Legal Challenges for the Regulation of the European Health Data Space

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Abstract

In the present context of the so-called 'Digital Society', an important process of legislative reform is taking place inside the European Union. In areas such as the digital transformation of the health sector, these actions have a considerable impact on traditional legal concepts and categories such as privacy or informed consent. This is especially relevant in the realm of health science research in the context of Big Data. The nature of this type of research projects requires a new model of consent, which is called broad consent. The legislator faces the challenge of having to respect, on the one hand, the balance between the possibility of obtaining consent in a simple and feasible way, and on the other, the need to provide data subjects the necessary information and control over their sphere of privacy. Likewise, a formula must be found that protects individuals, but does not unduly hinder progress in biomedical research. This issue requires an assessment from both an ethical and a legal perspective. Here comes into play the role of Research Ethics Committees that is reinforced by these new legislative measures, so that the concept of data ethics is coined. In the drafting of this work, my experience as a member of the Research Ethics Committee of the University of Valencia has been fundamental.

Keywords

Informed Consent, Data Protection, Big Data, Health Research, eHealth

1. Introduction

Undoubtedly, new technologies are called upon to play an important role in the advancement of medicine, especially in what is known as personalized medicine, whose aim is for people to receive the kind of treatment most appropriate

to their specific conditions, considering their genetic makeup and other medical characteristics. For these therapies to be widely implemented, it is necessary to previously carry out research that requires a huge amount of health data, but also genetic data, which fall within the special categories of personal data, according to the terminology of Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (GDPR).[1] Therefore, we are faced with two conflicting interests, on the one hand, the necessary scientific progress, and on the other, the protection of the privacy of the subjects. GDPR uses instruments such as anonymization and pseudonymization of data with certain guarantees to harmonize these two positions.

Furthermore, the Data Governance Act introduces the concept of 'data altruism' aimed at facilitating non-profit data sharing, by fixing incentives for particulars in a trust environment.[2] This Regulation is part of the Commission's plan of establishing a single European Data Space. Particularly the Proposal for a Regulation on the European Health Data Space[3] '"will address health-specific challenges to electronic health data access and sharing, is one of the priorities of the European Commission in the area of health and will be an integral part of building a European Health Union'.[4]

2. 'eHealth': the digital transformation of the health sector in the European Union

The need to regulate research in Genomics and the so-called Biobanks has had a great impact on traditional legal concepts and categories such as personal data protection or informed consent. In relation to the first question, the social function of data is valued, as an element that can contribute to the advancement of scientific knowledge. For the minimization of risks concerning privacy the concept of anonymized or pseudonymized data arises. Such data no longer identifies the subject and can be used for research in Big Data environment with guarantees. On the second issue, the subject's consent to participate in a

1 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation or GDPR) [2016] OJ L119/1.

2 Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) [2022] OJ L152/1.

3 Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space', COM (2022) 197 final.

4 Explanatory memorandum 'Reasons for and objectives of the proposal'.

research project, as it was shaped in the European Bioethics Convention, needs to be reformulated so that it is best suited for these new forms of research, as it will be discussed in more detail below.[5]

The European Union is issuing new rules aimed at the new regulation of the digital society. One of the issues to which special attention is paid is what is called 'eHealth' (eHealth Action Plan 2012-2020),[6] which is conceived as preventive, predictive, personalized, participatory and populational medicine and through technological devices developed for therapeutic or care purposes.[7] Truly, this is going to mean a change in the model of healthcare as we know it today.

As previously mentioned, the implementation of this new health system requires prior research work, where the so-called Big Data in health is bound to play an important role. In this form of research, personal data is essentially valuable. Much of this data comes from what is called the 'Internet of Bodies', a subcategory within 'Internet of Things' that facilitates practices such as monitoring people's health data. Among the advantages of these technologies, it can be mentioned that the treatment of this huge amount of data will allow scientific progress in the field of Genetic Medicine, since it will make possible to understand the interaction between genetics and the environment of the person to contribute to the discovery of new diagnostics and therapies. However, this technology is not exempt from risks, such as possible discrimination of the person due to his or her genetics, which is prohibited by Constitutional texts and International Treaties on the matter, as well as possible violations of privacy, since although pseudonymization or anonymization techniques exist, re-identification is sometimes possible. This last question is especially serious, since genetic data and health data are highly sensitive data, subject to a higher level of protection in the corresponding personal data protection regulations.

Returning to the topic of the so called 5P Medicine, one of the main objectives of the 'eHealth Action Plan 2012-2020' of the European Union is to obtain better data to promote research, disease prevention, and personalized health care.[8]

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5 In relation to this question cf Barbara J Evans, 'Big Data and Individual Autonomy in a Crowd', I. Glenn Cohen and others (eds), *Big Data, Health Law, and Bioethics* (CUP 2018) 19, 26. In the context of Big Data, the traditional norms on informed consent are not adequate for the main purpose for which they were designed: to empower the individual to protect themselves against research-related risks.

