

GDPR obstructs cancer research data sharing



The EU's General Data Protection Regulation (GDPR) is having unforeseen, deleterious consequences on the progress of international health research according to a report co-authored by the Federation of European Academies of Medicine (FEAM), the European Federation of Academies of Sciences and Humanities (All European Academies or ALLEA), and the European Academies' Science Advisory Council (EASAC).

The report is the product of an initiative between the three academic networks and contains almost 2 years of evidence of the obstructive impact the GDPR is having on areas of public health that are a global priority, such as cancer heterogeneity. The GDPR, which came into effect in EU law on May 25, 2018, and was designed to safeguard Europeans from general data and privacy breaches, has caused untold delays and disruptions to international collaborative health research by prohibiting the sharing or transferring of health data outside the EU or EEA, resulting in an estimated 5000 projects affected in 2019 alone.

Such data sharing is essential to the public health of EU and EEA citizens, the report argues, as it ensures that the results of international studies are valid for the particular genetics, risk factors, and other socio-environmental determinants of health within home populations. Any unwarranted impediment to data sharing might therefore prove detrimental to public health, and jeopardise Europe's position as a global leader in collaborative health research.

"Complexities with the implementation of the GDPR have affected at least 40 cancer studies funded by the US National Institutes of Health (NIH) and data flows to the

WHO's International Agency for Research on Cancer (IARC), and we might be seeing just the tip of the iceberg," explained George Griffin (FEAM, Brussels, Belgium). "Brexit might create similar obstacles, unless a decision on the adequacy of UK data protection is confirmed by the EU Commission soon. Simple solutions to facilitate the exchange of pseudonymised data between researchers while protecting patients' personal data are needed. Researchers need these solutions urgently, but there is also a risk of losing the value of research for patients and society at large".

Given the exigent nature of the problem, the report issues an urgent request to policy makers to find a workable solution that complies with Article 46 of the GDPR, respects the fundamental right to personal data protection, and does not contravene the laws and regulations of other countries and international organisations in the process. It also calls upon the European Data Protection Board to provide operational guidance in this area, as well as examples of good practice from the health sector to help ensure that existing data transfers and ongoing collaborative research projects can continue. Failure to do so, they warn, will inevitably result in some attempt to circumnavigate the GDPR, thus creating an insecure data sharing environment.

"Unintended consequences of the EU's GDPR have resulted in major challenges for international medical research, affecting collaborations between public sector researchers in Europe and organisations affiliated with the US government, such as medical centres, public universities, and the NIH," confirmed Antonio Loprieno (ALLEA, Berlin,

Germany). "Health crises, such as the COVID-19 pandemic, show that efficient sharing of personal health data is crucial to ensure that locally conducted research can be used at the world level. We need a solution that maximises the individual and societal benefits to be obtained from research participants' contributions in order to improve the diagnosis and treatment for patients in both global regions and beyond".

"The COVID-19 pandemic has shown us the importance of collaboration and sharing information within and across borders," agreed Paulo Giovanni Casali (European Society for Medical Oncology [ESMO], Lugano, Switzerland). "It has also shown us the fragmented implementation of GDPR and the difficulties researchers have had to collaborate with each other, not because the will is not there, but because the framework is challenging".

"As ESMO, we have been highlighting the importance of a harmonised GDPR for years, specifically with respect to two crucial points: one, the ability of patients being able to donate their data and tissues for retrospective observational research, including biobanks (recital 33, GDPR); and two, ensuring the functioning of population-based disease registries (recital 157, GDPR). Supported by the main European oncology societies and patient representatives, we are concerned regarding the recent interpretations of these recitals by the European Data Protection Board, and we urge that these recitals be implemented without unjustified restrictions. A harmonised GDPR is the only way to protect science and move research forward."

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