



## Data Protection Regulation: Keeping Health Research Alive in the EU

### Report of a Roundtable Event hosted by MEP Nessa Childers

17 September 2013, European Parliament, Brussels

Health research is essential for better public health and health care. The EU has a strong, productive health research base and surveys of public opinion indicate that a majority of the public is interested in health research.

Individual patient records provide a vital resource for this health research for the benefit of society. To capitalise on these potential 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 protecting the rights and interests of individuals.

The European Institutions are currently engaged in the crucial stage of the legislative process that will produce a Data Protection Regulation (DPR) to replace the current Data Protection Directive. Many Parliamentary amendments have been proposed to the DPR and there are concerns that amendments could hinder the vital research that Europe excels in.

A Roundtable, convened by the Medical Committee of Science Europe, the Wellcome Trust, the Federation of European Academies of Medicine (FEAM) and the European Alliance for Personalised Medicine (EAPM) and hosted by MEP Nessa Childers, brought together stakeholder representatives including patients, health research professionals and industry to discuss what is needed from the DPR to ensure that cutting-edge health research can continue in Europe.

In opening the event, Ms. Nessa Childers emphasised the importance of this discussion for Europe, where industry and academia are at the forefront of research for novel therapeutics and diagnostics and where new approaches to providing quality health care promises to benefit European citizens. There is a shared interest in creating the legal framework to set the right balance between protecting the individual and encouraging research; the amendments to the DPR raised by the Parliamentary Committee on Civil Liberties, Justice and Home Affairs (LIBE) introduce some key challenges that need to be resolved by drawing on advice from the scientific community and patient perspectives. Among these major issues are: assuring state-of-the-art procedures for the safe processing of personal data, the maintenance of a robust ethical framework compatible with seeking broad consent

for future use of data for research purposes, and facilitation of cross-border transfer of data for health research.

Consideration of these issues pervaded the event. Co-chair of the meeting, Prof. Robert Souhami (FEAM Scientific Adviser) noted that, in order to support population-based research, nothing is more important than getting the DPR framework right, and this confers a responsibility on researchers to articulate clearly to the public and to policy-makers why health research is important and what needs to be done to allow it.

Dr. Stephen McMahon (Chairman and co-founder of the Irish Patients' Association) provided a perspective based on the objective to keep patients at the centre of the decision-making process. The Irish Patients' Association has a history of engagement with medical and pharmacy regulatory bodies and is very supportive of the right of all for access to innovation. There has been significant increase in the number of clinical trials conducted in Ireland and it is increasingly important to involve patients in decisions about clinical research and its procedures. Patients need to understand what it is they are consenting to when broader consent is sought. Guidance on good research ethics from the Irish Council for Bioethics provides sound principles for evaluating some of the issues associated with the DPR. For example: (i) data management practices need to focus on the principles of autonomy and informed consent as well as on privacy and confidentiality and (ii) sharing the results of research by publication is vital to maximise the potential benefits of that research and of the patient's involvement, and not doing this can be construed as unethical.

Prof. Richard Frackowiak (Chair of Medical Sciences Committee, Science Europe) contributed an academic perspective, emphasising the interest of Science Europe in growing EU competitiveness and focusing on key issues for privacy.

- *Privacy and health.* Because of state involvement in European health systems and public investment in research, society as well as the individual has a legitimate interest in maximising the value of health information for all. It is not possible to have excellent health care without excellent research. There are many types of medical research (e.g. observational studies, clinical trials, research using biobanks and registries) to be supported and there is need to bring data together from different sources, while at the same time acknowledging that the policy-maker desires a single regulatory system for this heterogeneity.
- *Balancing rights.* The right to privacy is one of many other rights, for example the right to equal access to excellent health care, the right to a healthy environment, the right to expect efficient use of taxes. Satisfying these rights requires the efficient use of personal data in research within a facilitative administrative framework and a clear legal context, to be provided by the DPR.
- *Types of privacy.* Personal data for research use can be anonymised (although it may never be possible to guarantee privacy) or, depending on research requirement, pseudonymised (key-coded to protect privacy while permitting justified access) or identifiable. The latter are essential for some research purposes, for example the study of orphan diseases of childhood. It is also important to appreciate the value of the re-use of data. This is already allowed in EU policy, as in EU-funded collaborative research such as the Human Brain Project, but there are many

additional opportunities, such as to generate properly powered cohort studies for more effective drug development.

