

UPDATE from the office

We hope you have had a great start to the New Year! Firstly, thank you for your warm support at SIOPE Boston and we were happy in particular to hear of the interest in the SIOPE/ EONS/ ECCO Special Project, which was presented by Project Coordinator Prof. Faith Gibson and Belgian team member, nurse Jaklien Bistoën. Information on the project, 'Collaboration between nurses and doctors in paediatric oncology: a multi-site action research laboratory' and numerous resources and articles that would be of interest to all disciplines are available online – [CLICK HERE TO VIEW](#).

After a busy November and December finalising the necessary preparations with the European Commission for ENCCA – the European Network for Cancer research in Children and Adolescents, we experienced an even busier January and February, with the ENCCA and PancareSurfUp kick-off meetings, the International Childhood Cancer Day in the European Parliament and the launch of the European Clinical Research Council (ECRC) which essentially takes the place of the SIOPE Clinical Trials Committee and encompass all the clinical trial groups in Europe as well as the heads of the national groups. This important initiative is discussed in further detail in the newsletter. To find out more information on ENCCA, you can also view Gilles Vassal's interview with eminent journalist Peter Goodwin at the ECCO Oncology Forum in Brussels in October – just [CLICK HERE](#).

Another important day in February is Rare Disease Day (28 February). This year Rare Disease Day focuses on inequalities, which ties in nicely with our European Standards of Care for Children with Cancer project with the Polish Ministry of Health and the Communication without Barriers Foundation. As a member of the Council of European Rare Disease Federations, we warmly support Rare Disease Day; for further information on the many events taking place, please [CLICK HERE](#).

Finally, the Eurocancercoms project produced the results of its project based on paediatrics. This exciting project gathered information from the key experts in each European country to gauge the common challenges facing those working with children and adolescents with cancer and a wealth of information has been collated and will be disseminated within the cancer community as well as toward EU decision-makers. A synopsis of the results are available here.

Please do not hesitate to contact us should you have any questions on your activities,

The SIOPE office

P.S. Congratulations to Jimmyteens.tv who won 'Best Charitable Initiative in Oncology' in the 2010 Excellence in Oncology Awards!

Message from the President

I was happy to meet many of you during the highly-successful SIOPE Boston meeting.

Our General Assembly, held during the conference, aimed to give an overview of the many activities SIOPE is engaged in and we would be happy to hear from you should you have any queries on these initiatives. Activities of SIOPE are gaining increasing visibility and this was also recognised at the Boston meeting. Gilles Vassal from Institut Gustave Roussy was confirmed as SIOPE's President-Elect so congratulations to him, he has been very active in promoting SIOPE since he joined the Board. Just for your information, the General Assembly will be back in Europe in 2011, taking place during the European Multidisciplinary Cancer Congress in Stockholm, Sweden (23-27 September); we have worked on an exciting paediatric track oncology programme and are embedded in a vibrant and growing field of oncoscience: for more information on this meeting, [click here](#). SIOPE as a Founding Member of ECCO is proud of these developments and achievements that also support our community to grow further and we hope that this congress will become a high-profile scientific meeting for paediatric oncology in Europe and a turning point to communicate our common future activities in advancing research, clinical trial platforms and liaising with policymakers on important European tasks.

As Project Coordinator of ENCCA I am very happy to announce a successful lunch of this pivotal FP7 EU-funded project that will help us to make the future for paediatric haemato-oncology better. The ENCCA (European Network for Cancer research in Children and Adolescents) Kick-off meeting took place on 13-14 January in Brussels. This major project for the paediatric oncology community spans the paediatric oncology spectrum, from basic and translational research areas to drug development aspects integrating data from clinical trials, fostering clinical trials platforms, improved registry data, long term follow up and survivorship needs. Strong connections with ICCPO are built as well as strong links with the PanCare SurfUp Project which just had its Kick-off meeting also. Congratulations to Lars Hjorth and his team for what I've been informed was a very successful meeting indeed!

Further tasks include improved and continued education, the TYA issue and many more. As you may know, SIOPE is leading on dissemination for ENCCA so we will be regularly updating you on the latest developments in the project and of course should you have any queries, please do not hesitate to contact SIOPE's office in Brussels by emailing office@siope.eu (please replace<at> with @).

Another project we are very proud of is the Eurocancercoms project, an FP7-funded initiative addressing communication in the SIOPE



2011



community. The paediatrics report, which is the first major deliverable of the project has just been published in the online journal, [ecancermedicalscience](#). [Click here to view](#).

The event in the European Parliament on 09 February to mark International Childhood Cancer Day was a roaring success! A packed room full of high-profile stakeholders from the EU Cancer Policy arena, topics included the European Commission's revision of the EU Clinical Trials Directive, the EU Paediatric Regulation and SIOPE's European Standards of Care for Children with Cancer project as part of the European Partnership for Action against Cancer. To view speaker presentations, [CLICK HERE](#).

The following day the foundation of the European Clinical Research Council took place in Brussels aiming to create a common forum for the European clinical trial groups and their needs. This exciting venture featured some lively discussion on the future of paediatric haemato-oncology and will work closely with ENCCA on the needs for our community in Europe.

Finally, thank you for your warm support of SIOPE in 2010 and our ambitions to promote optimal standards of care for children and young people with cancer in Europe. We are looking forward to a year full of new endeavours and to fully engage in the upcoming task on behalf of our patients.

Ruth

SIOPE Europe's Community ENCCA Kick-off meeting



On 13-14 January 2011, over 70 participants came together in Brussels, Belgium, for the first meeting of [ENCCA – the European Network for Cancer research in Children and Adolescents](#). An EU FP7-funded project coordinated by SIOPE President, Assoc. Prof. Ruth Ladenstein of CCRI – the Children's Cancer Research Institute in Vienna, the main objective of this project is to restructure knowledge-sharing through the integration of the whole chain of stakeholders and to support the acceleration of the development of innovative therapeutic strategies for children and adolescents with cancer.

