

Medical Sciences Committee Opinion Paper



The Benefits of Personal Data Processing for Medical Sciences
in the Context of Protection of Patient Privacy and Safety

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**SCIENCE
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Context

The European Union (EU) is currently revising the legal framework for the processing and free movement of personal data. The revision is motivated by a need to reduce legal fragmentation among Member States and thus to improve the right to privacy accorded to EU citizens, without impeding the functioning of the internal market.

The European Commission (EC) issued its proposal for a General Data Protection Regulation (DPR)¹ in January 2012. The EC proposes a Regulation rather than a Directive, meaning a single piece of legislation directly applicable at national level. The EC proposal contains a number of provisions and exemptions crucial to facilitating vital medical and health research, thus reconciling the social right to better health within a framework of protection of individual rights to privacy.

The rapporteur of the Civil Liberties, Justice and Home Affairs (LIBE) Committee of the European Parliament (EP) produced in January 2013 his draft report on the DPR (the Albrecht Report)² with amendments that disturb this balance and dramatically weaken the provisions and exemptions applicable for medical and health research.

The Scientific Committee for Medical Sciences of Science Europe (MED Committee) wishes to alert the EU institutions to the devastating implications of such amendments, if passed. Our position is in line with many public statements and position papers elaborated by prominent stakeholders from the European medical and health research community³ on the crucial need to structure a legal framework for data protection which continues to promote medical research in Europe for the benefit of individuals in society, while ensuring a proportionate requirement for patient privacy.

Summary Opinion and Recommendations of the MED Committee of Science Europe

- ▶ The MED Committee of Science Europe welcomes the EU initiative to revise the current legal framework for personal data protection. The MED Committee sees the EU proposal for a DPR as an important step towards facilitating co-operation in medical and health research by ensuring appropriate harmonised arrangements for the protection of personal data. The Regulation is especially pertinent for regulating transfer of personal data across national boundaries in an era of research based on 'Big Data' and collaborative international consortia.
- ▶ The MED Committee of Science Europe asks the EU institutions to acknowledge that medical and health research operates within a robust ethical framework and urges them to structure a legal framework for data protection which, while ensuring patient privacy, guarantees the right of EU citizens to better healthcare resulting from advances in medical sciences.
- ▶ The MED Committee of Science Europe supports Article 83 of the Commission Proposal and its associated provisions and derogations that apply to medical and health research. The MED Committee calls upon EU institutions to prioritise the protection afforded by Article 83 and to ensure that the derogations for medical and health research are retained and further clarified as the Regulation moves through the legislative process.
- ▶ The MED Committee of Science Europe asks EU institutions to clarify how the proposed EC Regulation relates to the different types of data processed in medical and health research (anonymised, pseudonymised and identifiable).
- ▶ The MED Committee recommends adoption of a risk-managed approach in the case of pseudonymised data, which recognises explicitly the need for a level of protection between that of identifiable and anonymised data.
- ▶ The MED Committee of Science Europe is highly disconcerted by the position of the rapporteur of the LIBE Committee of the EP, which regards facilitation of medical research as "not as urgent or compelling as public health or data protection".
- ▶ The MED Committee is greatly concerned that the many amendments proposed by the LIBE Committee rapporteur will dramatically hamper medical and health research and calls on the LIBE Committee and the European Parliament to broadly oppose these amendments⁴.

The Benefits of Personal Data Processing for Medical Sciences in the Context of Protection of Patient Privacy and Safety

A commentary and recommendations on the General Data Protection Regulation from the Scientific Committee for Medical Sciences of Science Europe

▶ Personal Data are often of critical value to medical research

Medical research data on humans are basic elements of modern medical research, which is itself carried out for the joint benefit of all European Union (EU) citizens. The EU has been at the forefront of innovative medical and health research, providing means to generate promising research concepts, strengthen research infrastructures, and facilitate the creation of cross-cutting, multi-disciplinary research partnerships and networks based on excellence.

