

## News from the office

Dear Readers,

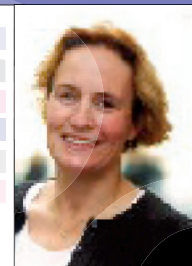
We hope you all had a relaxed summer vacation. We had a great summer with lots of sunshine and hot temperatures in Brussels which indeed brought the office team lots of energy and a bright atmosphere!

The third edition of **SIOPE** news introduces our newly elected SIOPE Board Members, announces the launch of the SIOPE website, updates on the latest activities of the SIOPE Clinical Trials Support Desk, features reports from the two SIOPE grant awardees who attended the 10th joint ECCO-AACR-ASCO Workshop on "Methods in Clinical Cancer Research", 21-27 June 2008, Flims, Switzerland as well as news surrounding SIOPE advocacy and networking activities.

We hope that this issue of **SIOPE** news fully informs our supporters, readers and community about the office activities and achievements since May 2008. Should you have any comments and suggestions please contact the SIOPE office at: **office@siope.eu**



## Message from the President



Prof. Kathy Pritchard-Jones  
SIOPE President

This newsletter sees the launch of the SIOPE website which will be our main channel for communicating with our membership and we hope will become a major resource for you all. First, as an information exchange portal where you can easily access information on developments in Europe that might affect childhood cancer research, education and training opportunities. You can even advertise jobs! A major initiative with the launch of the SIOPE website is the formation of the Clinical Trials Support Desk. This is being coordinated by Samira Essiaf and chaired by Professor Ruth Ladenstein who has already sent out a call for people to get involved in three main working group areas – we encourage you to become involved in this important piece of work.

The Education and Training Committee is becoming increasingly involved with e-learning opportunities made available through ECCO - the European CanCER Organisation. We have the opportunity to develop a project to produce up to ten training videos which can be hosted on their site. Please see inside for more details and send us your suggestions.

Many SIOPE members will be attending the SIOPE Congress in Berlin shortly. It is a very stimulating experience to host a SIOPE Congress and the next one to return to Europe is in 2012. SIOPE is expecting a new pre-selection process at the Continental level to be in place by then. We therefore urge all interested groups or host cities to let the SIOPE Office know at the earliest opportunity if they are interested in hosting the 2012 congress.

Finally, SIOPE is launching a new subscriber category which will allow all those health professionals working in childhood cancer in Europe to have individual access to the entire resources of the SIOPE website including a contacts database and information on clinical trials. We would also like to encourage the clinical trial groups to use the website as a portal for trial communication, with information available at varying levels of access according to pre-defined groups. Of course, this expanding activity requires resources and we look to our membership to help build a pan-European resource that will underpin our collaborative international efforts both by becoming SIOPE subscribers and putting themselves forward for positions of responsibility and activity.

So... welcome to the new look SIOPE! This is our resource to build together for the future. We hope you find it useful and look forward to your suggestions for improvements.

# SIOP Europe's Community

## SIOPE Board Election 2008

Thank you to those of you who kindly participated in the SIOPE Board election 2008. This year witnessed the highest number of votes ever cast.

We are glad to inform you that Professor Gilles Vassal (FR) and Professor David Walker (UK) have been elected to take up new positions on the Board with effect from October 2008.



Professor Gilles Vassal

### ■ Professor Gilles Vassal

(MD, PhD), Paediatrician  
– Oncologist – Pharmacologist,  
Professor of Oncology.

**Current position:** Head of Clinical and Translational Research Division, Institut Gustave Roussy, Villejuif, France.



Professor David Walker

### ■ Professor David Walker

General Paediatrics and Professor of Paediatric Oncology.

#### **Current position:**

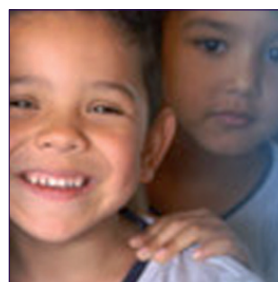
Professor (Honorary Consultant) of Paediatric Oncology, Division of Child Health, School of Human Development, Faculty of Health Sciences, University of Nottingham, Nottingham, UK.

## SIOPE Database Update

We would also like to thank those of you who kindly took the time to complete our database survey at the beginning of the summer. We received an overwhelming number of replies and have updated our database accordingly.

