ESMO Position Paper on EU Data Protection Regulation

Clinical retrospective research, biobanks and cancer registries are under threat by new data protection rules in the EU

The new European Union (EU) proposal for a General Data Protection Regulation is under review by the European Parliament, the Council of the European Union and the European Commission (1). It sets the rules under which personal data will be handled in the EU. It will thus affect many areas of our everyday life including health and research. ESMO and the cancer community are deeply concerned about some unintended consequences of the current wording of the draft Regulation (2), which may put at stake the survival of retrospective clinical research, biobanking, and population-based cancer registries in the EU. The EU Parliament’s current position on the Regulation is far from improving the ability of health researchers to carry out retrospective studies because it imposes the requirement for medical professionals to ask for a patient’s ‘specific’ consent every single time new research is performed on already available data and/or tissues. This would lead to the necessity of researchers continuously asking patients to “re-consent” for every single use of their data. Likewise, it would hinder the very collection of vital health information by requiring consent for the recording of data in population-based disease registries, which by definition need be all-inclusive, i.e., must collect all of the data of all individuals belonging to a given population.

We would like the ongoing legislative negotiation process to find the right balance to fully protect the privacy of patient data, while maintaining ease of access to data for translational, clinical and public-health research. We believe a safe balance between all rights concerned can be achieved, and conflicts among different rights can be avoided, especially where we feel that such conflicts in reality may not exist at all. It is vital that we continue the progress in health research made over the last 40 years both on infectious diseases and non-communicable diseases, such as heart diseases and cancer.

Data protection and confidentiality

Since the time of the Hippocratic Oath, the confidentiality of patient data has been protected. Additional safeguards exist through medical codes of ethics and the approval of research projects by independent review boards and/or ethics committees. Patient representatives should be included in these committees as well as in those overseeing the storage of patient tissue in biobanks. Full transparency should be provided on the mechanisms of research and the functioning of biobanks, through online facilities for example, so that the public is kept updated on their evolution.
ESMO agrees that every safeguard should be put in place to minimize the risk of breaches in confidentiality, including resorting to forms of pseudo-anonymisation of data whenever possible (3). Data and tissues, such as tumour samples, are stored within hospital archives for medical and legal reasons, where breaches to confidentiality are generally negligible. Risks are further minimized when tissues are stored within biobanks, which place safety amongst their highest priorities.

When publishing the results of research studies, patient data are disseminated only as aggregate information and summary results. The identity of individuals remains completely undisclosed. ESMO agrees that additional legal protection of patient data and tissue samples should be conferred by the EU that legally prohibits patient data being processed for purposes not related to health research or in such a way as to create discrimination against any single individual. In effect we believe that the protection of a person’s privacy can well be fulfilled through safeguards that should be monitored and adapted to new situations over time. These safeguards to protect patient data should work effectively, regardless of what kind of consent a patient has given.

Data protection and ethical issues

Ethically speaking, the need for patient consent can be viewed as a consequence of the principle of individual autonomy, i.e., one of the four pillars of current medical ethics, along with beneficence, nonmaleficence and justice (4). This means that a patient must exert his/her autonomy when choosing whether to accept to undergo a treatment, as well as to enter a clinical trial. However, when research is done retrospectively on patient’s data and/or residual tissues (i.e., tissues which have not been collected specifically for research purposes and/or are left over after all clinically useful diagnostic assessments have been done), there are wide discrepancies as to whether a patient’s consent is needed. Current legislations across the EU diverge to some extent. Some countries require specific patient consent for any retrospective research. Others allow patients to explicitly opt-out of future research to be done on their data and tissues. Still others allow retrospective research without any form of patient consent (5). While ESMO respects cross-cultural discrepancies about the requirement of patient consent, our view is that, if required, patient consent should be a ‘broad’ consent (6, 7). In other words, patients should have the right to give a broad ‘one-time’ forever consent for their data and/or tissues to be processed for research purposes. We also feel that the EU Regulation could well state that this consent can be withdrawn by the patient at any time.