- *Consent.* The DPR emphasises informed and explicit consent but this may not always be practicable, for example in disease registries, research on rare diseases, statistical re-evaluation of data using new mathematical techniques or refined hypotheses, data base linkage, and in the monitoring of a range of variables over time.
- *Protecting privacy robustly.* Health researchers have already adopted various practices to safeguard privacy, for example in ethical review, using safe systems for processing of personal data, safe data warehouses and data contracts for international exchange.

From the academic perspective, some of the LIBE amendments will create major obstacles to the balance of the DPR facilitating medical research while respecting individual privacy. The following points are priorities (and see also Appendix 1):

- The European Commission's provisions in Article 83 and the associated derogations should be supported.
- Pseudonymisation of data – the status must be clarified to ensure such data are handled proportionately by the DPR. There are also some research circumstances where identifiable data are required.
- Processing data without consent when needed, has to be possible.
- Broad consent, which is commonly used in research (e.g. for biobanks and registries) should be compatible with the Regulation.
- There must be a limit to the administrative burden put on researchers and administrators.

The industry perspective, from Dr. Greg Rossi (European Federation of Pharmaceutical Industries and Associations) reinforced many of the previous points, noting that the DPR must be considered within the context of the many other guidelines and regulations that already provide the framework for research activities. The DPR will be critical for operation of the collaborative endeavour between industry, patients and academia that has already delivered considerable benefits to EU citizens. For example, there has been a reduction of more than 60% in cardiovascular mortality during the last three decades. The pharmaceutical industry is a major investor in EU research and EU research tools. For example, the observational databases, are second-to-none, but there are still many unmet medical needs, for example in antibiotics and oncology. Many new research opportunities are now coming into range and linking genetic and clinical-laboratory databases will provide major resources for research.

From the health care industry perspective, the use of patient information is crucial for various purposes: for observational research to identify causes of disease, for clinical trials to develop new medicines, and for monitoring the safety and efficacy of prescribed drugs. Privacy protection is integral to medical research and, to reiterate, is already soundly based on the provisions of the EU Clinical Trials Directive, independent ethics review, informed consent for interventional research and good clinical practice. However, the analysis and use of data across the EU is still subject to a range of different standards and the DPR intent to standardise and harmonise is welcome. Nonetheless, it is necessary to ensure that

the DPR allows the international transfer of key-coded (pseudonymised) data, that it avoids unnecessary administrative burden, that it enables the re-use of data for research and reconsiders the presently too broad definition of genetic data (that is, it should adopt the standard international definition).

Prof. Jean-Marie Maloteaux (FEAM and Academie Royale de Médecine de Belgique) contributed an ethical perspective. Citing examples from research on leukaemia and orphan drugs to highlight the importance of EU contributions, it was noted that it is important and ethical to be able to use personal data without specific, explicit patient consent in certain areas of research. Ethics committees have a defined role in the legal framework for health research with critical responsibilities in the evaluation of medical research protocols and the protection of the patient. Drawing on the experience of ethics committees, Prof. Maloteaux amplified points made by the previous speakers: progress in personalised medicine is dependent on personal data collection, disease registries have many important functions, for example in supporting recruitment into clinical trials, pseudonymised data have many research uses and must be regulated in proportion to the risks of re-identification of the subject. In the view of FEAM, it is vitally important to continue explaining that patients' data are a core resource for health research and that many safeguards protect the rights and interests of individuals. FEAM welcomes the principles of the DPR but, together with the other organisers of this event (Appendix 1), expresses concern at some of the LIBE amendments which could compromise EU health research.

