOPE Europe over the term ahead.

This fruitful meeting not only enriched the communication between the umbrella associations (SIOPE Europe and ICCCPPO) but also concluded with a joint proposal to revise the document on the 'Recommendations for the organisation of a paediatric cancer unit.'

For further information on all these developments please contact the SIOPE Europe Office directly at: Jocelyne.wang@ecco-org.eu



SIOPE/ICCCPO meeting: 21 delegates from 18 countries



Prof Kathy Pritchard-Jones (SIOPE President) and Mrs. Marianne Naafs-Wilstra (Director of the Dutch Parents Association) during the meeting

Dates to Bookmark

1. **10th Joint ECCO / AACR / ASCO Workshop on 'Methods in Clinical Cancer Research'**, 21 - 27 June 2008 in Flims, Switzerland. For further information, please **CLICK HERE**.
2. **European Symposium on Ethics & Paediatric Clinical Research in Europe**, 19 - 20 June 2008 in Marseille, France. For further information, please **CLICK HERE**.
3. **The 40th Congress of International Society of Paediatric Oncology**, 2 - 6 October 2008 in Berlin, Germany. For further information, please **CLICK HERE**.
4. **The 11th International Paediatric Haematology and Oncology Update Meeting**, 23 - 24 October 2008 at the Royal College of Physicians of Edinburgh, Edinburgh, UK. For further information please **CLICK HERE**.
5. **ESO-SIOPE Masterclass for young paediatric oncologists**, 7 - 13 November 2008 in Ascona, Switzerland. For further information, please **CLICK HERE**.