6 European Parliament, 'Resolution on the eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century (2013/2061(INI))' [2016] OJ C482/14.

7 Paragraph 6 of Art. XXIII Carta de Derechos Digitales 2021.

8 Virginia Sanchini and Luca Marelli, 'Data protection and ethical issues in European P5 eHealth' in Gabriella Pravettoni and Stefano Triberti (eds), *P5 eHealth: An Agenda for the Health Technologies of the Future* (Springer 2020) 173.

In the same vein, measures must be adopted that allow the assemblage of genomic data and other health data, guaranteeing full compliance with data protection legislation and the corresponding respect for ethical principles. The European Commission underlines the advantages of a coordinated European action in this field by 'making it possible to tackle major health challenges such as cancer or brain disease, epidemics of infectious disease, or rare disease'.[9] Furthermore, the intention is to fix coordination between authorities across the EU to implement the secure exchange of genomic and other health data to advance research and implement personalised medicine. 'This should be based on a transparent system of governance, with the aim of linking national and regional banks of '-omics' data, biobanks and other registries across the EU'.[10]

The expected result of all this is the conjunction of information from molecular profiling, diagnostic imaging, environmental and lifestyle data, microbiological genomics and environmental data as well as links to electronic health records.

The purpose is to implement predictive methods regarding digital patients with the support of high-performance computing, data analytics and artificial intelligence.

3. Towards the European Health Data Space: legal instruments

3.1. The Regulation (EU) 2016/679

In this task aimed at achieving personalized and predictive medicine, the GDPR plays an important role as a legal instrument. The Regulation allows the promotion of research and provides an opportunity to strike a fair balance between the protection of individual rights and scientific progress.

In recital n 34 a concept of genetic data is provided as 'personal data relating to the inherited or acquired genetic characteristics of a natural person which result from the analysis of a biological sample from the natural person in question, in particular chromosomal, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) analysis, or from the analysis of another element enabling equivalent information to be obtained'. Likewise, in Recital 35 among the personal data related to health, it must be included all data related to the state of health of the subject which provide information about the state of physical or mental health, past, present, or future, as well as those obtained from biological

9 Commission, 'Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society', COM (2018) 233 final, 7.

10 ibid 8.

samples. This interpretation is in line with the case law of the European Court of Human Rights, which in *S. and Marper v UK* ruled that the cell samples constitute personal data (in the opinion of the Court, the analysis of the biological sample of the plaintiff implies an interference with the right to privacy due to the potential risks that such analysis could derive from).[11]

Health data and genetic data of people fall within the special categories of data of art 9 GDPR. However, there is a paradigm shift in the understanding of health data, which is called upon to achieve a social function.

In the first place, according to recital n 4 GDPR: 'The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right; it must be considered in relation to its function in society and be balanced against other fundamental rights, in accordance with the principle of proportionality. This Regulation respects all fundamental rights and observes the freedoms and principles recognised in the Charter as enshrined in the Treaties, in particular the respect for private and family life, home and communications, the protection of personal data, freedom of thought, conscience and religion, freedom of expression and information, freedom to conduct a business, the right to an effective remedy and to a fair trial, and cultural, religious and linguistic diversity'.

Secondly, in recital n 53 GDPR reference is made to health data and genetic data as special categories of personal data 'which merit higher protection' *and that* 'should be processed for health-related purposes only where necessary to achieve those purposes for the benefit of natural persons and society as a whole, in particular in the context of the management of health or social care services and systems'. However, as it continues to be pointed out, these data may also be processed for 'archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, based on Union or Member State law which has to meet an objective of public interest, as well as for studies conducted in the public interest in the area of public health'.

How is it possible to harmonize individual interest and social interest in this balanced analysis? The answer must be found in art 89 GDPR that establishes a series of guarantees and exceptions applicable to the processing of data for

11 *S. and Marper v UK* App nos 30562/04 and 30566/04 (ECtHR, 4 December 2004, para 73, stating: 'Given the nature and the amount of personal information contained in cellular samples, their retention per se must be regarded as interfering with the right to respect for the private lives of the individuals concerned. That only a limited part of this information is actually extracted or used by the authorities through DNA profiling and that no immediate detriment is caused in a particular case does not change this conclusion (see Amann cited above, § 69)'. Among scholars cf Dara Hallinan and Paul De Hert, 'Many Have It Wrong – Samples Do Contain Personal Data: The Data Protection Regulation as a Superior Framework to Protect Donor Interests in Biobanking and Genomic Research' in Brent Daniel Mittelstadt and Luciano Floridi (eds), *The Ethics of Biomedical Big Data* (Springer 2016) 119.

scientific research purposes.[12] Among them it is mentioned that 'technical and organisational measures are in place in particular in order to ensure respect for the principle of data minimisation'. Likewise, said measures 'may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where those purposes can be fulfilled by further processing which does not permit or no longer permits the identification of data subjects, those purposes shall be fulfilled in that manner'. It is about respecting the principle of data minimization, which according to art 5(1)(c) personal data shall be 'adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ("data minimization")'.

