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

A Roundtable Event Hosted by Nessa Childers MEP

European Parliament, Brussels

Tuesday 17th September 2013 from 16:00 - 17:30
(followed by cocktail reception from 17:30 - 18:30)

Foreword

The European Institutions are currently engaged in the crucial stage of the legislative process that will produce a **European General Data Protection Regulation (DPR)** to replace the current Data Protection Directive.

To date, more than 3000 amendments have been proposed to the Regulation in the European Parliament's Committee on Civil Liberties, Justice and Home Affairs (LIBE). The draft report of the LIBE committee was released in January 2013 and there are serious concerns that amendments in this draft report would prevent or hinder the vital health research that Europe excels in.

Accordingly, the 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, brings together key stakeholder representatives including patients, health research professionals, ethicists and industry **to discuss what is needed from the Regulation to ensure that cutting-edge health research can continue in Europe.**

Setting the scene

Data relating to individuals are fundamental to modern health research that is **carried out for the shared benefit of all European Union citizens**. The processing of personal data is vital for clinical trials and observational research performed by researchers in industry and academia. The European Union has been at the international forefront of innovative research that has improved understanding of the causes of disease and led to the discovery and development of new treatments and diagnostics.

It is vital that the DPR enables patients and the public to benefit from the advances of health research by creating a legal framework that strikes an appropriate balance between facilitating the safe and secure use of personal data in health research and the rights and interests of individuals. We broadly support the Commission's proposal as a step towards this. The research community is therefore particularly concerned that the amendments proposed in the draft report of the LIBE committee would hinder cutting-edge studies and prevent much health research from continuing in Europe. The rapporteur of the LIBE committee argues that the processing of data for scientific research purposes is not "as urgent or compelling as public health". Since progress in healthcare and public health is impossible without health research, **there is clearly an 'urgent and compelling' case for health research to secure the wellbeing of European citizens for the benefit of individuals and society.** Important examples include work done in the past to control the HIV epidemic, understand vaccine safety in children and work for the future into the neurodegenerative diseases of ageing.

Health research is conducted within a **robust ethical framework** with strong safeguards supported by internationally recognised guidelines such as the *Declaration of Helsinki*. In health research, Ethics Committees play a crucial role in balancing risks and benefits of research projects, for example ensuring that the data of patients and citizens are safely processed in a way that is also proportionate to the potential benefits to society as a whole. Furthermore, **state-of-the-art procedures for the safe processing of personal data** have been developed by the health research community to protect the privacy of individuals participating in research and minimise the risks of identifying individuals where this is not necessary. These technical and organisational procedures build on the longstanding experience of many European centres of excellence for data processing.

It is crucial that the DPR takes account of these existing safeguards and procedures to create a legal environment that promotes the interests of data subjects while providing EU citizens with better healthcare resulting from advances through health research. In addition, the EU must remain a viable and globally competitive location for health research to capitalise on economic benefits of research that include more efficient healthcare systems; healthier citizens; and the promotion of innovation and growth.

It is challenging to produce legislation with a broad scope that protects citizens while taking into account the needs of different sectors. However, **we urge the legislators to recognise the societal benefits of health research and existing safeguards in this area, and to produce a DPR that enables vital health research to continue in the EU.**

Legislative analysis and voting recommendations

1- Processing for historical, statistical and scientific research purposes

We broadly support Article 83 of the Commission's proposal and the associated provisions for scientific research. Combined with existing regulatory and ethical safeguards this provides a proportionate mechanism for protecting privacy, while enabling health research to continue.

It is important that the intention of the Commission's proposal is clear. The Regulation sets out that data can only be processed where this is compatible with the purposes for which they were initially collected. Health research often relies on data collected previously, for example as part of an individual's health record. We therefore welcome **clarification that the further processing of personal data for scientific research purposes is a 'not incompatible' purpose and support amendments 821, 3062, 3065, 3069 and 3084**. These amendments would ensure that the Regulation is consistent with the current Directive.

