FEAM
Federation of European Academies of Medicine

Data Protection Regulation

A FEAM Statement

June 2012

The Federation of European Academies of Medicine (FEAM)

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Content

Summary

We welcome the provisions in the European Data Protection Regulation to support health research that is vital to improve the health of people in the European Union (EU). To ensure that the Regulation does not inhibit ground-breaking medical science it is now necessary to clarify certain points and to address current barriers to health research. In particular:

- it is essential that Article 83 and the associated derogations that facilitate research are maintained as the Regulation moves through the legislative process;
- amendments are needed to clarify and strengthen the research provisions to ensure these achieve their intended purpose; and
- amendments are needed to clarify the scope of the Regulation and ensure that the use of pseudonymised data in health research is regulated proportionately.

1 Why patient data is important to health research

Health research is essential for better public health and health care. The EU has a strong, productive health research base[1]: in 2008 the EU was responsible for around 37% of world biomedical research publications and 44% of clinical research publications[2]. According to the Eurobarometer survey of opinion across the EU, a majority of the public (71%) is interested in medical and health research[3].

Individual patient records provide a vital resource for this health research for the benefit of society. These records form the basis, for example, for observational studies of the factors underpinning health and disease. Observational studies have led to breakthroughs such as understanding the association between smoking and lung cancer, and the association between high blood pressure and cardiovascular disease.

Access to patient records also helps researchers identify suitable participants to invite to take part in studies, such as clinical trials that test how well new treatments or diagnostic screening programmes work. Increasingly, these trials also include genetic analysis of participants, for example to study the factors that determine how an individual responds to a specific treatment. This is a crucial component of stratified (personalized) medicine.

By supporting patient recruitment, the use of patient data has an important role to play in creating a facilitative environment in the EU for public, charitable and commercial collaboration on clinical trials and other studies that promote economic growth.

To capitalise on these benefits, it is vital that the EU strikes an appropriate balance between facilitating the safe and secure use of patient data for health research and the rights and interests of individuals.

1 EMRC (2011), White Paper II, A stronger biomedical research for a better European future, http://www.esf.org/uploads/media/emrc_wpII.pdf.
2 UNESCO (2010), UNESCO science report, 2010, http://www.unesco.org/new/en/natural-sciences/science-technology/prospective-studies/unesco-science-report/unesco-science-report-2010.
3 Eurobarometer (2007), Medical and health research: a special Eurobarometer public survey. http://ec.europa.eu/public_opinion/archives/ebs/ebs_265_en.pdf.

2 How is the use of patient data in research governed?

Generally, researchers use anonymised patient data wherever possible. However, sometimes it is necessary to access information that can, directly or indirectly, identify a specific individual (Box 1).

Box 1: Health data can be accessed by researchers in different forms

Identifiable data – these include information in patient records such as names, addresses, dates of birth. There are also aspects of health data that could become identifiable when they relate to a diagnosis of a rare condition or when combined with other data. Identifiable data are needed when future contact is established with the participant, for example to contact them to take part in a study, or to link information across different data sets.

Key-coded or pseudonymised data - these cannot directly identify an individual, but are provided with an identifier that enables the patient's identity to be re-connected to the data by reference to separate databases containing the identifiers and identifiable data. Pseudonymised data can often, but not always, be used in place of identifiable data.

Anonymised data – these data cannot be connected to the original patient record. Anonymised data are suitable when no contact is needed with the participant or where the data do not need to be linked to any other data sources.

In the EU, the use of patient data is currently governed by the EU Data Protection Directive, transposed into Member State legislation. This data protection framework has been criticized for being overly complex and sometimes ambiguous and, in some Member States, has been an obstacle to epidemiological and other research[4]. Furthermore, variability in the implementation of the Directive in different countries has been an impediment in the collection and use of complete, accurate and homogenous data in multi-centre studies, for example using diabetes registries[5].

