SIOP Europe
the European Society for Paediatric Oncology

SIOPE News

SIOPE's Community Newsletter
May 2012 Issue 12

Message from the President and the Office

Since the last edition of the newsletter, we have celebrated our biggest day of the year, International Childhood Cancer Day. Taking place on 15th February, SIOPE has been actively promoting this day for the last two years and is likely to continue to do so. On both occasions, Members of the European Parliament (MEPs) hosted events in the European Parliament in Brussels, to mark this important day. Co-Chair of the European Parliament's Health Working Group, Glenis Willmott (UK), kindly hosted the meeting on 09th February this year, a lunch-time event which involved high-level stakeholders from the paediatric oncology and health policy community discussing key topics in our field. Photos and a report from the event are of course featured in this edition.

February is always a busy month for SIOPE, as it is not only includes International Childhood Cancer Day, but also World Cancer Day (04 February) and Rare Disease Day (28 February). This year on Rare Disease Day we issued a press release on the need for early diagnosis of childhood cancer and the importance of raising awareness amongst the general public about the 'warning signs', particularly of brain tumours. This stems from a campaign in the UK called 'HeadSmart' and we are delighted that several other European countries are interested in taking up the successful campaign in other countries! Thanks to our partners in ICCCPO for helping us to drive this initiative!

We also prepared the SIOPE-ENCCA educational initiative 'Case Study of the Month'. Hosted by ECCO - the European CanCer Organisation, this online educational tool allows participants to diagnose a 'case study' and gain CME points in the process. This is a key deliverable of the education and training work package of ENCCA. The paediatric oncology community is warmly encouraged to send in their own 'case studies': in fact, this is a unique opportunity for young investigators to be profiled and gain recognition on European platforms, under mentor leadership on European platforms.

The next few months for the SIOPE Board and office are pivotal, mainly due to the current revision process by the European Commission of the highly controversial EU Clinical Trials Directive. SIOPE has strongly advocated for legislative changes; in particular, we want to ensure that Phase III paediatric oncology trials benefit from low-risk categorisation, even with off-label use of drugs.

While waiting with baited breath for the revised proposal from DG Health and Consumers, expected in summer 2012, the SIOPE Board and office is participating in a series of high-level stakeholder conferences on this issue and meeting with key policy drivers of the legislation, including European Commission and Parliament representatives, in order to voice our needs and concerns.

Moreover, right now we are contacting childhood cancer national society representatives directly to query whether national group membership to SIOPE could be a possibility. SIOP Europe has never had direct membership as the continental branch of SIOP. There was a possibility at one time to 'subscribe' to SIOPE but a new membership system is needed, not only to ensure the office continues to be sustainable, but also to ensure it has the critical mass and large representation to be influential on the EU scene. SIOPE is the only pan-European multidisciplinary multi-professional organisation dedicated to paediatric oncology and is dedicated to ensure that children and young people receive optimal standards of treatment and care. Its competence – and some confidence – as an organisation continues to grow and this should only continue. However a sustainable membership structure is required where members of national societies could automatically become members of SIOPE. Several national societies are currently discussing this opportunity, both at Board level and at their annual meeting and to date, feedback from the societies and groups has generally been very positive! The target is to have SIOPE national group membership up-and-running by the SIOP conference in London. On that point, don't forget to pencil in the SIOPE General Assembly, which takes place on Monday, 08 October during the conference.

Finally, the SIOPE team is growing, as is our languages! Italian Giulia has joined the office in Brussels. With a background in international affairs and excellent administrative skills, Giulia will be busy ensuring the office administration runs smoothly, as well as focussing on communication and marketing. This is why you may have noticed our website being updated, and we are actively working on building our presence in social media, with SIOPE featured in the online professional networking website, LinkedIn and the hugely popular Twitter. Follow us on Twitter now @SIOPEurope.

Ruth, Samira, Edel and Giulia.

SIOPE Europe's Community

Outreach and awareness-building throughout Europe

Latest News from ENCCA

Overview of ENCCA Achievements to Date

The EU-funded Seventh Framework Programme (FP7) network of excellence, ENCCA, is arguably the most exciting project to take place at European level for the paediatric oncology community. Commencing in January 2011, a lot has already happened! For more information on ENCCA, check out www.encca.eu

Overview of ENCCA Work Packages and Leads

WP no	Title	WP Leader/Institution
WP1	Management Activities	Ruth Ladenstein *CCRI - The Children's Cancer Research Institute*
WP2	European sustainable strategy for clinical trial paediatric oncology	Ruth Ladenstein *CCRI - The Children's Cancer Research Institute*
WP3	Establishment of the Virtual Institute information portal	Guenter Schreier *AIT - Austrian Institute of Technology*
WP4	Clinical Trial Facilitation development	Ruth Ladenstein *CCRI - The Children's Cancer Research Institute*
WP5	Biology to guide innovative targeted therapy	Angelika Eggert *UKE - Universitätsklinikum Essen*
WP6	Standardised and innovative methodology for clinical trial design and analysis	Maria Grazia Valsecchi *UNIMIB - Università degli Studi di Milano-Bicocca*
WP7	Integrating clinical trials and tumor biology research in bone sarcoma	Stefan Bielack *OLGA - Klinikum Stuttgart*
WP8	Early evaluation and prioritisation of new anticancer drugs	Gilles Vassal *IGR - Institut Gustave Roussy*
WP9	Improved therapeutic strategies using predictive biomarkers in leukaemias	Martin Schrappe *CAU - Christian-Albrechts-Universitaet zu Kiel*
WP10	Risk adaptation of therapeutic strategies using prognostic biomarkers in malignant solid tumors	Adela Cañete *LaFe - Fundación para la Investigación Hospital Universitario La Fe*
WP11	Clinical epidemiology and prospective registries for patients on standardised protocols	Kathy Pritchard-Jones *UCL - University College London*
WP12	Clinical research in very rare tumours	Piotr Czauderna *MUG - The Medical University of Gdansk*
WP13	Quality of survivorship	Riccardo Haupt *IGG - Istituto Giannina Gaslini*
WP14	Dissemination activities	Samira Essiaf *SIOPE - European Society for Paediatric Oncology*
WP15	Education and training	Riccardo Riccardi *UCSC - Università Cattolica del Sacro Cuore*
WP16	Facilitation of Industry Collaboration with Pharmaceutical Companies and SME for dissemination, exploitation and technology transfer	Gilles Vassal *IGR - Institut Gustave Roussy*
WP17	Improving Outcomes for Teenagers and Young Adults with Cancer Trust	Ian Lewis *LTHTNHS - The Leeds Teaching Hospitals NHS*
WP18	Ethical aspects of clinical trials	François Doz *CURIE - Institut Curie*

Deliverables of the project to date include:

A project identity set (logo, flyers, and PowerPoint templates) including most importantly the ENCCA project website (www.encca.eu) was created to facilitate information and workflows.

A quality assurance plan (QAP) was delivered for ENCCA partners.

The European Clinical Research Council (ECRC) was established with a common mission and rules all summarided in bylaws along with ENCCA advisory committees (Patients/Parents Advocacy, Scientific Advisory, Ethics Advisory).

Multiple reports summarised the current challenges for running paediatric oncology clinical trials under the current clinical trials directive and suggested possible solutions for its revision.

A harmonised GCP-based Phase I-III clinical trial template for investigator driven trials and contract templates for international trials were developed, circulated to members and approved.

The statistical consortium completed several publications regarding dose-finding methodology, methods for biomarker's relationships to survival data, risk stratification rules and methods for recurrent events.

Wet-lab and bioinformatics' testing were initiated to assess comparability of methods with regards to RNA and DNA isolation and mRNA profiling approaches. Efforts ultimately will lead to common guidelines and harmonised standard operating procedures. The consortium agreed to use a common online bioinformatics analysis platform (R2) previously developed in FP6 as central bioinformatics platform.

The bone sarcoma consortium established an International Steering Group encompassing 11 networks (EURAMOS, EuroBoNeT, EURO-E.W.I.N.G., COSS, EOI, EORTC- STBSG, EuroSarc, ISG, SFCE/GSF-GETO, SSG) within the first intergroup bone sarcoma biology meeting and agreed and published their future key research objectives.

A strategy for the development of new drugs was defined for four malignancies, with one clinical trial initiated and three more in preparation. A task force to collaborate with the European Medicines Agency (EMA) has been established. A two-day workshop was held in London in December, 2011, organised by the Biotherapy Development Association (BDA) in association with ITCC, EMA and ENCCA to discuss 'New Oncology Drug Development for Children and Adolescents in Europe: Current Status and where to go?' and was supported by French Member of the European Parliament, Françoise Grossetete.