Discussions at the meeting included an introduction to the project, history of the proposal and review of the project objectives, including the organisational structure, in particular a presentation of the three activity areas – the Spread of Excellence Activities coordinated by the Vice-Chair Prof. Gilles Vassal, Integrating Activities by Prof. Kathy Pritchard-Jones and Joint Research Activities by Prof. Martin Schrappe. Naturally the European Commission contractual rules and regulations were outlined; Dr. Jan van de Loo from the DG Research and Nuno Andrade from CCRI presented these all-important technical details required for the ENCCA project.

The breakout sessions which took place on the second day of the kick-off meeting were highly important as

it allowed for a true exchange of ideas and debate on the project deliverables themselves. As this is a large, multi-faced project, it was decided to group key work packages together as many of the issues and objectives of ENCCA are cross-cutting.

The meeting was well-received by all participants and the management team were very positive about the next steps for the project, particularly as many of the work package leaders had already a detailed plan of how the deliverables would be met with a clear set of deadlines and objectives. Long-term planning for the sustainability of the network is already being considered and it will be in the interest of all partners to work together on methods for sustaining this dynamic initiative.





Despite being 'cured' from cancer, the several late effects both physically and psychologically as a result of rigorous treatment can affect the quality-of-life of a survivor for the rest of their lives. Research on this issue is expected to be accelerated through an EU-funded FP7 project, [PanCareSurfUp – Pancare childhood and adolescent cancer survivor care and follow-up studies and the kick-off meeting was held in Lund, Sweden](#)

Childhood cancer survivors, though being 'cured' of cancer, often experience late physical and psychological effects secondary to their cancer or its treatment. To accelerate the search for new successful treatments and improve the quality of life after cancer, 16 research institutes from 11 European countries have decided to join forces and launch a groundbreaking study funded by the EU.

Coordinating the PANCARESURFUP project is paediatric oncologist Lars Hjorth from Lund University in Sweden. Epidemiologist Julie Byrne with the Boyne Research Institute in Ireland is also involved in the project, along with 34 other specialists.

Building on the recent advances of paediatric cancer research, this five-year project is committed to ensuring that more adolescents and young adults gain access to clinical trials. So far, this age group has been highly under-represented in cancer trials, mainly because adolescents and young adults are not usually referred to paediatric cancer centres for treatment. And yet, these are precisely

the institutions that offer the most appropriate trials for adolescent cancers which are different to the types of cancer common in adults.

Furthermore, experts predict that almost 20,000 young people aged up to 19 years will be diagnosed with cancer this year. Early diagnosis and new revolutionary treatment approaches increases the cure rate. The good news is that currently 80% of children and adolescents are expected to survive.

However, many of these survivors may face significant long-term risks to their health and well-being. The most serious health risks are late recurrence of the disease, as well as second cancers, cardiovascular diseases, endocrinological and neuropsychological abnormalities.

Although late effects of cancer treatment are not unique to survivors of childhood cancer, since the cancer treatment is received during periods of growth and development, they are usually more severe than those experienced by adult cancer survivors. Knowledge of health risks can result in changes in therapy to obviate untoward effects.

Call for signatures for an Open Letter to delegates attending the September 2011 UN Summit on Non-Communicable Diseases (NCDs)

[Sign here now!](#)

IBTA The UN Summit on Non-Communicable Diseases (NCDs) in September 2011 will be an important meeting and has the potential to compare in significance to the 2001 high level UN Summit on HIV/AIDS, which marked a crucial turning point in the treatment of that disease.

There is an emerging tension in 2010-2011 between those who believe that such a meeting should concentrate on prevention, and those who believe that support and research into a cure for NCDs are also crucial. This is particularly so in regard to cancer, which is a major NCD affecting people in all areas of the world.

A number of the signatories to this open letter are involved with the support of patients who have a so-called rare cancer, or a less common, or intransigent, cancer. Very often the causes of these cancers are unknown, hence prevention is impossible. Therefore, for rare and less common cancers, the focus should be on increased research and support. IBTA International Brain Tumour Alliance believe that it should be a major aim of the cancer input to the UN Summit on NCDs to ensure that the voices of those with

unpreventable cancers are not ignored. This is particularly so with regard to all paediatric cancers which, because of low incidence rates, are by definition categorised as rare. However, rarity does not reduce the devastating impact such a diagnosis has on both the individuals concerned and on the wider society in general.

The President of the United States said in September 2010: "...Cancer is still the leading cause of death by disease for young Americans between infancy and age 15." He added: "Tragically, the causes of cancer in children are largely unknown" and indicated his support for a greater research effort. While recognizing that for a few cancers prevention strategies are very relevant and admirable, we call on those associated with the 2011 UN Summit to ensure that – for people with rare and less common cancers – a greater effort is made for enhancing support and significantly increasing research.

SIOPE endorses such an initiative and warmly thanks the International Brain Tumour Alliance for this important initiative. To sign the Open Letter, [CLICK HERE](#).

International Childhood Cancer Awareness Day

Creating a brighter future for young people with cancer



Members of the European Parliament remember Children with Cancer

For the first time, the European Parliament marked this important event at a high-level multistakeholder meeting hosted on Wednesday, 09 February, by Member of the European Parliament (MEP), Mr. Alojz Peterle in association with SIOPE Europe – the European Society for Paediatric Oncology (SIOPE). Young patients from Belgium and their families joined MEPs, experts in paediatric oncology and other cancer policy stakeholders to discuss how the rapid rate of progress previously established in childhood cancer is being forcibly arrested by the implementation of recent EU legislation.