The Directive is now being revised, as a Data Protection Regulation, with the objective further to harmonise data protection across the EU, facilitate the flow of data across borders and enhance privacy protection. A Regulation is a legislative act of the European Union that becomes immediately enforceable as law in all member states simultaneously, unlike a Directive that needs to be transposed into national law. However, discussion of the revisions has paid rather little attention to the value of data in health research; imposing more restrictive rules on how data should be handled might jeopardize the use of personal data in health research[6].

4 Academy of Medical Sciences (2010), A new pathways for the regulation and governance of health research, http://www.acmedsci.ac.uk/p47prid88.html.
5 Di Zorio, CT & Carinci, F (2010), Cross-border flow of health information: is "privacy by design" sufficient to obtain complete and accurate data for public health in Europe? The case of BIRO/EUBIROD diabetes registers. Eur J Public Health 20 (Suppl 1) 101-102.
6 Verschuuren, M, Badeyer, G, Carnicero, J, Sisler, M, Asciak, RP, Sakkeus, L, Stenbeck, M & Deville, W (2008), The European data protection legislation and its consequences for public health monitoring: a plea for action. Eur J Public Health 18 550-551; Stenbeck, M & Allebeck, P (2011), Do the planned changes to European data protection threaten or facilitate important health research? Eur J Public Health 21 682-683; Hakulinen, T, Arbyn, M, Brewster, DH, Coebergh, JW, Coleman, MP, Crocetti, E, Forman, D, Gissler, M, Katalinic, A, Luostarinen, T, Pukkala, E, Rahu, M, Storm, H, Sund, R, Tornberg, S & Tryggvadottir, L (2011), Harmonization may be counterproductive – at least for parts of Europe where public health research operates effectively. Eur J Public health 21 686-687.

3 Ensuring the Data Protection Regulation facilitates research

In previous work, FEAM has expressed concern about the impact of other EU legislation on health research, in particular the problems associated with the Clinical Trials Directive[7]. In the present Statement, we focus on specific points in the proposed draft of the Data Protection Regulation. Our Statement draws on the work of the UK Medical Research Funders[8] that formed the basis for discussion by a group of experts nominated by FEAM member Academies, and the Academies themselves, during the period March-May 2012.

Outlined below are specific suggestions that we ask to be taken into consideration during the discussion of the Regulation by the European Commission, European Parliament and Council of Ministers.

The proposed Regulation clarifies some of the previously ambiguous areas while attempting to maintain a proportionate mechanism for protecting privacy and enabling health research to continue. We are, therefore, broadly supportive of the intention to strengthen the safeguards for the processing of personal data within the EU as long as balancing protection for health research remains in place.

(i) Article 83 and associated research derogations

The draft Regulation appears to provide a number of derogations – or exceptions – from particular requirements for the use of "personal data" for scientific research. To qualify for these derogations, personal data must be processed in accordance with the conditions set out in Article 83: personal data should not be used if anonymous data would be sufficient and, if possible, any identifying information should be kept separately from other information. The derogations do not exempt research studies from all the requirements set out in the Regulation. However, the derogations do, for example, enable the processing of personal data without consent and for personal data to be held for extended periods for research purposes. We warmly welcome this approach since it provides a framework that balances the facilitation of research and its associated benefits, with the protection of the interests of research participants (see UK case study in Box 2).

We call on the EU Institutions to prioritise the protection of Article 83 and ensure that the associated derogations for research are maintained as the Regulation moves through the legislative process.

Box 2: UK case study of where it is not practical or possible to obtain consent for the use of patient data in research – Power lines and the risk of childhood leukaemia

Cancer registries were used to identify 33,000 children with cancer, aged up to 14 years. The study showed that, compared with children who lived more than 600 metres from a power line at birth, those who lived within 200 metres had an increased risk of leukaemia (relative risk: 1.69). This study involved information that a child of a particular age lived in a specific postcode. These two pieces of information alone could enable the identification of an individual child. However, it would not have been feasible – or proportionate – to seek individual consent from all 33,000 children.

This shows the importance of protecting Article 83 and the associated derogations for research.

