

Upcoming events

SIOPE Congress 2013

25-28 September 2013 - Hong Kong, China

17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress

27 September - 1st October 2013 Amsterdam, The Netherlands

2nd European Bone Sarcoma Networking Meeting on 'Integration of clinical trials with tumour biology'

26-27 September 2013 - Leiden, The Netherlands

Children without Cancer Run/Walk, 2nd edition 29 September 2013

Domaine National de Saint-Cloud, France

Meeting of the European Clinical Research Council for paediatric oncology (ECRC)

30 September 2013 - Amsterdam, The Netherlands

Online Post Graduate Certificate in Cancer Care for Teenagers and Young Adults

From 30 September 2013 - Coventry, UK

MSC Cruise - PanCareSurFup-PanCare event 'Against Leukaemia There Are Still Routes That Should Be Explored'

24 October 2013 - Genoa, Italy

BDA Paediatric Workshop 'Improving oncology drugs development for children and adolescents'

18-19 November 2013 - Paris, France

7th International Conference on Children's Health and the Environment

20-22 November 2013 - Jerusalem, Israel

Training Course 'Paediatric Oncology for Cancer Registries'

25-29 November 2013 - IARC, Lyon, France

2013 ESTRO Paediatric Radiation Oncology course

5-7 December 2013 - Brussels, Belgium

ENCCA General Assembly

15-17 January 2014 - Vienna, Austria

Message from the President and the Office

SIOPE Europe's Community

Promoting better policies for children with cancer

- Update on the *Clinical Trials Regulation*
- Paediatric Regulation: Has there been a progress on medicines for children?

EU Project Updates

- Horizon 2020: Time to pair research with innovation

Latest News from EPAAC

- Survey on the Standards of care for children with cancer: well on track!

Latest News from ENCCA

- First Announcement ENCCA General Assembly
- ENCCA Symposium 'Clinical research in 2013: Burning issues'
- A virtual institute for paediatric oncology research: ENCCA Work Package 3 and 'ABCD-4 E'
- LINES neuroblastoma clinical trial: An ENCCA achievement
- The views of TYA with cancer: ENCCA Work Package 17 survey

Latest News from PanCareSurFup

- PanCareSurFup cruise event: There are still routes to explore

Our Community Profiled

- Paediatric Oncology in Europe: From national activities to pan-European research approaches

Special Features

- ExPO-r-Net: SIOPE's new EU project
- SIOPE and SIOPE as European branch: recent developments

SIOPE Courses and Workshops

- Paediatric Oncology at the European Cancer Congress
- Come to Paris and join the discussion on drug development for children with cancer in Europe

Parents & Patients news

- Cooperation necessary for better results in paediatric oncology care
- Meeting of the ENCCA Parent and Patient Advocacy Committee (PPAC)

About us

Message from the President and the Office

Our President, Prof. Gilles Vassal, provides a short overview on the recent achievements of SIOPE and the 'hot topics' we are currently working on in order to further progress in the improvement of research and cure of children and adolescents with cancer.



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SIOPE Europe's Community Promoting better policies for children with cancer

Update on the EU Clinical Trials Regulation

SIOPE has been proactively engaged in advocating effective changes to European clinical trials legislation. Last year, the European Commission has proposed a new EU Clinical Trials Regulation (CTR), which aims to address many of the problems clinical trialists face in their daily work. Our Society still has something to say as concerns this Regulation, currently in the last phase of the EU decision-making process.



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Paediatric Regulation: Has there been a progress on medicines for children?

Each year, more than 3,000 children and adolescents die of cancer in Europe and, to date, they have been denied access to the many truly innovative anticancer therapies developed for the treatment of adult cancers. Although the Paediatric Regulation paved the way to improve this situation, there is still an urgent need to speed up the development of safe and effective therapies for children and adolescents with cancer.



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EU Project Updates

Horizon 2020: Time to pair research with innovation

In 2014 the new Framework Programme for research of the European Union will kick off: for over 3 years Horizon 2020 has been prepared by policymakers and it is finally about to see the light.



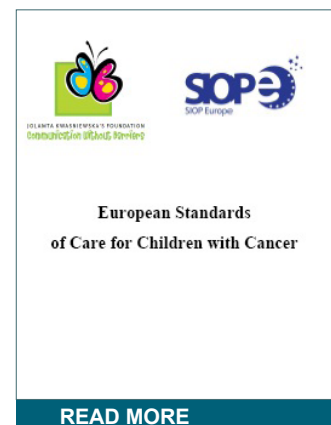
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■ Latest News from EPAAC



Survey on the Standards of care for children with cancer: Well on track!

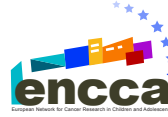
As part of the European Partnership for Action Against Cancer project, experts from 31 European countries provided comprehensive responses to the survey on the 'European Standards of Care for Children with Cancer'. Assessing the quality of treatment and care received by young cancer patients, this country-by-country analysis will provide essential information to address the current health inequalities across different European states. We are very glad of this high rate of responses to the survey questionnaire from outstanding experts (almost 89% of the total contacted), and we will proudly present you the preliminary results at the SIOPE General Assembly on 29 September 2013 in Amsterdam.



European Standards
of Care for Children with Cancer

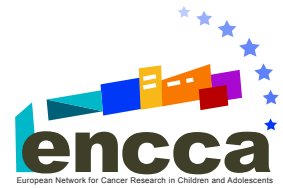
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■ Latest News from ENCCA



First Announcement: ENCCA General Assembly

Ruth Ladenstein, ENCCA project coordinator, is very glad to announce that the third annual General Assembly meeting will be held in Vienna on 16-17 January 2014. The whole ENCCA community, the stakeholders and the collaborators are invited. The event will be associated to an ECRC meeting. The preliminary program, details and registration modalities will be available at the beginning of October on the ENCCA website (www.encca.eu).



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ENCCA Symposium 'Clinical Research in 2013: Burning Issues'

The Symposium on 'Clinical Research in 2013: Burning Issues' organised by ENCCA last 6th June in Vienna was a great success. All presentations from the 14 high-level speakers promoted very interesting discussions and exchange of opinions that will surely lead to new collaborations in the field of paediatric oncology research.



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A virtual institute for paediatric oncology research: ENCCA Work Package 3 and 'ABCD-4-E'

The ENCCA Work Package 3 'Establishment of the Virtual Institute information portal' aims to create an infrastructure that will meet the specific needs and requirements of the European paediatric oncology research community. Since the ENCCA website is now available, all efforts will focus on the design, implementation, and evaluation of ABCD-4-E (Advanced Biomedical Collaboration Domain for ENCCA)



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LINES neuroblastoma clinical trial: An ENCCA achievement

Neuroblastoma is the most frequent childhood solid (extracranial) tumour, and represents 8-10% of all cancers in children. LINES, an international clinical trial stemming from the ENCCA project (Work Package 10) focuses on this specific disease.



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The views of TYA with cancer: ENCCA Work Package 17 survey

Improving access to care and ensuring timely diagnosis is essential for teenagers and young adults (TYA) with cancer. This is why ENCCA Work Package 17 promotes healthy lifestyles for survivors and aims to develop a large European network of support groups, organisations and active patient/survivor groups that work on TYA issues. Its latest initiative is a survey to assess the point of view of TYA current and former patients, whose results will impact the future healthcare and research priorities in Europe.



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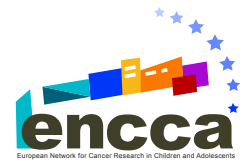
■ Latest News from PanCareSurFup

PanCareSurFup cruise event: there are still routes to explore

About 1,200 invited guests are expected to attend a high-level event taking place on a cruise boat in Italy next 24-25 October. Aiming to raise funds to carry out research studies into late effects of cancer treatment as well as leukaemia, this event represents a unique opportunity to inform the general public on what the PanCareSurFup project is doing to support long-term cancer survivors.



Our Community Profiled



Paediatric Oncology in Europe: From national activities to pan-European approaches in clinical and translational research

To better tackle the challenges of treating childhood cancer, paediatric oncologists conducting multicentre and cooperative clinical trials joined their forces during the last 50 years, progressively from the national to the continental level. Today, SIOPE effectively represents their unified and strong voice in Europe.



Special Features

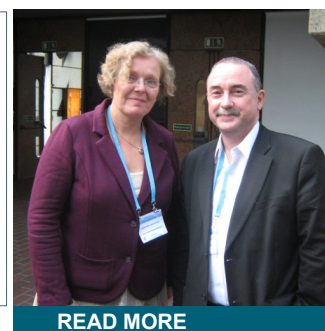
ExPO-r-Net: SIOPE's new EU project

SIOPE joined forces with other 32 high-level partners from all over Europe to build a new European Reference Network for paediatric oncology. The ExPO-r-Net project proposal is the result from these strenuous joint efforts, and it aims to reduce the current inequalities in childhood cancer healthcare access and provision in the different European countries. Recently recommended for funding, it will probably be our next project in the pipeline!



SIOP and SIOPE as European branch

Apart from being one of the founding members of ECCO, SIOPE (paediatric oncology in Europe) is also the continental branch of SIOP International (paediatric oncology at the global level). Each one representing its members and advocating the issues that are inherent to its specific geographical scope, SIOPE and SIOP are today two cooperating partners in a global effort to advance research, treatment and care for young people with cancer.



