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PM+: EU data rules threatening health research

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Opinion Plus

‘Balance’ needed on patient consent, argues Paolo Casali.

As a medical oncologist, everyday I have patients asking what I can do to help them. My answer depends on the vast body of health research that has been built up over many decades.

This is not just research stemming from clinical trials: it is also from observational, translational and epidemiological research. This is the result of years of information stored in hospital archives, tissue banks and population disease registries across the world.

Therefore, the cancer research community was very surprised when the European parliament voted for a new data protection framework that restricts the gathering and processing of data for this kind of health research.

As we, the European oncology community, recently argued in an article published in the Annals of Oncology journal, the parliament’s position might have inadvertently but seriously, put health research in the EU at stake.

We understand that the new regulation needs to cover all sectors of life as far as privacy is concerned, so, we recognise that the rules may be strict. However, implementing several tiers of red tape between a patient and the use of their data and tissues for research will not benefit society.

> "The parliament's position might have inadvertently but seriously, put health research in the EU at stake"

On the contrary, it will slow down research and will negatively affect research conducted for new treatments and cures for diseases. We must find a balance. We believe a balance is possible.

Two issues in particular can have a detrimental effect on health research when applying this approach: the need to go through re-consent procedures every time data or tissues are used, and the requirement that population-based disease registries rely on consent.

Registries, which are databases that gather very basic information on the frequency and mortality of a disease across entire populations, are incompatible with the requirement of consent.

If just one patient refused to have their case registered, our data on incidence, prevalence and mortality of that disease would be false. Cancer registries have been instrumental for research on areas such as identifying causes of cancer, such as radiation or smoking, in understanding the evolution of diseases and in looking at patient outcomes in different countries, which is vital in making public health decisions.

As far as retrospective research and tissue banks are concerned, the need for consent for every re-use of data after the initial collection of data or tissues would add a significant burden and delay.

Researchers would have to contact every patient, years after their disease episode. Often this is simply impossible, or at least extremely burdensome, and possibly poorly accepted by patients who may well have forgotten a disease they had many years before.

> "A reasonable possibility for the patient is to decide once - whether to give their consent, a so-called 'one-time consent'"

However, we value the ethical principle of having patient's consent when their data or tissues are used for research purposes. A reasonable possibility for the patient is to decide once - whether to give their consent, a so-called 'one-time consent'.

This consent should be retractable at any time, but this would be a patient's active choice. Clear safeguards should be implemented to guarantee the protection of data, but this can be easily done through appropriate regulations.

By the way, technologies are continuously changing, so if we want to really protect a patient's privacy, we must also continuously update regulations. And of course, any new research will never be complete without the clearance of ethics committees and the like.

Fortunately, the parliament's position is not the final step in the process of adopting this important legislation. EU governments in the council of ministers also have to agree to it.

My colleagues in the cancer community and I hope that the three European institutions will find a way to protect not just data, but also the hopes of patients suffering from cancer and other major

diseases, as well as the work of the researchers searching for the cures.

About the author

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