There are a number of issues around Article 83 and the associated derogations that would benefit from clarification. Generally, the lack of clarity in the current Directive has contributed to a risk-averse culture among those sharing and using data for research. Misinterpretation of the current regulatory and governance framework has led in some Member States to delays to, and even halted, research that would otherwise be

7 FEAM (2010), Opportunities and challenges for reforming the EU Clinical Trials Directive: an academic perspective. http://www.feam.eu.com.
8 UK Medical Research Funders (2012), Joint statement on the draft European Data Protection Regulation. http://www.acmedsci.ac.uk.

in the public interest. To avoid replicating these difficulties, it is essential that any lack of clarity is minimized in the new Regulation, including:

- clarifying that the reference to Article 83 (processing for historical, statistical and scientific research purposes) within Article 81 (processing of personal data concerning health) is intended to link the two sections, rather than to impose an additional restriction on research;
- clarifying that Recital 40 and Article 6.4 about processing of personal data for other purposes intends scientific research to be viewed as a compatible purpose in itself;
- clarifying that Article 83 is intended to allow individuals and organisations to use identifiable data in research where this is necessary and subject to appropriate standards of confidentiality. For example those responsible for on-site monitoring of clinical trials would not be able to use pseudonymised data and will require identifiable information.

We call on the EU Institutions to seek clarification of Article 83 and the associated derogations to ensure that these provide the intended support for research.

(ii) Scope of the Regulation

It is important that the research community is clear about how "personal data" relate to the different types of data used in research (Box 1), since the scope determines which research studies are brought within the remit of the Regulation and, therefore, must comply with its requirements.

The Regulation is not explicit on whether pseudonymised data are intended to be included within its scope. Under current data protection legislation in some Member States, pseudonymised (key-coded) data are treated the same as fully identifiable data and this presents an obstacle to health research. Pseudonymised or key-coded data underpin a substantial amount of research, for example in genetic studies, when using Biobanks or other large-scale, population-based studies (Box 3).

Box 3: Example of the importance of pseudonymised data in health research – the Collaborative Oncological Gene-environment Study

There are 440,000 cases and 190,000 deaths annually in Europe from breast, ovarian and prostate cancer. The Collaborative Oncological Gene-environment Study (COGS) is a European Commission Framework Programme 7-funded project involving 140 groups worldwide and a total of 200,000 individual participants, that seeks to study these cancers. It incorporates many existing consortia into one large project and, so, adding value to money already spent on research. The project analyzes the genetic variation associated with developing these cancers together with information on environmental and lifestyle factors. The project combines genotyping, statistical modeling and examination of ethical, legal and social issues to develop a comprehensive understanding of how knowledge of genetic factors can enable better tailoring of interventions to individuals in the prevention and treatment of these cancers. Individual participant's data will be pseudonymised so that it can be shared securely between researchers. An overly restrictive approach to pseudonymisation has the potential to compromise the genetic analysis of samples and use of data by the research groups because of the strict regulatory requirements this would impose. Excessive restriction would delay the translation of the findings into more effective interventions for patients.
Further details of the project can be found at http://cogseu.org.

It is vital that pseudonymised data are handled proportionately by the Regulation.

Inclusion of pseudonymised data within the scope of the Regulation would dramatically

increase the regulatory burden on health research. If pseudonymised data are intended to be included in the scope, we suggest that amendments will be needed to protect the status of well-established uses of pseudonymised data in health research and to ensure that the regulatory burden is proportionate to risk. For example, international transfers of pseudonymised data between collaborators play an essential role in research and must be treated appropriately to ensure that they are not unduly inhibited by the legislation. This should reflect the fact that although re-identification from pseudonymised data may be technically possible, conditions have been established in health research to minimize the opportunity of re-identification. It is important for the European health research community to share this best practice in ensuring confidentiality.

Anonymised data fall outside the scope of the Regulation. However, the act of removing identifiers to ensure that data are no longer personal – anonymisation – could fall within the definition of processing. This would mean that the process of anonymisation itself would have to comply with the requirements of the Regulation to be lawful. We suggest that the Regulation should be revised expressly to permit anonymisation while prohibiting re-identification of data that has been anonymised.