The rapporteur of the LIBE committee has proposed a number of amendments that restrict the processing of health data for research on the basis that "processing of sensitive data for historical, statistical and scientific research purposes is not as urgent or compelling as public health or social protection." However, advances in public health and medicine are impossible without research and these amendments would have a severe negative impact on progress in this area. We therefore **strongly oppose amendments 27, 327, 328, 334, 335, 336, 337 and 3060.**

In particular, **amendments 328 and 337** would enable Member States to pass a law permitting the use of pseudonymised data concerning health without consent, but only in cases of "exceptionally high public interest" and with authorisation of the competent supervisory authority. Health research clearly serves the public interest. However, the words **"exceptionally high"** suggest that the LIBE rapporteur intends the exemption to be used only in a very limited set of circumstances. This is likely to be problematic for many studies, particularly because the results and impact of the study are not known at the outset. Since health research is already highly regulated these amendments also create an **additional and unnecessary layer of regulation** and will result in **inconsistent requirements across Member States**, contrary to the Regulation's goal of harmonisation.

Article 81(2) of the Commission's proposal clarifies that the processing of data concerning health for research is to be regulated according to the research provisions under Article 83, rather than as healthcare or public health activities under Article 81. We **oppose amendments 327 and 328** that undermine this approach by introducing research provisions in Article 81 in addition to Article 83, **creating confusion and legal uncertainty**.

Health research with personal data takes place within a robust ethical framework supported by guidelines such as the international *Declaration of Helsinki*. This ensures that an individual's personal data are only used in research when this is proportionate to the potential benefits for society as a whole. Project approval by an ethics committee is a particularly important safeguard when data are to be processed for research without consent of the data subject.

This safeguard is not reflected in the current Commission proposal for a Regulation, which could be strengthened to clarify this, therefore **we support amendments 3057, 3059 and 3068**.

2- Anonymised, Peudonymised and Identifiable data

Where it is not possible to use anonymised data, research often relies on the use of **pseudonymised or key-coded data**. These data cannot directly identify an individual, but are provided with an identifier that enables the data subject's identity to be re-connected to the data by reference to a separate database containing the identifiers.

Pseudonymisation is important in health research since it protects the privacy of data subjects while giving researchers access to important individual-level detail. For example, pseudonymised data allow connections to be made between different sources of information, for example to link work-related exposures and disease risk. Pseudonymised data underpin a substantial amount of health research, for example large-scale population-based research involving hundreds of thousands of participants, such as biobanks and patient and population cohorts.

A range of **safeguards are used to minimise the risk of re-identification from pseudonymised data in research**, including:

- state-of-the-art safe-havens exist through Europe to facilitate the use of pseudonymised data and data linkage in research, 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;
- encryption and key management to restrict access to the data;
- technical and organisational security measures; and
- the restriction of access to *bona fide*, trained researchers with contractual requirements and sanctions if they breach the conditions.

Good practice has been established in the health research communities to minimise the risk of reidentification from pseudonymised data to efficiently protect individual rights to privacy. Whether data falls within the scope of the Regulation depends on whether identification of an individual using the data is deemed "reasonably likely". **Further guidance would be needed to understand how this might be interpreted with respect to robustly pseudonymised data used in health research**.

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. This could be achieved by clarifying that in certain situations **robustly pseudonymised data can be out of the scope of the Regulation, or by ensuring that the regulatory burden is lighter where the associated privacy risks are very low**. Proportionate regulation will facilitate the continued use of pseudonymised data in health research and incentivise data controllers to use pseudonymised data in preference to identifiable data, providing greater privacy protection.

The LIBE rapporteur's amendments appear to include pseudonymised data within the scope of the Regulation. However, pseudonymised data would then be subject to most of the same requirements as identifiable data, for example relating to international transfers. This would increase the regulatory burden for research and create a regulatory system that is not proportionate to the privacy risks to an individual. **We therefore oppose amendments 14, 84 and 85.**

The **processing of anonymous data is not and should not be in the scope of the Regulation, therefore we oppose amendment 3061.**

3- Consent

Under the Regulation, personal data could only be processed when there is an appropriate legal basis. The Commission's proposal would enable personal data to be processed for historical, statistical and scientific research without the need for consent provided that it fulfils the requirements of Article 83.1.