Thus, the further processing of personal data will be carried out when the data controller has evaluated the feasibility of fulfilling these purposes through data processing that does not allow the identification of interested parties, such as pseudonymization.[13]

In addition, it is possible to establish exceptions to the rights of access, rectification, deletion, limitation and opposition to the processing and portability of the personal data of the subject, when they may make it impossible or seriously hinder the achievement of the scientific and when those exceptions are necessary to achieve those purposes.

3.1.1. Broad consent model for health research and research for public interest in the realm of Big Data

Another useful instrument mentioned above is the broad consent model referred to in recital n 33 GDPR. Due to the new ways of research in the context of Big Data, it is often not possible to 'fully identify the purpose of personal data processing for scientific research purposes at the time of data collection'. That is why 'data subjects should be allowed to give their consent to certain areas of scientific research when in keeping with recognised ethical standards for scientific research'. Consequently, data subjects must be given the opportunity

12 About this issue cf Menno Mostert and others, 'From Privacy to Data Protection in the EU: Implications for Big Data Health Research' (2018) 25 European Journal of Health Law 43, 53. In the opinion of the authors, in the tension between scientific progress and the protection of the individual, the European Data Protection Regulation allows exceptions to certain consent requirements for the sake of scientific research, but also requires that said exceptions are subject to appropriate guarantees. In accordance with art 89, para 1, of the GDPR, technical and organizational measures must be adopted to guarantee respect for the principle of data minimization. The question of what specific safeguards should be provided by law regarding data-intensive health research remains unclear. The authors point out, among others, accountability to an independent supervisory entity, respect for the principle of transparency, allowing interested parties to invoke their rights, among others. However, the adoption of inflexible or rigid data protection measures could hinder the establishment of adequate information governance frameworks, and ethics and law must be reconciled.

13 As established in recital n 156 GDPR.

to give their consent 'only to certain areas of research or parts of research projects to the extent allowed by the intended purpose'.

The current regulations on data protection rest on the concept of informed self-determination of the subject ('informational self-determination'), that is, in the ability of data subjects to take control over the assignment or use that will be given of their personal data based on their free and informed consent ('privacy self-management'). However, given the nature of research projects in the context of Big Data, the traditional informed consent model may be impractical. Art 60 of the Spanish Act 14/2007 on Biomedical Research (Biomedical Research Spanish Act) establishes that consent will be specifically obtained for a specific investigation.[14] However, the 'broad consent' models, to which the mentioned recital n 33 refers, have the problem that people are often no longer capable of making significant decisions about the use of their personal data as a consequence of the complexity of health research in the context of Big Data. In this environment, a balance cannot always be struck between obtaining consent in a simple and feasible way, and providing data subjects with sufficient information and control, when personal data is to be linked to others, reused, and analysed in future unspecified research projects.[15]

The general rule, according to art 9 GDPR, is that it is not possible to process genetic data, data related to the health of the person, among others within the special categories of data. However, this limitation will not apply when the interested party has given 'explicit consent to the processing of those personal data for one or more specified purposes, except where Union or Member State law provide that the prohibition referred to in paragraph 1 may not be lifted by the data subject' (for example, there are States where the processing of genetic data by insurance companies for risk assessment in life or health insurance is prohibited).[16]

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14 Ley 14/2007 Investigación biomédica.

15 cf Markus Christen and others, 'On the Compatibility of Big Data Driven Research and Informed Consent: The Example of the Human Brain Project' in Brent Daniel Mittelstadt and Luciano Floridi (eds), *The Ethics of Biomedical Big Data* (Springer 2016) 199, 201. In the opinion of the authors, any form of informed consent is embedded in an "information framework" that indicates the general context in which the data is generated, what type of data is actually obtained, and, although not exhaustively and in rather general terms, what kind of results could be expected from the analysis of the data.

16 This is the case, for example, of Belgium: in this country the Loi du 4 Avril 2014 relative aux assurances specifically regulates the use of genetic information by insurance companies. Art 58 establishes that genetic data cannot be communicated to insurance companies for the purposes of risk assessment. Likewise, as regulated in art 61(3), the medical examinations necessary for the conclusion and execution of the contract can only be based on the current state of health of the insured person and not on genetic research techniques to predict the future state of health. Therefore, even if the subject's consent was given, insurers would not be able to use the person's genetic information for the purposes of risk assessment within the scope of the insurance contract.

This consent can be broad consent within the meaning of recital 33 GDPR when the processing of genetic or health data is for research purposes.[17] As an argument in favour of this new model, it is cited that due to the complexity and dynamism of modern biomedical research, research participants may not be aware of all the current implications derived from the provision of their consent. In addition, it is often not possible to obtain renewed informed consent because it is usually not possible to find the subjects participating in the research (for example, because they have died). At the same time, maintaining a record of contact data would represent a high cost for any project, and could even generate new risks in the protection of privacy due to possible unauthorized access to this information.

