The impact of the EU General Data Protection Regulation on childhood cancer research in Europe

The EU General Data Protection Regulation (GDPR)[1] was implemented on May 25, 2018, stipulating rules on the protection of individuals regarding the processing and free movement of personal data. 3 years later, the European Society for Paediatric Oncology (SIOP Europe) conducted a survey among clinicians and academics from across Europe to investigate the impact of the GDPR on childhood cancer research, and to identify the challenges and opportunities in this field.

For more on **data protection in the EU** see https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en

Cross-border sharing of personal health and research data is fundamental to advancements in childhood cancers as a collection of rare and ultra-rare diseases. The GDPR includes provisions that justify the processing of personal data, including health data, for scientific research purposes, while simultaneously respecting the fundamental rights of individuals.[1] A strong legal framework on health data sharing for research purposes is essential to respond to the practical challenges in international scientific collaboration and reinforce high-quality research activities in paediatric haematology and oncology.

In November, 2021 SIOP Europe surveyed its members, including clinicians and researchers from across 35 European countries, on the GDPR's impact on childhood cancer research in Europe. 128 paediatric haematology-oncology professionals from 28 countries (23 EU member states and 5 non-EU countries) participated in the survey. The aggregated findings clearly articulated the value of the regulation in protecting EU citizens' rights but also revealed a high degree of complexity perceived by researchers and the negative consequences of the GDPR on the implementation of research programmes.

See **Online** for appendix

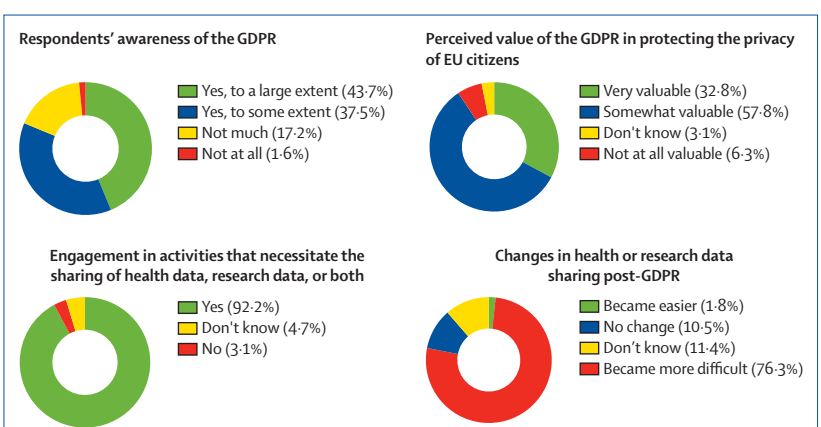

Figure: **Results of SIOP Europe's survey on the impact of the GDPR on childhood cancer research in Europe**
The survey by SIOP Europe was conducted in November, 2021. SIOP Europe=European Society for Paediatric Oncology. GDPR=General Data Protection Regulation.

Many of the survey respondents were aware of the GDPR and understood the value of the regulation in terms of protecting EU citizens' privacy (figure). Of the 128 respondents, 118 (92%) are involved in activities requiring health or research data sharing and access to tissue samples, highlighting that integrating research and care is a hallmark of paediatric oncology. However, 87 (76·3%) of 114 (114 of 128 answered the non-mandatory question) respondents indicated that those research and care activities became more difficult since the GDPR's implementation. More than 50% of respondents (56 of 95 people, as fewer people answered the non-mandatory question) experienced difficulties across a range of activities, including basic and translational research, the conduct of clinical trials, patient consenting procedures, and research with long-term outcomes (appendix). Overall, individual contributions revealed that the principles of the GPDR are implemented differently from one country to another, and even between institutions in the same country.

Based on these results, SIOP Europe formulated recommendations for improving the current legislative framework as follows: (1) a harmonised implementation and interpretation of the GDPR across all EU member states and within institutions in the same country, including clarity on the definition of the legal basis for data sharing in academic research as public interest; (2) a one-time broad consent from patients, parents, or legal guardians, and the possibility of a second broad consent at the age of 18 to facilitate seamless data sharing and processing for secondary use of data and tissues; (3) consider pseudonymised data as anonymised data in certain circumstances; (4) support for privacy-preserving data linkage; (5) population-based cancer registration without the obligation for explicit patient consent to ensure

data representativeness, with the possibility to share data internationally with appropriate safeguards; and (6) facilitation of secure data exchange outside the EU or European Economic Area for public health and academic research purposes.