For instance, the Innovative Medicines Initiative (IMI) is a good example of a successful public-private partnership between the EU and the European biopharmaceutical industry that fosters the advancement of biomedical research through collaboration at 'pre-competitive' stages of the research process. Many medical and health research projects funded through IMI rely on the possibility to process individual medical data from large datasets emanating from individual samples stored in various European databanks. The reality is that recent years have seen an explosion in the number of databases containing medical and research data: Electronic Health Records (EHRs), cohort studies (in which a group of individuals is followed for a number of years), disease-specific studies and biobanks, to name a few. Moreover, collections of patient-generated data inside and beyond the clinical domain are growing rapidly in number and size. Because these data are scattered across diverse platforms, they cannot be fully exploited. In October 2012, the 'European Medical Information Framework' (EMIF)⁵ project funded by IMI started, aiming to tackle these challenges with the objective of developing a common information framework that will not only facilitate access to existing data sources, but ease the creation of links between sources and, where needed, collect additional information. Linking up the data will allow scientists to significantly advance medical and health research and drug development.

As a further example, the EU, as part of its digital agenda for competitiveness and growth, has recently awarded one of the Future and Emerging Technology (FET) Flagships⁶ to the large-scale, cross-sector, multidisciplinary medical research project entitled 'The Human Brain Project'⁷, whose medical informatics division proposes an extensive programme of research into improved diagnostics of brain diseases using modern informatics and data mining procedures on legacy data from hospitals and large-scale research databases. Access to, and the processing of, these data need to be appropriately regulated so as not to impede progress while guaranteeing a proportionate degree of protection of personal privacy. For example, patients with mental health disorders or neurodegenerative diseases of ageing have a right to improved medical care and an appropriate degree of personal privacy. These rights need to be proportionately reconciled with each other. This is not a new situation. The same issues arose with diseases such as HIV/AIDS and with neurogenetic disorders such as Huntington's disease. Appropriate practice based

on common sense and regulation has already been developed in these areas, which therefore provide precedent for the proposals of the MED Committee of Science Europe.

Medical and health research are data-intensive fields. In this 'Big Data' era, the interconnection between ICT, computer-science and health research is becoming increasingly pervasive. The wish to produce a unified cross-sector DPR for the EU is therefore laudable from the viewpoint of clarity of purpose and protection of privacy in the context of facilitation of safe data transfer within and across borders. However, the commercial and academic environments in which medical and health research are performed are different. So the DPR needs to contain specific derogations relevant to the appropriate research environment, otherwise there is a clear danger that one branch of the EU will make the work of other branches impossible.

The medical and health research communities are therefore particularly concerned that the DPR is specified in such a way that access to and sharing of personal data for research purposes is protected as well as individual privacy. In the context of the development of the legal framework of the DPR, and given the innovative potential of European medical and health research, it is of particular concern that the proposed Regulation is specified in a way that does not run counter to the Innovation Union's priorities and major medical research projects for which EU support has already been committed.

- **The MED Committee of Science Europe asks the EU institutions to structure a legal framework for data protection so that, while ensuring patient privacy and safety, it facilitates medical and health research in Europe to realise the high societal benefits that accrue from it.**
- **The MED Committee of Science Europe supports Article 83 of the Commission Proposal and its associated provisions and derogations that apply to medical and health research. The MED Committee calls upon the EU Institutions to maintain the proposals of Article 83 and ensure that associated provisions and derogations for medical and health research are retained and further clarified in the legislative process.**

▶ Taking into account ethical safeguards already implemented for medical research

Medical and health research operates within a robust ethical framework with strong safeguards supported by internationally-recognised guidelines such as the international Declaration of Helsinki⁸, the Belmont report⁹, or the CIOMS/WHO guidelines¹⁰. Medical and health research projects that intend to process identifiable personal data undergo review by an independent Ethics Committee/Ethics Review Board for approval. According to the EU's Directive 2001/20/EC¹¹ on Clinical Trials, an Ethics Committee is "an independent body in a Member State of the European Union, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and well-being of human subjects involved in a clinical trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the clinical trial protocol, the suitability of the investigators involved in the trial and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent".