With the launch of the SIOPE website, individuals subscribing to our network can easily update their personal data by downloading and completing the respective form online and returning it to the SIOPE office via email, fax or post. For further information, please visit the SIOPE website at: [www.siope.eu](http://www.siope.eu)

The screenshot shows the SIOPE website interface. At the top, there is a navigation menu with links for Home, Organisation, Members, Clinical Trials, Drugs & Tox, Education, and SIOPE - EU. Below the menu, the 'Members' section is active, displaying a list of links: 'What We Offer', 'Become a Member / Subscriber Subscription (for subscribers only)', 'Update Your Profile', 'Member Database', and 'Jobs'. To the right, there is a section titled 'Update Your Profile' with instructions: 'To update your coordinates within the SIOPE database, please complete the form and send it back to the SIOPE office via email at: [office@at.siope.eu](mailto:office@at.siope.eu) (please use 'coordinates update' or via fax at: +32 2 775 02 01.' Below this, there is a link for 'Information update form'. At the bottom of the screenshot, a green banner contains the text: 'select 'Member' > 'Become a Member' > 'Update your Profile''.



## Introducing the New SIOPE Website

In our last newsletter in May 2008, we informed you about this exciting development and are pleased to announce that after several months of careful construction, essential input and guidance from our SIOPE experts, the SIOPE website is now live and ready to receive visitors! The SIOPE website has been especially structured to provide easy access to a wide range of news, information and services. Key features on the SIOPE website include:

### Public Domain

- General information on the SIOPE Office and its activities.
- Latest news on paediatric oncology, events and training courses.
- Recommended web links and other information sources.

### Subscriber - 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 reporting on current trials throughout Europe.
- The latest information on SIOPE's advocacy at the European level.

Initially, the SIOPE website will publish most of its information within the Public Domain. After a trial period of a few months, certain sections will then be password-protected and can only be accessed by subscribers who will be duly issued with their personal login/password details.

For further information about the SIOPE website, please contact the SIOPE office at:

**[jocelyne.wang@ecco-org.eu](mailto:jocelyne.wang@ecco-org.eu)**

# Reminder:

## the SIOPE General Assembly and Clinical Trials Meetings in Berlin.

Over the past few months the SIOPE office has been enthusiastically developing and implementing new initiatives to serve the European paediatric oncology community. The office has been up and running for a year now and the team would like to mark the occasion by kindly inviting you to attend SIOPE's **Annual General Assembly and Clinical Trials and National Childhood Cancer Groups Meeting** which will be held during the 11th SIOP Congress, 2-6 October 2008, Berlin, Germany as follows:

### ■ SIOPE General Assembly, (All Members)

12h30 – 14h, 4 October, 2008  
Room Estrel, Hall C

### ■ SIOPE Clinical Trials & National Groups Meeting, (Representatives only)

13h – 16h, 3 October, 2008  
Room Estrel, Hall A

The respective meeting agendas and support documentation will be circulated during the last week of September. For further information, please contact the SIOPE office at: **[office@siope.eu](mailto:office@siope.eu)**

# Committee Reports and Roundups

## **SIOPE Clinical Trials Support Desk chaired by Professor Ruth Ladenstein (AT)**

With the scientific support from experts of the European Clinical Trials Groups as well as input from the National Childhood Cancer Organisations and Parents Groups, the main goal of the SIOPE Clinical Trials (CT) Support Desk is to provide support and facilitate paediatric clinical trials in Europe for scientists, patients and parents.

Led by Professor Ruth Ladenstein (AT), and coordinated by Ms. Samira Essiaf, the latest activity of the SIOPE Clinical Support Desk has involved launching a Call for Experts for its Clinical Trials Working Groups. The preliminary structure of SIOPE CT Working Groups has been set up as follows:

### **Protocol Guidelines Working Group**

#### **AIM & TASKS**

- Standardisation of protocol templates for Phase II and III trials
- Creation of standard templates for data collection and CRF design including the following:
  - I. Defining the minimum and maximum required data.
  - II. Advising on toxicity data collection and definitions of reasonable exclusions from SAE reporting.
  - III. Creating the end of treatment summary forms.
  - IV. Standardising procedures for long term follow up beyond the trial.



