

SIOPE CLINICAL RESEARCH COUNCIL (CRC)

TERMS OF REFERENCE

(22 DECEMBER 2015)

1. Background

The SIOPE Clinical Research Council (SIOPE CRC) follows the European Clinical Research Council (ECRC) that was created with the FP7 funded European Network for Cancer research in Children and Adolescents (ENCCA). Within ENCCA, SIOPE has defined its Strategic Plan to improve cure rate and quality of survivorship over the next 10 years.

The SIOPE CRC is convened as an on-going Council to SIOPE that will fully represent all participating countries and clinical trial groups engaged in clinical research for children and adolescents with malignant diseases in Europe and willing to contribute to the SIOPE agenda.

The SIOPE CRC will support SIOPE in its missions and contribute to the implementation of the long term SIOPE Strategic Plan.

2. Remit of the Council

To represent the paediatric and adolescent haematology oncology clinical research community across Europe.

The Council will embody the needs and opinions of the Community with respect to the delivery of international clinical trials for children and young people with cancer and leukaemia. The remit will encompass highlighting the specific challenges to the paediatric and adolescent oncology community imposed by EU regulations relevant to clinical research. The SIOPE CRC will contribute to define possible solutions and proposals for changes in policy that can be presented to the relevant bodies within the European Commission and EU.

The Council will represent the collective experience of the constituent groups and will facilitate the sharing of good research practice between International co-operative groups working in the field of paediatric adolescent oncology.

The Council will promote a European-wide infrastructure to deliver academic sponsored clinical trials with the established paediatric and adolescent oncology network.

The Council will facilitate the implementation of the seven SIOPE Strategic Plan objectives by the ECTGs and the NaPHOS.

The remit of the Council concerns issues relating to research in the field of paediatric and adolescent oncology and haematology as well as providing knowledge and expertise for the implementation of the Paediatric Oncology European Reference Network.

The remit of the SIOPE CRC does not include general education and training of paediatric-haemato-oncologists, but may contribute to clinical research education programmes.

3. Constitution of the Council

The members of the Council should include:

1. The Chair (or nominated representative) of the National Paediatric Haemato-Oncology Society or Group (NaPHOS)
2. The Chair (or nominated representative) of the European Clinical Trial Groups (ECTGs)

Nominated representatives should be part of the ECTGs and NaPHOS executive committee or board of directors and endorsed by them.

A member of the Council may represent only one role within the Council.

Decisions will be passed based on a majority vote (Appendix 1). The Council will be considered quorate if at least 2/3rd of the members have voted.

The Council shall have a NaPHOS Representative and a ECTGs Representative. The Council shall elect a NaPHOS Representative and a ECTGs Representative among its members. The term of the NaPHOS Representative & ECTGs Representative is 3 years. Terms are not renewable. The NaPHOS Representative and a ECTGs Representative are full members of the SIOPE Board.

4. Application for Membership

Each chair of NaPHOS and ECTGs will be invited by SIOPE to become a SIOPE CRC member. They will be asked to submit a brief description of their organization/study group, including the clinical research activity undertaken or supported (see annex 1).

Any other request for applications should be submitted to the Representatives of the SIOPE CRC for consideration and discussed with the SIOPE Board.

When a new chair of an ECTG or NaPHOS is elected or nominated, the ECTG or NaPHOS may decide to change the representative in the SIOPE CRC.

Each SIOPE CRC member accepts to establish a link between his/her group or society website and the SIOPE website.

The ECTGs, members of the SIOPE CRC, provide SIOPE with the names of their board members and committee chairs along with the list of their members.

5. Meetings

The Council will meet in full annually. The meeting will require the attendance of the NaPHOS Chairs and the ECTG's Chairs or a nominated representative. The meeting would be linked to a European or International Scientific Conference, such as the ECCO Congress or the SIOPE Congress.

6. Funding

The SIOPE CRC has no funding stream, therefore any expenses incurred by the members of the Council will need to be met by their own institutions or their own funds.

