

DRAFT

Supporting Childhood Cancer Research and Care in Europe

Position Paper from SIOP Europe

22nd May 2006

Background

SIOP Europe has coordinated two very informative meetings of existing multinational clinical trial groups and national organisations working in the field of childhood cancer in Europe, in May 2005 and March 2006. The main conclusions from these meetings were that we face many challenges in common to continue our previous level of clinical research activity and that we wish to have a more unified voice for the childhood cancer research community in Europe to solve these problems. It was clear from these meetings that SIOP Europe has been given a mandate to act as a unified voice for childhood cancer in Europe. It is also clear that we must now be much more proactive and take concrete steps towards achieving practical help and increased coordination between clinical trial groups and between national childhood cancer organisations, where they exist. For those countries that do not yet have a national childhood cancer organisation, there is an urgent need to assist in the development of these and avoid duplication of previous effort. We also recognise that, of course, there will always be country-specific issues that must be tailored to the national resources and interpretation of the EU Clinical Trial Directive.

Entry into a clinical trial is viewed as the “best standard of care” for the treatment of the majority of childhood cancers. The majority of these front line therapies involve ‘off-label’ use of long established cytotoxics that are out of patent. Due to their long established use in paediatric oncology, despite their ‘off-label’ use, the side effect profiles and well tolerated doses and schedules of these drugs are largely known in the paediatric age group. Most of these trials therefore aim to improve efficacy while in many cases also reducing acute and long term side effects. Up to now, these academic-led Phase III trials have been delivered by very knowledgeable healthcare professionals largely on the basis of good will. There are more recent concerns that enrolment in clinical trials is now decreasing due to the increased resource requirements for opening trials and for entering patients. This may well have a negative impact on the outcome of treatment for children’s cancer in the future in Europe.

Another priority is to address the clear survival difference for children with cancer from Eastern European countries. Although survival in Eastern countries is improving generally, it still lags behind survival levels achieved in Western Europe by as much as 10-20% depending on disease type. Part of the reason for this difference may be the lower participation in clinical trials and less easy access to standard protocols for healthcare professionals working in the East.

The consensus view is that the next step must be for childhood cancer groups to become something more than a simple ‘talking shop’ of existing groups. SIOP Europe is prepared to take on this challenge and move things forward to create something more concrete. In order for this aim to be achievable, the initial focus will be on clinical trials, in the first instance, looking at the best way to provide information and support groups through the design and implementation of their trials. In the long term, we would aim for a unified approach to providing sponsorship for clinical trials, remote data entry platforms etc.

The Mission of SIOP Europe is:

“To assure the best possible care and outcome for all children and young people with cancer in Europe”

This will be achieved by:

- Promoting comprehensive cancer registration for all affected children and young people
- Encouraging maximum recruitment to clinical trials
- Facilitating basic research
- Setting standards for appropriate professional education
- Working in partnership with parents and patients
- Lobbying governments and administrations to ensure that appropriate resources are available

The long term vision of how to achieve these aims is to have an umbrella organisation for childhood cancer in Europe. This would draw on the existing expertise to provide a common structure for collaborative working and a common interface to provide information and links for health professionals, parents and patients, pharmaceutical companies and other organisations. SIOP Europe is committed to assuming the responsibilities of this umbrella organisation.

In the first instance, we have prioritised:

- facilitating clinical trials
- providing the common interface for information exchange
- providing a common voice for communicating with regulators
- providing a common link to initiatives under ‘Medicines for Children’.

Future work will include addressing the childhood cancer community’s needs in the following areas:

Clinical trials/’best practice’ guidelines:

- To develop common standards for best practice by tumour type.
- To develop common standards for design and implementation of clinical trials.
- To provide education and training for healthcare professionals working in the field of childhood cancer, building on the standard curriculum that has already been developed by SIOP Europe.

Note that it is healthy to allow groups to run parallel studies answering complementary questions. There is thus no intention to aim for a single trial by tumour type across the whole of Europe, unless this was the preferred option for a particular tumour type agreed by the relevant expert groups.

Common issues for patients and their families:

- Easy access to understandable information about childhood cancers
- Support for families
- Access to care for adolescents
- Access to new drugs for patients with high risk or relapsed tumours
- Survivorship, how to maximise this and quality of survivorship

Proposed Actions

We recognise that much of the expertise to accomplish the above already exists within Europe. We therefore aim to provide a focus for better coordination, skills, resources and information. SIOE Europe plans to set up an office and a SIOE Europe Website to achieve the above. We ask that all clinical trial groups and national groups or representatives consider this Position Paper and provide an official statement of their support or other comments by 12th July 2006.