We would like to avoid the terminology of “specific” consent, which would result in researchers needing to obtain continuous patient re-consent ever time new research is performed. Continually obtaining ‘specific’ consent is practically unfeasible, time-consuming, administratively burdensome, expensive, and also intrusive into patients’ lives even many years after their disease experience. It is important to note that our position of advocating for a ‘one-time’ consent means that patients will be informed that their data / tissues will be used for future research, and they will be informed about the conditions under which their data and tissues will be stored, making the protection safeguards a part of their consent. Under this scenario, the patient retains the right to deny the consent and to withdraw it at any time. Thus, a broad, ‘one-time’, withdrawable consent would allow patients – if, and only if, they are willing - to ‘donate’ their data and/or tissues to promote the public interest of future health research. In this way, the ethical principle of a patient’s autonomy would be fully respected, since the choice is made by the patient and is withdrawable at any time. Along this line of reasoning, ‘opt-out’ choices, dynamic consents (8), and similar options, would be variations of the same principle. Indeed, there is evidence of favourable attitudes of patients towards the concept of broad consent (9).
Data protection, epidemiological research and population-based disease registries

A derogation from the obligation of any form of consent for public-health epidemiological research through population-based disease registries is essential (10). In the field of public health research, disease registration is now well established and has led to many major advances. In oncology, it provided reliable population-based data on incidence, prevalence and survival rates of cancers. These data have been crucial in understanding trends in cancer occurrence – i.e. to trace cancers to their specific causes, to correlate survival with changes in health organization, to assess the outcome of newly implemented treatments, to plan new actions in health policy, to establish cancer plans and measure their effectiveness, and so on. By definition, cancer registries can only fulfil the essential goals of public health if they can collect and scrutinize entire patient populations. For this reason, they are incompatible with any requirement of individual consent. If a patient is allowed not to consent, the data provided by the relevant registry will be incomplete or unrepresentative, and can lead to incorrect conclusions. Even if the number of patients denying their consent could be negligible, the actual process of obtaining consent from every individual within a country or region would be almost impossible. The Data Protection Regulation therefore should not include an option for patients to ‘opt-out’ of having their data recorded in population-based disease registries. In return for this exemption, disease registration should be carried out by public bodies, or publicly endorsed bodies, should comply with stringent safety requirements and should be overseen by public bodies in a fully transparent manner.

Recommendations

In summary, we believe that patients should have the right to ‘donate’ their data and tissues to health research. Where patient consent is required, it should be a fully informed, withdrawable, broad, ‘one-time’ consent for unlimited use of data or tissue for health research. Denial of this right would make patients less free, because they would be denied a civil right, i.e. to contribute to research, which advances new discoveries and ways of improving their health and that of other patients. There need to be put in place legal provisions to protect data confidentiality, reviewing mechanisms for overseeing retrospective researches and biobanks, and a system allowing full transparency of research processes and storage of patient tissue in biobanks. Cancer registries should be able to register cancer cases and patient data without the requirement of patient consent, in order to provide society and health administrators with crucial health data.

We, from the European cancer community, urge all EU decision-makers to save research, as well as protect the right of patients to donate their data and tissues to advance research and find cures. We are convinced that a balance between the right to privacy and the right to health can be achieved by reasonably addressing all concerns, fully complying with those relating to confidentiality and ethical use of personal health data.
References

1) European Commission Proposal for a Regulation on the protection of individuals with regard to processing of personal data and on the free movement of such data (General Data Protection Regulation) COM (2012) 11 final; 2012

2) Di Iorio CT, Carinci F, Oderkirk J. Health research and systems’ governance are at risk: should the right to data protection override health? J Med Ethics; 2013 Dec 5 [Epub]

3) van Veen E-B. Obstacles to European research projects with data and tissue: solutions and further challenges. Eur J Cancer 2008; 44: 1438-1450.


Endorsements
This ESMO position paper on the EU General Data Protection Regulation is endorsed by the following organisations, and under review for endorsement by additional organisations:

European Organization for Research and Treatment of Cancer

European, Middle Eastern & African Society for Biopreservation and Biobanking

Eurocan Platform

European Society of Surgical Oncology

European Society of Pediatric Oncology

European CanCer Organisation