The European Data Protection Board (EDPB) has explained that although recital 33 seems to bring some flexibility to the degree of specification and granularity of consent in the context of scientific research, "it should be noted that recital 33 does not disapply the obligations with regard to the requirement of specific consent".[18]

The GDPR establishes other legal basis, other than consent, that legitimize the processing of genetic and health data. For instance, substantial public interest (art 9(2)(g)), preventive or occupational medicine, for the assessment of

17 Aaro Tupasela and Sandra Liede, 'State Responsibility and Accountability in Managing Big Data in Biobank Research: Tensions and Challenges in the Right of Access to Data' in Brent Daniel Mittelstadt and Luciano Floridi (eds), *The Ethics of Biomedical Big Data* (Springer 2016) 257, 263. Broad consent is understood to mean that samples and associated data may be collected for a wide range of future research purposes by using a general description of the intended research object. The specification is produced by a description of the research area which, in the field of biobanks, can be quite broad. It has been warned, however, that the regulations on data protection must be respected, which is made possible by coding the samples that are delivered to the researchers detached from the personal data of the source subject. Also, as a counterbalancing measure to this broad consent, and in addition to extensive supervision by authorities, individuals have in turn been granted extensive control over the use of their samples and data.

18 EDPB Opinion Guidelines 05/2020 on consent under Regulation 2016/679, adopted on 4 May 2020, 30–31: 'This means that, in principle, scientific research projects can only include personal data on the basis of consent if they have a well-described purpose. For the cases where purposes for data processing within a scientific research project cannot be specified at the outset, Recital 33 allows as an exception that the purpose may be described at a more general level. The notion of scientific research "may not be stretched beyond its common meaning" and understands "scientific research" in this context means a research project set up in accordance with relevant sector-related methodological and ethical standards, in conformity with good practice'. Furthermore, 'the controller may apply further safeguards in such cases. Article 89(1), for example, highlights the need for safeguards in data processing activities for scientific or historical or statistical purposes. These purposes "shall be subject to appropriate safeguards, in accordance with this regulation, for the rights and freedoms of data subject." Data minimization, anonymisation and data security are mentioned as possible safeguards. Anonymisation is the preferred solution as soon as the purpose of the research can be achieved without the processing of personal data'.

the working capacity of the employee, medical diagnosis, provision of health or social care (art 9(2)(h)), public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical device (art 9(2)(i)). Finally, archiving purposes in the public interest, scientific or historical research purposes or statistical purpose (art 9(2)(j)).

Returning to consent as the cause that legitimizes the processing of data, initially, the Biomedical Research Act – collecting the broad lines existing up to this moment in the field of bioethics, especially the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine ('Oviedo Convention')[19] –regulates in art 60 consent requirements, firstly, the consent for the use of the biological sample in research must be granted for a specific investigation. However, as established in para 2, the sample may be used for other lines of research related to the one initially proposed if so provided for in the specific consent. Otherwise, the source subject must be asked for a new consent.[20]

Accordingly, in the 'Report of the UNESCO International Bioethics Committee issued on 15 September 2017 on Big Data and Health',[21] in para 59 the Committee understands that in the event that an investigation is intended to be carried out is outside the range of the broad consent that was obtained for the use of these data, a specific consent is necessary for the subsequent treatment of these. This is an essential principle to guarantee the confidentiality and privacy of data. So far there is nothing new with respect to what is established in the mentioned art 60 of the Biomedical Research Spanish Act. However, the possibility of a secondary use of the data that could be ethically admissible without a new informed consent is admitted below, provided that all the following requirements are met: a) adequate legal basis; b) evaluation by the Research Ethics Committee; c) adequate technical procedures to prevent researchers and third parties from accessing personal data, such as pseudonymization; d) the overriding public interest in this health research; e) infeasibility of obtaining a

19 Council of Europe, Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 4 April 1997, ETS 164.

20 In the Basque Country Superior Court, 14 June 2017 (JUR 2017, 232851) the use of biological samples from the patient without their consent to carry out research activity is considered a very serious infringement of the data protection regulations. In this case, the data were used for different purposes from the studies that motivated the collection of biological samples and that were initially consented to. The patient had given his consent for the use of his biological samples in the 'EM Molecular Study' and later they were used in other lines of research, particularly in a thesis and in a study published in a scientific journal. This interpretation is in line with art 60(2) of the Biomedical Research Act.

21 Full text at <https://unesdoc.unesco.org/ark:/48223/pf0000248724> accessed 30 May 2024.

new consent; f) the data must have been collected in compliance with ethical and legal requirements.

This was already provided for in art 58(2) of the Biomedical Research Spanish Act, as an exception to the general rule of art 60. According to art 58(2), the 'consent of the subject will always be necessary when it is intended to use biological samples obtained for a different purpose for biomedical research purposes' (for example, for healthcare purposes), regardless of whether they were object of anonymization. However, 'exceptionally, codified or identified samples may be processed for biomedical research purposes without the consent of the subject, when obtaining the consent is not possible or represents an unreasonable effort within the meaning of art 3(i) of this Act. In these cases, the favourable opinion of the corresponding Research Ethics Committee will be required, which must take into account, as a minimum, the following requirements: a) That it is an investigation of general interest; b) That the research is carried out by the same institution that requested the consent to obtain the samples; c) That the research is less effective or is not possible without the identifying data of the source subject; d) That there is no express objection of the subject; e) That the confidentiality of personal data is guaranteed'.