The AIEOP-BFM and DCOG leukaemia clinical trials groups performed surveys on diagnostic procedures aiming at publication of guidelines.

The Low and Intermediate Risk Neuroblastoma European Study (LINES) was launched with the trial's RDE data base developed by AIT. Guidelines were published for genomic profile studies of tumours in multicenter multinational studies. Also the low-risk medulloblastoma investigator driven trial protocol was finalised and funding applications were made.

The next Wilms Tumour (WT) trial will run on the ACGT platform and will prioritise the understanding of residual viable blastema's biology aiming at 'real time' collection of relevant tissues and imaging data files to improve biomarker discovery.

A questionnaire gathered information about training standards in paediatric oncology in different European countries. Interestingly, no significant difference between Eastern and other European countries was found.

Key leaders and stakeholders in teenage and young adult cancers (TYA) have been identified in 18 countries resulting in a European Steering Group to develop a TYA Oncology framework dealing with their particular needs allowing early diagnosis and better models within health care to improve the currently poor outcome of the TYA population.

The ethical working group (WP18) has undertaken an extensive review of literature related to clinical and research themes and has liaised closely with the European branch of the International Confederation of Childhood Cancer Parent Organisations (www.icccpo.org) in workshops on informed consent procedures for research, tissue banking and participation in clinical trials and data protection issues.

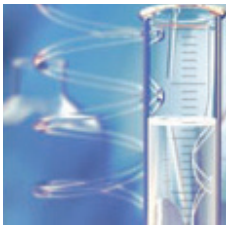
ENCCA, efficiently structuring and enhancing collaboration within the field of paediatric oncology in Europe

Key actions to raise awareness of ENCCA included various publications, workshops, scientific sessions and congresses (at least 7 events in 2011), establishment of strong relations with policy makers (DG Sanco, EMA, members of the European Parliament) and to engage with other EU-funded projects (i.e., Pancare SurfUp, CONTRACT, EUROCANCERCOMS, the European Partnership for Action against Cancer (EPAAC), EUROCHIP and the EuroCan Platform).

European Clinical Research Council

It has been exactly one year since the first steps were taken to create the European Clinical Research Council (ECRC), which aims to incorporate the European clinical trials groups and national societies through the ENCCA project. On the occasion of **International Childhood Cancer Day organised by SIOPE at the European Parliament** (07 February 2012), the ECRC took the opportunity to meet prior to this event in Brussels (06 February 2012). During this one-day meeting, Ruth Ladenstein stressed out again the importance of acting together (with SIOPE) and to create one voice for the paediatric oncology community, as this will strengthen our influence to tackle many of the current 'hot topics' such as risk-adapted approaches and risk categorisation of investigator-led clinical trials, as well as harmonised IMPD and insurance issues. Not only will the ECRC work on these current common needs, but also will collaborate on our community's needs in the future.

The progress made so far, such as the agreement on the Bylaws by Pam Kearns and Thomas Klingebiel, was presented at this 4th ECRC meeting. On the level of the ENCCA clinical trial templates, Pam Kearns introduced the final templates that have been tested and are now ready for use. These clinical trial templates and contracts are now available on request from the SIOPE office. Magdalena Góralczyk, representing the EU-funded Seventh Framework Programme (FP7) project CONTRACT (Consent in a Trial & Care Environment), provided an overview of the status of 'Informed Consent' as well the outcomes obtained by this project. These results will be very helpful



in the future for the ECRC and the harmonisation process. An overview from the first results of Work Package 18 on the ethical aspects of clinical trials within the ENCCA project was also presented by Jean-Claude Dupont. In his presentation he introduced a survey that would set the most suitable workflow. (For more information on this survey please contact Ms Samira Essiaf).

Ruth Ladenstein concluded the meeting by launching a call, asking all the groups to provide as much feedback as possible to the SIOPE office when asked, in order to accelerate the efficiency of the ECRC and accommodate the needs of the groups. In the evening, Member of the European Parliament (MEP) Carvalho from Portugal joined members of the ECRC for a networking dinner in Brussels. This was an excellent opportunity to underline the challenges our community faces.

Remit of the Council

- The Council will embody the needs and opinions of the Community with respect to the delivery of international clinical trials for children and young people with cancer and leukaemia.
- The remit will involve highlighting the specific challenges to the paediatric and adolescent oncology community imposed by the EU Clinical Trials Directive and the associated regulations.
- The Council will represent the collective experience of the constituent groups and will facilitate the sharing of good research practice.
- The Council will promote a European-wide infrastructure to deliver academic sponsored clinical trials.
- The Council undertakes to interact with industry to foster innovative therapies and paediatric drug approval.

Constitution of the Council

The members of the Council should include:

1) The Chair (or nominated representative) for paediatric oncology clinical research from each National Group

2) The Chair (or a nominated representative) from each of the SIOPE disease-specific co-operative groups, the ITCC and the I-BFM Study Group

3) A nominated representative for adolescent oncology clinical research from each National Group (where available)

4) A nominated representative from ICCCPO

5) Legal advisory members representing expertise in the regulations associated with clinical research and international contracts and agreements

Next ECRC Meeting Date to bookmark

We look forward to welcoming you to the next ECRC meeting in London (Barbican Centre) on Monday 08 October 2012, at the SIOP Congress. For more information about the European Clinical Research Council (ECRC) please contact Ms Samira Essiaf at office<at>siope.eu (please replace <at> with @).

Latest News from PanCareSurFup

9th PanCare Meeting Bucharest, Romania

The 9th PanCare meeting will begin on 10th of May in Bucharest and will continue until 11th of May. The conference will take place in the Hotel Pullman Bucharest World Trade Center.

Visit beautiful Bucharest! You will be intrigued by the city's eclectic mixture of architecture, from Curtea Veche (the remains of Prince Vlad Tepes 15th century palace, who was the city's founder as well as the inspiration for "Dracula") to Orthodox Churches, Second Empire mansions, the Stalinist architecture of the communist years and the colossal 6,000 room Parliament House, the second largest building in the world after the Pentagon.

You can register to the event website: www.pancare-srohp-2012.ro. The conference will take place in the Hotel Pullman Bucharest World Trade Center. Please book your accommodation through the www.pancare-srohp-2012.ro website in order to benefit from our 40% discount special rates.

- The PanCare meeting will be immediately followed by the annual meeting of the Romanian National Society of Paediatric Hemato-Oncology (SROHP), and all its members have received a preliminary invitation already to PanCare as well.

- On 12th of May, there will be a working meeting for PanCareSurfUp project participants between 9.00 am and 12.30 pm.

For any queries on registration difficulties, please contact katie<at>thelittle-people.org (please replace <at> with @)

Survivors' cycle race to raise awareness in Italy in May

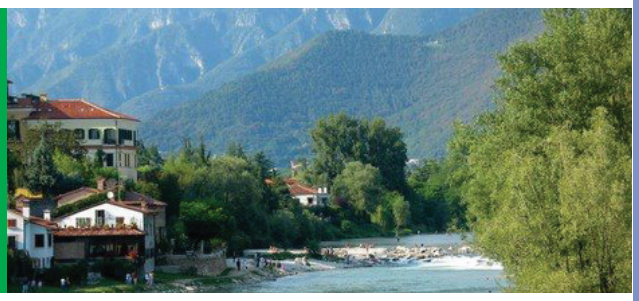
On Saturday and Sunday 5th and 6th May 2012 the "Race of Brave Bikers" will take place for the first time in Marostica near Treviso, Italy. The organisers of this 10km cycle race are looking for around 30 enthusiastic cyclists who are long-term survivors of cancer in childhood or adolescence. Participants, aged between 18 and 40, will come preferably, but not exclusively, from one of the 11 PanCareSurFup project partners' countries.

This race is not only a great opportunity for survivors to experience cycling in a beautiful part of Italy, but also to meet other survivors from across Europe and increase awareness about survivorship after childhood and adolescent cancer.

This event is sponsored by the EU 7th Framework Programme (FP7) project PanCareSurFup **(www.pancaresurfup.eu)**, in which SIOPE is involved. This pan-European consortium involving professionals, survivors and their families, aims to increase awareness amongst survivors and families, as well as the general public. The industrial group "Near" is also sponsoring the event.

A first PanCareSurFup initiative took place last year in Ireland, organised by the Boyne Research Institute. The keynote speaker was Irish MEP Nessa Childers, who reminded survivors to take control of their health. A total of 111 guests attended that conference, and about 70% were survivors and family members.