Informed consent is a key ethical requirement for investigators conducting biomedical research on humans and the MED Committee of Science Europe is supportive of the high visibility given to consent in the DPR proposal as a basis for trust. The MED Committee notes however that informed specific explicit consent, though the current norm, has been criticised increasingly on the grounds of achievability in some patient populations, especially where cognitive functions are impaired. The MED Committee therefore asks regulators to realise that medical and health research projects exist where it is not possible to seek specific explicit informed consent from every study participant, and even in cases where seeking such consent is just not possible at all. This can be the case for instance in emergency care research where many subjects are physically unable to consent, in studies where an extremely large sample size is needed for obtaining a robust result, which makes it practically difficult to seek specific explicit informed consent, or in studies where seeking consent would actually introduce bias and distort the scientific conclusions. Likewise, in research on legacy data stored in databases, or in low-risk research situations, where re-consenting research participants creates undue bureaucratic and financial burdens and evidence shows that participants typically do not want to be re-consented¹². These are contexts that are categorically different from the standard clinical trial. In such medical and health research contexts Ethics Committees also play a specific role, and may decide on the basis of strong ethical grounds that personal data of study subjects may be processed without informed consent. The overarching role of Ethics Committees here is to ensure that a balance between risks and benefits of the proposed research is struck, so that personal data of a patient or citizen are only processed when this is proportionate to the potential benefits to society as a whole. Such processing must be regulated so that appropriate protection of individual privacy is maintained.

- The MED Committee of Science Europe recommends that the proposed DPR is amended to specifically acknowledge Ethics Committees in medical and health research for their role in ethically balancing risks and benefits of a medical or health research project and ensuring that personal data of patients and citizens are safely processed, with appropriate privacy protection, when this is proportionate to the potential benefits to society as a whole.

► **Recognising the different types of patient data used in medical and health research and the need to regulate them proportionally**

It is very important that the DPR defines how privacy protection relates to the different categories of data used for medical and health research. These definitions will determine which research projects fall under the scope of the proposed DPR and the need to comply with its different requirements.

The implication of personal data in medical and health research differs according to three categories:

Identifiable data relate to data including information in patient records such as names, addresses, and 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 envisioned with participants, for example to contact them to take part in a study, a clinical treatment trial, or if it is intended to link information across different data sets.

Pseudonymised (or key-coded) data cannot directly identify an individual, but include an identifier 'key' or algorithm that enables a patient identity to be re-connected to data. This is usually implemented by storage of data and 'key' in separate places. Pseudonymised data can often – but not always – be used in place of identifiable data.

Anonymised data can no longer be connected to patient records at all. Anonymised data are used when no contact is needed with participants. Unlike pseudonymised data, anonymised data cannot be cross-linked across different datasets by individual. Anonymised data cannot under any circumstance be associated with their individual donors and hence should be used and re-used for research. Indeed anonymised data, the re-use of which is facilitated by modern data storage infrastructures, represent a resource with potential savings for research expenditure and of researcher effort.

- **The specific characteristics and added value of each of the three categories of medical and health research data need to be recognised explicitly by the EU institutions, and their adequate clarification is recommended in the proposed DPR.**

Anonymised data must be stated to be explicitly outside the scope of the DPR. This cannot be left implicit, as confusion, and so a loss of competitive edge due to procrastination, and a need for case-by-case clarification will result. This principle is critical for efficient use of databases, cloud computing, data mining and the like in medical and health research. Data such as those resulting from publicly-funded research or public hospitals should be recognised, on the principle of added-value for taxpayers' money, as explicitly usable in anonymised form for medical and health research.

