EU Data Protection, Obstacle in the Way of Medical Scientific Research?

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ABSTRACT

At European level there are intense preoccupations to harmonise legislation in the field of scientific research in connection with data protection.

We intend to highlight the most important regulations in this area and also to emphasize the fact that in what medical research is concerned a clear and precise legislation can sometimes be a life saviour.

KEYWORDS: *scientific research, data protection, EU regulations.*

1. Introduction

The data protection regulations can sometimes concern different specific domains or disciplines.

So, we can observe that the General Data Protection Regulation (GDPR) gives scientific research a special highlight and also, we can see that there is little attention on the application of data protection rules to scientific research.

The European Data Protection Supervisor[1)] has the opinion that research and personal data protection have to be compatible because personal data protection is considered a support for science, thus personal data ensures the quality of life improvement.

2. Data protection and scientific research in EU Regulations

The Copyright Directive from 2019[2)] establishes that we can identify scientific research in both the natural sciences and the human sciences and also makes a difference between not-for-profit and public interest bodies and organisations operating under commercial influences.

To understand what scientific research represents we have to establish what research organisations stand for. So, we can identify a variety of such entities, from higher education

1) The European Data Protection Supervisor (EDPS) is an independent EU authority, responsible under Article 52(2) of Regulation 2018/1725 'With respect to the processing of personal data… for ensuring that the fundamental rights and freedoms of natural persons, and in particular their right to data protection, are respected by Union institutions and bodies', and under Article 52(3)'…for advising Union institutions and bodies and data subjects on all matters concerning the processing of personal data'.

2) Directive (EU) 2019/790.

institutions and their libraries, research institutes and hospitals that perform research. Although, the regulations regarding scientific organisations may vary a lot within the Member States, they may have in common that they act either on a not-for-profit basis or in the context of a public-interest mission recognised by the State, represented by public funding or by provisions in national laws or public contracts. Still, when it is about organisations that commercial undertakings have a decisive influence on by allowing them to exercise control, situation that can lead to preferential access to the results of the research, they should not be considered research organisations.

The latest revision of the Public Sector Information Directive, adopted in July 2019[3)], requires Member States to 'support the availability of research data' with measures to make 'publicly funded research data openly available'. We could believe that this openness is unlimited, but the European Commission mentioned in the revised Recommendation on access to and preservation of scientific information that research data have to be 'as open as possible, as closed as necessary'.

Article 85 of the GDPR regulates a regime set out for data processing for 'journalistic purposes and the purposes of academic, artistic or literary expression'. So, we can observe that the regulation aims to have exemptions from the GDPR broader than the special regime for scientific research. Thus, we can see that the processing of personal data for the purposes of 'academic expression' means: processing directly linked to the freedom of academics to disseminate information; their freedom to distribute knowledge and truth without restriction, such as with publications, dissemination of research results and the sharing of data and methodologies with peers and exchanges of views and opinions.

The Directive 95/46/EC, the former Data Protection Directive, had allowed Member States to regulate specifying further the regime for data processing for research purposes, and we can observe that the GDPR also allows derogations that can be introduced by EU or Member State regulations. We can easily say that GDPR can be a barrier to scientific research or that it can breach some data subjects rights, the same thing also being observed within Regulation 2018/1725 governing data protection in EU institutions and bodies that have a similar content with the GDPR's provisions.

An important document of the EU, the Charter for Fundamental Rights, also regulates the way scientific research have to be considered at European level. So, article 13 of the Charter of Fundamental Rights states that 'The arts and scientific research shall be free of constraint. Academic freedom shall be respected'.

Also, by article 179(1), the Treaty of the Functioning of the European Union is highlighted the fact that there is an important objective of strengthening the scientific and technological bases by achieving a European research area in which researchers, scientific knowledge and technology circulate freely, and encouraging it to become more competitive, including in its industry. So, we can see that, by these regulations is promoted the sharing of research data.

And in this context, of encouraging the sharing of research data, was created in 2009 the Open Access Infrastructure for Research in Europe[4)], OpenAIRE, aiming to develop open interfaces and to exchange research information between research data repositories. Its vision is to "transform society through validated scientific knowledge, to allow citizens,

3) Directive (EU) 2019/1024.

4) OpenAIRE partners over the years are a total of 65 European universities, research centres and institutions.

educators, funders, civil servants and industry find ways to make science useful for themselves, their working environments, the society"[5].