Last year's national event to raise awareness took place in Ireland and was attended by MEP Nessa Childers



More information:

- PanCare SurFup: www.pancaresurfup.eu
- Irish conference on survivorship after childhood cancer: www.ccs2011.ie
- Contact Ms. Carla Manganini at c.manganini<at>hsgerardo.org (please replace <at> with @) for information on the “Race of Brave Bikers”

Promoting better policies for children with cancer

SIOPE meets Polish Member of the European Parliament

From l-r: Piotr Czauderna (Gdansk, PL), Edel Fitzgerald (SIOPE), Sidonia Jedrzejewska (MEP), Jerzy Kowalczyk (Lublin, PL) and Elzbieta Pomaska (Communication without Barriers, PL)

Leading experts from the paediatric oncology community recently met Polish Member of the European Parliament (MEP) Sidonia Jedrzejewska to discuss the impact of the EU Clinical Trials Directive in Poland. Former SIOPE Board member Prof. Jerzy Kowalczyk, who leads the European Standards of Care for Children with Cancer initiative, joined ENCCA Work Package Leader Prof. Piotr Czauderna, Elżbieta Pomaska from the Communication without Barriers Foundation and Edel Fitzgerald from the SIOPE office, and raised their concerns to this important policy-maker in February 2012.

Due to recent legislative changes, carers of childhood cancer patients in Poland are increasingly unable to meet the demands set by regulatory authorities, and it is causing huge bureaucratic burdens in treating young people. The group appealed to Mrs. Jedrzejewska to act quickly and raise their concerns at national level. Since then, the group has been in contact with the Polish Ministry of Health in order to move this issue along as quickly as possible, in order to treat young patients with the best possible care and treatment.

International Childhood Cancer Day

International Childhood Cancer Awareness Day

Creating a brighter future for young people with cancer

International Childhood Cancer Day is marked around the world on 15 February each year. SIOP Europe (SIOPE) marked International Childhood Cancer Day on 7 February 2012 at the European Parliament to raise awareness of the challenges facing children and adolescents with cancer in Europe, and those who care for them.

Hosted by Member of the European Parliament, Glenis Willmott (UK), this event involved a range of stakeholders involved in paediatric oncology and health policy issues who debated the many challenges childhood cancer presents to jointly find a political pathway to instigate change. Willmott was joined by fellow MEPs Alojz Peterle (SL) and Linda McAvan (UK) who participated in a session on the importance of early diagnosis of paediatric brain tumours. MEP Maria Graça Carvalho (PT) spoke about the next research framework programme of the EU, Horizon 2020 and the importance of integrating childhood cancer and other rare diseases into this programme, under the topic, 'Societal Challenges'.

The revision of the EU Clinical Trials Directive and the EU Paediatric Regulation were also discussed. Glenis Willmott chaired both of these sessions, and has since wrote a blog on the event. "We need to do everything we can to encourage more research and more clinical trials, specially designed for children and adolescents. There is no known treatment that can save a child with some types of brain tumour. We need new clinical trials to provide hope to these children and their families", stated Glenis. The revision of the EU Clinical Trials Directive and progress made in drug development since the introduction of the EU Paediatric Regulation was debated by representatives from academia and the pharmaceutical industry. View the event programme here and photos here.

Parents and patients were central to the event. Patricia Blanc (FR) from the charity 'Imagine for Margo' told the multi-stakeholder audience about the tragic experience of her daughter and pleaded to EU regulators to encourage the pharmaceutical industry to create innovative drugs for both adults and children with cancer. The International Confederation of Childhood Cancer Parent Organisations (ICCCPO) was represented by Director Anita Kienesberger (AT) and her colleague Sabine Karner (AT). Sabine in particular showed the bravery of young cancer patients: she now works with survivors of paediatric cancer. Ela Pomaska (PL), parent of a child with cancer, spoke about the number of campaigns she has worked on in Poland, including a programme educating GPs of the warning signs when children with cancer come in for a check-up. Participants also heard the story of a young teenager from the UK, Charlie, who spoke about the poor detection of her brain tumour; watch Charlie's video here or download it from www.jimmyteens.tv.

Presentations of this high-level meeting are available on the SIOPE website here.

SIOPE President-Elect Prof. Gilles Vassal and President of the French charity, 'Imagine for Margot', who both spoke at the event on the need for improvements in drug development for young cancer patients

Prof. Lars Hjorth, Coordinator of PanCare SurFup, chats to Dominika Traszka from the European Commission

From l-r: Members of the European Parliament Maria Graça Carvalho (PT), Glenis Willmott (UK), Sidonia Jedrzejewska (PL), Alojz Peterle (SL), Frieda Brepoels (BE) and Linda McAvan (UK) participating at the event.

HeadSmart child brain tumour initiative launched in Europe

HEADSMART be brain tumour aware

INTERNATIONAL CONFEDERATION OF CHILDHOOD CANCER PARENT ORGANIZATIONS

Rare Disease Day



From l-r: MEP Glenis Willmott and SIOPE Board Member David Walker; the conference at the European Parliament; Gabriele Calaminus, SIOP President, MEP Glenis Willmott, and Ruth Ladenstein, SIOPE President

The new pan-European HeadSmart campaign was launched on 29 February to raise awareness of the symptoms of brain tumours in children and young people. The aim is to accelerate diagnosis by promoting enhanced awareness of the range of red flag symptoms of childhood cancer, in particular brain and bone tumours. Early diagnosis of brain and bone tumours can make a real difference in outcome and long-term effects, and reducing the time to diagnose can also reduce the long-term disability that many children currently experience.

As late diagnosis is a problem and needs to be dealt within all European countries, this formerly UK-based campaign is now set to be rolled out in Denmark, Sweden, France, Germany, Austria, Poland and Spain. Consistent with "Solidarity", the theme of Rare Disease Day 2012, HeadSmart aims to promote a strong international partnership between health professionals, patients and parents groups and all people active in the field of paediatric brain tumours. SIOP Europe and ICCCPO, the International Confederation of Childhood Cancer Parent Organisations, are working together to raise awareness of the symptoms to watch out for in young people, including:

- Persistent / recurrent vomiting
- Persistent / recurrent headache
- Abnormal balance / walking / co-ordination
- Abnormal eye movements
- Blurred or double vision
- Behaviour change
- Fits or seizures
- Abnormal head position such as wry neck, head tilt or stiff neck.

The initiative discussed on 07 February during an event hosted by Member of the European Parliament (MEP) Glenis Willmott in Brussels. "The EU has funded a lot of research into childhood and adolescent cancers, and has legislation in place for paediatric medicines, clinical trials and treatment of rare diseases, all relevant for children with cancer. But whilst we have made a lot of progress, we must continue to improve the situation. The earlier the cancer is diagnosed, the higher the chances are that the child can survive", stated Willmott. SIOPE Board Member Prof. David Walker said that "earlier diagnosis would offer the opportunity for better clinical outcomes and, in some cases, the saving of lives."

The next step for this project is to set a new target for speed of diagnosis across the EU Member States as a trigger for a systemic change in this field. National groups are set to share best practice tools and techniques to roll-out such a campaign on the 'warning signs' for children, targeting both GPs and the public.

More information:

- Headsmart UK campaign: www.headsmart.org.uk
- Headsmart European campaign - Launch at the European Parliament: CLICK HERE
- Rare Disease Day: www.rarediseaseday.org

Clinical Trials Directive

SIOPE has been strongly advocating for change in the highly controversial EU Clinical Trials Directive (2001/20/EC). In this article, we highlight the needs and concerns of the paediatric oncology community in Europe, in advance of the proposed revision of the legislation, expected to be published by the European Commission in June, 2012.

Children and Young People and European Clinical Trials

- Currently within Europe, there are around 10,000 children diagnosed with cancer participating in clinical trials annually. Moreover, 1 out 1000 adults today is a childhood cancer survivor.

- Childhood cancer is treated in clinical trial settings where 'off-label use' is standard practice.

- In paediatric oncology, Phase 3 clinical trials are standard practice which is the basis for excellent success rates. They are a vital tool for quality control involving standardised quality-assured diagnostics: hence, they identify the patients' individual risk and lead to stratified, risk-adopted treatment involving complex drug combinations (mainly 'off-label' and most already 'off-patent) and varying degrees of treatment intensity.

- Such standard treatment schemes are the basis of current high success rates for children with cancer - patient survival rates in Europe reach 80% from previously less than 10%.

- These trials are non-commercial, sponsored and conducted by academic institutions and funded by public money and/or charity support to cover the trials' organisational structures to comply with GCP and regulatory requirements.

- There is neither economic interest, nor sufficient incentive, for the pharmaceutical industry to engage in the field of off-patent drug development for rare diseases like childhood cancer.