According to the Spanish Data Protection Agency, this non-restrictive interpretation should be considered by Research Ethics Committees in cases in which they authorize the treatment of codified samples, without consent when it is not possible to obtain it, in accordance with art 58(2) of the Biomedical Research Spanish Act.[22]

The secondary use of data that was obtained for a specific purpose with the prior consent of the subject for a different purpose (for example, they were obtained for healthcare purposes, and it is intended to use them in research) requires an assessment from both an ethical and a legal perspective. This proportionality test can be carried out, on a case-by-case basis, by an independent body such as the Research Ethics Committee (whose role is reinforced in Additional Disposition 17th of the Spanish Act 3/2018 on Personal Data Protection).[23]

In the transposition of the European Data Protection Regulation into Spanish law, these issues have been regulated in Additional Disposition 17th of the Spanish Act 3/2018, in lett (b) of which even allows avoiding the consent of the interested party to carry out scientific studies in situations of exceptional relevance and seriousness for public health by health authorities and public institutions with competences in public health surveillance. This implies the materialization of the legal bases of letts (g), and (i) of art 9(2) GDPR, referred

22 Report of the Spanish Data Protection Agency on the incidence that the full application of the Regulations could produce in the field of biomedical research as of 25 May 25 2018, as well as the approval of a new Organic Act on Data Protection (Report 073667/2018) 8.

23 Ley Orgánica 3/2018 de Protección de Datos Personales y garantía de los derechos digitales.

above. In this case, these are studies framed within the strict sphere of public authorities.

Likewise, lett (d) establishes that the use of pseudonymized personal data for health research purposes and particularly biomedical research, is considered lawful. For this, a technical and functional separation will be required between the research team and those who carry out the pseudonymization and keep the information that makes re- identification possible. In addition, it is specified that the pseudonymized data is only accessible to the research team when there is an express commitment to confidentiality and not to carry out any re-identification activity and when specific security measures are adopted to prevent re-identification and access by unauthorized third parties. Re-identification will be possible when the existence of a real and specific danger to the safety or health of a person or group of people is appreciated, or a serious threat to their rights or when it is necessary to guarantee adequate health care.

In this other case, research of interest to public health would be included, which is carried out by research groups in both the public and private spheres,[24] without the need for a new consent, with pseudonymization of the data and with a report from a Research Ethics Committee (Additional Disposition 17th lett (d)).

Furthermore, lett (c) Additional Disposition 17th considers the reuse of personal data for health and biomedical research purposes lawful and compatible when, having obtained consent for a specific purpose, the data is used for purposes or research areas related to the initial research project.

To comply with the requirement of adequate guarantees of art 89(1) GDPR the Spanish Act articulates the following safeguards:

a) The publication of the information required by art 13 of the GDPR by the data controller on the corporate website of the research centre.

b) Notification by electronic means to those affected informing of the existence of said information.

c) A favourable report of the Research Ethics Committee.

In addition, in lett (f) Additional Disposition 17th of the Spanish Act 3/2018 on Personal Data Protection establishes certain requirements that biomedical research projects must meet, among them an impact assessment must be carried out. The so-called impact assessment should consider how the rights and freedoms of the subjects are affected, the measures aimed at guaranteeing the

24 As stated in recital n 159 of GDPR: 'Where personal data are processed for scientific research purposes, this Regulation should also apply to that processing. For the purposes of this Regulation, the processing of personal data for scientific research purposes should be interpreted in a broad manner including for example technological development and demonstration, fundamental research, applied research and privately funded research'.

security of the information and, where appropriate, the quality of the pseudonymization or anonymization instruments that are adopted.[25]

As revealed in the 'Report of the Bioethics Committee of Spain on the Ethical-Legal requirements in Research with Health data and Biological Samples in the Framework of the Covid-19 pandemic of 28 April 2020'[26] the secondary use of health data for health research in the realm of the public interest requires a prior weighted analysis of the interests at stake.

As noted in this report, the classic model of the informed consent of the subject comes from the main international charters in the field of Bioethics such as the Nuremberg Code or the Declaration of Helsinki.[27] In these investigations the physical integrity and dignity of the person were at risk. In the current context of Big Data, research deals with information ('informational research'), referring, indeed, to a person, but the interest at stake is different, it is about preserving his or her privacy.[28]

As mentioned, in Additional Disposition 17th of the Spanish Act 3/2018 on Personal Data Protection, specifically in its second section, in the realm of health research, it's a question of weighing up the great benefits that it brings to society without ignoring the fundamental right to the protection of personal data. Therefore, this regulation represents a necessary paradigm shift for a new model of health research.