In the general discussion there was significant support expressed for these concerns. Several key points emerged:

- *Cross-border transfer of data.* In chairing the discussion, Prof. Helmut Brand (EAPM) observed that the Cross-Border Directive which specifies “data have to follow the patient” seems at variance with the proposed amendments to the DPR. It is important to resolve these policy disconnects so as to facilitate consistent cross-border transfer of pseudonymised data.
- *Broad consent.* Some have perceived a conflict between the ethical objectives fully to inform the patient and the desire to elicit broad consent. However, there are different models of consent and different interpretations of “informed” adjusted according to the clinical situation, for example in emergency medicine or for the confused patient. The consent process must be proportionate and broad consent can be justified as part of ethical committee review for observational studies.
- *Quality of care and patient safety.* Patient care also requires database linkage and pseudonymisation of data. Thus, the DPR is relevant for collection and use of purposeful health data more generally with broader implications for governance, audit and the introduction of an appropriate level of administration.
- *Preparing for IT innovation.* Policy-makers need to understand that there are very rapid IT advances in analysing, aggregating and transferring data. The legal framework must have the flexibility to cope with future changes and policy-makers must take the time needed to enact proportionate legislation.
- *Challenges for long-term follow-up of patients.* In consequence of advances in medical practice, many treatments are successful, for example in oncology, but there might be late complications that currently cannot be described to patients and that

require long-term follow-up. Simple disease registries may not be sufficient for this purpose and there will be growing need to link registries.

In concluding the event, Ms. Nessa Childers urged those present to continue communicating with politicians about the implications of the DPR amendments for patients, academia and industry. Some of the priorities have not always been well understood outside the research community; it remains important to clarify specific issues, for example with regard to the value of pseudonymised information and the consent taking process, and to show where there is agreement on the main messages.

Brussels, September 2013

## Appendix 1: Key messages

The co-organisers of the event, Science Europe, the Wellcome Trust, FEAM and EAPM have published a joint briefing on key issues as summarised below. Further details on these points and examples of research approaches that are now at risk are provided in the source documents listed in Appendix 2.

### Key areas relating to the DPR and LIBE amendments: the view from the Roundtable co-organisers

#### **1. Processing for historical, statistical and scientific research purposes.**

We broadly support Article 83 of the European Commission's proposal and the associated provisions for scientific research. These provisions must be maintained and amendments that restrict the processing of health data for research must be opposed to ensure that Europe does not miss out on the societal benefits of research.

#### **2. Anonymised, pseudonymised and identifiable data**

The processing of anonymised data should not be in the scope of the Regulation. It is vital that the use of pseudonymised data in scientific research is regulated proportionately, taking into account the minimal risk of re-identification when safeguards are in place. There are also some circumstances in research where it is necessary to use identifiable data.

#### **3. Consent**

The DPR should enable the use of broad consent for collecting and storing data for future research purposes. In some circumstances in research it is not possible to seek any form of consent at all (e.g. where very large sample size or where seeking consent would introduce bias). It is therefore essential that the DPR permits the use of identifiable data without consent for scientific research purposes, provided that there is no practicable alternative and that appropriate safeguards, such as ethics committee approval, are in place.

#### **4. Definitions of genetic data**

The DPR definition is not consistent with widely-used definitions, creating uncertainty about the intended scope. The definition should be amended to make it consistent with international guidelines, for example the UN International Declaration on Human Genetic Data.

#### **5. Data breaches**

We support the risk-based approach to breach notification, which emphasises the importance of the safeguards applied by the controller and processor of the data.

#### **6. Data protection impact assessments**

A new data protection impact assessment should be required only where the data processing involved in a project poses substantially new or different privacy risks from processing that has been conducted in the past.

#### **7. Cross-border transfer**

The DPR should facilitate cross-border transfer of personal data for health or research purposes.