- Currently, 80% of the standard treatment chemotherapy are in 'off-label' use, although licensed but mostly 'off-patent'. There is little pharmaceutical or regulatory interest in bringing forward these off-patent drugs into label, for the relevant cancer types, which correspond to approx. 60 different diseases, and even more if biological biomarkers are considered. Moreover, this field spans several age groups, from neo-natal to adolescent, further indicating the complexity of this field.

- Since the EU Clinical Trials Directive has been introduced, there has been an increasing ethos to avoid undertaking clinical Phase 3 trials for children and young people with cancer. If this continues, survival rates of our young patients are likely to dramatically drop by 20-30% in uncontrolled settings, outside the rigorous guidance structures currently in place within our multinational trials in Europe, involving often up to 20 Member States per trial.

- Rather than encouraging innovation, finding better cures and optimising survival for our young patients, current research funding in paediatric oncology, including funds from charities and patient/ parent organisations, is funding insurance companies.

- While insurance appears to be justified in higher risk Phase 1 and 2 trial settings, the best standard treatment for young patients with cancer is through Phase 3 trials and should not involve additional insurance costs.

Investigational Medicinal Product (IMP)

Currently, over 80% of chemotherapy agents of childhood cancer treatments are used 'off label' as standard practice: the use of these drugs in this way is based on extensive experience built up over 40 years, much of which is published in peer-reviewed journals. Under the EU CTD current broad definition, all the drugs in the compared regimes are designated IMPs, but what is the benefit of applying the same high level of regulation to a drug whose identical use outside a clinical trial is well-established? The collected data will not provide any useful additional information on single drugs as it stems from complex combined treatment involving up to 10 drugs within a treatment cycle. The toxicity profile of such combination treatments can only be understood and interpreted through a comprehensive understanding of a given trial setting for a given indication via experts in the field. The situation could be improved if drugs used in childhood cancers were licensed for this use; however there is little prospect of this happening due to the low commercial value of this rare form of cancer.

Moreover, the interpretation of an IMP differs between individual Member States. This results in substantial inconsistencies in the number of drugs designated as IMPs in the same trial. SIOPE is aware of a trial which has between 3 and 17 designated IMPs depending on the participating MS's competent authorities' viewpoint, which is not an acceptable way to conduct a study.

In the upcoming CTD revision, a common understanding of the IMP definition needs to be created – in its current state it is unclear. We welcome the fact that IMPs and auxiliary medicinal products are being addressed.

Such auxiliary medicinal treatments need to allow 'off-label' drugs. An IMP definition should not be created for all drugs in the comparator arm, which equals the drugs used as auxiliary treatment (example is enclosed).

We would favour a streamlined definition of the IMP to the new drug under investigation in a standard treatment concept, particularly in the case of life-threatening diseases, such as for young people with cancer.

Drugs within non-randomised, single arm disease risk-based treatment strata, using standard approaches, should not be considered as IMPs. Often, in such rare diseases, they represent the best, evidence-based treatment available, particularly in a field where drug development is poor.

The SIOP Europe community recommends that the European Commission consider the concept of a 'waiver decision process' for drugs in off-label use in these rare, life-threatening disease indications. In such a case, an exempted drug should have a long and successful history of usage in published, peer-reviewed trials.

Risk-adapted approach

A recent development in the UK has been welcomed by the SIOPE community: The competent authority, the Medicines and Healthcare products Regulatory Agency (MHRA), has taken a pragmatic approach to clinical trials, accepting that trials can be categorised according to an assessment of their risk compared to current standards of therapy (MRC/ DOH/ MHRA joint project 1). The implementation of this approach should be commended, but to be truly successful, it must be incorporated into the revision of the EU CTD, and attention to harmonious implementation in all MS will be crucial.

The paediatric oncology community would like to see a risk categorisation that is based on relative risk as not all childhood cancer trials should automatically be categorised high-risk if the disease itself is high-risk. The major risk comes from the underlying cause: cancer in young people is an aggressive and life-threatening disease.

Most of our paediatric oncology trials are established standard treatment and should be considered within the low-risk category, within the forthcoming CTD revision, taking into account that off-label use is accepted as standard practise.

Insurance

The EU CTD dictates that a clinical trial sponsor is required to make provision for insurance or indemnity to cover the liability of the investigator and sponsor. The precise liability of the sponsor and investigator is defined differently in each MS, creating confusion. We strongly advocate for the introduction of proportionate risk management to the EU CTD, with consideration of the specific circumstances encountered in childhood cancer trials.

Rather than encouraging innovation, finding better cures and optimising survival for our young patients, current research funding in paediatric oncology, including funds from charities and patient/ parent organisations, is funding insurance companies.

While insurance appears to be justified in higher risk Phase 1 and 2 trial settings, the best standard treatment for young patients with cancer is through Phase 3 trials and should not involve additional insurance costs.

We applaud the proposal in the CTD revision, allowing insurance for academic clinical trials to be taken on by the government of a Member State. We advocate that this should be strongly considered for children and young people with cancer who are victims of major inequalities in drug development.

Sponsorship

As rare diseases, the majority of childhood cancer trials enrol patients in more than 10 European countries and even up to 20 countries can participate in academic, non-commercial trials. However, many barriers affect the running of paediatric trials in relation to sponsorship: (a) the legal and language diversity between Member States, (b) the fragmentation in the duties and liabilities of the different Member State trial participants, coupled with (c) the concern by academic institutions to participate in such a costly and bureaucratic non-commercial trial deter research. Solutions other than the current situation of single sponsorship need to be created to address these challenges.

We propose to create the following roles with a defined task profile:

- **Co-ordinating Sponsor**: this is the central contact point (main contact similar to a 'one-stop-shop' principle) to be addressed for key trial queries and results, hence controlling the integrated data of the whole multinational trial.
- **National Sponsor**: the first point-of-contact for country-specific questions and responsible for ensuring conformity at national level of the regulatory and good clinical practice (GCP) issues. This ensures an efficient and successful trial as country-specific issues are dealt with at national level: a sponsor of a trial involving 20 Member States will be under severe pressure otherwise due to legal and cultural variations.

Horizon 2020

'Horizon 2020' is the future EU-funded framework programme, the research financial instrument for the period 2014-2020, worth €80 billion Following the Seventh Framework Programme (FP7), Horizon 2020 will implement 'Innovation Union', the new programme for research and innovation in the framework of 'Europe 2020', EU's growth strategy for the next decade.

Research is considered as one of the main areas to be addressed in order to create new growth and jobs in Europe: Horizon 2020 will be complemented by further measures to create the 'European Research Area' by 2014, in order to create a genuine single market for knowledge, research and innovation. Horizon 2020 aims to simplify all research and innovation funding. Through a single set of simpler and more coherent rules, successful applicants will get working more quickly (average time to grant is expected to lower to 100 days, from 350 days under FP7) and there will be a stronger participation of the private sector and Member States in the projects.

Financially speaking, Horizon 2020 is composed of three sections:

- 'Excellent science', with a dedicated budget of € 24,598 million;
- 'Industrial leadership', with € 17,938 million;
- 'Societal challenges', with € 31,748 million.

Only € 8,033 million have been allocated to health research, under the 'Societal challenges' section: this means that there has been a decrease in the financing from 12% of the budget under the Seventh Framework Programme (FP7) to only 10% under Horizon 2020.

This decrease in the health research spending is regrettable, especially considering that, at the same time, non-communicable diseases are the cause of 86% of deaths and 77% of the disease burden in the European regions (source: WHO). While largely preventable through research-intensive treatments, over the next two decades non-communicable diseases will cause an output loss of €35 trillion worldwide.

Investment in biomedical research is essential to tackle European health, societal and economic challenges. Moreover, the return on investment in medical research is significant, it could create employment and improve health, reducing the growing economic burdens Europe faces in the healthcare sector.

The health and biomedical community considers that the EU should adopt a more strategic long-term planning to ensure that scientific discoveries will actually promote better health in our continent. The Alliance for Biomedical Research in Europe (BioMed Alliance) is trying indeed to advance this strategy: representing research-oriented medical societies and more than 200.000 researchers across Europe, it is promoting the creation of a 'European Council for Health Research (EuCHR)' to provide the best strategic scientific leadership to EU programmes in health research and help finalise the Horizon 2020 instrument. Prof. Julio Celis, ECCO's Policy Committee Chair, is leading this initiative on behalf of ECCO. SIOPE is a Founding Member of ECCO, and this is yet another example of how our membership to this federation is beneficial. The oncopolicy activities of ECCO benefit the entire cancer continuum, including those in paediatric oncology.

Member of the European Parliament Maria Graça Carvalho spoke about Horizon 2020 at the SIOPE event in the European Parliament in Brussels marking International Childhood Cancer Day.

