Is Europe putting cancer research at risk?

July 25 2014

The European Society for Medical Oncology (ESMO), the leading pan-European association representing medical oncology professionals, has expressed concern that the proposed EU General Data Protection Regulation could make cancer research impossible and add a significant burden to both doctors and cancer patients.

The proposed wording of the regulation stipulates 'explicit and specific patient consent', meaning that researchers would have to approach patients every single time research is planned in order to consult their data or use tissue samples stored for research purposes.

"Hope for patients facing a life-threatening disease like cancer is based on advances in research," said Kathy Oliver, Chair of the International Brain Tumour Alliance. "And research progress requires access to a wide pool of patient data, even from patients who have since passed away and can no longer provide consent to allow for research that could save lives in the future."

"This could put a halt to many public health research efforts," said ESMO President Rolf A. Stahel. ESMO proposes that the text of the EU General Data Protection Regulation includes a 'one-time consent' for research, ensuring patients are aware of what they are consenting to —with the appropriate safeguards in place, and that they can withdraw their consent at any time. "Our proposal achieves the correct balance between the right to privacy and the right to health," the ESMO President continued. "It actually 'empowers' patients, allowing them to choose whether to donate their data and tissue for public health research,

whose ultimate goal is to find cures."

"As a cancer patient, I cannot think of any reason not to allow access to my data to help other patients receive better care and contribute to advancing cancer research," noted Hans Keulen, a Dutch rare cancer patient from the Chordoma Foundation.

Paolo G. Casali, ESMO Public Policy Committee Chair, author of the official ESMO Position Paper on the risks of the new Data Protection Regulation, said: 'We understand the need for the EU to address data privacy concerns in many sectors, with the surge of risks brought about by the use of digital information, but its effect on public health research may have been unintentionally overlooked."

Population-based cancer registries, for example, storing information to monitor disease trends, are intrinsically incompatible with any requirement of individual consent: "If a patient is allowed not to consent use of his/her anonymised data for the registry, the data provided by that registry will be unrepresentative and can lead to incorrect conclusions for public health actions," noted Casali.

ESMO is in favour of the inclusion in the EU General Data Protection Regulation of the withdrawable 'one-time consent' concept – already foreseen in the Clinical Trials Regulation adopted by the European Union in 2014, which allows to use data already stored beyond the end and the specific scope of a trial, with the usual strict safeguards.

"We are calling upon the European Union to assure that all forms of public health research will survive and be able to function within the safeguards that are in place, without adding the nearly impossible administrative burden of re-consenting each patient, every time, for every single project, which could irreversibly slow down the accelerated pace that cancer research has gained over the past decades."

More information: www.europarl.europa.eu/sides/g … ence=P7-TA-2014-0212

Provided by European Society for Medical Oncology