## **Regulation Working Group**

#### **AIM & TASKS**

- Balance of clinical trials versus best practice guidelines
- Pan-European clinical trial sponsorship
- Pharmacovigilance and safety
- I. Monitoring and audit requirements in clinical academic trials.
- II. Pan-European harmonisation and implementation of expedited reporting of SAEs and SUSARS.

### **Role of Data Monitoring Committees**

- Pan-European harmonisation of sponsor duties in academic trials
- Declaration of IMPs
- Creation of CTA (Clinical Trials Application process)
- Risk based requirements for insurance in clinical trials
- Central European registration and information on clinical trials open to public
- Recommendation to standardise documents such as the structure of trial master files (TMF)

## **Ethics Working Group**

#### **AIM & TASKS**

- Review and provide information on key ethical differences for paediatrics across Europe
- I. Age of competency.
- II. Need for parental consent.
- III. Attitude to phase I trials.
- IV. Educational programmes.
- V. Ethical review standards and procedures for EU member states.

For further information about the SIOPE Clinical Trials Support Desk and its working groups, please contact the SIOPE Office at : [samira.essiaf@ecco-org.eu](mailto:samira.essiaf@ecco-org.eu)

## SIOPE's First Publication

We are pleased to inform you that SIOPE's first publication: "Clinical trials for Children with cancer in Europe - still a long way from harmonisation: a report from SIOPE", authored by Professor Kathy Pritchard-Jones, has been published in the European Journal of Cancer (EJC) on 29 August 2008 (Epub ahead of print).

This report summarises difficulties which clinical trials for children with cancer have encountered under the current EU Clinical Trials Directive implemented in 2004. Coming from a non commercial background with rare commercial sponsorship, these trials struggle to obtain the financial resources necessary to fulfil the complex bureaucratic requirements under the current CTC scheme.

The paper also summarises issues raised during conferences and debates regarding the revision of the current Clinical Trials Directive in order to relieve the burden weighing heavy on non-commercial trials - for childhood cancer in particular.

For further information please visit the SIOPE website at: [www.siope.eu](http://www.siope.eu) (select 'Publication' > 'Other SIOPE Publication' > 'Clinical Trials for Children with Cancer in Europe.')

## SIOPE Education and Training Committee

chaired by Professor Riccardo Riccardi (IT)

**Reports from the two SIOPE grant awardees who attended the 10th joint ECCO-AACR-ASCO Workshop on "Methods in Clinical Cancer Research", 21-27 June 2008, Flims, Switzerland**



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

**Project title: A randomised phase II trial of TVD +/- bevacizumab for refractory metastatic neuroblastoma**

Attending the 10th joint ECCO-AACR-ASCO Workshop on "Methods on Clinical Cancer Research" in Flims, Switzerland last June was an amazing experience. The first impacting realisation was to learn that the number of young researchers in the cancer field has been decreasing over the past 10-15 years. Importantly, the leitmotiv of the workshop is to involve junior oncologists in cancer research and the development of clinical trials.

In an unparalleled setting - late spring, high up in the Swiss mountains, isolated from outside noise, disturbances, and the fast pace of life, 80 trainees led by almost 40 faculty members worked together to each develop a specific clinical trial and explore the challenges that lie ahead, to be faced in the future.

For the first time, a group of 8 young paediatric oncologists was formed. Our projects ranged from a small phase I of an anti-leukemic drug to a wide multinational protocol for brain tumours. Our faculty members G. Blackledge, R. Riccardi and S. George were devoted to us, and vice versa. They went to great lengths to underline all issues regarding paediatric research and clinical trials in children to maximise our training.

Our learning involved much more than statistics and sample size calculation. We were taught how to obtain funding, involve the industry, to deal with regulatory authorities, publish our results and finally, that clinical trials development is a challenge requiring immense enthusiasm and effort.

We experienced long nights in front of computers, were against the clock to finish our templates on time, but importantly, made friends and had fun as well. I have to thank George, Ricardo and Stephen once again for all their expertise, support and advice as well as Victoria Castel for her mentorship.

Lastly, but by no means least, I have to thank ECCO, AACR and ASCO, as well as SIOPE for this unforgettable experience.



