SIOP Europe
the European Society for Paediatric Oncology

Impact of the GDPR on Childhood Cancer Research in Europe

Survey Outcomes and Recommendations (December 2021)

EXECUTIVE SUMMARY

In November 2021, the European Society for Paediatric Oncology (SIOP Europe) conducted a survey among its members regarding the impact of the EU General Data Protection Regulation (GDPR) on childhood cancer research in Europe since the legislation's entry into force in 2018.

128 paediatric oncology professionals from 28 countries across Europe responded to the questionnaire. The majority affirmed to be overall aware of the GDPR (44% to a large extent, and 38% to some extent). More than 90% believe there is value in the regulation with respect to protecting EU citizens' privacy. A similar majority of respondents declared to be actively involved in processes that necessitate the sharing of health and/or research data. Moreover, in their overriding majority (around 95%), respondents admitted to facing difficulties in health and/or research data sharing. Approximately 75% of respondents believe health and/or research data sharing had become more difficult since the GDPR's entry into force, whereas approximately 10% indicated not to have experienced any change in the degree of complexity. With regard to specific activity areas pertinent to paediatric oncology, upon the entry of force of the GDPR:

- Discovery and translational research were perceived as more difficult by more than 50% of the respondents.
- The conduct of clinical trials was considered to have become more cumbersome by 70% of the participants.
- Patient control over their own data was thought to have become easier by about 30% of respondents. However, around 25% believe it has become more difficult and another 23% did not think there had been any change.
- Patient (re-) consent procedures were categorised as more difficult with the GDPR in place by around 60% of respondents.
- Long-term outcomes research became more difficult according to around 63% of respondents.

In addition, participants had the opportunity to share real-life examples of improvements or obstacles to health and/or research data sharing from their daily professional practice to elucidate the current reality in paediatric oncology across Europe.

On the basis of the survey results, SIOP Europe formulated recommendations for improving the current legislative framework on the (re-) use of health data for research purposes. The following six recommendations intend to support the work of EU policy makers towards facilitating data-sharing for the benefit of young cancer patients, survivors and their families.

SIOP Europe, c/o BLSI | Clos Chapelle-aux-Champs 30, Bte 1.30.30 | 1200 Brussels, Belgium | Tel: +32 2 880 62 84
Web: www.siope.eu. Email: office@siope.eu

RECOMMENDATIONS

1. 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 or parents/legal guardians and the possibility of a second 'broad' consent at the age of majority to facilitate seamless data sharing and processing for secondary use of data and tissues.
3. Consider pseudonymised data (i.e. key-coded data) as anonymised in certain circumstances.
4. Support privacy-keeping data linkage such as by means of state-of-the-art technologies.
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.
6. Facilitate secure data exchange outside the EU/EEA for public health and academic research purposes.

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