SIOPE Courses and Workshop

Paediatric Oncology at the European Cancer Congress

SIOPE is delighted to invite you to the European Cancer Congress, the largest multidisciplinary and multi-professional oncology congress in Europe. At the Congress, the SIOPE Paediatric Track will feature outstanding speakers from our community. Moreover, this unique event will also host the General Assembly of SIOPE, as well as the SIOPE Lifetime Achievement Award ceremony. From 27 September to 1 October 2013, come and find us in Amsterdam!



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Come to Paris, and join the discussion on drug development for children with cancer in Europe

Aiming to provide better medicines for children, the EU Paediatric Medicines Regulation came into force in 2007. Based on incentives for pharmaceutical companies, it tried to increase the development of drugs for paediatric diseases with no expected direct return on investment. In 5 years however the Regulation did not improve the access to anticancer drugs for children: you are all invited to the BDA Workshop in Paris in order find solutions to redress this situation.



[READ MORE](#)

Parents & Patients' news

Cooperation necessary for better results in paediatric oncology care

Attracting more than 50 parents and survivors from 18 different European countries, the 4th Europe-wide ICCCPPO-meeting took place last 24-26 May in Basel. It was a unique occasion for childhood cancer patients, survivors and parents from all over Europe to be updated on the most important developments in our community, as well as to strengthen their common links and better advocate at the European level



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Meeting of the ENCCA Parent and Patient Advocacy Committee (PPAC)

Taking place on 11-13 July 2013 in Sarajevo, the last Meeting of the ENCCA Parent and Patient Advocacy Committee (PPAC) helped the Committee to better define its priorities for the future.



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About Us



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



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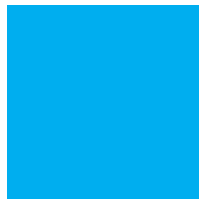


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Message from the President and the Office

Our President, Prof. Gilles Vassal, provides a short overview on the recent achievements of SIOPE and the 'hot topics' we are currently working on in order to make further advances in the improvement of research and cure of children and adolescents with cancer.

In just a few days, the most important meeting of the year is going to start! At the **European Cancer Congress (ECC 17)**, the major biannual event that all of us working in paediatric oncology really cannot miss, you will have the chance to present or be informed about the most recent discoveries, results and innovative treatments that will help improve the cure-rate and the quality-of-life of all childhood cancers' patients.

I really hope to see all of you in Amsterdam, where we will exchange views and experiences on topics such as the biological basis of personalised cancer therapy, the experience of cancer for teenagers and young adults and the 'survivorship passport' initiative developed within our community. Moreover, we will discuss the common challenges encountered within clinical trials, the existing EU funding opportunities for research, as well as the topics of targeted drugs and personalised medicine in paediatric oncology. Most of these inspiring sessions are part of the Paediatric Track of the Congress, which we prepared with great care in order to update you on the most relevant topics which will impact the future of our discipline.



As a Founding Member of ECCO, our Society will have a visible presence and we will also hold our annual General Assembly during this major event. We strongly encourage you to assist to the **SIOPE General Assembly**, where we will inform you on our past and current activities, including the advances in the dissemination of the Standards of Care for Children with Cancer in Europe and the latest developments concerning the Clinical Trials Regulation. On this occasion we will also inform you on how our community has considerably grown: since last year, when we started our new **membership** model, more than 800 paediatric oncology professionals from 22 European countries (both inside and outside the EU) decided to join our Society. This has been possible thanks to the kind cooperation of all the national paediatric oncology societies, who understood the added-value of working at pan-European level in our field and showed their interest in joining a bigger community.

At the General Assembly we will introduce the new members of the **SIOPE Board**, as well as a new staff member of our office. Unfortunately, after 4 years working for SIOPE, Ms. Edel Fitzgerald made the decision to move to another job position.

I would like here to deeply **thank Edel** for the great work she performed in SIOPE: many of the outstanding results we have achieved, in particular as concerns the revision of the Clinical Trials Regulation, simply prove that our Society would not have reached the same level of high and wide-spread consideration it has today without her dedicated efforts, and I am sure that her professionalism will be equally valued in the future.

After a competitive selection procedure, SIOPE recently hired Mr. **Francesco Florindi** from Italy who, with his enthusiasm and motivation, will greatly continue the SIOPE's efforts in advocacy and EU public affairs.



Last but not least, I am very proud to announce that a new European project is in the pipeline: **EXPO-r-Net**. Since the publication of the [DG Sanco](#) call at the beginning of this year, which was inspired by our European Standards of Care, SIOPE has been consistently involved in the creation of this “European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment”. EXPO-r-Net has now been recommended for funding and, although the award decision will arrive only in October (we are now in the negotiations phase), it was rated the highest score. EXPO-r-Net will pilot the implementation of the [EU Directive on the application of patients' rights in cross-border healthcare](#)) in paediatric oncology. The project will create European Reference Networks by linking paediatric oncology centres of excellence, in order to help patients and their families to access paediatric cancers' treatment and care in the most effective and less costly way, addressing thereby the existing inequalities in Europe. We could achieve this impressive result only thanks to the hard joint efforts of our partners, outstanding and dedicated experts from the paediatric oncology community: together, we can make the difference in Europe, and ensure the best possible outcome for all children with cancer.

Update on the EU Clinical Trials Regulation

SIOPE has been proactively engaged in advocating effective changes to European clinical trials legislation. Last year, the European Commission has proposed a new EU Clinical Trials Regulation (CTR), which aims to address many of the problems clinical trialists face in their daily work. Our Society still has something to say as concerns this Regulation, currently in the last phase of the EU decision-making process.

The European Parliament and Council are reviewing the legislation and providing [amendments](#) to the Commission's proposal. To date, SIOPE has also proposed [its amendments](#) to this piece of legislation, which mainly focus on three simple messages:

- 1) **Fair and proportionate risk categorisation** of childhood cancer trials, where the use of medicinal products is often outside the terms of the marketing authorisation (off-label use) but is based on high-level expertise, standard practice and decades of success.
- 2) **Fair insurance for academic trials treating children with rare diseases**, secured through 'national indemnity schemes'.
- 3) **Fair and proportionate transparency measures**, with provisions for reasonable and secure reporting that protects young cancer patients and their personal data.

European Parliament discussions: update



SIOPE President, Prof. Calaminus, together with MEP Willmott and SIOPE Past President, Prof. Ladenstein

On 29 May, the Committee in the European Parliament focusing on the EU CTR discussions, ENVI, strongly supported the amendments of the Rapporteur, MEP Glenis Willmott. You can find this report [here](#): we strongly recommend you review it and see how the amendments could affect your daily practice. A feedback on your assessment of the amendments is important: please e-mail office<at>siope.eu (please replace <at> with @) with your comments, we will work closely with Ms. Willmott in the coming months to ensure our needs are taken into account.

Member States (Council) discussions: update

The EU Presidency led by Ireland finished on 30 June and is now handed over to Lithuania, who will preside over the CTR negotiations until the end of 2013. Many of the critical issues related to the simplified centralised procedure, timelines, ethics committees, 'what is standard practice' and insurance have been debated already amongst national governments.

More information on the EU Clinical Trials Regulation and how you can help will be provided at the European Clinical Research Council meeting in Amsterdam (30 September 2013, 17h-19h)!



REGULATE TO MEDICATE!
The EU Clinical Trials Regulation:
Improving clinical research for children and adolescents in Europe?

The paediatric oncology community calls for a pragmatic approach to trial governance for children and adolescents with cancer in Europe.

SIOPE and ENCCA call for:

- **FAIR and proportionate risk categorisation of childhood cancer trials** where the use of medicinal products is often outside the terms of the marketing authorisation (off-label use), but based on high-level expertise, standard practice and decades of success
- **FAIR insurance** for academic trials treating children with rare diseases **secured through 'national indemnity schemes'**
- **FAIR and proportionate transparency measures**, with provisions for reasonable and secure reporting that protects young cancer patients and their personal data

To enhance and optimise paediatric clinical research through the EU Clinical Trials Regulation, SIOPE and ENCCA will continue to call for legislation that **reflects well the realities of academic research and can help improve research for young people with cancer in Europe.**

  For more information contact:
SIOPE Europe – European Society for Paediatric Oncology (SIOPE) www.siope.eu; office@siope.eu
ENCCA – the European Network for Cancer research in Children and Adolescents; www.encca.eu
Funded by the European Union's Seventh Framework Programme (FP7/2007-2013) under the project ENCCA, grant agreement HEALTH-F2-2011-261474

Paediatric Regulation: Has there been a progress on medicines for children?

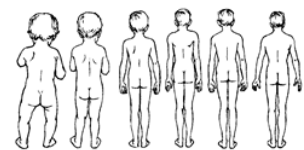
Each year, more than 3,000 children and adolescents die of cancer in Europe: to date, they have been denied access to the many truly innovative anticancer therapies developed for the treatment of adult cancers. Although the Paediatric Regulation paved the way to improve this situation, there is still an urgent need to speed up the development of safe and effective therapies for children and adolescents with cancer.