However, a number of amendments have been proposed that would mean that scientific research would almost always require consent as the legal basis for the processing of personal data. Consent is an important ethical principle in health research. In the clinical research context, for example clinical trials, consent is obtained as a matter of good clinical practice. The Commission's proposal requires consent for processing to be "specific, informed and explicit", which is often difficult to achieve in health research. The combination of these amendments and the requirements for consent is therefore highly problematic for research. For example many studies assessing the risks associated with specific medical treatments, such as unexpected side effects, or the links between the health of pregnant mothers and the health of their babies would become very difficult or impossible to conduct. **We therefore strongly oppose amendments 27, 327, 328, 334, 335, 336, 337, 2974, 2986, 3060, 3067 and 3071.**

The need for **"specific" consent is a particular problem**. Many research resources such as biobanks, rely on broad or generic consent where the participants give consent for their pseudonymised data to be used for a variety of research studies under certain conditions. These research resources would become very difficult, or impossible, to run if consent for processing had to be sought for every new research project. We therefore **support amendments 498, 3066, 3076 and 3079 that recognise the importance of broad consent** in collecting and storing data for future research purposes that can only be described in broad terms at time that data is collected.

However, in some studies it is not possible to seek consent at all, either because a very large sample size is needed to generate a robust result and this would be practically difficult to obtain, or because seeking consent would introduce bias. Including an option for **broad consent is a step in the right direction, but an exemption from consent will still be needed in some circumstances**.

Lessons learned from German cancer registries:
In the 1980s, informed consent was made a statutory requirement for inclusion of data in cancer registries in two German regions. Subsequently, it was reported that cancer registries in these regions were unable to collect more than 70 per cent of cancer cases. The Hamburg registry, the oldest cancer registry in the world, broke down and was no longer able to add its results to international cancer indexes. These difficulties led to new guidance from the Federal Government in 1994, which relaxed the requirement for consent in all regions.

Pseudonymised data provide the basis for many research studies in order to protect the privacy of data subjects. However, in some cases pseudonymised data will not be sufficient for the research purposes. Sometimes researchers need details such as age, postcode and information on a health condition. Together, this information could disclose the identity of an individual but the study would not be possible without it. The exemptions proposed in **amendments 328, 335, 337 and 3060** would only apply to pseudonymised data. This means that research with identifiable data could *never* be used without consent, regardless of the safeguards in place. We strongly **oppose these amendments** and **call on MEPs to ensure that the Regulation 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- Definition of Genetic Data

The definition of "genetic data" in the Commission's proposal (Article 2(10)) is not consistent with widely-used definitions, creating legal uncertainty about its intended scope. We **support amendments 772, 773, 774 and 776** which would ensure that the definition is consistent with international guidelines, notably the United Nations International Declaration on Human Genetic Data. However, **we oppose amendments 775 and 777**, which do not provide sufficient legal clarity that "genetic data" relates to data obtained by nucleic acid analysis.

5- Data Breaches

The Commission's proposal recognises that personal data breaches may lead to substantial economic loss and social harm, giving identity fraud as an example. We support the risk-based approach to notification proposed by the Commission, which emphasises the importance of the safeguards applied by the controller and processor of the data and notes that certain types of processing may, for various reasons, carry greater risks than others. This will help ensure that the data protection authorities' resources are focused on serious breaches. The language of the relevant articles in the proposal could be brought more clearly into alignment with the philosophy expressed in the recitals by making it clear that the notification obligation applies where there is a risk of harm arising from the breach. **We support amendments 1950, 1953, 1955, 1956, 1959 and 1999, which introduce a risk-based approach to breach notification into the relevant articles.**

Potential breaches of pseudonymised or key-coded data demonstrate the need for a risk-based approach. The risk of reidentification from pseudonymised data is very low, as discussed in section 2 of this document. Therefore, in most circumstances, a data breach

involving key-coded data is unlikely to pose a risk to an individual unless the code keys that are held separately from the other data have also been compromised.

The rapporteur supports the promotion of high standards of data protection measures to be adopted by controllers and processors to minimise the risk of data breaches. We agree with these principles and **support amendment 44**.

