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Article

Challenges and perspectives in biomedical research with data in the European Union in the Digital Era

Retos y perspectivas en la investigación biomédica con datos en la Unión Europea en la Era Digital

Desafios e perspectivas na pesquisa biomédica com dados na União Europeia na Era Digital

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Abstract
The Digital Age in which we live requires the rethinking of current legal paradigms, both from the point of view of regulation and governance, and this particularly affects data, and scientific research with data. This work attempts to provide an overview of the challenges and opportunities that arise in this area, seeking a multidisciplinary legal research methodology adapted to the emerging (European) law of science and technology. It concludes the need to work so that in its development, both regulation and governance follow a series of ethical and legal principles that allow the guarantee of the rights and freedoms of people.
Keywords: Health Data; Big Data; Technology; Artificial Intelligence.

Resumen
La Era Digital en la que vivimos exige el replanteamiento de los paradigmas jurídicos actuales, tanto desde el punto de vista de la regulación como de la gobernanza, y esto afecta de forma particular a los datos, y a la investigación científica con datos. Este trabajo trata de realizar una panorámica a los desafíos y oportunidades que se plantean en este ámbito, buscando una metodología de investigación jurídica multidisciplinar que se adecúe al emergente Derecho (europeo) de la ciencia y la tecnología. Concluye la necesidad de trabajar para que en el desarrollo de este nuevo Derecho, tanto la regulación como la gobernanza siga una serie de principios éticos y jurídicos que permitan la garantía de los derechos y libertades de las personas.
Palabras clave: Datos sanitarios; Macrodatos; Tecnología; Inteligencia Artificial.

Resumo
A Era Digital em que vivemos exige repensar os paradigmas jurídicos atuais, tanto do ponto de vista da regulação como da governação, e isso afeta particularmente os dados, e a investigação científica com dados. Este trabalho tenta fornecer uma visão geral dos desafios e oportunidades que surgem nesta área, procurando uma metodologia de investigação jurídica multidisciplinar que se adapte ao emergente Direito (europeu) da ciência e da tecnologia. Conclui a necessidade de trabalhar para que no seu desenvolvimento, tanto a regulação como a governança sigam uma série de princípios éticos e legais que permitam a garantia dos direitos e liberdades das pessoas.

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Palavras-chave: Dados de Saúde; Big Data; Tecnologia; Inteligência Artificial.

Introduction

The Digital Era in which we live requires a rethinking of the current legal paradigms, both from the regulatory and governance point of view, and this particularly affects data, and scientific research with data.

Thus, it is clear to no one that the use of massive data (Big Data) in research, as in other areas, can enhance the efficiency and effectiveness of the activity, with better and faster results; and the law cannot remain unaware of this, since it must protect both the freedom of scientific research, as a fundamental right, and the other legal assets at stake, some of which are also rights (right to health, right to the protection of personal data, etc.).

In this field, some authors have considered the existence of a tendency to call for a kind of new paradigm, or new paradigms, going beyond the traditional model of data protection, anchored in the informed consent of the subject, to seek, and this is particularly evident in the European Union, a system that - we could qualify as horizontal, plural and cooperative - based on general principles and guarantees (public health, collective interests), albeit with certain individual guarantees (confidentiality, pseudonymization of personal data), in the development of what has come to be known as the new European privacy model following the approval of the General Data Protection Regulation (GDPR)[1-4].

In the balancing of the individual rights of the subject, on the one hand, and the general interest and public health, on the other, the consolidation of a homogeneous legal framework must be sought that guarantees a genuine scientific research area, at least at the European level - but the search for a global data area for scientific research could be considered - including health data - understood in a broad sense, and including genetic and biometric data - based on the following principles[5-6]:

a) Principles of information and transparency in the use of data;
b) Principle of confidentiality;
c) Minimization of data processing.