Extremely **innovative drugs** with new mechanisms of action – targeting intra-tumour molecular pathways and the immune system – have been successfully developed in adults. These drugs represent major opportunities to improve the cure rate and the quality-of-cure of young people and, most importantly, they represent hope for patients and parents. This is why 10 years ago the [ITCC](#) (Innovative Therapies for Children with Cancer) network was created to engage in new, biology-driven paediatric oncology drug development in Europe, in collaboration with the existing European tumour groups within SIOPE. Experts in several diseases such as neuroblastoma (through the [SIOPE-NET](#) group), leukaemia (through [I-BFM](#)) and soft tissue sarcomas (coordinated by [EpSSG](#)) partnered with pharmaceutical companies to accelerate drug development initiatives. Over 10 years, 600 children participated to early phase trials of new oncology drugs in Europe, yet the vast majority of patients with a non-curable malignancy have been denied access to new drugs under evaluation.

Are Children Different ?



„ Children are not miniature adults“
...from a clinical trial operational point of view either



Heterogeneous in many aspects!

20% of the European Population
100 Millions < 18 Years !

In 2007 the European Commission launched the [Paediatric Medicines Regulation](#) to encourage pharmaceutical companies to study their drugs in the paediatric population when there is a need for it. This Regulation changed the field of paediatric oncology drug development, by creating more opportunities for interactions with the pharmaceutical industry. However, the needs of children with cancer have not been adequately addressed so far, as the Regulation has not yet succeeded in increasing the number of new paediatric oncology drugs in Europe.

One of the main reasons is that the Regulation inappropriately waives the paediatric development of drugs of major interest for paediatric malignancies, because the adult condition does not exist in the paediatric population, although its mechanism of action is perfectly relevant for a paediatric use. For instance, the 'Crizotinib' drug is indicated for the treatment of a specific type of lung cancer, ALK (anaplastic lymphoma kinase) positive non-small cell carcinoma. As lung cancer does not occur in children, its paediatric development was waived by the European Medicine Agency ([EMA](#)), in agreement with the law. However, ALK is a key oncogene which can be found altered in paediatric anaplastic lymphoma, as well as in neuroblastoma, and an academic early phase trial in the US showed more than 80% complete response in lymphoma. Nevertheless, during the last three years, European children and adolescents have been denied access to Crizotinib.

Last June the European Commission published a [Report on the first five years of the Regulation](#), following a "[Public consultation on the experience acquired with the paediatric regulation](#)". The report concluded that the situation for young patients greatly improved, and that paediatric development has become a more integral part of the overall development of medicinal products in the EU. However, the report did not propose changes in the implementation of the regulation to address the specific issues in paediatric cancers raised by Health Professionals and Advocacy groups, considering that the Orphan Medicine Regulation is more appropriate to deal with the rare paediatric malignancies.

Based on their considerable experience in the field, both [SIOPE](#) and [ITCC](#) reacted to this **Public Consultation** by explaining that – although the pharmaceutical industry now consider paediatric development to be an integral part of the overall product development – the number of new paediatric oncology drugs available for clinical research remains very low in Europe, with a 10-fold difference if compared to the US. This situation entails major **safety, ethical and societal concerns** for childhood cancer patients and their families. One of the major consequences of this situation is that, when a new drug is not available in a clinical trial, European paediatric oncologists are often compelled to prescribe it 'off-label' for a given child or adolescent. When a drug is given outside a clinical trial, toxicity and efficacy data are not collected according to a protocol and secure evidence that children are not exposed to unacceptable risks. Finally, parents are often tempted to go to the US to have their child participate in clinical research studies that use more innovative drugs.

There is a major need to increase access to innovative drugs for children and adolescents with cancer in Europe, and the European paediatric oncology community is ready to run new, high-quality drug development programmes. Collaboration to study new drugs in very rare paediatric cancers has been already set up with the US, Canada and Australia.

There is a major need to increase access to innovative drugs for children and adolescents with cancer in Europe, and the European paediatric oncology community is ready to run new, high-quality drug development programmes. Collaboration to study new drugs in very rare paediatric cancers has been already set up with the US, Canada and Australia.

In conclusion, the EU Paediatric Medicines Regulation should be urgently modified in order to find solutions to better address patients' needs. This is why SIOPE is delighted to be associated with [BDA](#) (Biotherapy Development Association) in a [Paediatric workshop](#), which will allow experts from our community – as well as regulators, policymakers, parent and patient advocates and representatives from industry – to discuss strategies to improve oncology drug development for children and adolescents in Europe. Taking place on 18-19 November in Paris, this meeting is also being organised in association with [ENCCA](#) and [ITCC](#).

More information:

BDA-SIOPE-ENCCA-ITCC Workshop '[Improving oncology drug development for children with cancer](#)': 18-19 November 2013, Paris, France

BDA website, www.bdaoncology.org

ENCCA website, www.encca.eu

ITCC website, www.itcc-consortium.org

Horizon 2020: Time to pair research with innovation

In 2014 the new Framework Programme for research of the European Union will kick off: for over 3 years Horizon 2020 has been prepared by policymakers and it is finally about to see the light.

30 years of European successes

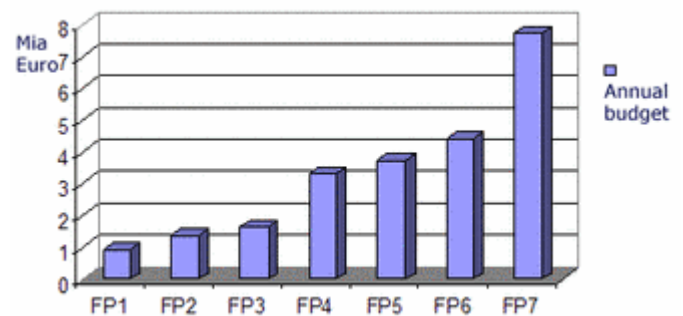
In 2014 the new EU Framework Programme for research will kick off: Horizon 2020 has been moulded by policy makers for over 3 years and it is finally about to see the light. Formerly called 'framework programme' (FP), 2014 will also mark the 30th anniversary of this famous financial instrument set up by the EU to support and sustain scientific research at the European level. The longevity of the programme is remarkable. Few other EU initiatives managed to last in time as long as the FPs. Some of them, like the financing of the [JRC](#) and [Euratom](#) programmes, even converged in the bigger FPs' pot, further demonstrating its growing importance.

Before analysing the future of this kind of programmes, it is worth having a look at their development. A fairly trustworthy perspective comes from the analysis of the budget allocated by EU Member States to research programmes. It is no secret that politically sensitive initiatives manage to attract more conspicuous EU budget lines, despite their effectiveness. One example over all: the famous Common Agricultural Policy still freezes an enormous part of the EU budget, although its functioning and rationale are more of an inheritance of the past rather than a need for the new EU. What about research? Did research attract enough funding at the EU level?

The graph below compares the average annual budget of the first seven Framework Programmes: as you can see, it scaled up almost 8 times in just three decades.

The FP7, with its 55.8 billion EUR budget, almost tripled its predecessor (FP6, 19.3 billion EUR). We can assume therefore that the importance of pan-European and multidisciplinary research projects increased year after year, FP after FP. Allocating more and more euros to the FPs, Member States awarded what is, in fact, one of the biggest added values of the European Union: its unparalleled research programme.

Notwithstanding the several political crisis and stalemates experienced by the EU across the last thirty years, FPs' budgets kept growing steadily, making FP7 the largest research programme worldwide, ever. Until Horizon 2020 will be launched.



Even though the economic crisis hit hard all EU economies, the eighth FP (Horizon 2020) will be provided with a budget of around 70 billion EUR, approximately 20% more than the FP7.

This is impressive, especially considering that this happens at times when, for the first time since the creation of the European Economic Community in 1958, the overall budget of the organisation will decrease compared to the previous budgetary period. The 2014-2020 Multiannual Financial Framework (MFF), i.e. the EU documents setting up size and composition of the EU budget, is likely to allocate fewer resources than the 2007-2013 MFF. This unprecedented compression of EU budget however should not hamper Horizon 2020.

Details to be discussed

So far, we discussed Horizon 2020 with approximate estimations. Unfortunately, we are not able to provide more accurate figures on the exact amount of money that will be devoted to research.

The MFF is currently being discussed and, in official documents, the various budget lines are not expressed in EUR but in percentage of the total budget. These number results from the long, tense negotiation between the European Parliament and the Council of the European Union on the original European Commission's proposal and no final agreement has been reached.

As imaginable, the European Parliament is calling for a higher budget, which would guarantee the EU the resources to keep sustaining integration among the Member States and support of the fundamental EU policies. On the other hand, Member States are eager to decrease expenditures.

This panorama is further endangered by the novelties brought by the Lisbon Treaty, which reformed the rules governing the EU. In particular, it amended the way legal acts of the EU (such as the MFF) are adopted: the Lisbon Treaty extended the [codecision procedure](#) – which implies the perfect agreement by both the European Parliament and the Council on a legal text – to more policy areas. The 2014-2020 MFF is the first EU budget to be voted upon following the codecision procedure: before the entry into force of the Lisbon Treaty in 2009, the European Parliament had a merely consultative role, while the final decision resulted solely on the Council. As imaginable, given the economic crisis and the still-to-be-experimented new procedure, the negotiations resulted particularly difficult. However, we expect the European Parliament and the Council to reach an agreement by the end of the year. So far, the Council unanimously approved its proposal, amounting to 959.99 billion EUR (still inferior to the European Parliament *desiderata*).

Horizon 2020 vs FP7

Horizon 2020 renovates the concept of Framework Programme both in the content of the future calls as well as in the way the programme rolls out. We can see the main differences between FP7 and Horizon 2020:

- 1) The structure of the programme;
- 2) The application procedure.