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25 Cf Ricard Martínez Martínez, 'Big data, investigación en salud y protección de datos personales. ¿Un falso debate?' (2017) 62 Revista Valenciana d'Estudis Autonòmics 235, 269.

26 Full text at <https://comitedebioetica.es/> accessed 30 May 2024.

27 'Permissible Medical Experiments'. Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg October 1946 – April 1949, Washington. U.S. Government Printing Office (n.d.), vol. 2, 181–182.
Ethical Principles for Medical Research Involving Human Subjects Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964.
On this topic see Federico De Montalvo Jääskeläinen, 'Uso secundario de los datos de salud en el marco del Big Data: ¿Hacia un cambio jurídico del "Paradigma Helsinki?"' in Miguel Angel Recuerda Girela (ed), *Tecnologías disruptivas: regulando el futuro* (Aranzadi Thomson Reuters 2019) 423.

28 However, the European Data Protection Board in 'Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak', adopted on 21 April 2020, 13 mentions that: 'in certain situations, in particular where transfers are performed by private entities for the purpose of medical research aiming at fighting the COVID-19 pandemic, such transfers of personal data could alternatively take place on the basis of the explicit consent of the data subjects. Public authorities and private entities may, under the current pandemic context, when it is not possible to rely on an adequacy decision pursuant to Article 45 (3) or on appropriate safeguards pursuant to Article 46, rely upon the applicable derogations mentioned above, mainly as a temporary measure due to the urgency of the medical situation globally. Indeed, if the nature of the COVID-19 crisis may justify the use of the applicable derogations for initial transfers carried out for the purpose of research in this context, repetitive transfers of data to third countries part of a long-lasting research project in this regard would need to be framed with appropriate safeguards in accordance with Article 46 GDPR'.

3.2. The Data Governance Act

The Data Governance Act introduces the concept of "data altruism" aimed at facilitating non-profit data sharing, by fixing incentives for particulars in a trust environment.[29] This Regulation is part of the Commission's plan of establishing a single European Data Space.

As stated in art 2(10): "'data sharing" means the provision of data by a data subject or a data holder to a data user for the purpose of the joint or individual use of such data, based on voluntary agreements or Union or national law, directly or through an intermediary, for example under open or commercial licenses subject to a fee or free of charge'. According to recital n 45 'There is a strong potential for objectives of general interest in the use of data made available voluntarily by data subjects on the basis of their informed consent or, where it concerns non-personal data, made available by data holders. Such objectives would include healthcare, combating climate change, improving mobility, facilitating the development, production and dissemination of official statistics, improving the provision of public services, or public policy making. Support to scientific research should also be considered to be an objective of general interest".

Consent still has a great role as a legitimate basis for the data to be processed, in art 2(5) 'consent' means consent as defined in art 4 (11) of Regulation (EU) 2016/679. It is distinguished between data and non-personal data.[30] Consequently, data altruism would rely on consent.[31]

Furthermore, it is foreseen in the Data Governance Act a so-called "data altruism consent", a new model of consent for making data available for reuse,

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29 Corina Kruesz and Felix Zopf, 'The Concept of Data Altruism of the Draft DGA and the GDPR: Inconsistencies and Why a Regulatory Sandbox Model May Facilitate Data Sharing in the EU' (2021) 7 European Data Protection Law Review 569.

30 The Regulation (EU) 2018/1807 of the European Parliament and of the Council of 14 November 2018 on a framework for the free flow of non-personal data in the European Union [2018] OJ L303/59provides a negative definition in art 3(1) as "data other than personal data". The non-personal nature of such data might include a wide range of information: machine-generated data and commercial data, whether they have never been personal (not relating to an identified or identifiable person), or later anonymized.

31 Recital n 50: 'Typically, data altruism would rely on consent of data subjects within the meaning of Article 6(1), point (a), and Article 9(2), point (a), of Regulation (EU) 2016/679 that should be in compliance with requirements for lawful consent in accordance with Articles 7 and 8 of that Regulation'.

Also, EDPB-EDPS Joint Opinion 03/2021 on the Proposal for a regulation of the European Parliament and of the Council on European data governance (Data Governance Act), adopted on 10 March 2021, 39: 'underline that one of the main objectives of the GDPR is to ensure that the data subject keeps control over her or his personal data. In this context, the EDPB and EDPS underline that all requirements related to the consent, as set in the GDPR, need to be fulfilled'. There must be compatibility of data altruism consent with the consent requirement under the GDPR.

including by particulars for altruistic grounds. A common European data altruism consent form will be developed to reduce the costs of collecting consent and to facilitate portability of the data (in case data to be made available is not kept by the individual).[32]

Therefore, an altruism consent form has to be developed for boosting a trustful environment for particulars to consent the processing of their data, particularly in the realm of scientific research.[33]

Additionally, Chapter IV regulates data altruism (data voluntarily made available by individuals or companies for the common good). It establishes the possibility for organisations engaging in data altruism to register as a 'Data Altruism Organisation recognised in the EU' in order to increase trust in their operations.