All this, without detriment to the necessary effectiveness of the research, with adequate quality assurance and ethical and legal control of the research through the Research Ethics Committees; and without forgetting of course the person or subject source of the data, studying not only their position as owner of the data, and the control rights they can exercise (and their limits to ensure effective research), but also trying to enhance the possibilities of their participation in the benefit or benefits of the results of the research that their data have helped to achieve.[5-6]

The progressive scientific-technological progress with a progressive acceleration[7] , and with the use of large amounts of data (big data), and the development of artificial intelligence systems, and the consequent digital transformation, impact both on scientific research itself - the way it is investigated, the object of research, the ethics of research itself - and also on people and their status, posing ethical and legal challenges of unquestionable relevance, both for the people themselves[8], as well as for scientific research itself.

Scientific research as a concept and as a fundamental right in the Digital Era and its insertion in the emerging European law of science and technology

Certainly, the approach to scientific research as a concept is not something that is completely delimited. Thus, the Dictionary of the Spanish Language defines research, from the Latin investigatio-onis, as the action and effect of investigating, specifying that "basic research" is "research that aims to expand scientific knowledge, without pursuing, in principle, any practical application", and having as synonyms or related terms "exploration, inquiry, investigation, search, survey, inquiry, question, survey"[9].

The Diccionario de la lengua Española understands investigation to have different meanings, including"1. Tr. To investigate to discover something"; "2. Tr. To investigate to clarify the conduct of certain persons suspected of acting illegally"; and "3. To carry out intellectual and experimental activities in a systematic way with the purpose of increasing knowledge on a certain subject"[9].

When we refer to research with the surname "scientific", perhaps we want to say something more, we want to specify or delimit that research is carried out within the framework of science, and that it may or may not be basic, that is, it may be basic or it may be practical. And indeed, if we look at the Diccionario de la Lengua Española[9], it defines scientific as "1. Pertaining or relating to science"; or "3. Adj. Having to do with the demands of precision and objectivity proper to the methodology of science".

From the point of view of European constitutional law[10-11], which studies the phenomenon of constitutionalization of the process of European integration, while integrating European constitutional issues into constitutional law, considering in it, with a broad and integrating perspective, the constitutional spaces of the Union and of the Member States themselves, freedom of scientific research constitutes a fundamental right; and its recognition can be found, implicitly, in art. 19 of the 1948 Declaration of Human Rights and explicitly in both the Treaty on the Functioning of the European Union (TFEU, art. 16.1) and the Charter of Fundamental Rights of the European Union (CFREU, art. 13) [12-13]. It can also be found, either implicitly or implicitly, in the constitutional texts of the Member States of the Union; and in other countries.

From the university point of view, we must consider that freedom of scientific research is linked to or framed within the broadest academic freedom, which includes both teaching freedom and research freedom, in what has traditionally been called "academic freedom", which has received great attention from the scientific academy and at the institutional level[14-15].

From the perspective of the fit of freedom of research in the legal framework, in European law, we must insert it in the development of the incipient or emerging European law of science and technology, in whose construction has been working from various Jean Monnet Chairs, from a multidisciplinary perspective, in order to study the challenges and opportunities posed by scientific innovation, which include, of course, the use of data[2]; as well as European constitutional law, since

[2] Thus, for example, it is worth noting the work of Professor R. Cippitani in the construction of the "European law of science and technology", through his Jean Monnet Chairs, from the Jean Monnet "teKla" Chair on *The European Knowledge Legal Area*, Grant Decision no. 2011-3067, 2011-2014, to the most recent Jean Monnet Chair on the 5th Freedom, Freedom *of* Research as the 5th *Freedom 5fth*Freedom, Freedom of Research as EU Fifth Freedom*), 619985-EPP-1-2020-1-IT-EPPJMO-CHAIR; together with the Jean Monnet Centers of Excellence, from the Center of Excellence *Rights & Science*, 2015-2018, to the Baldus Center of Excellence (*Building the Age of a Lawful and sustainable Data-Use*), 101047644, 2022-2025; which is now intended to be joined by the Jean Monnet Chair Governance and Regulation in the Digital Age (*GovRedig*) - Project 101127331 GovReDig, which I direct; and the "ISAAC" Chair Individual Rights,

some of the problems and challenges are necessarily constitutional in nature, which has motivated the need to broaden the field and object of study of constitutional law, paying attention to digital transformation and technological innovation[16-19].