The principal difference you would notice is the fact that Horizon 2020 is not sub-divided in macro-thematic blocks. Horizon 2020 unifies three old programmes: FP7, the Competitiveness and Innovation Framework Programme ([CIP](#)) and the EU contribution to the European Institute of Innovation and Technology ([EIT](#)). For this reason, Horizon 2020 is structured around **3 main priorities**:

- 1) **Excellent science**: here we can find tools sustaining European leadership in breakthrough scientific **basic research**. It comprises the activities of the European Research Council ([ERC](#)), [Marie Curie](#) actions, Research infrastructures and Future Emerging Technologies actions.

- 1) **Industrial leadership:** this cluster of actions aims to support the needs for strategic investments in key technologies to make Europe more innovative and boost growth and employment. It is composed of three actions: leadership in enabling and industrial technologies (such as ICT, nanotechnologies, biotechnologies...), access to risk finance and innovation in small and medium enterprises (SMEs) (which account for the 99% of EU enterprises).
- 2) **Societal challenges:** it will fund researches aimed at finding solutions in socially relevant fields such as climate, environment, energy, transport, health. Particular attention will be reserved to demonstrative projects.

As you can see, Horizon 2020 dismantles the old thematic approach, introducing innovation at the core of the programme. The only remnant of the old FP7 structure is the 'Societal challenges' cluster, within which Health managed to attract the highest shares of funding: 8.03 billion EUR for 2014-2020. In comparison with FP7, directly **health-related research calls** were awarded 6.1 billion EUR.

Horizon 2020 unifies three previously separated programmes. Therefore, the new **rules of participation** have to take in consideration the wide range of subjects that were able to participate to FP7, EIT and CIP. FP7 demonstrated to be heavily burdening to consortia (especially to the Project Coordinators). The application process has been streamlined and simplified through a single unified Horizon 2020 online application hub. Fewer and better targeted reporting and audit control controls will take place, and selection criteria have been simplified as well. As for the funding format, Horizon 2020 introduces measures to favour the marketability of research outcomes.

A new mind-set

The reason why Horizon 2020 has been designed with such a strong economic perspective is clear: to support the [Europa 2020 strategy](#) in re-placing Europe at the helm of global economy. Much has been done by the European Commission in the last year to advocate the need for a closer relationship between science and industry. In a nutshell, the core political message of [DG ENTR](#), [JRC](#) and [RTD](#) is "Europe needs science to develop new innovative products and services, making Europe an excellence hub". The positions of the various stakeholders involved are, however, contradictory: some wish to bring manufacturing back in Europe, providing new (cheap, non-qualified) jobs, while others focus on the development of specialised industrial/scientific centres (science parks). A big role is believed to be played by the local governments, which can foster the scientific and industrial specialisation of universities, making EU regions more interdependent and better connected ([S3 platform](#)).

What can the cancer research in general (and the paediatric oncological research in particular) get from this new mind-set? The funds provided by Societal challenges/Health are in fact just part of the funds that the cancer research can attract. SMEs will play a huge role in Horizon 2020: around 15% of the total budget for Societal challenges (including Health) and LEITs will go to SMEs. Therefore, cancer research will profit the most from Horizon 2020 if it will manage to draw funding from all three priorities of the programme, pairing oncology research capacity with innovation.

More information:

Horizon 2020: [presentation of the programme](#)
[Europa 2020 strategy](#)



Survey on the Standards of care for children with cancer: Well on track!

As part of the European Partnership for Action Against Cancer project, experts from 31 European countries provided comprehensive responses to the survey on the 'European Standards of Care for Children with Cancer'. Assessing the quality of treatment and care received by young cancer patients, this country-by-country analysis will provide essential information to address the current health inequalities across different European states. We are very glad of this high rate of responses to the survey questionnaire from outstanding experts (almost 89% of the total contacted), and we will proudly present you the preliminary results at the SIOPE General Assembly on 29 September 2013 in Amsterdam.



European Standards of Care for Children with Cancer

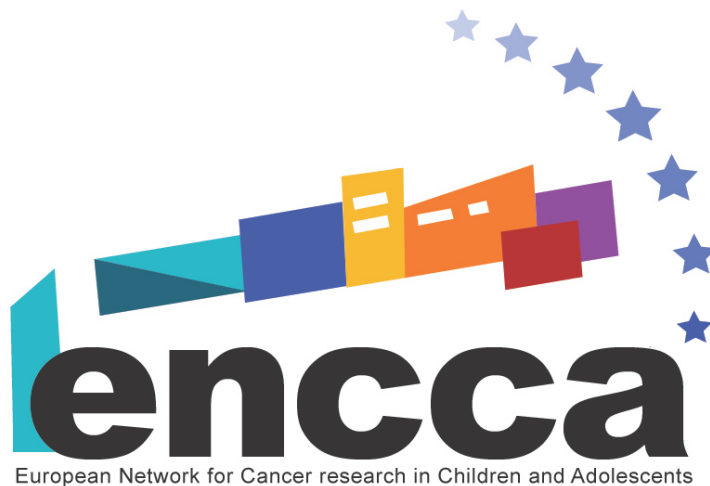
Warsaw, 14 October 2009

First Announcement: ENCCA General Assembly

Ruth Ladenstein, ENCCA project coordinator, is very glad to announce that the third annual General Assembly meeting will be held in Vienna on 16-17 January 2014. The whole ENCCA community, the stakeholders and the collaborators are invited. The event will be associated to an ECRC meeting. The preliminary program, details and registration modalities will be available at the beginning of October on the ENCCA website (www.encca.eu).

More information

[ENCCA](http://www.encca.eu) website



ENCCA Symposium 'Clinical research in 2013: Burning issues'

The Symposium on 'Clinical Research in 2013: Burning Issues' organised by ENCCA last 6 June in Vienna was a great success. All presentations from the 14 high-level speakers promoted very interesting discussions and exchange of opinions that will surely lead to new collaborations in the field of paediatric oncology research.

European cooperation and paediatric networks

The first of the main Symposium sessions opened with a presentation from the moderator, Dr. Gerald Gries (SSFP, Vienna), on the general management of cooperation networks and the international harmonisation of legal and scientific aspects of research ("law meets science"). Prof. Ruth Ladenstein (CCRI, Vienna) introduced the mission and aims of the **European Clinical Research Council for paediatric oncology (ECRC)**, the single voice representing the paediatric and adolescent oncology clinical research community across Europe, as well as the new-born Austrian Medicine for Children Network (Okids). Prof. Peter Helms (Univ. of Aberdeen) summarised the latest initiatives of [Enpr-EMA](#) (the European Network of Paediatric Research at the European Medicines Agency) and the Scottish Children's Research Network ([ScotCRN](#)). This first session ended with two presentations on the possible collaborations with the pharmaceutical industry: Prof. Thomas Klingebiel (KGU, Frankfurt) presented the academic perspective as concerns the possibility of collaborating and start new clinical trials in Europe, while Dr. Jan Oliver Huber (Pharmig, Vienna) presented the industry's point of view.

The Clinical Trials Regulation: The paediatric scope

The second part of the Symposium focused on the current achievements and expected evolution of the advocacy activities related to the Clinical Trials Regulation of both SIOPE and the ECRC. Prof. Ruth Ladenstein (CCRI, Vienna) underlined the main issues concerning paediatric academic trials, focusing on the need for low risk trials and national indemnity schemes, while Prof. Ernst Singer (Medical Univ. Vienna) presented the point of view of the Ethics committees.



The discussion then moved to the current challenges of informed consent in clinical trials with minors: while Prof. Andrea Heckenberg (Medical Univ. Vienna) and Jean-Claude Dupont (Institut Curie, Paris) explained the ethical problems that arise from the need to ensure a truly informed consent, Sabine Karner (ICCCPO, Vienna) presented the perspective of patients and parents and Dr. Martina Gantschacher (SFU, Vienna) broadly illustrated all the legal aspects involved.

Pharmacovigilance in academic trials

The session's moderator, Dr. Martina Gantschacher (SFU, Vienna), explained the needs, proposed solutions and education aspects concerning drug safety in paediatric oncology trials, while Dr. Bettina Schade (BASG, Dpt. of Pharmacovigilance of the Austrian competent authority, Vienna) described the existing interactions between the European competent authorities and the academic trial networks as concerns patient safety. Finally, Dr. Michael Demel (Medical University, Vienna) presented the first results from the implementation of a pharmacovigilance quality system and their "best practice" evaluation.

Registries and biobanking

Prof. Angelika Eggert (Charité, Berlin) illustrated her position on the current frontiers in paediatric oncology biobanking practices, and how our community could overcome them. While Dr. Martina Gantschacher (SFU, Vienna) provided an overview of the legal aspects linked to a good biobanking practice, Dr. Günter Schreier (AIT, Graz) introduced the technical solutions proposed by [ENCCA](#) for academic networks.

Discussions during this high-level meeting were very fruitful, with several important issues raised and open questions. Therefore, at the end of the meeting, participants agreed in planning a follow-up meeting in the near future.