3. Some insights about medical scientific research and data protection

The European Data Protection Supervisor considers that responsible research can also offer respect for personal data and that the two concepts can be compatible. In this context, scientific research can lead to a better understanding of diseases, the development of new therapies and generally improvement of quality of life and in the same time to protect individuals data needed on this development.

The most important field affected by personal data protection is the medical one. Nowadays, we can observe an important market for genetic testing services that are said to predict medical risk factors, although not being considered itself scientific research can lead to the use of the collected data based on consent that can be used in the future for research.

So, it is not all about data protection and the scientific approach of it, it is also about ethical standards for research and we can say that this had an obvious evolution especially regarding medical experiments on humans.

We have to mention the regulations contained by the Charter of Fundamental Rights of the European Union in its article 1 and article 3 stating the fact that 'free and informed consent of the person concerned' must be respected in the field of biology and medicine. So, we believe that it is especially important to respect ethical standards and to have a strict control over this, respecting in this way the regulations of the EU Charter for Fundamental Rights.

Across the EU Member States, there are similarities in what the consent from participants at scientific research projects is concerned, and generally the consent is obtained before the processing of health data, but in emergency situations national provisions are different within EU Member States. When this situation occurs, when ethical questions regarding the suitability of deferred consent or consent from an independent physician are the issue in question, there is not a moment for a clear answer as this is an intense subject of discussion within the medical research community.

Nowadays, there is an EU legal instrument that regulates the scientific research in the clinical trials domain, Regulation (EU) No. 536/2014. But, although this Regulation entered into force in 2014, it didn`t become applicable yet because it depends on the full functionality of the Clinical Trials Information System[6].

This Regulation, if becomes applicable, intends to harmonise the EU Member States legislation by introducing an authorisation procedure based on a single submission via a single EU portal and this eventually will lead to a single decision. When this becomes applicable, the Regulation emphasises what the consent will represent, by establishing a definition for it: a subject's free and voluntary expression of his or her willingness to participate in a particular clinical trial, after having been informed of all aspects of the clinical trial that are relevant to the subject's decision to participate or, in case of minors

[5] https://www.openaire.eu

[6] The Clinical Trials Information System it is expected to go live by December 2021, according to the European Medicines Agency.

and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the clinical trial[7]. Also, a very important aspect is that the research participant have to give consent to use his or her data outside the clinical trial and it can be withdrawn at any time.

As it was expected, the issue regarding the possibility of applying in the same time the Regulation regarding the Clinical Trials and the GDPR was raised and the European Data Protection Board[8] has adopted an Opinion (3/2019)[9] on the interplay between the EU Clinical Trials Regulation (536/2014) and the GDPR, following a request from the European Commission.

In its opinion the European Data Protection Board tries to establish some differences between the primary use-meaning processing of personal data in the context of clinical trials and secondary use of clinical trial data for other scientific purposes and in this context there also have to be differentiated the processing of personal data related to reliability and safety purposes and the processing of personal data related to research activities, seen as part of the primary use.

So, the European Data Protection Board intended to clarify the notion of consent under the two regulations mentioned above. The first observation is regarding the fact that consent requirements regulated by the GDPR are not to be confused with informed consent regulated by the to the EU Clinical Trials Regulation. The second one is about the fact that the GDPR and also the EU Clinical Trials Regulation can generate a disproportion of power between clinical trial operators and participants. So, we believe that the two aspects regarding especially the consent have to be well taken care of by the organisations involved in clinical trials, so that they respect both regulations.

4. Conclusions

The aim of EU data protection regulations has always been to facilitate the data exchange between EU Member States, but also it is very important to mention its role to respect and protect fundamental rights and freedoms of any individual.

Scientific research plays an important role, especially in the medical field and we believe that it is not impossible for the authorities to balance the two concepts- data protection and scientific research- when applying the regulations in force regarding these domains.

We believe that the question in our title will still remain without an answer for another period of time, at least until the EU Clinical Trials Regulation (536/2014) becomes applicable and harmonises the regulations within all EU Member States.

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7) Regulation (EU) No. 536/2014 chapter V, Article 2(2)(21).

8) The European Data Protection Board (EDPB) is an independent European body, which contributes to the consistent application of data protection rules throughout the European Union, and promotes cooperation between the EU's data protection authorities. For more details access https://edpb.europa.eu.

9) Opinion 3/2019 concerning the Questions and Answers on the interplay between the Clinical Trials Regulation (CTR) and the General Data Protection regulation (GDPR)(art. 70.1.b)) adopted on 23 January2019.

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