6- Data Protection Impact Assessments

Article 33 of the Commission's proposal introduces an obligation for controllers and processors to carry out a risk assessment prior to "risky processing operations" which should address the measures, safeguards and mechanism proposed to ensure compliance with the Regulation. Article 33 suggests that aspects of processing for health research may be considered as carrying specific risks and this position is clarified in the rapporteur's amendment 207. This would mean that processing for health research would require data protection impact assessments. We consider that data protection impact assessments can be a useful tool in managing the risks associated with data processing. However, as noted in recital 72, many processing operations are essentially similar in the risks they present, although different data may be processed in different cases. We therefore consider that article 33 would benefit from clarification to recognise that a single assessment shall be sufficient to address a set of processing operations that present similar risks. **We support amendments 2018, 2022 and 2023, which propose that a new privacy 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- Codes of Conduct

Recital 76 highlights the role that codes of conduct may play in delineating specific measures in different sectors to ensure that the Regulation is effectively implemented. Approved self-regulation instruments like Codes of Conduct should be encouraged and enable those adhering to such codes to reduce the administrative burdens associated with regulatory compliance for regulators, data controllers and data processors, while safeguarding the interests of individuals. We therefore **support amendments 2348 and 2350.**

8- Cross-border transfer

Sharing of data is at the centre of modern health research. Health research is an intensely collaborative effort, where individual data often need to be shared or transferred to different research groups organised into joint research consortia across national borders. The form of the legislation as a Regulation has the potential to address the current fragmentation of regulatory systems for privacy protection that has made cross-border co-operative research in the EU difficult at times.

The Regulation should seek to facilitate cross-border transfers of personal data for health or research purposes. Therefore we **strongly support amendments 2432, 2437, 2438, 2439, 2510, 2997, 3075, 3077, 3094** that introduce requirements for these transfers in Article 81 and Article 83 and **oppose amendment 2497.**

9- Prior authorisation

We consider that a request for prior authorisation from the supervisory authority will add burden and delay data processing, although we recognise the benefits of processors and controllers being able to seek advice from the authorities in specific cases. We therefore **strongly support amendments 2094, 2095, 2096, 2097, 2442, 2445 and 2446.**

10- Right of data subject to information

The right of the data subject to information in Article 14 requires data controllers to inform data subjects how their data are being used. This could be problematic for research in situations where notifying the participants would create a disproportionate burden that could prevent research from proceeding, for example because of the study is very large or because data were collected a long time ago.

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. Creating a specific “disproportionate effort” provision for research, in line with the current Data Protection Directive, will ensure that research is not inappropriately restricted. **We therefore strongly support amendments 1256, 1257, 1263 and 1267 and oppose 1245.**

Summary table

Key:

++	**Strongly support**	**-**	**Oppose**
+	**Support**	**--**	**Strongly oppose**

Amdt	Provision	Vote	Explanation	MEP
27	Recital 42	--	Restricts the processing of health data for research, which would have devastating consequences for health research that leads to life-saving advances in public health and medicine.	Albrecht (Greens/EFA, DE)
44	Recital 66	+	Data controllers and processors should also promote organisational measures to ensure security of processing, technological neutrality, interoperability and innovation.	Albrecht (Greens/EFA, DE)
327	Article 81 (2)	--	Makes the exemption for the use of health data in research very narrow, which will prevent valuable health research that is currently legal. Also creates legal uncertainty in the relationship between Articles 81 and 83.	Albrecht (Greens/EFA, DE)
328	Article 81 (2) a new	--		
334	Article 83 (1)	--	Restricts the use of personal data in research, which will prevent or inhibit important research in the public interest. Adds additional layers of regulation that are not required as research is already tightly regulated under European and Member State law. Delegating exemptions to Member States will also lead to a variety of regulatory approaches across the EU, reducing scope for harmonisation.	Albrecht (Greens/EFA, DE)
335	Article 83 (1)b	--		
336	Article 83 (1)a new	--		
337	Article 83 (1)b new	--		
498	Recital 53a (new)	++	Introduces the potential for broad consent for historical, statistical or scientific research purposes instead of specific consent. Broad consent is commonly used in medical research where it is not possible to specify the details of a study. Broad consent promotes the reuse of data or samples for other studies that are consistent with the consent.	Voss (EPP, DE)
772	Article 4 (1) (10)	+	Ensures the definition of genetic data is consistent with international definitions, notably the United Nations International Declaration on Human Genetic Data.	Luhan (EPP, RO)
773				Alvaro (ALDE, DE)
774				Voss (EPP, DE)