ECCO Policy Committee Chair and President of the European Association for Cancer Research (EACR) Julio Celis has been pivotal in advocating for more bottom-up approaches to health research strategies

Europe has a considerable structural innovation gap in health research, lagging behind its competitors. Although the research innovation cycle is long in this field (approximately 10 years), the European research framework programmes mainly focus on short-term collaborative projects of 3-5 years, a fact which often hampered the possibility to translate discoveries made into concrete treatment advancements. For advances in the molecular understanding of a disease to actually improve human health, there is a need for a broad and systematic effort to be made at European level.

Medical disciplines in Europe have traditionally worked independently of each other, but different diseases often share similar basic mechanisms, and thus wasteful duplication of research takes place. Therefore, there is a need to go beyond the current model of individual projects' funding, and move towards a definition of EU research programmes capable of triggering global multidisciplinary partnerships between experts from both the biomedical and non-biomedical field.

In the field of rare diseases, like childhood and adolescent cancer, expert stakeholders must collaborate at a transnational level in order to acquire the critical mass and expertise, due the characteristic nature of diseases that are rare.

Next steps:

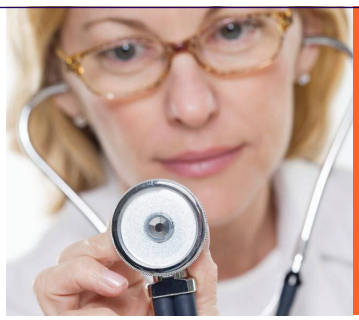
- Ongoing: European Parliament and Council negotiations on EU budget 2014-2020 (including overall budget for Horizon 2020)
- Mid 2012: Final calls under FP7 to bridge gap towards Horizon 2020
- Mid 2013: Adoption of legislative acts by Parliament and Council on Horizon 2020
- 1/1/2014: Horizon 2020 starts, launch of first calls

More information:

- Presentation on Horizon 2020: CLICK HERE
- Innovation Union: CLICK HERE
- Framework Programmes for Research: CLICK HERE
- European Research Area: CLICK HERE
- BioMed Alliance: www.biomedeurope.org

In the Spotlight:

Cross-border Healthcare



In this article, we focus on the new EU Directive that aims to provide clarity about the rights of patients who seek healthcare in another EU Member State and supplements the rights that patients already have at EU level through coordination of current social security scheme legislation.

Trying to tackle "medical tourism", the Cross-border Healthcare Directive (Directive 2011/24/EU of 9 March 2011 on the application of patients' rights in cross-border healthcare) establishes the rules and criteria by which EU citizens are entitled to receive healthcare in any Member State (MS). To ensure patient mobility, enhanced co-operation in healthcare between EU MS is encouraged. The reimbursement of healthcare provided in a MS other than that in which the patient is resident is a key objective of the Directive.

Any MS has to reimburse the costs incurred by an insured person who receives cross-border healthcare (including medicinal products purchased in another MS). Moreover, prescriptions issued abroad will be recognised and, where a medical follow-up proves necessary, the same medical follow-up should be available as would have been if the treatment was provided in its territory. At the same time, any MS should provide healthcare - in accordance with national and EU law, quality and safety standards - together with all relevant information to help patients

make an informed choice. MS are expected to designate one or more national contact points in order to ensure the smooth running of this cross-border healthcare initiative and help patients seeking assistance and advice.

Article 13 of the Directive particularly focuses on rare diseases, encouraging MS to make patients and health professionals aware of the possibilities offered for referral of patients with rare diseases to other MS for treatment (following Regulation No 883/2004) and to cooperate in the development of diagnosis and treatment capacity, e.g. through the Orphanet database. Thus this Directive is likely to be hugely beneficial with patients suffering from rare diseases as they can acquire treatment from the expert of their disease, who could be based in another EU country.

It is clear that the obligation to reimburse costs of cross-border healthcare is limited to healthcare to which the insured person is entitled according to the legislation of his/her MS; it does not apply to long-term care services (e.g. home care services) and to the allocation of organs for the purpose of organ transplants. Finally this Directive does not affect the existing framework on the coordination of social security systems for employed, self-employed persons and members of their families.

Although a set of operating principles are shared by EU health systems, decisions about the mechanisms used to finance and deliver that healthcare must still be taken in the national context. MS are therefore free to decide on the entitlement for a person to enter or reside in the MS to receive healthcare, on the definition of social security benefits and on fundamental ethical choices. Moreover, public health protection can justify restrictions to the freedom of movement, and a MS may provide for a system of prior authorisation for reimbursement when cross-border healthcare involves overnight hospital accommodation of the patient, requires use of cost-intensive medical equipment, or involves treatments presenting a particular risk for the patient or the population.

The Directive is in force since 24 April 2011, but MS have time - until 25 October 2013 - to put into force the laws, regulations and administrative provisions necessary to comply with it. Starting in 2015, and subsequently every 3 years thereafter, the Commission will draw up a report on the operation of this Directive.

More information:

- Text of the Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare: CLICK HERE.
- Text of the Regulation (EC) 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems: CLICK HERE.

French MEP Françoise Grossetête was European Parliament Rapporteur for the Cross-border Healthcare Directive

SIOPE Community Reports and Roundups

Welcome Giulia!

Giulia Petrarulo is the new SIOPE Communication Administrator and has been working in the office since January of this year. Due to the ENCCA project, SIOPE was able to strengthen its Brussels team, with the addition of Giulia. She is providing administrative support in the management of the SIOPE office, mainly but not exclusively for membership, website and event logistics. She also deals with communications and dissemination activities – including EU-funded projects – and organisational support for events.

Giulia holds a Master Degree in European Studies (which she acquired at the Institute of European Studies, ULB in Brussels) and a Bachelor's Degree in International Relations (received from the University of Milan). Previously responsible for the projects' recruitment for the humanitarian NGO Emergency – an activity which involved contact with medical professional associations and the organisation of events – she also worked in Brussels as Junior Programme Fellow for the think tank Carnegie Europe (Carnegie Endowment for International Peace) and as Policy and Research Assistant for the European Centre for Research in Asia, Africa and Latin America.

She always combined her studies with professional activities: working on EU legal and policy affairs for the Performing Arts Employers Associations League Europe (PEARLE), she monitored all EU legislation relevant for the members' interests, created policy reports and liaised with key EU stakeholders. Moreover, she also completed an internship at the Italian Permanent Representation to the EU.

To ensure our increasing activites in policy and communication, we will need to look beyond ENCCA, a short-term EU-funded project.

We are sure Giulia will be a superb asset to the SIOPE office. We now speak English, Dutch, French, Italian, Moroccan, German, Spanish and Irish!

Five years of SIOPE

In November 2012, SIOPE celebrates five years established as an office in Brussels. This may not be a big birthday but for a five-year old child, it is most definitely a celebration!

Current President Ruth Ladenstein, former President Kathy Pritchard-Jones and future President Gilles Vassal at the conference that started the European Standards of Care for Children with Cancer project, now part of the EU-funded European Partnership for Action against Cancer initiative.

The SIOPE statutes were written into law into 2007 by the following 'visionaries':

- Andrea Biondi (IT), first President of SIOPE
- Ruth Ladenstein (AT), current President of SIOPE
- Bruce Morland (UK), former Board Member and Treasurer
- Kathy Pritchard-Jones (UK), former President
- Riccardo Riccardi (IT), former Board Member and Chair of Education and Training Committee
- Mike Stevens (UK), former Board Member

Jocelyne Wang, the first employee of SIOP Europe and Michel Ballieu, CEO of ECCO, celebrate SIOPE's participation at the SIOP conference in 2008.

Over the coming months, we will be looking back at some of the highlights and achievements of the SIOPE office, since its establishment under Belgian law, in 2007.

SIOPE Education and Training

As the Chair of the SIOPE Education and Training Committee I have the pleasure of announcing the launch of the monthly Education E-Blast that will provide you on a monthly basis with all information related to SIOPE educational courses, workshops, congresses and many other educational activities. With the launch of this E-Blast I would like to take the opportunity to encourage you all to to promote your educational activities amongst the Paediatric Oncology Community.

In this first edition of the SIOPE Education E-Blast we took the opportunity to highlight the EU-funded "Oncovideos" project, hosted on the ECCO website – an educational resource for the young oncologists all over Europe who need practice-oriented training. Professor Riccardo Riccardi (Rome, Italy), has developed three paediatric oncology videos for this project illustrating techniques on Bone Marrow Biopsies and Aspiration as well Lumbar Puncture.

- Send all details of educational conferences, courses etc. to Samira Essiaf (samira.essiaf<at>ecco-org.eu, please replace <at> with @).