**Dr. Shaun Wilson (UK)**  
Birmingham Children's Hospital  
Department of Paediatric  
Oncology

**Project title: A phase I study of PXD101 in childhood acute leukaemias**

The "Methods in Clinical Cancer Research" in Flims this year was a landmark for at least two reasons. First, it was the 10th anniversary of this annual meeting and secondly, it was the first time in at least five years that I spent more than 45 minutes in a lecture hall. Right from the beginning the course was superb. The venue tucked away in the Swiss Alps was breathtaking and the organisation was excellent. With such a large number of participants it was immensely impressive how smoothly everything ran.

The sheer breadth of the topics covered was fantastic. Lectures included a wide range of subjects from the design of trials, understanding of pharmacokinetics to the legal importance of regulatory issues in establishing and conducting clinical trials.

The course was well structured, with a good balance between didactic lectures and small group

discussion groups. These discussions were led by experts in the field and were very useful as the smaller numbers of students allowed for closer interaction on and around more focussed issues.

The protocol development groups were intensive planning sessions where the proposed clinical trials were critically assessed and the author helped to understand all the required aspects of their trial.

It is extremely rare to have such a wealth of eminent professionals under the same roof for such a protracted period of time. Being able to easily access such luminaries to ask about small details in one's protocol was quite an overwhelming opportunity. The staff were helpful, knowledgeable but most of approachable and fun to work with.

I think the greatest benefit had to be arriving in Flims with a kernel of an idea and then - with expert guidance - watch it come to fruition. I could not believe the hard work required and did not previously appreciate how much detail is required in the initial conception of a protocol.

This intensive educational experience has certainly crystallised my desire to pursue further research in the field of early phase trials.



Group photo, taken during the third project seminar,  
13-15 June 2008, Prague (CZ)



## Reports on the SIOP Europe/EONS/ECCO Special Project 'Collaboration between Nurses and Doctors in Paediatric Oncology'

This three year project involving centres in Eastern and Western Europe is now drawing to a close with many of the individual projects completed and several countries presenting their collaborative work during the 40th Congress of the International Society of Paediatric Oncology (SIOP), 2-6 October 2008, as part of the nursing programme.

In all, eleven teams completed the programme despite local challenges such as changing personnel, heavy clinical workloads, language difficulties and a lack of enthusiasm in some working environments.

Selected projects fell under several categories including communication with families and children, education and service improvement.

At the final workshop, held in Prague in June 2008, the participants shared their work and the lessons learnt. While collaborative working was new to some, all - doctors and nurses alike - were very positive about the experience both personally and to the benefit of their respective centres. Some had completed their local programmes, while others still had some way to go. As a result, an additional application to continue the project for one more year to allow for completion and ensure that the changes are embedded in practice, has been submitted.

**Dr. Faith Gibson, Project Leader (UK)**

## Information needs on standards in paediatric oncology

We would like to remind you that the SIOPE office has launched a call to collect information required for "standards in paediatric oncology". Led by Professor Jerzy Koawalczyk (CZ), the purpose of the survey is to identify any regulations existing in different European countries related to standards for paediatric oncology/haematology wards. The collected data from European countries will enable SIOPE to eventually propose the basic requirements for Centres specialising in the treatment of children with cancer in EU.

Please note that the deadline to submit this survey has been postponed to **15 October 2008**. The report of this survey will be prepared by Professor Koawalczyk and published on the SIOPE website and in the next edition of **SIOPE** news. For further information about this survey, please visit the SIOPE website at: **www.siope.eu**

(select 'Education' > 'Standards in Paediatric Oncology')

# SIOPE outreach and awareness building throughout Europe

## **Final comments by SIOPE and ITCC on revised off-patent medicines priority list, replying to EMEA consultation**

SIOPE and the Innovative Therapies for Children with Cancer Consortium (ITCC) jointly commented on the EMEA revised list in July 2008.

According to Professor Gilles Vassal (ITCC), *'... the list of compounds to be studied in infants through appropriate PK/PD/PG programmes has been extended to better cover the needs in both solid tumours and leukemia'*.