- **The MED Committee of Science Europe supports that anonymisation is explicitly stated to be outside the scope of the Regulation.**

The case of pseudonymised data is of utmost importance for the medical and health research community and requires special attention. Many large-scale research projects rely on pseudonymised data. These include, for example, population-based research involving hundreds of thousands of participants, the processing of personal data derived from large-scale biobanks, research based on population-wide registries. Progress in the use of such data for medical and health research has been particularly impressive in Nordic countries¹³, where national coverage and longitudinal collection of data permits the inclusion in databases of years of comprehensive information; this makes them an extremely valuable research tool as these comprehensive datasets of pseudonymised data can then be cross-linked to answer important medical and health research questions. For instance, Håberg, SE et al. (2013)¹⁴, using cross linkage between Norwegian national registries and medical consultation data demonstrated that flu vaccination during pregnancy reduced the risk of influenza and may have reduced the risk of influenza-related fetal death during pandemics. Similar type of datasets linkage in Nordic countries also allowed study of the risk of stillbirth and infant mortality associated with use of

SSRIs antidepressants drugs during pregnancy, demonstrating no significant association with risk of stillbirth, neonatal mortality, or post-neonatal mortality (Stephansson O. et al., 2013)¹⁵.

Two things are important when working with pseudonymised data in medical and health research. Firstly, pseudonymised data without access to decryption 'keys' make the possibility of re-identification of individuals very unlikely. Secondly, access to decryption 'keys' associated with data can be carefully managed, such that researcher access and use can be monitored and controlled. Many examples of state-of-the-art data safe-havens exist in Europe, for example, the National Institutes of Statistics of Denmark, Norway and Sweden, or the Longitudinal Study Centre (LSCS) and the Scottish Health Informatics Programme (SHIP) in Scotland. Thus, although re-identification from pseudonymised data is technically possible, good practice and management, including Ethics Committee control, have been established in the medical and health research communities to minimise any risk and efficiently protect individual rights to privacy.

In the context of the current revision of the legal framework for data protection, inclusion of pseudonymised data in the scope of the proposed Regulation must enable implementation that is efficient, performed with a light touch and based on past experience, such that the regulatory burden on research is kept to a safe minimum. Otherwise, many research projects will become unmanageable and the ability to respond rapidly to medical questions of importance will be limited. Hence, the MED Committee of Science Europe would prefer that pseudonymised data used for medical and health research be excluded from the scope of the DPR, subject to appropriate organisational and technical safeguards being put in place to minimise the risk of re-identification. Should the legislators decide to include pseudonymised data used for medical and health research, amendments are needed to protect well-established protocols for the proper and safe use of such data and to ensure that the regulatory requirements are proportionate to the very low risk of re-identification. Proportionate regulation will facilitate continued use of pseudonymised data in medical and health research and will incentivise the use of pseudonymised as opposed to identifiable data, providing overall greater privacy protection.

- **The MED Committee of Science Europe asks the EU institutions to clarify how the proposed EC Regulation relates to pseudonymised data.**
- **The MED Committee recommends adoption of a risk-managed approach in the case of pseudonymised data, recognising explicitly that they require a level of protection between that of identifiable and anonymised data.**
- **When re-identification from pseudonymised data is needed, the MED Committee recommends a case-by-case approach with guardians, clear procedures and appropriate controls for re-identification using specific decryption 'keys'. These procedures should build on existing, well-established, state-of-the-art procedures used in many European centres of excellence for data processing.**

► **Recognising specific issues related to patient consent and personal data privacy in medical and health research**