We strongly encourage you to disseminate this ACOE accredited free E-learning tool amongst trainees and other interested individuals.
(For more information please CLICK HERE.)

Call for "Case Study of the Month"

New this year is the launch of the "Case study of the Month" where specific cases within paediatric oncology are discussed via a free online platform. In particular young investigators are welcome to take part in this unique paediatric oncology platform. The participants to this ECCO-SIOPE-ENCCA initiative, are briefed with background information and are provided with the test chance to put their diagnosis to the test. The author of each study also provides discussion points to clarify the case as well recommending links for further reading. It is noteworthy that SIOPE Case Studies of the Month are ACOE accredited - worth 1 CME credit each, so well worth taking a look. Find out more about ACOE accreditation HERE.

Young investigators are welcome to partake in this unique e-learning platform and avail of the opportunity to showcase their cases online on the ECCO website, gaining a wide audience, not only in paediatric oncology. For more information on the cases and submitting please CLICK HERE or contact the SIOPE office at office<at>siope.eu (please replace <at> with @) for more information

Our Community Profiled

Interview with paediatric psycho-oncologist Dr. Marzena Samardakiewicz

Better outcomes and survival for children and adolescents with cancer is only achieved through a multidisciplinary and multi-professional team working together, with the patient and their family at the centre. The European Standards of Care for Children with Cancer initiative promotes this concept of multidisciplinarity and multi-professionalism, and the role of psychologists, play therapists, and psycho-social care are important partners in the paediatric oncology 'care team'.

In the second of a series of interviews with key personalities from our community, we spoke to Dr. Marzena Samardakiewicz, who works in Lublin, Poland, with Standards of Care project leader Prof. Jerzy Kowalczyk. She has been pivotal in ensuring psycho-oncology is standard practice in her institute and has promoted this important element of treatment in other institutions across Europe.

How did you get involved in psychosocial care? What made you specialise in paediatric oncology?

MS: I have always known that I wanted to be a paediatric psychologist. My daughter's disease pushed my interests into paediatric hematology. I became particularly involved in psychosocial care problems in 1992, when for the first time I took part in the International Society of Paediatric Oncology (SIOP) conference in Hannover, Germany, and in 1993 I took part in the founding conference of the International Confederation of Childhood Cancer Parent Organisations (ICCCPO) in Valencia, Spain.

When I started my work as a psychologist in a newly-created ward of paediatric hematology and oncology in Lublin, Poland (managed by Professor Jerzy Kowalczyk), I became very interested in everything concerning treatment of children diagnosed with cancer. There was a lack of systemic solutions concerning possible forms and methods of psychosocial support for this group of patients. Later, I worked on PhD and rehabilitation studies as well as on creating the Polish Paediatric Psycho-oncology Group.

What are the main challenges in your job?

MS: Now, the main challenge is to find a balance between my many duties, not only the scientific tasks, but also clinic and organisational.

What I would really like to do is to create a strong paediatric psycho-oncology centre in my country. To achieve this, we need to work on adapting assessment methods concerning patient's functioning on different stages of treatment. What I recently find the most interesting are the studies on the biomedical and psychosocial reaction of children and adolescents to indirect effects of treatment, and especially on neuropsychiatric conditions.

What do you love most about your job?

MS: I love direct contact with my patients and their families. I like to observe how well-supported children adapt to all problems connected with hospitalisation. I also like meeting my patients after treatment, when they are just happy and enjoy their life. Moreover, I enjoy teaching students and organising workshops on topics such as communication skills.

How did you get involved with the European Standards of Care for Children with Cancer initiative?

MS: In Poland I started creating planned psychosocial support programmes for children with cancer and their parents. Optimising support methods was the subject of many of my studies. As a result of this, I was considered to be the leader in the paediatric psycho-oncology field. This is why Prof. Jerzy Kowalczyk invited me to participate in the project on creating European standards.

Has the European Standards of Care initiative been helpful to you, your colleagues and of course to patients and families in Poland? If so, how?

MS: To my knowledge, many of the standards within the European Standards of Care Initiative are implemented in our paediatric onco-haematology wards. The idea of standards is very important. Standards as a document are necessary to keep the good direction and continuously improve conditions in which cancer children are treated. The standards should be an important point of discussions, advocacy and

negotiations with institutions which do not provide sufficient resources for psychosocial care.

What would you like to see happen next with the project?

MS: I hope that the Standards will become an official document accepted and implemented in all European countries. They are general enough to enable considering the specifics of every country. It would be interesting to organise questionnaires among patients themselves, to see how, in their assessment, the standards are realised and if they need correction.

Which famous person inspires you? Why?

MS: I admire people who are very passionate about their work. I admire all people who are successful in making their dreams come true as well as in work projects. I was lucky enough to meet a few masters on different stages of my education, who had a huge influence on my work.

Is your job stressful? How do you relax? Any hobbies?

MS: There are stressful moments at my work, but luckily I still have the ability to cope with difficult situations. I like travelling, listening to music and reading. I find gardening and taking care of plants very relaxing. I have been collecting different beautiful objects for a few years now.

What advice would you give to someone who wished to specialise in psychosocial care for young people with cancer?

MS: I keep saying that the paediatric oncology ward is the best place to work for a paediatric psychologist. It is a place for those who like challenges, are patient and can follow their patients even if they are not making fast progress. To be a good psycho-oncologist you need to have the curiosity and openness of a child, to stay flexible in your work and not to stop learning. This is a job for people demanding not only from others but also from themselves.

Rare Cancers Europe meeting

SIOPE President-Elect Professor Gilles Vassal, joined a range of stakeholders from the rare cancer community, to identify solutions on improving clinical research on rare cancers, as part of the Rare Cancers Conference in February in Brussels. SIOPE is a member of Rare Cancers Europe, and Vassal presented the paediatric oncology field in the opening session, entitled 'Clinical Research on Rare Cancers – An Introduction'.

Organised by the European Society for Medical Oncology (ESMO) and Rare Cancers Europe, the Rare Cancers Conference, held on 10 February 2012 in Brussels, provided a multi-stakeholder platform for rare cancer and rare disease experts from across Europe to exchange views and share insights into what can be done to improve the methodology of clinical research on rare cancers.

The first two conference sessions offered an overview of rare cancers and associated challenges for clinical research and drug development and also presented a variety of (potential) solutions as well as best practice examples. Where traditional clinical research approaches are not possible, due to the small numbers of patients, it is particularly challenging to make sure that rare cancer patients are not being left without appropriate clinical research and therapeutic progress.

The third session of the conference therefore also highlighted the need for reaching a broad multi-stakeholder consensus on a set of recommendations on improving the methodology of clinical research on rare cancers. These recommendations will be the product of an ongoing multidisciplinary and multi-stakeholder online consensus discussion, promoted by Rare Cancers Europe. They will focus on best methods, including innovative ones, for clinical research on rare cancers, and rare subgroups of frequent cancers, with the goal of encouraging:

- clinical researchers to exploit innovative solutions for the design and analysis of clinical studies;
- clinicians to exploit innovative solutions for the combination of all available knowledge;
- regulators to accept evidence built through these solutions;
- clinicians' and patients' communities to exploit all forms of

- collaboration to put together as large series as possible for prospective and retrospective clinical and translational research;
- methodologists to advance research into new methodological solutions better fitting the needs of studies on small series

All interested stakeholder groups are encouraged to actively participate in this open discussion, the result of which will be a consensus paper to be publicly presented in autumn 2012. This paper could then be used for related advocacy efforts. All parties interested in joining this discussion are invited to contact Rare Cancers Europe.

A final panel discussion rounded off the Rare Cancers Conference by giving all stakeholders the opportunity to share their respective views on what each stakeholder group can do to help drive clinical research on rare cancers.

To view the full programme, links for downloading the conference presentations and links to available audio webcasts CLICK HERE.

Clockwise from l-r: Ruxandra Draghia-Akli, Director of Health at DG Research and Innovation; Paola Testori Coggi, Director-General for Health and Consumers; Attendees at the European Rare Disease Day Symposium holding hands in solidarity with rare disease patients around the world; Keynote speakers of the event

Rare Disease Day: five years of solidarity

Rare Disease Day is an annual awareness-raising event, taking place both at the international and national level. To mark the 5th anniversary of Rare Disease Day, on 29 February a symposium organised by EURORDIS took place in Brussels and, for the first time, awards for outstanding accomplishments in the field of rare diseases were presented on the same day.

The EU considers a disease as rare when it affects less than 1 in 2000 citizens. However, although individually rare, collectively these diseases affect more than 30 million Europeans. Due to the low prevalence of each disease, knowledge is scarce, resources are limited and patients are often denied the benefits of research.