More information:

[ENCCA website](#) (information available soon)

A virtual institute for paediatric oncology research: ENCCA Work Package 3 and 'ABCD-4-E'

ENCCA Work Package 3 'Establishment of the Virtual Institute information portal' aims to create an infrastructure that will meet the specific needs and requirements of the European paediatric oncology research community. Since the [ENCCA website](#) is now available, all efforts will focus on the design, implementation, and evaluation of ABCD-4-E (Advanced Biomedical Collaboration Domain for ENCCA)

The two major objectives of ENCCA Work Package 3 are:

- **ENCCA website:** the establishment of an electronic communication and knowledge management platform providing information to the general public and the ENCCA project community (intranet/private area);
- **ABCD-4-E** (Advanced Biomedical Collaboration Domain for ENCCA): the design, development and evaluation of an ICT infrastructure that will integrate the various research activities of the European paediatric oncology research community. This infrastructure is designed as a sustainable and standardised platform, tailored to the specific needs and prerequisites of this community.

The [ENCCA website](#) is made up of two parts, namely the 'extranet' and the 'intranet'. The 'extranet' contains information for the general public, including multimedia content like videos and tweets. The 'intranet' is accessible only through a unique login and password: to date, more than 125 users have registered and received the necessary credentials to login to the portal. The intranet features dedicated sections for each ENCCA work package, with information on meetings, presentations, minutes, deliverables, etc. Moreover, this ENCCA 'private area' supports the Project Management Team in running the project, can be used to schedule audio/video online meetings and facilitates document collaboration and co-authoring.

The basic concept of **ABCD-4-E** has been refined during the annual meeting of Work Package 3 (17-19 July 2013, Vienna), where a comprehensive use case portfolio has been proposed (Figure 1). The new ICT infrastructure will integrate core datasets from different tumour networks and biobanks, and there will be:

- *Horizontal integration:* among the different European tumour groups. These groups will provide the standardised core datasets from their clinical trials, which will be then registered in the central repository;

- *Vertical integration*: among the levels of basic science, clinical research and healthcare. Clinical trials datasets will be shared and used by initiatives focusing on long-term survivorship, like the experts developing the 'survivorship passport' (healthcare level) or biomarker researchers (basic science level).

The concept of 'standardisation' plays a pivotal role in ABCD-4-E, and the ENCCA portal will be used in the upcoming months to devise the most effective structure to support the participating groups in providing the necessary datasets.

It is clear that, in order to establish the ABCD-4-E as a system for the daily collaboration and work of our community, more resources than those currently available within ENCCA will be needed. The ENCCA partners, as well as other stakeholders (industry, the European institutions, etc.) are currently looking for solutions to find these resources.

Finally, on behalf of all the WP3 partners, we would like to offer a **possibility to SIOPE members**: if you are working on a research proposal, please contact us (guenter.schreier<at>ait.ac.at), please replace <at> with @) in order to discuss how we can possibly help you and ensure that the IT infrastructure of your research project is compatible with the ABCD-4-E system. This way, the existing paediatric oncology research collaboration network can grow and, last but not least, this effort of unification, simplification and sustainability will be also appreciated by the European Commission (and this will increase the chances of receiving funding).

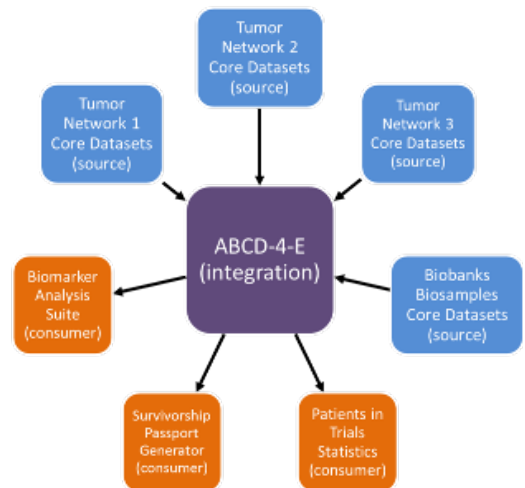


Figure 1 - Overview of the core system components derived from the short listed core use cases. The ABCD-4-E provides the infrastructure for registration, storage and discovery and download of datasets

Günter Schreier, on behalf of the WP3 partners
ENCCA WP 3 leader
AIT - Austrian Institute of Technology

LINES neuroblastoma clinical trial: An ENCCA achievement

Neuroblastoma is the most frequent childhood solid (extracranial) tumour, representing 8-10% of all cancers in children. LINES, an international clinical trial stemming from the [ENCCA](#) project (Work Package 10) focuses on this specific disease.

Although the current treatment of neuroblastoma substantially improved the cure rate of patients from all age groups, survivors from this disease often suffer from long-term and toxic side-effects. This is why the [ENCCA](#) partners from **Work Package 10** 'Risk adaptation of therapeutic strategies using prognostic biomarkers in malignant solid tumours' are working to assess the risk adaptation of therapeutic strategies, by using prognostic biomarkers in malignant solid tumours. The aim is to provide methodological strategies for the implementation of quality-controlled biological and imaging risk factors for neuroblastoma and medulloblastoma patients.

Neuroblastoma patients can be divided in different groups, based on their risk to suffer a "bad outcome", high, intermediate and low risk. Within this framework, the **LINES international clinical trial** focuses on patients with low and intermediate-risk neuroblastoma and aims to establish a treatment protocol with a fine-adjustment treatment dose and a greater control of the tumour's prognostic markers (radiology, biology, radiotherapy and pathology). Stemming from the [SIOPEN](#) network, it has been launched in July 2011 by [IIS LaFE](#) (Valencia, Spain), the leader of ENCCA WP 10 and the trial's sponsor. LINES takes place in 20 European countries where, in spite of a common European [Clinical Trials Directive/Regulation](#), national legislation and regulatory processes are still very different. LINES is currently running in Spain (28 sites), Austria (5 sites), Belgium (1 site), Denmark (3 sites), France (1 site), Israel (1 site) Norway (4 sites) and Italy (21 sites). The other 12 SIOPEN countries are still in the process of opening the trial.

Experts in several disciplines are closely collaborating in this clinical trial, and a panel of [SIOPEN](#) experts (Adela Cañete, Andrea di Cataldo, Vassilios Papadakis, Gudrun Schleiermacher, Kate Wheeler, Alisa Alspach and Vanessa Segura) are currently coordinating the clinical aspects of LINES.



The LINES trial includes 10 separate therapeutic groups (one of them randomised) and, since December 2011, 35 patients have been enrolled and stratified according to stage, age, tumour genotyping, resectability, clinical symptoms and histology using a structured algorithm. After ensuring the informed consent from every patient, all the cases are registered at [SIOPEN-R-NET](#), where the quality of prospectively entered data, biology and histology is carefully controlled through a system of check-points.

This active process implies very close collaboration among specialists from different disciplines (IT specialists, clinicians, biologists, pathologists and sponsor representatives), and this rapid central review system currently shows a successful rate of 85% evaluable genomic profiles, an encouragingly high figure in this prospective setting.

In conclusion, LINES and ENCCA WP 10 are doing their best to create a better future of children and young people with neuroblastoma.

*Adela Cañete, MD, PhD
Vanessa Segura, PhD*

More information:

[SIOPEN-R-NET](#) website

[ENCCA](#) website

Reference: 'Genomic profiling in Low Risk Neuroblastoma to refine treatment stratification and improve patient outcome - LINES: a SIOPEN trial', Schleiermacher G. et al., poster presentation at the 'Advances in Neuroblastoma Research' meeting, 18 - 21 June 2012, Toronto, Canada

The views of TYA with cancer: ENCCA Work Package 17 survey

Improving access to care and ensuring timely diagnosis is essential for teenagers and young adults (TYA) with cancer. This is why [ENCCA](#) Work Package 17 promotes healthy lifestyles for survivors and aims to develop a large European network of support groups, organisations and active patient/survivor groups that work on TYA issues. Its latest initiative is a survey to assess the point of view of TYA current and former patients, whose results will impact the future healthcare and research priorities in Europe.

Currently, the 'Teenagers and Young Adults with Cancer' (TYA) age group has less opportunity to enter clinical trials than younger children. Therefore, partners from [ENCCA](#) Work Package 17 ('Creating a European network for teenagers and young adults with cancer') are currently identifying solutions to promote awareness, increase the access to healthcare and to ensure timely diagnosis for young people with cancer. This Work Package also focuses on social inequalities, promotes healthy lifestyles for survivors of childhood cancers and works to improve the existing referral schemes.



This Work Package recently circulated a [survey](#) in order to 'map' the care of TYA with cancer in Europe. The survey questionnaire – already translated in several European languages ([Italian](#), [English](#), [Polish](#), [German](#), [French](#), [Spanish](#), [Romanian](#) and [Danish](#), soon available in Turkish) – asks the opinion of young people on what do they think the research priorities for TYAs with cancer should be. Moreover, the respondents to the Survey have the possibility to join an online group exchanging useful information with professionals about the recent developments in TYA care across Europe.

SIOPE members are strongly encouraged to send the online [link to the survey](#) to as many young people as possible, within their medical professionals/institutions and/or patient support communities. The survey respondents can remain anonymous, unless they wish to be part of the online community, and ENCCA partners from the Leeds University will use this information to determine the future direction of ENCCA Work Package 17.

We thank you for your interest and your help in ensuring that this survey reaches as many young people in Europe as possible.