Secondary use of data is defined in art 2(2): "'re-use" means the use by natural or legal persons of data held by public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the data were produced, except for the exchange of data between public sector bodies purely in pursuit of their public tasks'. Conditions for re-use are established in art 5 of the Data Governance Act.[34] Furthermore, public

32 Recital n 52: 'To promote trust and bring additional legal certainty and user-friendliness to the process of granting and withdrawing consent, in particular in the context of scientific research and statistical use of data made available on an altruistic basis, a European data altruism consent form should be developed and used in the context of altruistic data sharing. Such a form should contribute to additional transparency for data subjects that their data will be accessed and used in accordance with their consent and also in full compliance with the data protection rules. It should also facilitate the granting and withdrawing of consent and be used to streamline data altruism carried out by undertakings and provide a mechanism allowing such undertakings to withdraw their permission to use the data'.

33 Recital n 52: 'To promote trust and bring additional legal certainty and user-friendliness to the process of granting and withdrawing consent, in particular in the context of scientific research and statistical use of data made available on an altruistic basis, a European data altruism consent form should be developed and used in the context of altruistic data sharing. Such a form should contribute to additional transparency for data subjects that their data will be accessed and used in accordance with their consent and also in full compliance with the data protection rules'.

34 Among other requirements it is established that conditions for re-use 'shall be non-discriminatory, transparent, proportionate and objectively justified with regard to the categories of data and the purposes of re-use and the nature of the data for which re-use is allowed.' Furthermore, these conditions 'shall not be used to restrict competition'.

To guarantee the preservation of the protected nature of data, data have to be '(i) anonymised, in the case of personal data; and (ii) modified, aggregated or treated by any other method of disclosure control, in the case of commercially confidential information, including trade secrets or content protected by intellectual property rights'. Also, access and re-use of the data should be done 'within a secure processing environment that is provided or controlled by the public sector body' and 'within the physical premises in which the secure processing environment is located in accordance with high security standards, provided that remote access cannot be allowed without jeopardising the rights and interests of third parties'.

sector bodies which allow re-use of data may charge fees for allowing the re-use of such data (art 6(1)).

In the realm of data altruism, if the data processed are personal data, GDPR has to be applied additionally to the Data Governance Act.[35] Specifically, data subject rights provided by the GDPR are applicable in the context of the Data Governance Act.

Subsequently, organisations that process data altruistically should be considered controllers (co-controllers) insofar as they will determine the purposes of the processing of personal data, for example the framework conditions for a specific research project.[36]

The GDPR in art 89 contains also special rules in data processing for scientific research purposes which can collide with the norms of the Data Governance Act, particularly art 21 establishes specific requirements to safeguard rights and interests of data subjects and data holders with regard to their data. First of all, some duties to inform should be accomplished, among others the data subject should be informed about the objectives of general interest and, if applicable, the specified, explicit and legitimate purpose for which personal data is to be processed, and for which it permits the processing of his or her data. Furthermore, according to para 2, the data altruism organisation is not entitled to use the data for other objectives than those of general interest for which the data subject or data holder allows the processing. Otherwise, the GDPR in art 89(1) accepts further processing of personal data in the public interest, scientific or historical research purposes or statistical purposes. The general rule appears to be less restrictive than the more special one.

Furthermore, to ensure the safe processing of personal data additional measures are to be considered, and again the role of the ethics committee is highlighted.[37]

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35 Proof of this coordination is that the Data Governance Act mentions the broad consent in the realm of scientific research in recital n 50: 'In accordance with the GDPR, scientific research purposes could be supported by consent to certain areas of scientific research where in keeping with recognised ethical standards for scientific research or only to certain areas of research or parts of research projects'.

36 In this vein also art 51 of the Proposal for a Regulation on the European Health Data Space: '1. The health data access bodies and the data users, including Union institutions, bodies, offices and agencies, shall be deemed joint controllers of electronic health data processed in accordance with data permit'.

37 Recital n 46: 'Further safeguards should include making it possible to process relevant data within a secure processing environment operated by the recognised data altruism organisations, oversight mechanisms such as ethics councils or boards, including representatives from civil society to ensure that the data controller maintains high standards of scientific ethics and protection of fundamental rights, effective and clearly communicated technical means to withdraw or modify consent at any moment, on the basis of the information obligations of data processors under Regulation (EU) 2016/679, as well as means for data subjects to stay informed about the use of data they made available'.

In conclusion, the concept of general interest or common good seems to be very important for the use of data on altruistic grounds.[38] One of the objectives of general interest is to support scientific research as mentioned in the Recitals of the Data Governance Act. Still this concept has to be clarified, in the preamble of the GDPR has been included as an example of scientific research 'privately funded research'. However, apart from the nature of funding, other circumstances of the research should be taken into consideration, as the population under study, types of benefit sharing or equitable access to research databases.[39]

3.3. The Proposal for a Regulation on the European Health Data Space

This norm is aimed at providing for rules, common standards and practices, infrastructures, and a governance framework for the primary and secondary use of electronic health data (art 1). Among the measures it is included the creation of 'a mandatory cross-border infrastructure for the secondary use of electronic health data' (art 2(e)).

