

## **SIOPE Statement on EHDS: A Harmonised Data Sharing Framework is Vital for Life-Saving Research**

### **Health Data Sharing and Research in the Childhood Cancer Community**

A robust EU framework on health data sharing is vital to facilitate cross-border scientific collaboration, improve standards of care, and drive overall progress in childhood cancer. Due to the rarity of childhood cancers, cross-border collaboration and data-sharing is crucial to overcome small sample sizes in research and exchange specialist expertise in care delivery. Data sharing is systematically accompanied by strong measures securing personal data, such as “pseudonymisation”, state-of-the-art technologies and legally binding agreements.

The European Society for Paediatric Oncology (SIOPE) welcome the progress made in the path to adopting the Regulation for the European Health Data Space (EHDS), aimed at providing a harmonised health specific ecosystem to unlock the full potential of health data <sup>1</sup>.

### **Recommendation on the Secondary Use of Health Data**

The European Commissions proposal ensures individuals privacy through the use of anonymised or pseudonymised data (Art. 44), strong mechanisms to safeguard against abuse, including lists of permitted uses (Art. 34) and prohibited uses (Art. 35), and rules for governance and practical mechanisms <sup>2</sup>. Such a trustworthy setting for secure access and processing of health data, building on existing personal data protection legislation such as GDPR, is a welcome development. SIOPE fully support the need to ensure that health data shared for secondary use is safeguarded and secure, which is current practice in cross-border paediatric cancer collaborations.

The debate surrounding a potential consent mechanism for the secondary use of data is an important element in the current EHDS trilogue negotiations. With due consideration to the need to balance the safeguarding of data privacy rights while facilitating cross-border data sharing, if a consent mechanism is included SIOPE recommend a one-time “broad” consent from patients or parents/legal guardians covering all categories of electronic health data to facilitate seamless data sharing. Requiring consent for each project using data secondarily should be avoided, and one-time re-consent when the child reaches 18 years of age should be possible <sup>3</sup>.

Above all, harmonised implementation and interpretation of data sharing rules in the EU is vital to facilitate rather than impede cross-border healthcare delivery and high-quality scientific research, especially in a rare disease settings like childhood cancer. A one-time “broad” consent for secondary use can underpin a EU health data sharing framework that empowers patients and facilitates live-saving research and innovation. One time consent is also supported by parents of children and young people with cancer.

This approach would allow the childhood cancer community to continue with lifesaving cross-border research and care delivery to cure the youngest and most vulnerable in our society. We look forward to engaging with relevant bodies and EU institutions to enable research and expertise sharing activities for the benefit of children and young people with cancer.

With many thanks,

The European Society of Paediatric Oncology

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<sup>1</sup> ‘European Health Data Space - European Commission’. Available: [https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space\\_en](https://health.ec.europa.eu/ehealth-digital-health-and-care/european-health-data-space_en)

<sup>2</sup> Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space. Available: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0197>

<sup>3</sup> Vassal et al., ‘The Impact of the EU General Data Protection Regulation on Childhood Cancer Research in Europe’. Available: [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(22\)00287-X/fulltext](https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(22)00287-X/fulltext)