*Sue Morgan
University of Leeds, UK*

More information:

[Survey](#) website

[ENCCA](#) website

Contact Ms. Sue Morgan, (Sue.Morgan<at>leedsth.nhs.uk, please replace <at> with @)

PanCareSurFup cruise event: There are still routes to explore

About 1,200 invited guests are expected to attend a high-level event taking place on a cruise boat in Italy next 24-25 October. Aiming to raise funds to carry out research studies into late effects of cancer treatment as well as leukaemia, this event represents a unique opportunity to inform the general public on what the [PanCareSurFup](#) project is doing to support long-term cancer survivors.

Next 24-25 October in Genoa, Italy, a cruise boat will host a unique two-day VIP event, aiming to raise awareness and funds for research on the long-term effects of the treatment of leukaemia on adolescent and childhood cancer survivors.

Several **partners from [PanCareSurFup](#)** and the [PanCare](#) network are working to make this possible, in partnership with the main sponsor, [MSC Cruise](#), as well as other charities (like [AIL](#), the Italian association for research on leukaemia, lymphoma and myeloma). This is not only a fund-raising event: most importantly, it aims to inform the lay public on the need increase research on the late effects of cancer treatment, an aspect often neglected by people not directly involved in childhood cancer. In particular, the press conference will focus on the following aspects:

- a) the impressive success rate of childhood and adolescent cancer treatment in Europe in the last decades;
- b) the importance of the cooperative work of European research groups like [PanCare](#);
- c) the goal of achieving a complete cure in childhood cancer (including the monitoring of the health status of long-term survivors);
- d) equal access to treatment and care for all children in Europe.



A BORDO DI
MSC OPERA



The Mediterranean way of life



Childhood and Adolescent Cancer Survivor Care and Follow-Up Studies, and the upcoming PanCareLIFE).

Around 1,200 guests are expected to attend the event, whose title is “*Against leukaemia there are still routes that should be explored. Let’s come on board for research against leukaemia*”. A **gala dinner**, featuring movie and TV celebrities, will take place on Thursday, 24 October, and it will be followed the next day by a **press conference**. On this occasion several national, European and international paediatric oncology experts will respond to journalistic enquiries on childhood cancer (and, more specifically, leukaemia) current research endeavours and future perspectives, as well as on the ongoing European projects on this topic ([PanCareSurFup](#), the ‘PanCare

As the Chairman of Work Package 7 (Dissemination), I am delighted to announce that this high-level event will profile and showcase the results from the [PanCareSurFup](#) project, aiming to support long-term cancer survivors in their efforts to actively re-integrate society after their disease. In this context, the main sponsors’ name acronym (**MSC** cruises) could be interpreted as **Meglio Superare il Cancro** (to better overcome cancer). See you in Genoa!

Momcilo Jankovic
PanCareSurFup WP 7 leader
Azienda Ospedaliera San Gerardo, Monza, Italy

More information:

[PanCareSurFup](#) website

[Event brochure](#)

Should you be interested in attending this event, please contact the organisers (segreteria<at>mettiamociallopera.it, please replace <at> with @)

Paediatric Oncology in Europe: From national activities to pan-European approaches in clinical and translational research

To better tackle the challenges of treating childhood cancer, during the last 50 years paediatric oncologists conducting multicentre and cooperative clinical trials joined their forces progressively, from the national to the continental level. Today, SIOPE effectively represents their unified and strong voice in Europe.

Cancer in children and adolescents is rare in Europe. Although it accounts for only 1% of all childhood diseases, it is the leading cause of death from disease in children aged 1-15. To better tackle the challenges of treating childhood cancer, **national networks of paediatric oncologists** conducting multicentre, cooperative, standardized clinical trials were created in the 1970's. The primary goal of these networks was to obtain valid data from large patient groups with the same cancer, which could be used to optimise future diagnostic and treatment. Treatment protocols have traditionally been designed by national paediatric oncology societies, such as the [GPOH](#) - representing more than 70 treatment centres in Germany, Austria and Switzerland - and are continuously optimised based on the latest scientific knowledge obtained by previous trials. Overall, these clinical trials focused on the comparative testing of the effectiveness of multimodal treatment concepts, rather than the study of single drugs. The major goal was to further increase cure rates and reduce long-term side effects, thereby improving the quantity and quality of cure.

The establishment of these national cooperative groups furthered the development of paediatric oncology in Europe and worldwide and, thanks to their clinical trials' results, the progress made in treating cancer in young people became one of the undisputed **success stories** in modern medicine: today, more than 80% of children with cancer can be cured today using multimodal therapy. However, cure rates have reached a plateau after 1990, making new interdisciplinary **pan-European approaches necessary** to finally aim for 100% survival of children with cancer in the future.

During the last 50 years, the paediatric oncology **translational research** community has increasingly used innovative biological tools developing from the closely related natural sciences. Our discipline greatly benefited from advances made by colleagues in the areas of internal medicine and pathology, and interactions with them were mutually beneficial. However it remains true that, often, what appears to be the same disease in paediatric and adult patients actually presents significant differences, that many paediatric cancers do not occur in adults and vice versa and that drugs developed for adult cancers are only partially suited to target the different molecular characteristics of paediatric cancers. Therefore we



*Dr. Med. Angelika Eggert, MD
Leader of ENCCA Work Package 5*

can conclude that, also as concerns translational research in paediatric oncology, there is a need to develop networks specifically focussing on drug development for children and adolescents.

The tendency of paediatric oncologists to perform **clinical research** at the pan-European rather than the national level has increased in recent years, since many areas of paediatric oncology have become ever more complex and this situation resulted in the creation of more and smaller disease subgroups. Today, most Phase III paediatric cancer clinical trials are successfully performed at the European (or even international) level, as patient numbers are particularly low.

Likewise, also translational researchers joined their efforts through European consortia, like the successful "[EET-Pipeline](#)" and "[Kids Cancer Kinome](#)", (financed by the EU 6th Framework Programme).

To serve the growing needs of the European professionals working in paediatric oncology, **SIOPE**, the European Society of Paediatric Oncology, was founded in 1998 as the European branch of SIOPI International. It is the only pan-European organisation dedicated to enhancing cancer awareness, diagnosis and treatment of children. Since 1998, SIOPE has continuously promoted better policies for children with cancer and their specific needs, and raised awareness of the numerous challenges faced by paediatric oncology professionals to EU policymakers. SIOPE has also fostered pan-European multicentre trials and enhanced regulatory paediatric drug approval through enhanced collaboration with relevant stakeholders. In this way, standards of care in paediatric oncology have been improved all over Europe. Although professional, medical, scientific and educational co-operation and training across Europe has been greatly supported, facilitated and increased by SIOPE, in particular by supporting exchanges and meetings between doctors, nurses and other professionals involved in the care of children and adolescents with cancer, a certain fragmentation of clinical and translational research approaches across Europe still occurred.

To fill this gap, a European Network of Excellence for Paediatric Oncology named "[ENCCA](#)" was initiated in 2011. The mission of ENCCA – a project encompassing 34 partners from 11 European countries and 27 eminent paediatric oncology institutions – is to efficiently structure and enhance paediatric oncology research in Europe, by limiting knowledge fragmentation and improving communication channels. By bringing together existing informal clinical trial groups, ENCCA will create a sustainable "European Virtual Institute" for clinical and translational research in childhood and adolescent cancers. ENCCA successfully integrates the expertise and opinions of all relevant stakeholders, in order to ensure the multidisciplinary nature of the project. ENCCA applies an integrative strategy, providing all stakeholders with common tools and approaches to solve current bottlenecks in testing new therapeutic strategies for rare cancers in this vulnerable age group. In close cooperation with [ITCC](#), ENCCA implemented new harmonised therapeutic strategies to allow molecular targeted drugs, novel therapies and referral schemes to become standard practice, in cooperation with regulatory bodies, pharmaceutical companies, parents and patients. In January 2011 **ITCC** – that today gathers 42 European paediatric oncology departments and 9 research laboratories with expertise in early phase trials – was established as a European Category 1 Network for Paediatric Research at the European Medicines Agency ([Enpr-EMA](#)). Finally, the existing national clinical trials and tumour research groups recently decided to incorporate the 'European Clinical Research Council for Paediatric Oncology' ([ECRC](#)). The ECRC – by facilitating the exchange of information and best practices as well as the access

to equipment and tools for all those involved in the field of paediatric oncology research – represents an important step towards the establishment of a successful virtual European Paediatric Cancer Institute.

I would like to conclude here that, in the past 50 years, the **synergistic activities of national and European paediatric oncologists** had a pivotal role in transforming childhood cancer from a virtually incurable disease to one with a combined 5-year survival rate of 80%. With their close links to the national paediatric oncology groups, [SIOPE](#), [ENCCA](#), [ITCC](#) and [ECRC](#) are widely recognised today as the premier collaborative European research organisations in the field of childhood cancer. Future activities will focus on improving investigator-initiated and industry-sponsored Phase I/II multinational trials, as well as on removing the current bureaucratic and financial hurdles related to clinical trials in children and adolescents. The introduction of the [EU Clinical Trials Directive](#) in 2001 almost quadrupled the costs to initiate new childhood cancer trials and caused substantial delays and even the discontinuation of some trials: the new [EU Clinical Trials Regulation](#) proposal is a great chance to improve this unfavourable regulatory framework. Our community particularly welcomes the introduction of a single portal for clinical trial authorisation, the co-sponsorship model, the requirement to establish national indemnity schemes and the recognition that not all clinical trials pose an additional risk to subjects compared to normal clinical practice treatment. It is of the utmost importance for the future of paediatric oncology to specify in the new Regulation that, when trial treatment arms do not contain unlicensed drugs and only compare standard treatment approaches, they need to be considered within the 'low-intervention trial' category, regardless of whether the drugs are being used off-label. Other current barriers to developing new treatments include the specific biology of childhood cancers, and the difficulty of transferring identified targets suitable for drug treatment to industrial drug development. Fostering open collaborations with industry, regulatory bodies, academia, governments and patient advocacy groups will be crucial to speeding up drug development, an important task that can be only fulfilled through synergistic approaches between the national paediatric oncology societies and the pan-European efforts of SIOPE, ENCCA and ECRC.