It is fixed a list of categories of electronic data available for secondary use: '(a) EHRs (electronic health record systems); (b) data impacting on health, including social, environmental behavioural determinants of health; (c) relevant pathogen genomic data, impacting on human health; (…); (e) human genetic, genomic data (art 33(1))'.

Furthermore, a list of purposes for which electronic health data can be processed for secondary use is established (art 34): '(a) activities for reasons of public interest in the area of public and occupational health, such as protection

38 About the concept of public interest, EDPS Preliminary Opinion on Scientific Research, 2020 adopted on 6 January 2020, 23: 'necessity and the public interest imply a "pressing social need" as opposed to largely private or commercial advantages'. Furthermore, the important role of ethics committee is highlighted (25): 'Data protection authorities and data protection officers increasingly engage with ethical questions in the development and deployment of digital technologies. They should engage more closely with ethical review boards. Genetic research in particular has implications not only for the subject of the DNA tests but others in his or her family or with shared characteristics in this and future generations. Independent ethical committees could support the understanding of which activities qualify as genuine research and define the ethical standards referred to in the GDPR. Ethics committees can play a meaningful role in ensuring that the respect of human rights, including right to data protection, is embedded in the research project from the early planning stage. They are likely to continue to play an important role in ensuring that research projects are designed from the start with data protection principles in mind.'

39 Marieke Bak and others, 'You Can't Have AI Both Ways: Balancing Health Data Privacy and Access Fairly' (2022) 13 Frontiers in Genetics 1, 5.

against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices; (b) to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates; (c) to produce national, multi-national and Union level official statistics related to health or care sectors; (d) education or teaching activities in health or care sectors; (e) scientific research related to health or care sectors; (f) development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices; (g) training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices; (h) providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons'.

One of the goals of this secondary use of date is the training of artificial intelligence algorithms mentioned also in the Proposal for a Regulation on artificial intelligence,[40] it is in line with the implementation of new form of medicine more sustainable.[41]

40 Commission, 'Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) and Amending Certain Union Legislative Acts' COM (2021) 206 final, recital n 45: 'For the development of high-risk AI systems, certain actors, such as providers, notified bodies and other relevant entities, such as digital innovation hubs, testing experimentation facilities and researchers, should be able to access and use high quality datasets within their respective fields of activities which are related to this Regulation. European common data spaces established by the Commission and the facilitation of data sharing between businesses and with government in the public interest will be instrumental to provide trustful, accountable and non-discriminatory access to high quality data for the training, validation and testing of AI systems. For example, in health, the European health data space will facilitate non-discriminatory access to health data and the training of artificial intelligence algorithms on those datasets, in a privacy-preserving, secure, timely, transparent and trustworthy manner, and with an appropriate institutional governance. Relevant competent authorities, including sectoral ones, providing or supporting the access to data may also support the provision of high-quality data for the training, validation and testing of AI systems'.

41 cf Principle XXIII number 2 of the Spanish Digital Rights Charter: 'Public authorities shall promote that research and technology contribute to the achievement of a preventive, predictive, personalized, participatory and population-based medicine'. Of course, there are some risks to be eluded, as mentioned in number 6 of the same principle: 'Public authorities will promote universal access to telemedicine systems and telecare, as well as technological devices developed for therapeutic purposes or assistance in adequate conditions of connectivity. Efforts will be made to establish that access to such devices were provided free of charge by a manufacturer or supplier cannot be conditioned to the transfer to those of the patient's personal data'.

However, some purposes are explicitly prohibited: art 35(b) considers, for instance, 'taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums'.[42]

For the implementation of such future Regulation, it is necessary to develop a mandatory cross-border infrastructure for secondary data use. Consequently, 'Health Data Access Bodies' must be established in all member States, as the governance of the EHDS is assigned to Health Data Access Bodies (arts 36–43) that can issue data licenses to access data to potential data users, provided that some procedural and material conditions are fulfilled (including purpose limitation as stated in art 44 of the Proposal Regulation). It is regulated the possibility to fix a fee, in art 42 charged by health data access bodies and single data holders for making electronic health data available for secondary use.

Scholars have highlighted that drafters of the EHDS still have a difficult task to develop, considering the existing legal complexities for the consent requirements and uncertainties regarding the concept of scientific research for the public interest.[43]

42 According to Principle XXI number 4 of the Spanish Digital Rights Charter: 'The development of scientific and technological research likely to have an impact on the human being must respect the dignity and guarantee respect to every person, without any discrimination, related to the integrity and other fundamental rights and freedoms with respect to the applications of biology and medicine. Likewise, research will be governed by ethical principles and scientific integrity. All this within the framework of the Spanish Constitution and the laws'.

43 Bak and others (n 39) 3.