The high visibility given to 'consent' in the proposed EC DPR is to be praised, as consent can be the basis for safety and trust, though it must be recognised that many social science research studies show that it is often considered a tokenistic exercise by participants, trust being established by many other powerful mechanisms of greater importance than signing a piece of paper. In that respect, the use of human tissues in medical research provides a good example of why recognising the specific requirements for informed consent and capitalising on past experiences from Member States is important to moving forward with the development of the DPR. In the UK the Human Tissue Act¹⁶ 2004 [there is separate legislation for Scotland passed in 2006] established the Human Tissue Authority (HTA)¹⁷ with the interests of the public in mind. The Act aimed to ensure that human tissue is used safely and ethically, often with explicit informed consent. When first introduced in 2004 there were concerns that the Act would lead to such severe restrictions that research on human tissues might almost stop completely. In the following eight years the HTA progressively minimised bureaucracy and clarified appropriate levels of consent and governance in relation to the type of research proposed. This process has led to greater flexibility in the use of human tissue for medical research and a tailored approach to the consent required. Now, UK research institutions, rather than individuals, sign up to the principles and build these into their Ethics and Research Governance application forms for bio-resources. Similarly, in Sweden¹⁸ and Denmark¹⁹, legal Acts related to biobanks and health research regulate the process of consent when tissues are collected for medical research purposes, and do not require subsequent specific consent when the tissues or data need to be re-processed for further research projects. This broad informed-consent approach permits good and ethical medical research to proceed, which ultimately benefits the citizens of the EU while protecting their privacy in a proportionate manner.

Furthermore, sharing of data is at the centre of modern medical and health research. Medical and health research are intensely collaborative fields, where individual data often need to be shared or transferred to different research groups organised into joint research consortia across national borders. In that respect, the development of an EU DPR is welcomed by the MED Committee. Indeed the current fragmentation of regulatory systems for privacy protection has made cross-border co-operative research in the EU difficult at times. For instance, it is likely to be a reflection of the regulatory limitations affecting the sharing of data between countries that many international and European research consortia meta-analyse rather than truly pool raw data, which would potentially enable more complex analyses.

International collaboration with countries outside the EU in medical and health research is also of utmost importance. Article 45 of the proposed DPR recognises the importance of facilitating international collaboration. However, currently it is not always easy to share pseudonymised data with countries outside the EU, for example the USA. Controlled access to decryption keys for identification of data from individuals is sometimes regarded as an insufficient privacy safeguard, for reasons that are unclear.

- The MED Committee of Science Europe asks the EU institutions to acknowledge the specificity of the requirement for consent in medical and health research and to maintain derogations of Article 83 allowing for processing of appropriately protected personal data for scientific research without specific consent²⁰ or by using ‘broad-consent’²¹ procedures if they are practical.
- The MED committee asks the EU institutions to work towards developing a legal system that facilitates the international sharing of pseudonymised data for medical and health research.

▶ **Limiting the administrative and legal burdens associated with personal data privacy for medical and health research**

Compared to the current Data Protection Directive, the proposed DPR includes specific provisions for data storage (Article 5e), the right to information (Articles 14 and 15), the right to rectification (Article 16) and impact assessment (Articles 33 and 34) that have the potential to considerably increase the administrative and regulatory burden for health research without providing further levels of individual protection in an already highly-regulated area of research.

- The MED Committee of Science Europe calls upon the EU institutions for a DPR that does not increase the administrative burden for scientific research. Specifically, the DPR should not require periodic review of research data stored in research institutions, data subjects should have a right to information given disproportionate efforts are not needed to obtain it, there should be a limit to the extent to which researchers should be required to rectify data, and impact assessments should not be required when assessment has already been undertaken by a suitable national authority.

▶ **Establishing a harmonised legal framework for data privacy protection that takes account of and promotes the realisation of the societal benefits of medical and health research**

Many pertinent principles need to be taken into account when regulating the privacy of individuals and protecting personal data in the context of medical and health research. A key issue is how to reconcile the right of society to use and benefit from data collected with public money whilst respecting individual privacy. Medical and health research designed to benefit individuals and society (in the case of spreading epidemics [e.g., Severe Acute Respiratory Syndrome], new disorders [e.g., HIV/AIDS] and diseases of ageing [e.g., the dementias and other neurodegenerative disorders]) must not be impeded. The economic advantages issuing from research as well as the promotion of innovation, growth and competitiveness lead to benefits to society that impact on employment, public health and security. There are serious dangers from limiting research efficiency through injudicious or inefficient procedures related solely to the aim of personal data protection. Despite a uniform DPR, specific recognition of special circumstances is needed in the case of medical and health research.