More information:

[ENCCA](#) website

[GPOH](#) website

ExPO-r-Net: SIOPE's new EU project

SIOPE joined forces with other 32 high-level partners from all over Europe to build a new European Reference Network for paediatric oncology. The ExPO-r-Net project proposal is the result from these strenuous joint efforts, and it aims to reduce the current inequalities in childhood cancer healthcare access and provision in the different European countries. Recently recommended for funding, it will probably be our next project in the pipeline!

Childhood and adolescent cancer patients often need to move abroad to be treated, as their conditions require specialised expertise that is not available in the Member State of residence (because of the low case volumes or the lack of local resources). **ExPO-r-Net** is a project proposal that aims to reduce the current inequalities in childhood cancer healthcare capabilities in the different European countries, by linking pre-existing reference centres of excellence and seeking mechanisms to facilitate movement of information (rather than patients) whenever possible, through ICT and eHealth tools.

This new project proposal was submitted by a consortium of 32 partners at the beginning of 2013, in response to the European Commission [call on pilot networks of cooperation](#). Funded by [DG SANCO](#), the call was inspired by the wide spread recognition acquired by the SIOPE-led '[Standards of Care for Children with Cancer](#)', in the framework of the so-called '[Cross-border healthcare Directive](#)'. SIOPE was therefore considered as 'a natural partner' in the project and, once approved, our Society will be responsible for its dissemination.



The **overall objective** of the EXPO-r-NeT project is to build a European Reference Network for paediatric oncology that will improve the accessibility of high-quality health care for children with cancer. These reference centres – inherent to the cooperative paediatric oncology clinical trial groups – provide high-level diagnostic and medical expertise, as well as seeking mechanisms to facilitate movement of information and therefore reduce the current burden on families seeking cross border health care, i.e. lack of appropriate information on the specific cancer condition as well as social isolation for treatments that may extend over many months.

Project partners will identify the target groups who have conditions that require a particular concentration of resources or expertise, and will assess the current deficits in healthcare resources for specified tumour types across Europe, with a particular focus on the very rare tumour types and rare cancer conditions. High-quality, accessible and cost-effective healthcare for childhood cancer will be achieved by strengthening the integration of pre-existing knowledge and expertise, and fostering stronger cooperation between patients, professionals and healthcare authorities. ExPO-r-Net will support eHealth solutions based on interoperability and standardisation, helping professionals to work more efficiently and exchange information and data that are essential for tumour boards.

EXPO-r-NeT has been **recommended for funding**: the final decision that the project has been approved will arrive only in October, although the project was rated the highest score among all applications. The launch event of the EXPO-r-NeT project is planned for 2014.

EXPO-r-NeT will support the actions of the existing EU-funded projects – like [ENCCA](#), [PanCareSurFup](#) and [EPAAC](#) – and the information and tools developed will be disseminated to key stakeholders who can utilise them: health care professionals and providers, national parent/patient and survivor organisations, [EURORDIS](#), [ECPC](#), [Rare Cancers Europe](#), European Clinical Trial Groups and national paediatric oncology societies

This project will fulfil our vision of a more supportive environment for children with cancer with special needs. Through EXPO-r-NeT, our community will have a clear and complete framework - a roadmap to approved expert referral sites and tumour advisory boards for healthcare providers - that can help improve the implementation of the Standards of care for children and young people with cancer.

More information:

[Standards of Care for Children with Cancer](#) webpage

[Cross-border healthcare Directive](#)

European Commission [call on pilot networks of cooperation](#)

SIOPE and SIOPE as European branch

Apart from being one of the founding members of [ECCO](#), SIOPE (paediatric oncology in Europe) is also the continental branch of [SIOPE International](#) (paediatric oncology at the global level). Each one representing its members and advocating the issues that are inherent to its specific geographical scope, SIOPE and SIOPE are today two cooperating partners in a global effort to advance research, treatment and care for young people with cancer.

Last April the President of [SIOPE](#), Prof. Gilles Vassal, attended the **meeting of the Continental Presidents** of SIOPE international. On this occasion, the relationships between these two paediatric oncology entities have been better defined, as the synergies between the European and global level of activity sometimes have been complicated to understand.

Our Society has indeed a double role within the global paediatric oncology community: as a founding member of [ECCO](#) (which represents oncology at the European level) and as the European branch of [SIOPE International](#) (representing paediatric oncology at the global level), SIOPE today concentrates its efforts and resources on the topics that specifically affect European paediatric oncologists as concerns research, education and access to care, as well as advocacy on the legislative and policy initiatives of the European Union (in which our Society is very active).

On the other hand, SIOPE International contributes to the global vision and agenda of paediatric oncology, needing the support and feed of the continental branches, including SIOPE.

As a result, today we can affirm that **SIOPE and SIOPE are close partners** in ensuring the best possible care and outcome for ALL children and young people with cancer.

The next SIOPE congress will take place this year in [Hong Kong](#), while the next **SIOPE congress in Europe** will take place in 2016 and SIOPE, as continental branch, will be more involved in its organisation.

More information:

[SIOPE Website](#)

[SIOPE International Website](#)



Prof. Calaminus, SIOPE President, and Prof. Vassal, SIOPE President: a partnership for paediatric oncology

Paediatric Oncology at the European Cancer Congress

SIOPE is delighted to invite you to the [European Cancer Congress](#), the largest multidisciplinary and multi-professional oncology congress in Europe. At the Congress, the SIOPE **Paediatric Track** will feature outstanding speakers from our community. Moreover, this unique event will also host the General Assembly of SIOPE, as well as the SIOPE Lifetime Achievement Award ceremony. From 27 September to 1 October 2013, come and find us in Amsterdam!



The 17th ECCO, 38th ESMO, 32nd ESTRO **European Cancer Congress (ECC 2013)** is the largest multidisciplinary and multi-professional oncology opportunity to take place in Europe. A record number of participants from 110 countries attended Stockholm, and the 2013 **European Cancer Congress** will continue this trend to advance multidisciplinary throughout Europe and beyond. The Scientific Programme of the Congress ensures educational opportunities of excellent quality for all those working in the field of oncology. At this exceptional bi-annual congress, of which paediatric oncology forms an essential part, cutting-edge data that can have a significant impact on the practice of oncology are presented.

Organised and led by SIOPE, the comprehensive [Paediatric Track](#) will start on 28 September 2013 and will represent an excellent part of this unique meeting of experts from all over the world. In particular, this track will be of great interest for you, as it will make you experience all the scientific excellence developed within your discipline. You can find out the most interesting and highly topical sessions of our paediatric track [here](#). Moreover, the congress will also incorporate the usual favourites including the not-to-be-missed legendary Oxford-style debates, educational symposia and much more.

All SIOPE members avail of a [reduced registration fee](#) to attend the European Cancer Congress, but don't forget that **20 September 2013** is the deadline (late rate registration fee). The 'next generation' of paediatric oncologists can also avail of special reductions by [registering as "junior participants"](#) (providing a confirmation on their 'in training' status and a letter from their Head of Department).

We remind you that all our members are invited to attend the **General Assembly of SIOPE**, taking place on Sunday, 29 September (reception starting at 17.45, meeting 18.00-19.15, Room E107) during the



Congress. On this occasion, SIOPE Board members and the office team will report on **the scientific and political developments** that affect our community and engage with you to gauge your interest on where you think SIOPE should be going in the future. We will inform you on our **current and future activities**, and give you some feedback on the growth of the SIOPE members community as well as on our internal organisational structure. Please find [here \(page 10\)](#) the report from last General Assembly.

On Sunday 29 September, during the **SIOPE Society Session** (09.00-11.00, Room E104) we will award the **SIOPE Lifetime Achievement Award**, a prize awarded to an eminent personality of European paediatric oncology community for his/her outstanding dedication and contribution in advancing research and care for young people with cancer. Former winners of this prestigious award included [Prof. Helmut Gadner \(page 4\)](#), [Prof. Catherine Patte and Prof. Alfred Reiter \(page 14\)](#).

The European Cancer Congress is a great opportunity for SIOPE members to organise their meetings, as they can benefit from a dedicated '**SIOPE Lounge**' to network with their colleagues inside the congress' venue. Please [contact us](#) should you need more information on this possibility.



We also invite you to visit the **SIOPE booth** at the Congress (Booth 4500, Hall 1): here you can meet us, learn about the latest

developments in SIOPE and discover what our Society can offer you. Finally, you will have the opportunity to receive live updates during the congress: please use both #SIOPEurope and #ECC0213 to **tweet**, and you will be always updated on the 'hot topics' that are happening (visit our [Twitter page](#))!