Clarification is also needed about "genetic data" to ensure that the definition is only intended to apply to personal data that falls within this category, rather than all related data. That is, the definition of genetic data used within the Regulation should exclude genetic data not capable of identifying a subject – it should be defined in terms of it being personal data.

We call on the EU Institutions to seek clarification of the scope of the Regulation and to ensure that the use of pseudonymised data in health research is handled proportionately by the Regulation.

(iii) Biological samples

The definition of "data concerning health" must be consistent with the related Recital. Recital 26 includes "information derived from the testing or examination of a body part or bodily substance, including biological samples" in its description of data relating to health. However, no reference is made to biological samples in the definition of Article 4.12.

We ask for this inconsistency to be rectified to clarify that data concerning health does not include biological samples per se but rather to personal data obtained from testing such material.

(iv) Increases in the regulatory burden for health research

Apart from the potential increases in scope, the Regulation increases the regulatory burden in other ways compared to the current Data Protection Directive. If implemented, these additional burdens will make it increasingly difficult for Member States to conduct important research. The following issues present particular problems:

- Article 5(e) on **data storage** provides a welcome derogation that enables data to be held for extended, potentially indefinite, periods for research purposes. However, this derogation imposes a requirement to undertake periodic review to assess the necessity to continue storage. These reviews would be impractical since data are routinely held over long periods and it can be difficult to predict future uses or need for the data. Furthermore, these reviews would create a substantial burden for research institutions that currently hold valuable data and research resources, which may not be sustainable for the sector. We recommend amending Article 5 to remove the need for such review.

- The **right of the data subject to information** (Article 14) could be problematic for research in situations where notifying the participants would create a disproportionate burden that could prevent research from proceeding. The Regulation includes a "disproportionate effort" provision (Article 14.5(b)), but this only applies where the data are not collected from the data subject. **It would be helpful to clarify the situation for research by amending this Article to create a specific "disproportionate effort" provision for research, in line with the current Data Protection Directive.**
- The **right to rectification** (Article 16) is inherently problematic for health research since researchers routinely hold data generated through their studies that cannot be guaranteed to be accurate. For example, data generated by genetic sequencing in the laboratory environment will rarely meet diagnostic standards used in a clinical setting. As a result, such data cannot be considered analytically accurate. In addition, a person's health status changes over time, for example pregnancy. The Regulation does not contain any guidance as regards practical means for researchers to assess or rectify such "inaccuracies". **The Regulation should be amended to take this reality of health research into account, that is to propose limits as regards the steps that researchers should be required to take to assess, or to rectify, any potential inaccuracies.**
- Articles 33-34 require the **impact assessment** of operations presenting specific risks and the need for an approval of this assessment by the Data Protection authority. **We recommend that in the highly regulated area of health research, such authorization need not be required on a project by project basis when assessment has already been undertaken by another suitable national authority (Ethics Committee or National Competent Authority for Clinical Trials of Investigational Medicinal Products).**

(v) Transfer to third countries

Sharing data within international consortia is particularly important in studying rare diseases or for analyzing information across a wide range of different circumstances, for example in the global study represented by the International Childhood Cancer Cohort , pooling data to study various modifiable and genetic factors in relation to cancer risk. Article 45 recognizes the importance of facilitating international collaboration. However, currently there are difficulties in transferring pseudonymised (key-coded) data to countries outside the EU, for example the USA. Even though international research collaborators in these other countries lack the key and are unable to identify subjects, this is often not regarded as a sufficient safeguard. We suggest that, to address this obstacle, the recipients sign a legally binding document that they will not seek access to the key in any attempt to identify the individual, or communicate or transfer the individual's raw data.

Appendix: FEAM procedures and contributing individuals

The scope and content of this Statement were developed by a FEAM Working Group chaired by Professor Robert Souhami and the draft Statement was reviewed by independent experts and the FEAM membership.

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