



fighting heart disease
and stroke

european heart network

EU General Data Protection Regulation – Recommendations from the European Heart Network ahead of the trilogue negotiations

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Introduction

Data is everywhere. In a world where technology has embraced most of the human activities, individuals leave digital traces in every connected action. We have seen a transformation of the healthcare and research settings in recent times. The extraordinary growth of eHealth and mHealth, cloud storage services and big data aggregation allow for the collection and storage of enormous amounts of personal data, including health data.

In this context, the European Commission initiated in 2012 the revision of the existing EU data protection framework (notably, Directive 95/46/EC) in order to set the right balance between a simplified regulatory environment for businesses and the citizens' right to privacy and control over personal data.

More than three years after the Commission's proposal for revision, the European Parliament, the Council and the Commission have now entered trilogue negotiations in order to decide on a final legislative text. The objective is to end the trilogue discussions in December 2015 under the Luxembourg's current Presidency.

As a research-oriented alliance of heart foundations and cardiovascular patients' groups, the European Heart Network (EHN) favours a balanced approach allowing the progress of medical research under high quality privacy standards.

This paper enumerates our recommendations ahead of the trilogue negotiations on the General Data Protection Regulation.

About the European Heart Network

The European Heart Network (EHN) is a Brussels-based alliance of heart foundations and other like-minded non-governmental organisations throughout Europe. EHN has members in 25 countries in Europe. EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, capacity-building and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

Why is data so important for cardiovascular research?

Cardiovascular diseases (CVD) are the number one cause of death in the EU, causing over 1.9 million deaths in the European Union (40% of all deaths in the EU)¹. CVD is also a major cause of disability affecting millions of patients across the EU. Yet, mortality from CVD has decreased dramatically (more than 50%)² over the past decades; cardiovascular research has been instrumental in achieving this gain.

If today's risk factors for cardiovascular diseases are well-known, it is mostly due to discoveries made by analysing data from patient records. For example, seventy years ago, researchers demonstrated the link between smoking and its effects on the cardiovascular system. Since then, epidemiological research has unveiled many others factors underpinning heart diseases and stroke.

To assess the efficacy of new drugs, researchers need to identify eligible patients to participate in trials. Without access to patient data, finding volunteers would be almost impossible, especially for rarer conditions. Individual patient records provide a vital resource for researchers to make life-saving findings, and access is crucial.

Data protection and research – considerations

Consent is a central point in any discussion about access to data for research. No one can deny that it is a pillar principle in research and – wherever possible – researchers must and, indeed, do seek consent from data subjects before using their personal data. However, in some cases, it is not possible to do so.

For example, re-contacting participants involved in previous research to request their renewed consent prior to undertaking a new study would result in postponement and come at a prohibitively high cost. It would delay the translation of results into tangible benefits for patients and society.

It should be noted that most of the research on cardiovascular diseases carried out today is based on pseudonymised health data, rather than data whereby the subject can be identified. Based on experiences in other health research areas, restricting the use of these key-code protected data could endanger future cardiovascular research.

Clearly, all medical and epidemiological research does and will continue to be carried out in a safe framework, with important ethical and governance safeguards. This includes approval by a research ethics committee to ensure that data subjects are protected in research.

In 2014, EHN joined the European Data in Health Research Alliance (EDHRA)³ whose aim is to ensure that research can continue unencumbered, respecting the safeguards for personal data which are currently in place.

¹ Nichols M, Townsend N, Luengo-Fernandez R, Leal J, Gray A, Scarborough P, Rayner M (2012). European Cardiovascular Disease Statistics 2012. European Heart Network, Brussels, European Society of Cardiology, Sophia Antipolis; <http://www.ehnheart.org/cvd-statistics.html>.

² Ibidem

³ <http://www.datasaveslives.eu/>

The different positions of the EU institutions

The European Commission proposal introduced an explicit consent obligation for the use and storage of personal data. However, in order to take into consideration the particular needs of research, the proposal included an exemption for the use of data in research, subject to certain safeguards. In other words, the Commission proposal recognised the research imperatives. It acknowledges that specific consent is often not possible, whilst also seeking to clarify protection of personal data.

In March 2014, the European Parliament adopted its report. Amidst public fears following the disclosure of the PRISM scandal over the misuses of personal data by governmental authorities and private companies, the Parliament introduced more restrictive rules on the use of personal data. The Parliament's report is a cause for concern to the health research community. This is because it significantly reduces the scope of the research exemptions, particularly by introducing an extensive use of consent in medical and epidemiological data.

The last EU institution to give its opinion, the Council of Ministers, did so in June 2015. The Council's text maintains the European Commission's key exemptions for the use of data in research, whilst improving protection of data subjects and providing Member States with more flexibility.

Conclusions and recommendations

Personal data provide a vital resource for medical and epidemiological research which benefits society and saves and improves the lives of patients. It is essential that the European Union institutions agree on a legislative text for the new Data Protection Regulation which does not hamper such research.

Ahead of trilogue negotiations on the General Data Protection Regulation, EHN asks the Council of Ministers, the European Parliament, and the European Commission to demonstrate their shared commitment to research by finding a compromise position, that:

- ✓ maintains important exemptions for medical and epidemiological research, including an alternative means to allow processing of personal data for research where consent is not practicable;
- ✓ includes proportionate safeguards to protect data subjects' interests whilst ensuring that research exemptions are used appropriately; and
- ✓ seeks harmonisation where possible, but allows a degree of flexibility for Member States, allowing them to implement culturally and socially acceptable solutions.