“Your child has cancer”

This phrase is spoken many thousands of times in all European languages each year across European health systems. It is a parent’s nightmare as, most commonly their previously healthy and thriving child now faces the real prospect of distressing and rigorous treatment. Mother and daughter, Sandy and Olivia Ferrary, from London, UK, shared their story at the event. Olivia, at 11, was diagnosed with an extremely rare form of kidney cancer. Her assigned specialist was able to find unique life-saving medicines identified by recent research. The treatment worked and after extensive and successful surgery she is now back to health and school.

Her mother Sandy spoke of her hope that other families can have similar positive experiences: “It was our pleasure to have been asked to represent all the children and their families who will continue to face and deal with situations that are out of their control, and which don’t always end well”.

With the rapidly changing landscape for cancer patient treatment, there are new opportunities to design less toxic, more effective therapeutic approaches to save a child’s life. However, numerous challenges are facing young cancer patients in Europe, and their carers.

‘Regulatory Fundamentalism’

The Clinical Trials Directive has had a disproportionately negative effect on the initiation and conduct of trials for children, particularly due to the varying national interpretation of the Directive.

This challenge, according to speakers at the meeting last Wednesday, 09 February, will cost lives through missed opportunities. Indeed the significant progress made in paediatric oncology, resulting in approx. 80% cure rate, is under threat.

The ‘regulatory fundamentalism’ of this EU Directive, according to Prof. Stefan Bielack of Olga Hospital in Stuttgart, Germany, severely constrains the research-based approaches that have been developed and prevent newer Member States to offer new treatments. Referring to the newly published report, *The State of Research into Children with Cancer across Europe – New Policies for a New Decade*, Prof. Richard Sullivan from the Centre for Global OncoPolicy, London, UK, emphasised the need for the immediate reduction of the bureaucratic barriers that negatively impact on the conduct of investigator-led clinical trials. “This report points out that this Directive, whilst proposing a high standard of research conduct, has generated very significant blocks to trial development, particularly in smaller countries, making it almost impossible for them to participate. Indeed in Poland, not a single children’s clinical trial has opened since 2007!”

Some attempts have been made at EU level to speed up the licensing of new drugs suitable for children's diseases. The opportunity for the paediatric licencing of drugs, through the creation of the Paediatric Regulation can truly enhance the safety of medicines for children. However, according to Prof. Gilles Vassal, Head of Translational Research at Institut Gustave Roussy in Paris, France, "The new Regulation has not had the impact upon the pace of licensing we had hoped for. The pharmaceutical industry does not perceive the childhood cancer drug market as commercially attractive because of the rarity of our young people with cancer." He appealed to MEPs to take the special needs of young people into account and push for strategies to encourage the licensing of new drugs for seriously ill children.

Addressing Inequalities in Treatment and Care

Host of the event, MEP Alojz Peterle, noted how "Europe is still characterised by unacceptable inequalities in cancer control". The European Standards of Care for Children with Cancer project, to be rolled out through the European Partnership for Action against Cancer initiative (4), an partnership initiative between professionals and parents, was promoted as a way of

improving standards and will be highlighted by Poland when it holds the EU Presidency in the latter half of 2011. "Through partnerships between professional and family groups, these combined efforts are already improving the support and treatment that children suffering from cancer receive", says Benson Pau, chairperson of ICCPO – the International Confederation of Childhood Cancer Parent Organisations.

A network for change

SIOPE President, Assoc. Prof. Ruth Ladenstein from the St. Anna Children's Research Institute in Vienna, Austria, leads a new EU FP7-funded project, ENCCA – the European Network for Cancer research in Children and Adolescents that aims to address some of these issues. This ambitious project, involving 33 leading European institutions and organisations plans to re-structure knowledge-sharing within the paediatric oncology community and support the development of innovative therapeutic strategies for these rare cancers.

For further information on this event, contact the SIOPE office directly.

Launch of the European Clinical Research Council

10 February 2011

Taking place at the EORTC (European Organisation for Research and Treatment of Cancer) in Brussels, Belgium on the day after the International Childhood Cancer Day event in the European Parliament, SIOPE, as part of the ENCCA FP7 project, invited the heads of the European clinical trial and national paediatric oncology groups to the launch of the European Clinical Research Council (ECRC).

The European Clinical Research Council for Paediatric Oncology is based upon the SIOPE Clinical Trials Committee. Issues discussed at the Council included ENCCA of course as well as the various committees that are expected to be created, such as for example the Ethics Advisory Committee, the Parent/ Patient Advocacy Committee and the Scientific Advisory Committee to ensure the ENCCA has a truly global and comprehensive perspective.

Other topics associated with clinical trial facilitation included a presentation from Martina Gantschacher of

the Vienna office of the European Society for Quality in Healthcare (ESQH) on harmonised approved contracts for investigator-driven clinical trials. There was also an interesting presentation from Magdalena Góralczyk and Griet Verhenneman who both work on the FP7 project, CONTRACT – Consent in a Trial and Care Environment. This project aims to focus on the impact of EU legislation on health research in relation to informed consent. A survey will be carried out to identify the existing clinical, technical, legal and ethical practices and concerns with the handling of consent, especially for vulnerable patients involved in European projects. To find out more about this survey you may email Magdalena (goralczyk@iri.uni-hannover.de) or Griet (griet.verhenneman@law.kuleuven.be) directly.