775	Article 4 (1) (10)	-	Does not provide sufficient legal clarity that “genetic data” relates to data obtained by nucleic acid analysis.	Moraes (S&D, UK) Willmott (S&D, UK)
776	Article 4 (1) (10)	+	Ensures the definition of genetic data is consistent with international definitions, including the United Nations International Declaration on Human Genetic Data.	Vălean (ALDE, RO) Rohde (ALDE, DK)
777	Article 4 (1) (10)	-	Does not provide sufficient legal clarity that “genetic data” relates to data obtained by nucleic acid analysis.	Stadler (NI, AU)
821	Article 5 (1)b	++	Clarifies that historical, statistical and scientific research purposes are intended to be not incompatible purposes, in line with the current Data Protection Directive.	Ludford (ALDE, UK) Tannock (ECR, UK)
1245	Article 14 (5)b	-	Removes the disproportionate effort provision altogether. Some research studies would not be able to comply with this requirement it is not always possible or proportionate for researchers to provide information to data subjects.	Guillaume (S&D, FR) Castex (S&D, FR)
1256	Article 14 (5)da (new)	++	Introduces a specific disproportionate effort provision for research, which is important since it is not always possible or proportionate for researchers to provide information to data subjects because of the scale of the study or because data was collected a long time ago.	Moraes (S&D, UK) Willmott (S&D, UK)
1257				Essayah (EPP, FI)
1263				Griesbeck (ALDE, FR)
1267				Ludford (ALDE, UK) Tannock (ECR, UK)
1950	Article 31 (1)	+	The 24 hour timeframe for reporting breaches is impractical. Moreover, only breaches seriously impacting the data subject’s rights should need to be reported.	Díaz de Mera García Consuegra (EPP, ES)
1953				Camp (EPP, NL)
1955				Vălean (ALDE, RO), Rohde (ALDE, DK)
1956				Michel (EPP, FR)
1959				Ludford (ECR, UK)
2018	Article 33 (1)	+	Clarifies that a single privacy impact assessment can be used for multiple processing operations that present similar risks. This will reduce bureaucracy for health research studies.	Juvin (EPP, FR)
2022				Vălean (ALDE, RO) Rohde (ALDE, DK)
2023				Ludford (ALDE, UK)

2094	Article 34 (1)	+	A requirement for prior authorisation from the supervisory authority will add burden and delay to data processing.	Torvalds (ALDE, FI)
2095				Valean (ALDE, RO), Rohde (ALDE, DK)
2096				Kirkhope (ECR, UK)
2097				Ludford (ALDE, UK)
2348	Article 38a (new)	++	Approved self-regulation instruments like Codes of Conduct should be encouraged and enable those adhering to such codes to reduce the administrative burdens associated with regulatory compliance.	Voss (EPP, DE)
2350	Article 38c (new)			
2432	Article 42 (2)da new	+	Provides for the international transfer of data for historical, statistical and scientific research purposes. This will facilitate data sharing to promote international research collaborations, which are an important component of academic and commercial scientific research.	Luhan (EPP, RO)
2437	Article 42 (2)db new	+		Ludford (ALDE, UK)
2438				Vălean (ALDE, RO) Rohde (ALDE, DK)
2439				Voss (EPP, DE)
2442	Article 42 (3)	++	Relates to the addition of Article 42 (2)d a (new). Provides that prior authorisation of the supervisory authority should not be required for such transfers as the protections in Article 83 are already sufficient.	Luhan (EPP, RO)
2445				Vălean (ALDE, RO), Rohde (ALDE, DK)
2446			See justification for AM 2442. This amendment corrects the drafting errors of AM 2442 and 2445 by correctly referencing Article 42 (2)da or db, according to the usual customs for referencing new provisions.	Voss (EPP, DE)
2497	Article 44 (1)a	-	Each of para. 1, points a through h should be kept as separate and independent legal bases to transfer personal data to a third country, as proposed by the Commission. A requirement, as proposed in this amendment, to require consent for all cross-border data transfers is impractical and burdensome.	in 't Veld (ALDE, NL)
2974	Article 81 (1)aa (new)	--	Requires the consent of the data subject to process health data for research purposes, which is impossible to achieve in some studies.	Pietikäinen (EPP, FI)
2986	Article 81 (2)	--	Requires the consent of the data subject to process health data for research purposes, which is impossible to achieve in some studies.	Marian Harkin (ALDE, IE)
2997	Article 81 (3)a (new)	++	Cross-border transfers of health data should be allowed subject to the conditions of this amendment. Multinational research studies require the collection, aggregation, and analysis of health data from sites around the world.	Ludford (ECR, UK)