## Appendix 2: Source documents

[Joint Briefing](#) from Science Europe, EAPM, Wellcome Trust and FEAM, September 2013. Slides presented at the Roundtable Event are available on [the Activities page](#) of the FEAM website: [www.feam.eu.com](http://www.feam.eu.com).

Joint Statement FEAM/Wellcome Trust, [Realising the societal benefits of health research through the Data Protection Regulation](#), February 2013.

FEAM, [Data Protection Regulation, A FEAM Statement](#), June 2012.

Science Europe: [Position Statement: On the Proposed European General Data Protection Regulation](#) and [Medical Sciences Committee Opinion Paper: The Benefits of Personal Data Processing for Medical Sciences in the Context of Protection of Patient Privacy and Safety](#), May 2013, are available at: <http://www.scienceeurope.org/downloads>.

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## Roundtable co-hosts

### About the Medical Sciences Committee of Science Europe



Science Europe is an association of major European Research Funding and Research Performing Organisations, founded in October 2011 and with an office based in Brussels. Science Europe Member Organisations share a common mission: to fund and perform excellent research. Collective action and cross-border collaboration can contribute to achieving excellence in research, and Science Europe provides a platform for its members to pursue this objective and to speak with a common voice to the European institutions, national governments and other stakeholders. In its efforts to foster and strengthen the European Research Area (ERA), and in its reflections on policies, priorities and strategies, Science Europe is informed by direct representation of all scientific communities through its six Scientific Committees. The **Medical Sciences Committee of Science Europe** is co-hosting the roundtable.

Science Europe, Rue de la Science 14, 1040 Brussels, Belgium, [www.scienceeurope.org](http://www.scienceeurope.org)

### About EAPM



The **European Alliance for Personalised Medicine (EAPM)** brings together Europe's leading healthcare experts and patient advocates to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics. It is calling for the European Commission, the European Parliament and EU member states to help improve the regulatory environment so that patients can have early access to personalised medicine, and so that research is boosted. The EAPM is therefore calling to help encourage the introduction of personalised medicine by:

- i. Ensuring a regulatory environment which allows early patient access to novel and efficacious personalised medicine
- ii. Increase research and development for personalised medicine
- iii. Improve the Education and Training of Healthcare Professionals
- iv. Acknowledging new approaches to reimbursement and HTA assessment, which are required for patient access to personalised medicine and its value to be recognised
- v. Increase awareness and understanding of personalised medicine

EAPM, Rue De L'aqueduc 88A, 1050 Ixelles, Brussels, Belgium, [www.euapm.eu](http://www.euapm.eu)



## About the Wellcome Trust



The **Wellcome Trust** is a global charitable foundation dedicated to achieving extraordinary improvements in human and animal health. We support the brightest minds in biomedical research and the medical humanities. Our breadth of support includes public engagement, education and the application of research to improve health. We are independent of both political and commercial interests.

Wellcome Trust, Gibbs Building, 215 Euston Road, London NW1 2BE, UK, [www.wellcome.ac.uk](http://www.wellcome.ac.uk)

## About FEAM



Since 1993, **FEAM**'s mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe, to provide them with a platform to formulate their collective voice on matters concerning medicine, biomedical research and public health with a European dimension, and to extend to the European authorities the advisory role that they exercise in their own countries on those matters. Our vision is: (1) to underpin European biomedical policy with the best scientific advice drawn from across Europe, through the FEAM network of Academies representing over 3000 high level scientists from the whole biomedical spectrum; (2) to improve the health, safety and wealth of European citizens through research by promoting a nurturing, creative and sustainable environment for medical research and training in Europe. FEAM's strength lies in its member Academies that give it the authority to provide an EU-wide scientific opinion on the European medical science base and evidence to underpin European biomedical policy. The FEAM Academies represent the following EU Member States: Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Netherlands, Portugal, Romania, Spain, United Kingdom. Observers include the European Academies Science Advisory Council and the InterAcademy Medical Panel.

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