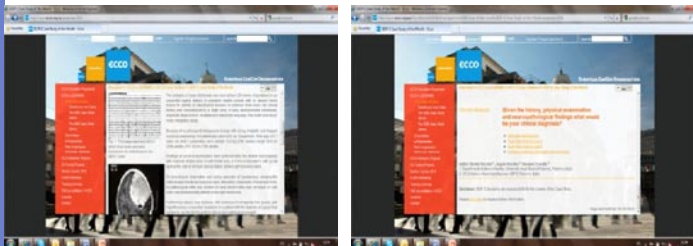
To find out more about the ECRC, kindly contact Samira Essiaf in the SIOPE office

SIOPE Community Reports and Roundups

SIOPE Education and Training Committee



Prof. Dragana Janic,
SIOPE ETC Chair



As Chair of the Education & Training Committee it is a great pleasure for me to present the “Case Study of the Month”, an easy accessible online project that will be hosted on the ECCO (European CanCer Organization) website with links to the SIOPE and (future) ENCCA website. Via a monthly email blast we will be informing you about each new “Case study of the Month” in order to reach out to many of you.

Each case that is received will be first reviewed by a team of experts and once this has been approved then the case will be presented indicating the target audience followed by a case discussion under the formula of questions that should be answered. By answering the case the participant is able to gain CME points.

The first case that was presented during our meeting in Boston in October last year related to the ‘Unusual awakenings in a preverbal three-year old child’. This case study is tailored towards cancer epidemiology cancer prevention and paediatric oncology.

The viewing of the case occurs via the following question where the correct answer should be given:

Given the history, physical examination and neuro-pathological findings what would be your clinical diagnosis?

- Sporadic meningioma
- Neurofibromatosis type1
- Neurofibromatosis type 2
- Familial syndrome of multiple meningiomas

With this E-learning project we are for sure increasing the visibility of SIOPE and reaching out to the Paediatric Oncology community and many other disciplines in oncology through the ECCO website. We also would like to point out that thanks to this project we will also easily have access to the adults “Case Studies of the Months” which are also hosted on the same ECCO website.

We look forward to presenting you our first “Case Study of the Month” soon and we also would like to take the opportunity to launch a call for cases that could be used as “Case Study of the Month”. For more information kindly contact Samira Essiaf at the SIOPE office.



SIOPE Annual General Assembly

Report from the 2010 General Assembly By SIOPE’s Secretary General, Samira Essiaf

It was a pleasure seeing so many dedicated SIOPE members attending the SIOPE General Assembly at the annual SIOP meeting in Boston last October. As reported and explained during the presentations given by several SIOPE Board members, we are very pleased to see how much SIOPE has been growing and establishing itself at the EU political level.

Some key highlights from the meeting include:

- ◆ The announcement of the final signature for approval of the ENCCA project and the scheduled kick-off meeting at the beginning of January is a reward of many intensive months of hard work by the entire ENCCA team.
- ◆ The involvement of SIOPE as a partner in several EU-funded projects such as Eurocancercoms, Oncovideos project, the PanCareSurFup project as well the European Standards of Care in the European Partnership for Action against Cancer

- ◆ The presentation of the “Case Study of the Month”, an online project that will be run under the supervision of SIOPE’s Educational & Training Committee. With this project we aim to reach out to many of you and make education accessible for all oncologists.
- ◆ The extensive Paediatric Track of 2.5 days within the 16th ECCO-36th ESMO congress. We kindly would like to remind you that the name of this European congress has changed and is now known as the [European Multidisciplinary Cancer Congress, Stockholm \(23-27 September 2011\)](#)
- ◆ The dedication of our SIOPE office, especially Edel Fitzgerald who has done a great job and has put a lot of efforts into the SIOPE Public Affairs/ political lobbying and translating the SIOPE message throughout the community.
- ◆ The finalisation and close-out of the successful SIOPE/EONS/ECCO Special Project, ‘ Partnership

to improve care: Collaboration between doctors and nurses in paediatric oncology’ presented by Prof. Faith Gibson.

- ◆ The turnover and introduction of our new Board Member Professor Dragana Janicas well the announcement of our President – Elect, Professor Gilles Vassal.
- ◆ And an overview about the financial status of SIOPE and the announcement of assessing the various options for future membership fees.

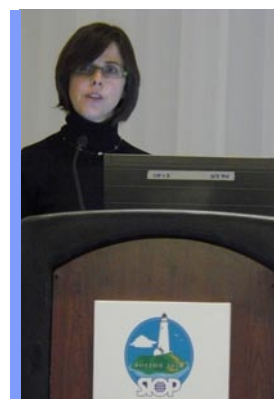
SIOPE has been growing and is still growing and therefore we would like to take the opportunity to thank you, our members and friends and we look forward to welcome you to our next General Assembly, taking place in September 2011 at the European Multidisciplinary Cancer Congress in the wonderful city of Stockholm, Sweden (23-27 September 2011).



Prof. Faith Gibson giving her final presentation on the SIOPE/ EONS/ ECCO Special Project to the SIOPE Europe community



Lars Hjorth presenting the EU FP7-funded project, Pancare SurfUp to the General Assembly



Belgian Nurse Jaklien Bistoën from Ghent presents the SIOPE/ EONS/ ECCO Special Project at SIOPE Boston with Prof. Faith Gibson

Special Features

A very special Thank you

A very warm goodbye and thanks to Prof. Kathy Pritchard-Jones and Prof. Riccardo Riccardi who must sadly step down from the SIOPE Board. Kathy and Riccardo have been wholeheartedly dedicated to the SIOPE organisation and its mission from the outset and were key instigators in its creation. Both will continue to be heavily involved in numerous activities: Kathy is an Activity Coordinator and Work Package Leader in the EU-funded Network of Excellence, ENCCA – the European Network for Cancer research in Children and Adolescents. Riccardo leads on Education and Training in ENCCA and he is SIOPE's representative in the EU-funded 'Oncovideos' educational

project. Riccardo will be counted on to continue promoting many of the educational courses and training opportunities in paediatric oncology in Europe.

