International Childhood Cancer Awareness Day

Creating a brighter future for young people with cancer

SIOP Europe
the European Society for Paediatric Oncology

Press Release

Brussels, 4th February 2015

The EU Data Protection Regulation and the Need for better Childhood Cancer Outcomes

On 3rd February 2015, more than 80 participants from all over Europe debated the projected consequences of the new EU Data Protection Regulation on childhood cancer research. The European Parliament kindly hosted the event *'Balancing Personal Data Protection and Research Progress: The Case of Childhood Cancer'*, chaired by MEP Ms Glenis Willmott, giving a unique opportunity for all relevant stakeholders to provide their perspectives on this controversial subject.

On this occasion, childhood cancer survivors and parents, healthcare professionals and representatives from the European institutions highlighted a few key aspects:

- **The childhood cancer community is concerned that the proposed Regulation – whilst aiming to protect patients – may unintentionally hamper biomedical research for children or prevent it altogether.**

  The necessary up-to-date research based on previous biomaterials and matured clinical trials data investigating biomarkers and mode of action pathways in childhood cancer biosamples is vital to foster innovative drug development enabling better cure rates and reduced long term side effects.

To maintain and accelerate research in childhood cancer, in the ongoing revision process the EU Data Protection Regulation should adopt the following:

1) A "broad one-time consent" procedure as a basic requirement in Childhood Cancer Research

Consent is an important principle in health research and researches will seek consent when it is possible. However, **Art. 4 (8) of the proposed Regulation requires specific and explicit consent** for the use of personal health data for any research purpose. Broad consent allows the use of personal data many times for various research projects, some of which cannot be predicted at the time first consent is requested. The principle of a broad and one-time consent is therefore vital in the case of childhood cancer, where re-contacting all former participants in a study for a new childhood cancer research project is not only cumbersome, resource-intensive and costly (many years later after the original study when consent was given), but often also logistically impossible (when study participants have grown out of paediatric age and have moved houses, country or even have changed names!). Limiting samples sizes in childhood cancer research - being a rare disease category by itself - endangers research to become inaccurate caused by the forced limitation of data sets. The current restrictions proposed in the Parliaments' Regulation draft require repeated explicit and specific informed consent for any research undertaken and potentially triggers an unforeseeable magnitude of repeated informed consent procedures imposed on patients and families even many years after cancer treatment when they often wish " to be forgotten" and desire a normal life
Notwithstanding, the right of withdrawal of consent was uniformly agreed upon by all stakeholders.

2) Authorisation to use pseudonymised data (not anonymised) involving trusted third parties in research based on a broad consent with safeguards in place

Personal data, such as individual patient records and data collected in research studies, enable researchers to answer questions about the risk profiles of respective childhood cancer types and how effective and safe cancer therapy and associated interventions are. Access to personal data is also important to identify previous childhood cancer patients for any long-term follow-up observations to learn about long lasting side-effects of previous cancer treatments, but also about their well-being and quality-of-life.

To keep personal data safe in research, it is masked, and the term for this is "pseudonymisation" implanted via state-of-the-art technologies. The individuals' identity is only unmasked when really needed,

and according to strict rules enrolling in such a process so called “trusted third parties or an honest broker”. Individuals behind the pseudonyms given are not directly identifiable for the researchers involved in a specific research task.

The current definitions of anonymised/pseudonymised data in the Regulation are imprecise and the associated risk and legal consequences uncertain. Clarification is needed under which conditions medical research may be undertaken on non-directly identifiable data.

3) A harmonised Data Protection Regulation that avoids European fragmentation in interpretation of laws for observational research

At present the Regulation, in reserving large parts of the rule-making to EU member states, risks leaving matters just as fragmented as under the existing Directive. The European legislator should use the present opportunity to set out a framework for achieving consistent approaches to health data use for research: this will significantly help researchers in trans-European projects and constitute a significant step towards a European-wide standardised approach to data protection.

Message from the Childhood Cancer community to the European policy stakeholders:

Childhood cancer patients, parents and survivors strongly **support data sharing** to enable research, a fact that was clearly pointed out during the meeting by their endorsement of the concept of “**broad and one-time consent procedure”.** This is essential for the **secondary use of data for up-to-date research** to be undertaken over the span of time, either for academic research questions or population-based cancer registry surveillance and outcome studies.

The important role of appropriate safeguards, and in particular **stewardship by accredited independent ethical committees regarding new research questions in the course of time,** were welcomed to avoid life-long reminders on their cancer history. However and noteworthy, childhood cancer survivors wish to take over responsibility and governance over their own personal data and biomaterials previously devoted to research when reaching the age of adulthood, i.e. 18 years, and wish to give a broad second consent at this point in their life.

The broader paediatric haemato-oncology community called for a **harmonised Data Protection Regulation** under EU legislation without Member State exemptions, to avoid fragmentation and to enable continued progress in the fight against cancer.

The request of the community: Law should acknowledge this consensus that a specific and explicit informed consent is not a workable approach. Instead, a clearer, public health-related exception of the need to consent in medical research scenarios on a European level (preferably in article 83) and a provision clarifying that *‘specific, yet general, revocable consent (broad one-time consent)’* can suffice to legitimate data processing. Both exceptions could apply with explicit safeguards in place such as ethical review, strong pseudonymisation and involvement of trusted third parties as well as legally binding contracts on the legitimate use of data between researchers involved. All high-level speakers, panellists and participants agreed on the importance of taking into account all perspectives – via a reinforced collaboration among all stakeholders – in order to carefully balance individual data privacy and the urgent need for research progress.

CONTACTS: Prof Gilles Vassal, SIOPE President (c/o Ms Samira Essiaf, office@siope.eu, +32 2 775 02 12)

EVENT INFORMATION: International Childhood Cancer Awareness Day (ICCD 2015)
‘Balancing Personal Data Protection and Research Progress: The Case of Childhood Cancer’
Tuesday 3rd February 2015 (10:30 – 12:30)
European Parliament, Brussels, Belgium

PROGRAMME: Available here (presentations, video and pictures soon downloadable on the same page)

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SIOPE (SIOP Europe)
The European Society for Paediatric Oncology
Web: www.siope.eu
Email: office@siope.eu
Tel: +32 2 775 02 01
Avenue E. Mounier 83, 1200 Brussels, Belgium