We are keen to work closely with you, and thus consider that a high turn-out of members from across Europe is very important. Please do **save the date of 29 September** and **join us in Amsterdam** for this meeting and excellent networking opportunity.

Be part of the premier cancer congress in Europe, meet your colleagues from all over the world, and make sure SIOPE and paediatric oncology is well represented in Europe!

More information:

[SIOPE at the European Cancer Congress 2013](#)

European Cancer Congress 2013: [Searchable Programme](#)

European Cancer Congress 2013: [Website](#)

Come to Paris, and join the discussion on drug development for children with cancer in Europe

Aiming to provide better medicines for children, the [EU Paediatric Medicines Regulation](#) came into force in 2007. Based on incentives for pharmaceutical companies, it tried to increase the development of drugs for paediatric diseases with no expected direct return on investment. In 5 years however the Regulation did not improve the access to anticancer drugs for children: you are all invited to the [BDA Workshop](#) in Paris in order find solutions to redress this situation

Last June the European Commission published the [interim report](#) on the first 5 years of the implementation of the EU [Paediatric Medicines Regulation](#). This report and additional publications showed positive changes as concerns the field of paediatrics, but they also identified hurdles and bottlenecks in paediatric oncology drug development.



BDA
WORKSHOP

18-19 November 2013
PARIS, FRANCE

Improving oncology drug development for children and adolescents

A UNIQUE opportunity to address hurdles and explore potential solutions together with experts from ACADEMIA, PHARMACEUTICAL INDUSTRY, REGULATORY AUTHORITIES, PATIENT ADVOCATES and POLICYMAKERS

At the moment, the number of new **oncology drugs in paediatric development** remains low in Europe, with still a 10-fold difference between Europe and the US in the number of new anticancer drugs available for clinical research. Moreover, while targeted therapies could open new opportunities for safe and effective anticancer paediatric drugs, young people in Europe have been denied access to many innovative therapies that have been developed for the treatment of adult cancers.

We consider new **therapies for our patients as a priority**: with more than 3,000 children dying of cancer each year in Europe, there is an urgent requirement to speed up the development of safe and effective anticancer therapies for children and adolescents.

This is why last November [SIOPE responded](#) to the European Commission's public consultation on the progress of the Regulation after five years and our President, Prof. Gilles Vassal, wrote [an outstanding article](#) explaining why innovative therapies for childhood cancer are essential.

Together with [BDA- the Biotherapy Development Association](#), [ENCCA](#) and [ITCC](#), SIOPE organised a high-level **Paediatric Workshop in Paris** next 18 and 19 November, in order to raise more attention on this issue and define a new strategy for future paediatric oncology drug development. We strongly encourage SIOPE members to attend this important meeting, where all stakeholders (academia, parents and patients, industry, regulators, policymakers) will share their views propose new solutions that may improve the implementation of the Regulation and better meet the needs of childhood cancer patients. In particular, the discussions will focus on three topics:

- Mechanism-of-action and biology-driven development of oncology drugs for children and adolescents;
- New and innovative partnering for improving cooperation between stakeholders;
- Innovative designs and development plans to improve feasibility and speed up introduction of new drugs in standard care.

We hope to see you all in Paris at very important meeting!

More information

Workshop: "Improving oncology drug development for children and adolescents", 18 -19 November 2013, Paris, France

[BDA Paediatric Workshop](#) website

[Venue Website](#)

Please contact the organising secretariat at [marjorie.recorbet<at>ecco-org.eu](mailto:marjorie.recorbet@ecco-org.eu) (please replace <at> with @)

Cooperation necessary for better results in paediatric oncology care

Attracting more than 50 parents and survivors from 18 different European countries, the 4th Europe-wide ICCCP meeting took place last 24-26 May in Basel. It was a unique occasion for childhood cancer patients, survivors and parents from all over Europe to be updated on the most important developments in our community, as well as to strengthen their common links and better advocate at the European level.



During the two days of the [ICCCPO](#) Meeting of European members, parents and survivors from all over Europe could learn more about relevant issues concerning childhood cancer within Europe. Many topics were addressed ranging from survivors' issues, long-term follow-up, clinical trials and the future goals of paediatric oncology in Europe.

The President of SIOPE, Prof. Gilles Vassal, introduced the current situation of paediatric oncology in Europe and stressed the importance of the **long-term sustainability** of the results stemming from the [ENCCA](#) project. After a vivid discussion, both SIOPE and ICCCP agreed to strengthen their joint efforts in working in this direction, to ensure the best care and research with less late-effect for children with cancer in Europe.

Participants were updated on the different **EU-funded projects** in which ICCCPO is an active partner - [ENCCA](#), [PanCareSurFup](#), EPOC and [IntReALL](#) – as well as on the progress of the [Survivorship Passport](#), the involvement of ICCCPO in studies on medication safety and the need to raise public awareness about the importance of long-term follow-up of childhood cancer survivors to improve their quality-of-life were addressed. Within the ENCCA project parents and survivors are asked to participate in ethical issues of clinical trials.

For the first time, an **educational workshop** was held, with presentations by Frédéric Arnold, Marianne Naafs-Wilstra and Lejla Kamerić about the key questions every parent should ask before consenting to enter their child into a clinical trial, the role of a parent organisation in medical research and the situation in the Balkan region, where many parents are not aware of clinical trials. Prof. Ruth Ladenstein, ENCCA coordinator and SIOPE Past President, provided feedback on the proposal for a new EU [Clinical Trials Regulation](#), showcasing a new two-steps informed consent procedure. The ENCCA partner (and French philosopher) Jean Claude Dupont asked the audience for their contribution in a questionnaire titled: "*Nothing about you, without you: Your input in ENCCA guidelines on clinical trials*".

At the previous 2012 ICCCPO Meeting in Luxembourg, the **Parent and Patient Advocacy Committee (PPAC)** was created as one of the milestones of ICCCPO's participation in the ENCCA project. This year, the PPAC members presented their work and future goals, and welcomed any suggestion to further improve their work as concerns all type of ethical and parent/patient related issues.

Several issues specifically related to **paediatric cancer survivors** were covered: Jaap den Hartogh presented the outcome of the collaboration between physicians, survivors and the Dutch parent group, and demonstrated how all stakeholders can work together and improve long-term care for survivors. Milos and Vladimir Radulovic presented the "[Radio MladiCe](#)" project, an internet radio by of and for survivors, while Morvan Dupont and reported on the activities of a new French survivors' group, "[Les Aquerris](#)".

To cheerfully end the meeting, the local hosts (Peter Lack, Birgitta Setz, Catia Gehrig and Daniela Dommen from "Stiftung für krebskranke Kinder, Regio Basiliensis" and "Kinderkrebshilfe Schweiz") organised a boat trip on the Rhine river. A big thank-you goes to them, who perfectly prepared everything for this meeting. Unfortunately, this time the weather was not on our side, but if the Swiss locals could have influenced it they would have arranged better weather too!

Gerlind Bode and Sabine Karner, ICCCPO

More information
[ICCCPO](#) website

Meeting of the ENCCA Parent and Patient Advocacy Committee (PPAC)

Taking place on 11-13 July 2013 in Sarajevo, the last Meeting of the ENCCA Parent and Patient Advocacy Committee (PPAC) helped the Committee to better define its priorities for the future.



The [Parent and Patient Advocacy Committee \(PPAC\)](#) is a European-wide committee of parent and survivor representatives recently founded within the [ENCCA](#) project to work closely with ENCCA in the design and implementation of its cooperative group clinical research strategy and access to clinical trials for patients. Currently, the PPAC consists of parent and survivor representatives from France, Spain, Germany, Bosnia and Herzegovina, Switzerland, Luxembourg, Austria and Greece (please find [here](#) the names and organisations of PPAC members).

The last **PPAC working meeting** took place in Sarajevo (Bosnia and Herzegovina) on 11-13 July 2013. On this occasion Ms. Sabine Karner, project worker for ICCCPPO within the ENCCA project, gave an update of the work ICCCPPO has performed so far and intend to carry on until the end of the ENCCA project in December 2014.

The planned actions to be taken forward are the following:

- To create a brochure about clinical trials for childhood cancer patients and parents, which will be available in several European languages to download and print;
- To train parent and patient representatives on clinical trial issues and research process (through meetings, existing training courses and a webinar), in order to empower them in their advocacy activity in this field;

- To support the creation and implementation of the [Survivorship Passport](#) in Europe;
- To review the ENCCA guidelines on biobanking and clinical trials;
- To improve the creation of links and networks among parent and survivors' groups/organisations in Europe.

The main question raised in these days was: what will happen after the end of the ENCCA project? Ms. Anita Kienesberger, ICCCPPO Board Member and responsible for European affairs, the long-term sustainability of our current work represents an essential aspect that our Committee will need to pay attention to next year. One important result stemming from the meeting was the definition of the PPAC members' priorities, as every member a specific background and expertise and can contribute in different ways. Beside ICCCPPO's mission "We care, we share", one important objective for the PPAC will be to close the gap between the Eastern and Western European countries as concerns patient and parent advocacy. Lejla and Neira Kamerić wonderfully hosted this meeting, providing also insight into the culture and the lifestyle in Bosnia and Herzegovina... thank you!

Sabine Karner, ICCCPPO

More information

[Parent and Patient Advocacy Committee \(PPAC\)](#) webpage

[ENCCA](#) website

[ICCCPO](#) website