Prof. Pritchard-Jones is based at the UCL Institute of Child Health in London. She is the Programme Director for Cancer, UCLPartners and Medical Director, a Consultant Paediatric Oncologist at the Great Ormond Street Hospital.

Prof. Riccardi is the Head of the Division of Paediatric Oncology at the Catholic University of the Sacred Heart in Rome, Italy.

Romanian PR Award for Poti si Tu campaign (EF)



The 'Little People' organisation in Romania was recently commended by the national PR awards for its survivorship campaign, 'Poti Si Tu' to all current and future young cancer patients in Romania and to the Romanian public. The Poti Si Tu campaign, or 'YOU CAN TOO!' was awarded within the category, 'Extraordinary Community Involvement'.

The TEMERARII club provides peer support and facilitates the successful reintegration of patients to teenage and young adult life after treatment.

Support for our young Romanian patients and survivors

Members of the Little People Association have been working in Romania for the past 14 years integrating psychosocial intervention programmes in support of patients and their families affected by cancer. Little People have developed a specific programme to support paediatric cancer patients currently in operation in the four main treatment centres in Romania.

In 2006 The Little People association founded the TEMERARII Club for cancer survivor teenagers and young adults from Romania.

In 2009 'Little People' represented Romania at the Lance Armstrong Global Summit and praised their fantastic efforts:

"The Little People Association is a leader the fight against cancer in Romania through its efforts to empower teenage cancer survivors caught between the worlds of paediatric and adult cancer. The Association's 'YOU CAN TOO!' Campaign has been instrumental in taking action to improve the survival rates of this demographic. As teenage survivors visit patients in hospitals across Romania, they offer critical support and encouragement to their peers fighting cancer. The Lance Armstrong Foundation applauds these acts of hope, courage and perseverance."

The 'Poti Si Tu' Campaign

The organisation recognised the need to transmit the message of survivorship of childhood and young adult cancer to all current and future cancer patients in Romania and to the Romanian public.

Promoting survivorship and the testimonies of those who have finished oncologic treatment is one of the most powerful weapons in the fight against cancer – and the best way of providing hope and support to current patients and their families. Young survivors talking and helping current patients in a campaign was a missing element of cancer care in Romania. To answer this need, in August 2009, the Poti si tu! (you can too) campaign was borne.

Working together with volunteer freelance photographers to design posters highlighting the message that childhood cancer can be cured, the organisation also created a website, www.potisitu.ro, with video testimonies of survivors, messages of encouragement and information.

The launch of the campaign was to be on the 15th of February 2010 on the international day of childhood cancer. Yellow is the international colour for childhood

cancer and thus a yellow wristband was produced: every news outlet in Romania was contacted and asked if their news and TV presenters could wear a band and talk about the international day of cancer; a press pack along with the “bands” was sent with each package. On the 15th of February every Romanian network

wore the bands live on air. 4 live TV interviews were given in Bucharest and Cluj – 14 national newsprints were published – 30 online reports – and 7 Radio broadcasts.

As a direct result of this media exposure 6000 bands were ordered within two days, with the profits going to the campaign.

Numerous celebrities support the campaign

Another success from the 'Little People' organisation is the creation of a brand new children's playroom in Sfanta Maria Children's Hospital in Iasi which gained a brand new children's playroom - this is the first time since the hospital was built in the mid 1970s that the children have a place to play away from their treatment beds.



SIOPE warmly supports Rare Disease Day 2011

Taking place on 28 February, the fourth International Rare Disease Day coordinated by EURORDIS is organised with rare disease national alliances in 25 countries. Hundreds of patient organisations from more than 40 countries worldwide will organise awareness-raising activities and converge around the slogan “Rare but Equal”. If you would like to find out more about this year's campaign, go to www.rarediseaseday.org.

In 2011, Rare Disease Day will seek to draw attention to the:

- ◆ Gaps in health that exist for rare disease patients between and within countries in the EU
- ◆ Gaps in health that exist for rare disease patients compared to other segments of society

The campaign will serve to advocate for:

- ◆ Equal access for rare disease patients to health care and social services
 - ◆ Equal access to basic social rights: health, education, employment, housing
 - ◆ Equal access to orphan drugs and treatments
- These aims fit well with SIOPE's European Standards of Care for Children with Cancer project, partnering with the Polish Ministry of Health and the foundation, 'Communication without Barriers' Project Lead Prof. Jerzy Kowalczyk, will speak at the Rare Disease Day event in Brussels on 28 February 2011.

To find out more about this project which will be rolled out within the European Partnership for Action against Cancer event, email office@tiope.eu (please replace<at> with @).

The Challenges for the Prescriber and the Pharmacist : **off-label and unlicensed use**

SIOPEurope is keen to create awareness of the many challenges facing the prescribers and the pharmacists in the paediatric oncology community. We welcome any contributions to this important debate.

Pharmacist Marc Doooms of the University Hospitals of Leuven in Belgium discusses here the daily challenges he faces when prescribing and compounding medicines for patients with rare diseases. He envisages greater co-operation on a pan-European level to ensure the creation of a comprehensive inventory of off-label and unlicensed use of drugs.

◆ **Off-label use** is the practice of prescribing authorised medicines “as is” (without any pharmaceutical intervention) in a condition (indication, age group, dose, form of administration) different than indicated on the package insert.

◆ **Unlicensed use** is the practice of prescribing chemical ingredients or authorised medicines to be compounded in a pharmacy such as dilution, incorporation in a different pharmaceutical dosage form, capsulation etc.