7. Administrative Support

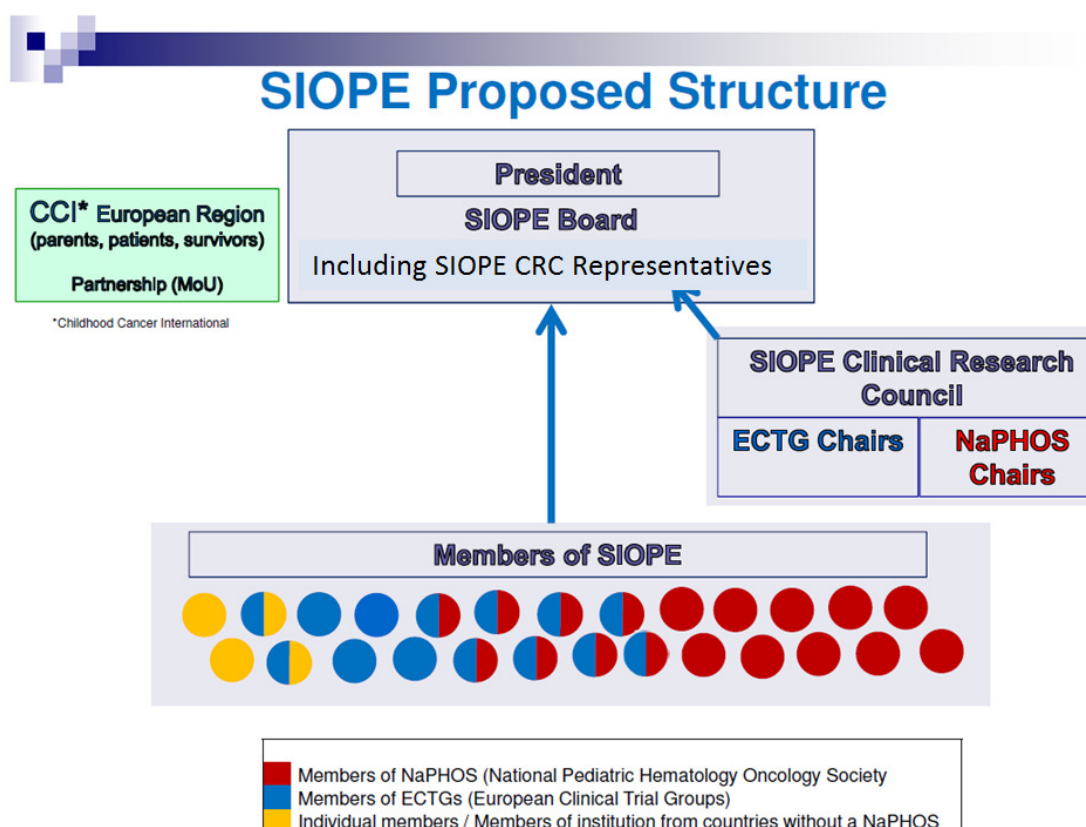
The SIOPE office will provide administrative support for the SIOPE CRC.

8. Reporting guidelines

The SIOPE CRC will be under the auspices of the SIOPE Board. There will be a bi-directional flow of information between the SIOPE Board and the SIOPE CRC (see fig 1). Minutes will be available on the SIOPE website. Copies of the Minutes of the SIOPE CRC Meetings will be provided to the SIOPE Board.

The Council will be able to propose new initiatives, policy documents and commentaries on European issues relating to clinical research and similar to the SIOPE Board. Equally, the SIOPE Board will be able to seek the collective and consensus opinions from the SIOPE CRC as representative of the views of the wider European Paediatric and Adolescent Oncology Community.

Figure 1: SIOPE Structure



Appendix 1

Each Chair of the NaPHOS and ECTGs will be invited to become member of SIOPE CRC.

Following information will be collected on updated on a regular basis by the SIOPE office:

1. Role Represented (Name)
 - a. National Group OR
 - b. Tumour Group OR
 - c. Other Group
2. Name of Chair/President
3. Additional Role represented
4. Contact details
5. Country