"Rare but stronger together" was the theme of this now annual event celebrating partnerships between rare disease patients. Several high-level speakers attended the event, including Member of the European Parliament (MEP) Nessa Childers, First Lady of Georgia Sandra Roelofs and representatives from the European Commission, the Director-General of DG Health and Consumers (DG Sanco) Paola Testori-Coggi and the DG Research and Innovation Director for Health, Ruxandra Draghia-Akli.

Some EU-funded projects were later presented, in order to illustrate the added-value of EU action in the field of rare diseases. Projects such as Treat NMD / Care NMD, TAG, EURO WABB and ENERCA aim to increase the available information on rare diseases and to connect all stakeholders, as only a "critical mass" can advocate the necessary improvements in research and patients' quality-of-life.

The new pan-European initiative HeadSmart was launched on Rare Disease Day 2012 to raise awareness of the symptoms of brain tumours in children and young people (see press release here). About 75% of rare diseases affect children, and about 30% of all patients with rare diseases die before their 5th birthday (Source: The importance of rare diseases: from the gene to society, Various Authors, Arch Dis Child, September 2011, Vol. 96, No. 9).

In some European countries mis-diagnosis of young patients can be common (isolated symptoms are sometimes mistaken for common diseases) and a proper diagnosis can take years. For paediatric brain tumours, early diagnosis can make a real difference in outcome and long-term effects, and needs to become a priority in Europe. Coordinated by SIOPE through a partnership between professionals and parents (the SIOP Brain Tumour Group and the International Confederation of Childhood Cancer Parent Organisations (ICCCPO), this formerly UK-based campaign is now set to be rolled out in other EU countries.

Rare Disease Day:
www.rarediseaseday.org

Launch of the HeadSmart pan-European Campaign:
CLICK HERE.

SIOP London 2012

SOCIÉTÉ INTERNATIONALE D'ONCOLOGIE PÉDIATRIQUE
SIOP
INTERNATIONAL SOCIETY OF PAEDIATRIC ONCOLOGY

SIOPE – the European continental branch of SIOP – will hold this year's General Assembly Meeting in London, in the context of the SIOP congress. This international event will be converging at the Barbican Centre to network and share knowledge on research and treatment of all cancer types in children and adolescents.

The 44th Congress of the International Society of Paediatric Oncology, the largest international annual paediatric cancer meeting, will be taking place from 5 - 8 October 2012 at the Barbican Centre, London, United Kingdom. This scientific meeting focuses on all aspects of paediatric oncology and is organised by the International Society of Paediatric Oncology (SIOP) on a yearly basis.

More than 2,000 children's cancer specialists are expected to attend the congress to present and discuss on the latest research and advances in the treatment of all cancer types in children and adolescents.

Not-to-be-missed keynote lectures will focus on a wide range of topics, including comparative cancer registry research, health communication and survivorship, predictive biomarkers, radiotherapy for medulloblastoma, non-coding RNAs, cancer services, radical surgery and clinical trials in low income countries. Evaluation and peer review of the scientific abstracts that will be presented during the Congress is currently ongoing.

Other Congress highlights are the symposia featuring presentations on new technologies for the work of paediatric oncologists. Other symposia will deal with topical subjects such as personalised medicine, genetic susceptibility to childhood cancer, supportive care, immunisation, cancer stem cells and psycho-oncology.

In addition to plenary sessions, there will be associated meetings for paediatric surgeons, radiation specialists, haematologists and specialist nurses involved in both hospital and community-based stages of the cancer pathway.

More information:

- SIOP 2012 www.siop2012.org
- International Society of Paediatric Oncology www.siop.nl

SIOP and World Child Cancer – Twinning

SIOPE supported Prof. Tim Eden's work last September, when he worked with other experts to advocate for childhood cancer at the World Summit on Non-Communicable Diseases (NCDs). Here, in this special article, he discusses twinning programmes and Europe's role between SIOP and World Child Cancer.

Since the 1960's childhood cancer survival has progres-sively increased to 75 – 80% in high-income countries (HIC).

However 80% of children live in low-middle income (LMIC) countries where survival remains stubbornly below 30%. SIOP has consistently advocated the need to raise awareness, improve cancer registration, concentrate expertise in paediatric cancer units and develop twinning between HIC and LMIC.

SIOP Committee on Developing Countries (PODC), restructured in 2010, has developed working groups to promote international collaboration.

Created in 2007 by the International Confederation of Childhood Cancer Parent Organisations (ICCCPO), with SIOP's support, World Child Cancer helps make true the statement that "No child should die unnecessarily". It raises funds to underpin twinning by donating £30 - 40,000 per year (5 years), with an inbuilt strategy to develop long-term sustainability.

There are 7 open projects (Malawi, Colombia, Mexico, the Philippines, Ghana, Mozambique and Cameroon) with an 8th opening early in 2012 (Bangladesh). Partner countries include: the Netherlands, UK, USA, Brazil, South Africa and Canada. Key objectives in all have been: raising professional and public awareness of cancer; reduction in diagnostic delay, treatment refusal, untimely cessation, and toxic deaths; increasing unit capacity, diagnostic precision and speed; family support and overall survival. The creation of data registries, educational and training workshops (in the LMIC) and online conferencing (e.g. Cure4kids.org, Medicines Africa) have been critical components with a guarantee of a consistent supply of affordable drugs (frequently subsidised). Unit refurbishment and development of satellite centres initiatives are also being devised.

The twinning group of SIOP PODC is mapping twinning activity worldwide to identify gaps in support, avoid duplication of effort and try to ensure we reach out to all children worldwide over the next 10 - 15 years. 37 partnerships involving at least 19 agencies/non-govern-mental organisations have so far been identified as assisting in twinning or collaborative therapeutic alliances, but there are more. SIOP PODC and World Child Cancer would together like to hear from anyone involved in a global partnership.

To fund the projects World Child Cancer raises money from parents groups, UK/European Foundations, corporate sponsors and web-based donations amongst others. In 2011, £400,000 was raised to fund the existing projects; over 500 doctors and nurses attended workshops in LMIC countries and we have estimated that since 2009 over 20000 children have been treated within the supported projects. But there remain at least 100,000 children who die "unnecessarily" around the world each year, often undiagnosed or misdiagnosed, without curative therapy and frequently in uncontrolled pain. SIOP and World Child Cancer think that we can and must do better.

Tim Eden
Co-Chair of SIOP PODC Twinning Working Group
Founding Medical Trustee World Child Cancer

More information :

The twinning website:
www.worldchildcancer.org
Contact Tim Eden by e-mail at:
tim.eden<at>edentob.co.uk (please replace <at> with @)

The evolution of Social Media

Companies and organisations all around the world are increasingly realising the need for a social media strategy. A 2010 survey in the US showed that social media adoption by small business owners doubled in 2009 and increased steadily since then: 91% are using at least one social media tool, 80% have a company page on a social networking site, 57% build a network through a site such as LinkedIn and 52% are active on Twitter (Source: www.expansionplus.com). Organisations are therefore encouraged today to take a strategic approach to incorporating social media into their PR and communication plans.

In an increasingly on-line era, driving word-of-mouth at scale and engaging with similar organisations working in the field of childhood and adolescent cancer is fundamental. Several social media can be found online: however, to be present on all of them can be counterproductive, as the quality of the information, the follow up of online posts and conversations, are affected. This is why SIOPE decided to focus on LinkedIn and Twitter, two of the main social media platforms; indeed, we share the spread opinion that "Facebook is good for marketing products to consumers, but it doesn't lend itself to raising awareness of new services for professionals" (Source: bit.ly/GG2UwP).

This year SIOPE launched both a **LinkedIn** Company page and a Group page. LinkedIn pages include basic information on SIOPE, such as the description, the address, and the website. LinkedIn is a good professional tool to raise awareness and encourage engagement on SIOPE's aims, initiatives and important developments, as for instance the new membership process.
From the LinkedIn search box in the navigation bar it is easy to find a page; moreover, when you follow a company or become member of a group, LinkedIn suggests you also how to track developments of similar companies/groups of interest.
Thanks to the SIOPE Company page, today everyone can stay in the loop on our news, events and activities ("status updates"), see an overview of our organisation and the organisations and individuals we are connected to. Moreover, on the section "services" we showcase some information on the ENCCA project and the Case study of the month. Finally, thanks to the "analytics" tab - only visible to the administrators of SIOPE Company Page (SIOPE Office) - we can keep track of who is viewing our page and what content appeals to them.
On the LinkedIn Group page, SIOPE members and connections can launch a conversation or a poll about a specific topic, have an active part in determining the top discussions by liking and commenting, see both member-generated discussions and news and find interesting discussions in a given professional field by seeing who liked a discussion and how many people commented. While the company page is visible to everyone, to see the SIOPE Group page you have to be a LinkedIn member and to be accepted by the SIOPE Office.