Off-label and unlicensed use is common, especially in the treatment of rare cancers because there has been very few clinical studies carried out. Only 3 cancer orphan drugs have been authorised for the use in children: Busilvex, Glivec and Mepact. It is a very complex and complicated issue.

Pharmaceutical companies are not allowed to mention this use in any external document but prescribers are keen to carry out these practices for the benefit of their patients (“therapeutic freedom”); on the other hand, authorities (such as the European Medicines Agency) are concerned about the safety and patients do not like to sign the “informed consent”. Moreover, it is further complicated by the fact that currently the legal responsibility remains with the prescriber.

Examples of off-label use:

Off-label use of “non-orphan” drugs in the treatment of rare tumours (Rola et al 2009):

Gemcitabine: biliary tree, pleural, sarcoma, testicular

Cisplatin: biliary tree, pleural

Etoposide: testicular, ovarian non-epithelial

5-Fluorouracil: anal

Mitomycin: anal

Oxaliplatin: peritoneal carcinomatosis, biliary tree

Paclitaxel: testicular, thymus

Carboplatin: thymus

Epirubicin: biliary tree

Tomudex: peritoneal carcinomatosis

Bevacizumab: glioma

Off-label use of orphan drugs in the treatment of rare tumours:

Cladribine: Non-Hodgkin Lymphoma

Clofarabine: Acute Myeloid Leukaemia

Examples of unlicensed use:

◆ Carmustine ointment compounding using an authorised pharmaceutical product such as BICNU.

◆ Compounding capsules with chemicals such as busulfan.

◆ Preparing oral liquids for the use in children with authorised capsules.

This pharmaceutical compounding for unlicensed use needs to be done following the same (European) validated manufacturing procedures in order to end up with the same medicine.

It is my belief and from my own experience working in this area, that we need to make a detailed (European) inventory of off-label and unlicensed use of orphan and non-orphan medicines in the treatment of rare tumours.

Moreover, I am of the opinion that off-label and unlicensed use should only be acceptable:

◆ If no other adequate treatment is available at that time.

◆ If it is prescribed by a treating physician with expertise in the treatment of this rare tumour based on exchange of information with other national and international experts.

◆ If a minimal scientific and clinical basis or consensus is available preferentially in guidelines.

◆ If a complete follow-up of the patient by the physician is maintained documenting outcomes, adverse effects, pharmacovigilance, dose, ...

◆ If this use is recorded in a central registry.

Because we consider here the treatment of rare tumours, EU collaboration is essential because of its characteristic rarity. Financing and eventually reimbursement needs further to be discussed.

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Pharmacist Marc Dooms, Hospital Pharmacy, University Hospitals of Leuven, Belgium
Contact: marc.dooms@uz.kuleuven.be

Pharmacist Marc Dooms studied pharmacy at the University of Leuven (Belgium) and St. John's University and Columbia University New York (USA). For 35 years now he has been working as a hospital pharmacist at the Leuven University Hospitals. He is a founding member of the Belgian National Board on Rare Diseases and Orphan Drugs.

Disclaimer: Any opinions expressed in this article (including attachments) are those of the author and do not necessarily reflect the organisation's opinions-

Creation of NORDS - National Organisation for Rare Diseases Serbia

Jelena Milosevic kindly informs us about the recent creation of NORDS - National Organisation for Rare Diseases in Serbia.

The National Organisation for Rare Diseases, Serbia (NORDS) was established in July, 2010. It is the union of seven associations which gather people with rare diseases and the members of their families. Its main goal is improving the quality of life of people with rare diseases and the members of their families by taking the initiative to establish the Fund and the Commission for Rare Diseases, create conditions for the budget financing of the prenatal and postnatal diagnosis, by creating awareness-raising campaigns and activities as well as by promoting the equal opportunities in education, employment and all other aspects of life.

Even though the idea of the establishment of the National Organization for Rare Diseases, Serbia, had already been announced in the media, this organisation had its first official media appearance at the Press Conference in November. The speakers at the Press Conference were Jelena Milosevic (the President of NORDS), Bojan Davinic (the Secretary General of National Association for Pharmacy Students, Serbia), Dr Maja Djordjevic (Mother and Child Health Care Institute of Serbia "Dr Vukan Cupic") and Jelena Danko (the Executive

Director of NORDS). They spoke about the goals and plans of NORDS, how everything began, the medical, social and personal challenges people with rare diseases and their families face.

The media coverage of this event was excellent. The story about the newly-established organisation appeared on a few TV and radio stations as well as in several newspapers. Afterwards, journalists and many people interested in joining the organisation have continued to call and showed their great interest in this subject.

The founders of NORDS and their representatives have plenty of ideas and plans for 2011 and a lot of energy and ambitions to fulfill them. In addition to this, they have awareness of the fact that the best way to achieve their goals is through the continuous cooperation and joint work with related national and international organisations and national and city authorities.

Together we can make a difference.

Jelena Milosevic

President National Organization for Rare Diseases, Serbia (NORDS)

To find out more, contact NORDS by emailing retke.bolesti.srbje@gmail.com



Marking International Childhood Cancer Day

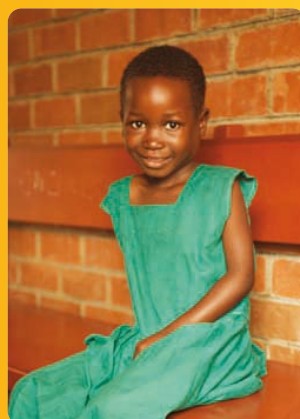
15 February 2011

ICCCPO, the International Confederation of Childhood Cancer Parent Organisations, is marking International Childhood Cancer Day again this year, focusing on global awareness and gathering the support of all their members in an effort to push for the World Health Organisation to put childhood cancer on the political map and allow for it to be officially recognised in its health promotion calendar.