Building on previous initiatives that contribute to a higher degree of harmonisation,[2,3] developing unambiguous implementation guidelines for member states on research activities could be regarded favourably, not only by paediatric haematology and oncology professionals, but across all fields of academic research. The European Commission proposal for the creation of a European Health Data Space holds further potential to support scientific research and envisages a common scheme for research projects conducted in multiple EU member states, as suggested by the European Data Protection Board.[4] SIOP Europe encourages the adoption of such an approach as highlighted in its Strategic Plan Update 2021–26, which states that sharing, integrating, and analysing extensive datasets as one is central to advancing childhood cancer research.[5]

Although the GDPR acts as an essential tool for protecting EU citizens' personal health data, the recommendations stemming from the SIOP Europe survey on its impact on childhood cancer research in Europe strive to improve and simplify the sharing environment for data and biological samples to facilitate research activities across all fields of research. To achieve long-term progress and foster effective cross-border data sharing, further concerted efforts are needed at both the EU and member state levels. SIOP Europe will engage in continued dialogue with relevant EU bodies, including the European Data Protection Board, to promote a harmonised implementation of the GDPR within and across EU member states for the benefit of health research.

We declare no competing interests.

Gilles Vassal, Deyan Lazarov, Carmelo Rizzari, Tomasz Szczepański, Ruth Ladenstein, Pamela R Kearns
gilles.vassal@gustaveroussy.fr

Department of Paediatric Oncology, Gustave Roussy, 94805 Villejuif, France (GV); University Paris Saclay, Gif-sur-Yvette, France (GV); European Society for Paediatric Oncology–SIOP Europe, Brussels, Belgium (DL); University of Milano-Bicocca, Haematology-Oncology Unit, MBBM Foundation, ASST Monza, Monza, Italy (CR); Paediatric Haematology and Oncology Department, Medical University of Silesia, Zabrze, Poland (TS); St Anna Children's Hospital and Children's Cancer Research Institute, Department of Studies and Statistics for Integrated Research and Projects and Department of Paediatrics, Medical University of Vienna, Vienna, Austria (RL); Cancer Research UK Clinical Trials Unit, National Institute for Health Research Birmingham Biomedical Research Centre, Institute of Cancer and Genomic Sciences, University of Birmingham, Birmingham, UK (PRK)

1 EU. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). May 4, 2016. https://eur-lex.europa.eu/eli/reg/2016/679/oj (accessed Feb 25, 2022).

2 European Science Foundation, All European Academies. The European code of conduct for research integrity, revised edition. May, 2017. https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/guidance/european-code-of-conduct-for-research-integrity_horizon_en.pdf (accessed Feb 25, 2022).

3 European Data Protection Supervisor. A preliminary opinion on data protection and scientific research. Jan 6, 2020. https://edps.europa.eu/sites/edp/files/publication/20-01-06_opinion_research_en.pdf (accessed Feb 25, 2022).

4 European Data Protection Board. EDPB document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research. Feb 2, 2021. https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf (accessed Feb 25, 2022).

5 Kearns PR, Rizzari C, Vassal G, et al. The SIOPE Strategic Plan update 2021–26: a European cancer plan for children and adolescents. Sept 8, 2021. https://siope.eu/media/documents/siop-europes-strategic-plan-update-2021-2026.pdf (accessed Feb 24, 2022).

Importance of clinical research for the UK's 10-year cancer plan

The ambition of the UK Government's 10-year cancer plan consultation document to transform cancer outcomes is highly welcome.[1] This consultation must reflect on the extraordinary role played by the UK research community in responding to COVID-19—a response enabled by clinical research delivery infrastructure embedded within the National Health Service (NHS), which allowed rapid clinical evaluation of novel treatments and vaccines to save and transform lives. This unique national research delivery capability is the legacy of more than two decades of national clinical research networks, with co-operation between government agencies, charitable funders, and many others. This national capability started in cancer with the inception of the National Cancer Research Network and the National Cancer Research Institute (NCRI) in 2001. Now, through the National Institute for Health and Care Research (NIHR) Clinical Research Network (CRN), it extends across the full spectrum of health and social care. Cancer outcomes have been

Chris Dorney/Shutterstock.com

Published **Online**
June 9, 2022
https://doi.org/10.1016/S1470-2045(22)00292-3