Moreover, *'... among the three transversal programs, we think that pharmacology in infants is the most relevant one for a US-EU funded project. There is a strong rationale to join forces considering the rarity of the population concerned. In addition, collaboration between EU and US is ongoing for several diseases in infants that may facilitate the implementation of a pharmacology program'*.

For further information about the joint SIOPE/ITCC response to this consultation, please visit the SIOPE website at: [www.siope.eu](http://www.siope.eu) (select 'SIOPE-EU' > 'Advocacy Activities' > 'Revised off-patent PD medicines priority list').

## **Joint SIOPE / ICCCPPO response to the EMEA consultation on the EMEA HCP WG Recommendations and Proposals for Action**

SIOPE and the International Confederation of Childhood Cancer Parents Organisation (ICCCPO) jointly commented on this EMEA consultation in July 2008.

SIOPE has supported all of the proposals made here and makes some suggestions about the annexes to ensure that any databases containing information on Health care professionals' organisations and their expertise is made publicly available to facilitate information exchange.

■ For further information about the joint SIOPE/ITCC response to this consultation, please visit the SIOPE website at: [www.siope.eu](http://www.siope.eu) (select 'SIOPE-EU' > > 'Advocacy Activities' > 'EMEA HCP WG Recommendations').

## **Introducing the ERA-NET PRIOMEDCHILD project**

As of spring 2008, SIOPE has been collaborating with the UK team of the ERA-NET PRIOMEDCHILD project by disseminating information and surveys.

The project involves a partnership between research funding organisations across Europe aiming at bringing coherence and cooperation to national research programmes and policies by setting up a pan-European research agenda/approach in relation to priority medicines for children. The aim of the UK work package for this project is to establish a common European research agenda for medicines for children by identifying key research priorities.

SIOPE has distributed surveys throughout the community. The first survey was to identify key areas for research through a review of current literature. The second Delphi survey was with major stakeholders and research topics summarised from the first survey to achieve consensus.

■ For further information please visit the PRIOMEDCHILD website at: [www.priomedchild.eu](http://www.priomedchild.eu)

■ To access Information and surveys distributed by the UK work package please visit the Medicines for Children Research Network (MCRN) website at: [www.mcrn.org.uk](http://www.mcrn.org.uk) (select the green bar for the project link)



## **SIOPE joins the network of the European Organisation for Rare Diseases (EURORDIS)**

We are delighted to inform you that in June 2008 SIOPE became an Associate Member of the European Organisation for Rare Diseases (EURORDIS). As childhood cancer is identified as rare disease in the current EMEA consultation on rare disease, SIOPE shares the same commitment with EURORDIS to empower patient groups and advocates for rare-diseases as well as promote scientific and clinical trials research in the field of rare diseases.

We look forward to further collaboration with EURORDIS at the European level, and in particular, to offering input regarding issues related

to childhood cancer as well as campaigning in relevant advocacy activities.

- For further information about EURORDIS, please visit the EURORDIS website at: **[www.eurordis.org](http://www.eurordis.org)**
- For further information regarding SIOPE's response to the EMEA consultation on rare disease, please visit the SIOPE website at: **[www.siope.eu](http://www.siope.eu)** (select 'SIOPE-EU' > 'Advocacy Activities' > 'Rare Diseases').

## **Dates to bookmark**

### ■ **The 40th Congress of the International Society of Paediatric Oncology (SIOP)**

2 - 6 October 2008 in Berlin, Germany. For further information, please [CLICK HERE](#).

### ■ **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](#).

### ■ **ESO-SIOPE Masterclass for young paediatric oncologists**

7 - 13 November 2008 in Ascona, Switzerland. For further information, please [CLICK HERE](#).

### ■ **The 5th ASPO Masterclass on Paediatric Oncology**

19 - 23 January 2009 in Noordwijk aan Zee, The Netherlands. For further information, please [CLICK HERE](#).

### ■ **The 3rd International Symposium on Childhood, Adolescent and Young Adult Non-Hodgkin's Lymphoma**

11-13 June 2009 in Frankfurt, Germany. For further information, please [CLICK HERE](#).

### ■ **The joint 15th Congress of the European Cancer Organisation and 34th Congress of the European Society for Medical Oncology**

20-24 September 2009 in Berlin, Germany. For further information, please [CLICK HERE](#).