Any money raised through member organisations can help support World Child Cancer's work which was initiated by ICCCPO and help fund Child Cancer Programmes in low-income countries.



World Child Cancer
No child should suffer



Working towards a world where every child
with cancer has access to treatment and care

www.worldchildcancer.org



Fellowships available again for **Films Workshop**

SIOPE is delighted to announce that fellowships were once again offered to the paediatric oncology community to participate in the 'Methods in Clinical Research' workshop held in Waldhaus, Flims Switzerland.

Taking place from 18-24 June, 2011, this 13th intensive workshop represents a unique opportunity for European junior oncologists, in any clinical research specialty area, to learn from the experts the essentials of clinical trial design. This is a highly regarded training opportunity for junior paediatric haemato-oncologists and we urge you to encourage your doctors in training to apply.

This year, SIOPE decided to sponsor two of the selected candidates with a proposal in the field of clinical trial development in childhood cancer.

Please note that the online application procedure opens 15 December 2010.

The deadline for receipt of applications was Monday 14 February 2011.

The two selected SIOPE participants will be awarded a fellowship covering part of the actual Workshop costs per student.

News Bites

RCPCH Annual Conference session: Speeding up the Diagnosis of Children's Brain Tumours in the UK

7th April 2011

7am-8am & 12.30pm-1.30pm

University of Warwick

Learn about the 'Diagnosis of Brain Tumours in Children' guidelines supporting healthcare professionals to identify, assess and investigate children presenting with symptoms and signs of possible brain tumours.

This session will show you how the guidelines and project align with the UK Department of Health Policy, and provide informational on the national awareness campaign being launched in June 2011. Speakers in the session include Professor David Walker (SIOPE Board member) and D Sophie Wilne.

For further information click on Brain Pathways Project

ITCC Course 2011 Rational Drug Development in Children with Cancer

Interest in our event in the European Parliament exceeded all expectations with interest in particular from local Belgian parents and their families.

Hosted by Member of the European Parliament, Mr. Alojz Peterle, this event consists of a platform for discussion on numerous key issues that affect this rare cancer – inequalities in access to treatment and care, off-label drug use, the burdensome EU Clinical Trials Directive and funding sources for further research development. Patients and their families have also been invited in order to get a true understanding of the difficulties facing our young people suffering from cancer. We will also have a video kindly produced by www.jimmyteens.tv on the complications involved in a late diagnosis of cancer, specifically discussing cancer in adolescents. We look forward to updating you on the outcome of this important date in the SIOP Europe calendar.

Revision of the EU Clinical Trials Directive: Next Steps

The European Commission is planning to put forward, in 2012, a legislative proposal to revise the Clinical Trials Directive 2001/20/EC. A concept paper has been produced for public consultation. SIOPE is very likely to respond to this paper in an effort to highlight the needs of the paediatric oncology community and we encourage you to do the same!

This concept paper seeks views on concrete ideas on the issues and gauge the viewpoints of key stakeholders following last year's consultation process. To view the concept paper and respond now, [click here](#).

SIOPE warmly supports Rare Disease Day 2011!

Taking place on 28 February, the fourth International Rare Disease Day coordinated by EURORDIS is organised with rare disease national alliances in 25 countries. Hundreds of patient organisations from more than 40 countries worldwide will organise awareness-raising activities and converge around the slogan "Rare but Equal". If you would like to find out more about this year's campaign, go to www.rarediseaseday.org. In relation to addressing inequalities in Europe, SIOPE will be doing its bit by promoting the European Standards of Care for Children with Cancer. To find out more, email office@siope.eu (please replace <at> with @).

Treasurers Corner

I had the opportunity to present the current financial position of SIOPE at the Annual General Assembly held during the SIOPE Congress in Boston. For those of you unable to attend I will provide a brief summary here.

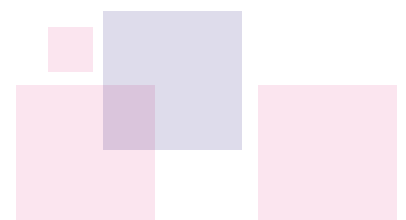
Our main source of income remains the profit share from the European Multidisciplinary Cancer Congress (previously known as the ECCO -ESMO Congress) held every two years. As a Founding Member of ECCO we receive a proportion of the profits based on the number of attendees registering for the meeting in the name of paediatric oncology. This income is vital lifeblood to our organisation as it covers the majority of our office running costs.

In addition to the office costs we currently spend ~€60,000 supporting the activities of SIOPE (meetings, travel etc). One of the most significant contributions we make however is to the educational activities of SIOPE by providing fellowships to individuals to allow them to attend meetings such as the Flims course which I wrote about in the September Newsletter. We feel that supporting our young and aspiring trainees in this way is a vital role for SIOPE. Regrettably we have very few sources of income that cover this additional expense and any reserves which the organisations have accumulated will be exhausted before the end of our financial year in May 2012.



At the SIOPE Congress a change to the statutes was approved (subject to some additional rewording and clarification) which allows all the Continental Branches affiliated to SIOPE to raise a separate subscription for their members. At the same time the SIOPE Office is moving to a new provider based in Switzerland (Kenes Associations Worldwide (KAW)) to manage its finances and operations. Once we have a clearer picture the Board of SIOPE will come back to the members with some proposals for membership fees.

