

Hosted by Glenis Willmott, MEP

Wednesday, 20 February 2013

Today, 15th February, is International Childhood Cancer Day. SIOPE is taking this opportunity to call for a pragmatic approach to clinical trial governance for children and adolescents with cancer in Europe.

It is widely recognised that the conduct of collaborative clinical trials across multiple Member States has been seriously impeded by the [EU Clinical Trials Directive](#) (2001/20/EC) and there is real potential for this to be reversed by the proposed

[EU Clinical Trials Regulation](#)

. A meeting is being organised on 20th February in the European Parliament kindly hosted by MEP Glenis Willmott, Rapporteur of the EU Clinical Trials Regulation, to discuss how paediatric clinical research can be improved through fair regulatory governance.

The principle objective of trials for children and young people with cancer is treatment optimisation using well-established chemotherapy drugs, and the introduction of new, safe and effective innovative medicine in standard care. These trials are non-commercial, sponsored and conducted by academic institutions, and funded by public money and/ or charity support to cover the trials' organisational structures.

SIOPE and E [NCCA, the European Network for Cancer research in Children and Adolescents](#) , on behalf of the European paediatric oncology community, call for:

FAIR and proportionate regulation of childhood cancer trials, where the aim is to improve survival using medicinal products that are already in common use

FAIR and proportionate insurance for academic trials treating children with rare diseases, secured through the proposed 'national indemnity schemes'

- Read [our position](#)

- Read [our proposed amendments](#)

Every year SIOPE organises a high-level meeting at the European Parliament in Brussels to mark International Childhood Cancer Day. SIOPE and MEP Glenis Willmott have invited experts and decision-makers to discuss key aspects of the Regulation. Exceptionally this year, experts from other paediatric diseases who are members of the [European Network of Paediatric Research at the European Medicines Agency](#)

will join as speakers and provide their perspective on the new legislation. We anticipate a lively and forward-looking discussion on how to improve clinical research for children and adolescents in Europe.

For more information, please contact us at [office\(@\)siope.eu](mailto:office(@)siope.eu).