The amendments²² proposed by the LIBE rapporteur demonstrate a limited understanding of the functioning of the medical and health research fields. They introduce requirements that will seriously stall medical and health research and kill any potential for innovation in the EU in these fields.

- **The MED Committee of Science Europe strongly rejects the position of the rapporteur of the LIBE Committee of the European Parliament (EP), which regards facilitation of scientific medical and health research as “not as urgent or compelling as public health or data protection”.**
- **The MED Committee is highly concerned with the many amendments from the rapporteur of the LIBE Committee of the EP that will dramatically hamper medical and health research and calls on the LIBE Committee to broadly oppose these amendments.**

Notes and References

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20. e.g., recruitment in CT, studies where there is a risk of introducing bias if participants are asked for their consent, large studies where seeking consent from each study subject is just not manageable
21. e.g., giving sample to a databank
22. Amendments [13-14-27-84-85-327-328-334-335-336-337] of the LIBE draft report would have devastating consequences for medical research:
 - Data concerning health could only be processed for research with the consent of individual subjects (amendments 27, 327 and 334-336)
 - Member States could pass laws permitting use of pseudonymised health related data without consent, but only in cases of “exceptionally high public interest” and with authorisation of the competent supervisory authority (amendments 328 and 337)
 - Pseudonymised data would be considered within the scope of the Regulation, even where a person or organisation handling such data does not have access to a decryption key enabling re-identification.

The Opinion Paper is endorsed by the Medical Sciences Committee of Science Europe

Science Europe – Medical Sciences Committee Members:

- **Professor Richard Frackowiak**, Chair of Science Europe Medical Sciences Committee and Head of the Department of Clinical Neurosciences at the Université de Lausanne, Switzerland
- **Professor Håkan Billig**, Head of the Endocrinology Research Group at the Sahlgrenska Academy of Gothenburg University, Sweden
- **Professor Jacques Marescaux**, Director of the IRCAD (Institut de Recherche Contre les Cancers de l'Appareil Digestif) and Head of Digestive and Endocrine Surgery at University Hospitals Strasbourg, France
- **Professor Jacques Melin**, Vice-recteur du Secteur des sciences de la santé at Université Catholique de Louvain, Belgium
- **Professor Lars Fugger**, Professor of Neuroimmunology at the Nuffield Department of Clinical Neurosciences of the John Radcliffe Hospital in Oxford, United Kingdom
- **Professor Marleen Temmerman**, Director of the Department of Reproductive Health and Research, and of the HRP programme at the World Health Organisation (WHO), Geneva, Switzerland
- **Professor Monique Capron**, Professor of Immunology at Lille University and Head of Department at the Pasteur Institute of Lille, France
- **Professor Nancy Pedersen**, Professor of Genetic Epidemiology at the Karolinska Institutet, Sweden
- **Professor Peter Krammer**, Head of the Tumourimmunology Programme at the German Cancer Research Center (DKFZ), Heidelberg, Germany
- **Professor Stephen Holgate**, Clinical Professor of Immunopharmacology at the School of Medicine, Southampton, United Kingdom
- **Professor Tullio Pozzan**, Professor of General Pathology at the University of Padova, Italy
- **Professor Henrique Barros**, Director of the Department of Clinical Epidemiology, Predictive Medicine and Public Health at the Medical School of University of Porto, Portugal
- **Professor Annette Grüters-Kieslich**, Dean of the Charité-Universitätsmedizin Berlin, Germany

Science Europe – Research Affairs Team support for the Opinion Paper

- **Dr. Bonnie Wolff-Boenisch**, Head of Research Affairs, Science Europe
- **Dr. Laure Sonnier**, Senior Scientific Officer, Medical Sciences

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For information please contact:

Dr. Laure Sonnier – Senior Scientific Officer, Medical Sciences

laure.sonnier@scienceeurope.org

Tel: +32 2 226 0311

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To contact Science Europe, email office@scienceeurope.org.