Interestingly several people at the SIOPE Annual General Assembly raised the possibility of institutional membership rather than individual membership and this is something we will explore further. Meantime the most effective way you can help with SIOPE finances are to register for the next European Multidisciplinary Cancer Congress which will be held in Stockholm 23-27th September 2011, confirming your affiliation with SIOPE.



Upcoming Events

AACR 102ND ANNUAL MEETING 2011

02-06 April, 2011, Orlando, Florida, USA

[Click here for more details](#)

37TH EBMT ANNUAL CONGRESS

03-06 April, 2011, Paris, France

<http://www.congrex.ch/ebmt2010/>

RCPCH ANNUAL CONFERENCE SESSION: SPEEDING UP THE DIAGNOSIS OF CHILDREN'S BRAIN TUMOURS IN THE UK

07 April, 2011, University of Warwick, UK

[CLICK HERE](#) for more details

7TH PANCARE NETWORK MEETING

27- 29 April, 2011, Brno, Czech Republic

<http://www.pancare.eu/en/>

22ND ANNUAL MEETING OF THE I-BFM STUDY GROUP

06-08 May, 2011, Gdansk, Poland

<http://www.bfm-international.org/>

THE FIRST INTERNATIONAL SYMPOSIUM ON CHILDHOOD, ADOLESCENT AND YOUNG ADULT HODGKIN LYMPHOMA (1-ISCAVAHL)

12-14 May, 2011, Washington DC, USA

To find out more, [click here](#)

ITCC (INNOVATIVE THERAPIES IN CHILDREN WITH CANCER) RATIONAL DRUG DEVELOPMENT IN CHILDREN WITH CANCER

25-27 May, 2011, Rome, Italy

To find out more contact manuela@morandini.ptsroma.it (please replace@ with @)

2011 ASCO ANNUAL MEETING

03-07 June, 2011, Chicago, Illinois

<http://chicago2011.asco.org/>

13TH JOINT ECCO - AACR - EORTC - ESMO WORKSHOP ON 'METHODS IN CLINICAL CANCER

Research'

18 - 24 June 2011, Waldhaus, Flims

<http://www.ecco-org.eu/Education/Flims/page.aspx/28>

JOINT ECCO 16 - 36TH ESMO MULTIDISCIPLINARY CONGRESS

23 - 27 September 2011, Stockholm, Sweden.

<http://www.ecco-org.eu/Conferences-and-Events/ECCO16-ESMO-36/page.aspx/217>

3RD EUROPEAN SYMPOSIUM ON LATE COMPLICATIONS AFTER CHILDHOOD CANCER

29-30 September 2011, De Rode Hoed, Amsterdam, the Netherlands

www.eslccc.org

8TH PANCARE NETWORK MEETING

01-02 October 2011, De Rode Hoed, Amsterdam, the Netherlands

<http://www.pancare.eu/en/>

EUROPEAN STANDARDS OF CARE FOR CHILDREN WITH CANCER CONFERENCE EUROPEAN PARTNERSHIP FOR ACTION AGAINST CANCER ORGANISED BY THE POLISH MINISTRY OF HEALTH, SIOP

Europe and the Communication without Barriers Foundation

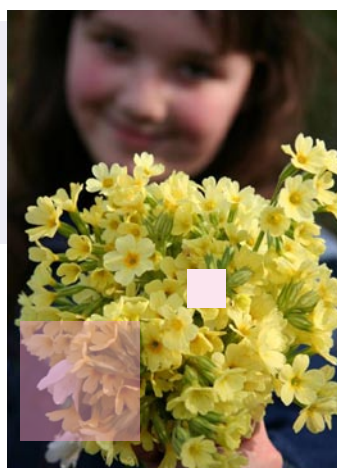
20 - 21 October, 2011, Warsaw Poland

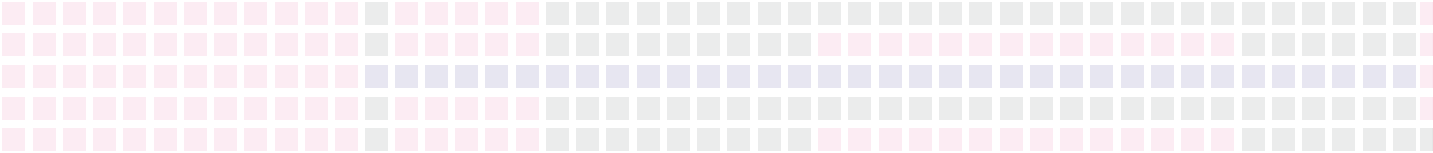
Contact SIOPE for more details

SIOP 2011 - 43RD CONGRESS OF THE INTERNATIONAL SOCIETY OF PAEDIATRIC ONCOLOGY

26 - 30 October, 2011, Auckland, New Zealand

<http://www.siop2011.com/>





About US



Working to ensure the best possible care and outcomes for all children and young people with cancer in Europe

www.siope.eu

Working to ensure the best possible care and outcomes for all children and young people with cancer in Europe SIOPE focuses on making a difference and improving the quality of life of young cancer patients.

To do this, SIOPE supports the pooling of initiatives and expertise of multidisciplinary stakeholders in paediatric oncology, building their common experience into a positive force and creating a brighter future for young people with cancer.

Support and facilitate professional, medical, scientific and educational co-operation and training across Europe

Integrate patients and parents and bridge the gap between family groups, professionals and policymakers in Europe

Optimise access to information and promote multi-centre and multinational clinical trials, forming a common platform for best practice guidelines in clinical research

Promote better policies for children with cancer and raise awareness of the numerous challenges faced by paediatric oncology professionals to EU policymakers

Elevate standards for training and care in paediatric oncology and develop European guidelines

To find out how you can help, please contact us at office@siope.eu (please replace [at] with @).

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