3057	Article 83 (1)ba (new)	+	Approval of a scientific research project by an independent ethics committee is an important safeguard where personal data is to be processed without consent, to ensure that the use of personal data is proportionate.	Moraes (S&D, UK) Willmott (S&D, UK)
3059				Torvalds (ALDE, FI)
3060	Article 83 (1)ba (new)	--	Restricts the use of personal data in research, which will prevent or inhibit important research in the public interest. Adds additional layers of regulation that are not required as research is already tightly regulated in European and Member State law. Delegating exemptions to Member States will also lead to a variety of regulatory approaches across the EU, preventing harmonisation.	Harkin (ALDE, IE)
3061	Article 83 (1)ba (new)	--	Undermines the principle that the Regulation applies to the processing of personal data, not anonymous data.	Juvin (EPP, FR)
3062	Article 83 (1)a (new)	++	Clarifies that historical, statistical and scientific research purposes are not incompatible purposes, in line with the current Data Protection Directive	Luhan (EPP, RO)
3065	Article 83 (1)a (new)	++	Clarifies that historical, statistical and scientific research purposes are not incompatible purposes, in line with the current Data Protection Directive	Vălean (ALDE, RO) Rohde (ALDE, DK)
3066	Article 83 (1)a (new)	+	Introduces the potential for broad consent for historical, statistical or scientific research purposes instead of specific consent. Broad consent is commonly used in medical research where it is not possible to specify the details of a study. Broad consent promotes the reuse of data or samples for other studies that are consistent with the consent.	Essayah (EPP, FI)
3067	Article 83 (1)a (new)	--	Requires the consent of the data subject to process health data for research purposes, which is impossible to achieve in some studies. Broad consent is not sufficient to facilitate research in all situations.	Torvalds (ALDE, FI) Korhola (EPP, FI) Manner (ALDE, FI)
3068	Article 83 (1)a (new)	+	Approval of a scientific research project by an independent ethics committee is an important safeguard where personal data is to be processed without consent, to ensure that the use of personal data is proportionate.	Hedh (S&D, SE) Ulvskog (S&D, SE)
3069	Article 83 (1)a (new)	++	Clarifies that historical, statistical and scientific research purposes are not incompatible purposes, in line with the current Data Protection Directive.	Ludford (ALDE, UK) Tannock (ECR, UK)
3071	Article 83 (1)b (new)	--	Requires the consent of the data subject to process health data for research purposes, which is impossible to achieve in some studies.	Ernst (GUE/NGL, DE)

3075	Article 83 (2)a (new)	**++**	Cross-border transfers of personal data for research purposes should be permitted subject to the requirements proposed in this amendment. Multinational research studies require the collection, aggregation, and analysis of data from sites around the world.	Luhan (EPP, RO)
3079	Article 83 (2)a (new)	**++**	Introduces the potential for broad consent for historical, statistical or scientific research purposes instead of specific consent. Broad consent is commonly used in medical research where it is not possible to specify the details of a study. Broad consent promotes the reuse of data or samples for other studies that are consistent with the consent.	Ludford (ALDE, UK) Tannock (ECR, UK)
3077	Article 83 (2)a (new)	**++**	Cross-border transfers of personal data for research purposes should be permitted subject to the requirements proposed in this amendment. Multinational research studies require the collection, aggregation, and analysis of data from sites around the world.	Vălean (ALDE, RO), Rohde (ALDE, DK)
3094	Article 83 (3)a (new)	**++**	Cross-border transfers of personal data for research purposes should be permitted subject to the requirements proposed in this amendment. Multinational research studies require the collection, aggregation, and analysis of data from sites around the world.	Ludford (ALDE, UK), Tannock (ECR, UK)

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 though its six Scientific Committees. The **Medical Sciences Committee of Science Europe** is co-hosting the roundtable.

Science Europe Office: Rue de la Science 14, 1040 Brussels, Belgium
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 Office: Rue De L'aqueduc 88A, 1050 Ixelles, Brussels, Belgium
http://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 Office: Gibbs Building, 215 Euston Road, London NW1 2BE, UK
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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 (EASAC – the European network of Academies of Sciences) and the InterAcademy Medical Panel (IAMP – the global network of Academies of Medicine).

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EFPIA brings together 33 European national pharmaceutical industry associations as well as 40 leading companies undertaking research, development and the manufacture in Europe of medicinal products for human use

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