Published on *The Parliament Magazine* (https://www.theparliamentmagazine.eu)

Data protection regulation set to benefit patient health

Written by Richard Bergström on 4 December 2015 in Thought Leader
Thought Leader

A balanced approach to data protection in research will boost patient health, writes Richard Bergström.

Patients and healthcare systems could benefit significantly from the improved use of health-related data.

Increased scrutiny of clinical data will not only help us to understand diseases and develop therapies, it will also speed the transition towards modern health systems, focused on health outcomes for patients.

The data protection regulation serves as one of the key governing factors that will oversee the use of "big data". The problem at present, though, is that the regulation in its current form may create significant uncertainty with regards to the potential use of real world patient data and patient registries.

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Ensuring that society achieves the correct balance to the big data issue, a system of regulation that offers a considerable level of protection for individuals with simultaneous high-quality data access for researchers and healthcare providers is a prerequisite.

For the pharmaceutical industry, it is abundantly clear that access to personal data ultimately depends on public confidence in how it is managed. What is therefore required is a forward-looking regulation that is proportionate, flexible and capable of adapting to technological progress.

Achieving this would contribute to a greater alignment of regulatory approaches between EU member states, improve conditions for data sharing across borders and provide a more consistent basis for the exercise of privacy rights.

Where possible, individual consent of new uses of existing data should be sought and modalities for supporting this should be explored, as should the role of patient-owned data resources.

Nevertheless, from the pharmaceutical industry's perspective it is essential that the regulation recognises that research is not a linear process and that it is rarely possible to foresee all the potential uses of patient data.

The value of broad consent cannot be underestimated as a means of making data available for re-use, ensuring that the vast amount of data already collected in patient registries remains accessible for innovation.

An effective regulation would therefore include a provision allowing for data - once it has been adequately protected - to be re-used for research or health-related purposes, without requiring the repeated consent of subjects each time. As such it would be counter-productive for the regulation to define the breadth of consent.

The regulation should also recognise that the processing of health data serves the public interest especially when it is undertaken to protect against public health emergencies.

It's in all our interests to better understand diseases, develop new therapies, and contribute to the effective and efficient management of healthcare systems. The best possible scenario would see member states aligning their approaches. It is important not to lose sight of the patient in this debate.

Safeguards must be put in place to shield individual patients from potential negative impacts resulting from the processing of their data. These may include: informed broad consents; ethics committee reviews; the pseudonymisation of data and provisions to ensure that data is not processed with the aim of singling out certain patients.

If a balance on the use of clinical data can be achieved, Europe will be able to improve the quality of patients' lives.

About the author

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