Twitter is a real-time information network that connects people to the latest stories, ideas, opinions and news, tailored on individual interests and tastes. At the heart of Twitter are small pieces of information called "tweets". Each tweet is 140 characters long: however, they can include links, photos, videos and conversations, and the message shortness makes Twitter very easy to use on mobile devices. Like countless individuals, businesses and international organisations, SIOPE uses Twitter to share information with people interested in its initiatives, to gather feedback and build relationships with other cancer-related organisations and partners. Interestingly enough, as researchers from the Centers for Disease Control recently demonstrated, billions of Tweets taken together can unlock insights to our public health (see http://stories.twitter.com/en/public_health.html).

With just a tweet, millions of people can learn about and show their support for positive initiatives that might have otherwise gone unnoticed.

That is why SIOPE thinks social media can be an optimal channel to make the voice of the paediatric oncology community, professionals, parents and cancer little patients, finally heard.

Links to SIOPE Social Media pages:

LinkedIn Company page:
linkd.in/GSxX8Q

LinkedIn Group page:
linkd.in/GQtwMK

Twitter page:
twitter.com/#!/SIOPEurope

News bites

Standards now in Multiple Languages

The European Standards of Care for Children with Cancer, part of the European Partnership for Action against Cancer initiative (www.epaac.eu) are now available for download in 6 languages – English, Greek, Portuguese, Spanish, Serbian and Polish, with more translations expected in 2012! To view, CLICK HERE.

The Importance of Partnership

SIOPE has presented at the International Confederation of Childhood Cancer Parent Organisations (ICCCPO) Europe meeting, in Luxembourg in April. Both SIOPE President Ruth Ladenstein and Edel Fitzgerald from the office will be making presentations on ENCCA and the need for increasing collaboration between parent/ patients and professionals. For more information on ICCCPO CLICK HERE.

SIOPE General Assembly in London!

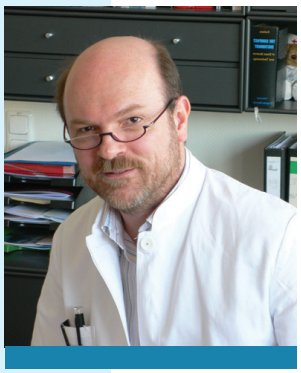
We are delighted to announce that the 2012 SIOPE General Assembly will take place at the SIOP London conference. We look forward to seeing you at the Barbican on Monday 8 October (11:20 – 12:50) in the Fountain Room! For more information, please contact the SIOPE office at office<at>siope.eu (please replace <at> with @).

Case study of the month March/April 2012

We are pleased to announce that the March/ April 2012 Case Study of the Month - hosted on the ECCO website - is online. The cases focus on specific and new treatment protocols within Paediatric Oncology. More specifically, the theme of this edition is 'prolonged fever and abnormal liver function in a 9-year-old girl'. For more information please contact Ms. Samira Essiaf, SIOP Europe Secretary General, at the following e-mail address: office<at>siope.eu (please replace <at> with @)

Treasurers Corner

The SIOPE Fundraising Committee, led by fellow Board member David Walker and I, have been steadily working with SIOPE President Ruth Ladenstein and the SIOPE office to initiate the creation of SIOPE membership for European national societies/ groups. This has involved systematically identifying the chairs of these groups and contacting them personally to query their interest in such an offer of automatic membership of their members to SIOPE. Currently an amount of 20€ per member within a society is under discussion and would be a basis to calculate the society contribution.



The majority of societies have responded at this stage and are generally very positive to the idea. Of course some European countries do not have established societies or groups and in this case institutional membership could be a possibility. The statutes of SIOPE will also need to be updated – this is going to be a complex process to legally explain this new scenario for SIOPE.

There are many advantages to being part of the SIOPE community: firstly in our field, more than most, the added-value of working at pan-European level is clear. None of our disciplines can work in isolation and SIOPE ensures that connections are built and maintained through our many activities. SIOPE is a Founding Member of ECCO – the European CanCer Organisation, which naturally opens many doors for the paediatric oncology community, including the opportunity to lead on a special 'track' in the largest cancer congress of its kind in Europe. It also allows us to bridge the current gap between adult and paediatric oncology and in the era of personalised medicine/ genomics, we need to learn from each other and move forward in a constructive way, rather than working in isolation. SIOPE has also solidly been working with the rare disease /rare cancer community across Europe and, in the near future, will build links with the European paediatric community.

It is only by collaborating and networking that we can move forward and ensure our issues are addressed. Another important step for SIOPE has been our linkage with the International Confederation of Childhood Cancer Parent Organisations (ICCCPO). Initiated through the ENCCA project, we have been linking with this important partner on other topics, such as early diagnosis (HeadSmart campaign), improving standards of care and outcome particularly in central and eastern Europe (European Standards of Care for Children with Cancer) and, of course, the ever challenging EU Clinical Trials Directive.

At the EU political level, there is no other organisation active in our field to date that provides the same expertise, experience and contacts. We have had three events in the European Parliament to date, with more expected; we are meeting Members of the European Parliament, health and research Ministries and the European Commission regularly now, through SIOPE's connections.

But without the support of the SIOPE office and its structure, it is apparent to me that we have a lot to lose. The office is already under-resourced, despite the involvement in EU projects, and we need sustaining support in order to move forward and accelerate our activities on your behalf.

Hopefully you will be informed about the need to join SIOPE membership at your annual meeting and/ or by the Chair of your group/ society. I hope you will fully support this cause, the details of which will be elaborated at SIOPE's General Assembly in London. See you there!

Martin Schrappe

Upcoming Events

THE RACE OF BRAVE BIKERS, ITALIAN BIKE RACE FOR LONG-TERM SURVIVORS
05-06 May 2012, Marostica, Italy
CLICK HERE for more details

9TH PANCARE ANNUAL MEETING
10-13 May 2012, Romania
CLICK HERE for more details

IPSO SYMPOSIUM AND APSA CONGRESS
19-23 May 2012, San Antonio, USA
CLICK HERE for more details

PRACTICAL, CLINICAL, RADIOLOGICAL AND PATHOLOGICAL DIAGNOSIS OF SKELETAL TUMOURS
21-23 May 2012, Leiden, Netherlands
CLICK HERE for more details

48TH ASCO (AMERICAN SOCIETY OF CLINICAL ONCOLOGY) ANNUAL MEETING
01-05 June 2012, Chicago, USA
CLICK HERE for more details

ADVANCES IN NEUROBLASTOMA RESEARCH CONFERENCE 2012
18-21 June 2012, Toronto, Canada
CLICK HERE for more details

15TH INTERNATIONAL SYMPOSIUM ON PEDIATRIC NEURO-ONCOLOGY (ISPNO)
24-27 June 2012, Toronto, Canada
CLICK HERE for more details

TEENAGE CANCER TRUST'S CONFERENCE ON TEENAGE AND YOUNG ADULT CANCER MEDICINE
25-26 June 2012, London, United Kingdom
CLICK HERE for more details

FLIMS 14 - JOINT ECCO/AACR/EORTC/ESMO WORKSHOP ON METHODS IN CLINICAL CANCER RESEARCH
23-29 June 2012 Waldhaus Flims, Switzerland
CLICK HERE for more details

44TH CONGRESS OF THE INTERNATIONAL SOCIETY OF PAEDIATRIC CANCER (SIOP)
05 - 08 October 2012, Barbican Centre, London, United Kingdom
CLICK HERE for more details

SIOPE GENERAL ASSEMBLY
08 October, SIOPE General Assembly, London, UK
CLICK HERE for more details

EUROPEAN CLINICAL RESEARCH COUNCIL (ECRC) MEETING
08 October, SIOPE General Assembly, London, UK
CLICK HERE for more details

6TH INTERNATIONAL SYMPOSIUM ON CHILDHOOD MYELODYSPLASTIC SYNDROME AND BONE MARROW FAILURE SYDROMES IN CHILDHOOD (EWOG MDS)
07 - 09 October 2012, Diplomat Hotel, Prague, Czech Republic
CLICK HERE for more details

ITCC GENERAL MEETING
18 -19 October, Institut Curie, Paris, France
CLICK HERE for more details

4TH ESO-SIOP EUROPE MASTERCLASS IN PAEDIATRIC ONCOLOGY
24 November - 29 November 2012, Castel Gandolfo (Rome), Italy
CLICK HERE for more details

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 view previous newsletters go to www.siope.eu

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

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