And it is in this framework that we must consider scientific research, and the development of the European Research Area, seeking, from the point of view of regulation and governance, an appropriate legal framework that responds to the challenges that the Digital Era presents for research, particularly with data.

Biomedical research with data: challenges and perspectives

Biomedical research, as part of scientific research, also presents challenges and opportunities, particularly in the use of data, taking into account the European Data Strategy, which aims to make the EU a benchmark model for "a society empowered by data." Its ultimate goal is to facilitate the adoption of (better) decisions in both the business sector and the public sector, including the health sector[20].

Thus, both data and the development of data-driven applications will bring a range of benefits - to citizens and businesses alike - to improve healthcare, create safer and cleaner transportation systems, generate new products and services, reduce utility costs, and improve sustainability and energy efficiency; so that the achievement of a single data market will, in turn, allow data to flow within the EU and across sectors, to the benefit of all.

However, in order to meet these objectives, the EU must develop and consolidate the best possible legal framework, which includes a solid protection of the principles and rights at stake, including adequate data protection, the rights and freedoms of individuals, security and cybersecurity; and this is the framework for the latest legislative initiatives, which cover both the regulation of data, as well as digital services, and digital security systems.

In relation to the legal framework for data, Rodríguez Ayuso and Montero Pascual[21] understand that, following the European Data Strategy, the regulations being developed include both personal and non-personal data, which is no longer the determining criterion for the distinction, and advocate that the relevant criterion becomes protection, and a distinction should be made between protected and non-protected data.

Regulatory initiatives in the EU include:

(i) 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 Regulation or Act), entered into force on 23 June 2022, and which is applicable from September 2023. This Regulation complements Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the reuse of public sector information (Open Data Directive), transposed into Spanish law by Royal Decree-Law 24/2021 of 2 November, and in turn implemented by Royal Decree 1495/2021 of 24 October, which amends Law 37/2007 of 16 November on the reuse of public sector information.

The aim is to ensure at the European level that the most potentially valuable public data is made available for reuse with minimal legal and technical restrictions and at no cost.

ii) Commission Implementing Regulation (EU) 2023/138 of 21 December 2022 establishes a list of specific high-value datasets and modalities of publication and restriction. It applies to data held by

Scientific Research and Cooperation, formed by the UNED in collaboration with the CNR-IFAC, and co-directed by prof. Cippitani and myself.

the public sector; and excludes from its scope data linked to privacy, personal data, confidentiality, national security, commercial interests, commercial secrecy and intellectual property rights of third parties.

The aim of the European Data Strategy and the Data Act is to make more data available and facilitate data sharing across sectors and countries in the EU to harness the potential of data for the benefit of European citizens and businesses, facilitating: (a) good data management and sharing so that industries can develop innovative products and services, and make many sectors of the economy more efficient and sustainable, as well as train AI systems, it is also essential to train AI systems; (b) with more data available, the public sector can develop better policies, which will lead to more transparent governance and more efficient public services; (c) Data-driven innovation will bring benefits for businesses and individuals by making our lives and work more efficient through: improved healthcare data (personalized treatments, offering better healthcare and helping to cure rare or chronic diseases); mobility data; environmental data: agricultural data; public administration data; etc.

iii) The Regulation on harmonized rules for fair access to and use of data (Data Regulation or The Data Act), which entered into force on January 11, 2024, will be applicable as of September 12, 2025; and which includes the transfer of data between companies (B2B), as well as the transfer of data in favor of institutional public sector bodies, when justified (B2A modality), and aims to facilitate switching or portability and interoperability of data, and the non-sharing of data outside the EU territory, as well as the development and implementation of different legal regimes for the so-called "European data spaces".

Thus, the development and implementation of different legal regimes for the so-called "European data spaces" or, better said, "common European data spaces" is intended, which include both strategic and public interest sectors, as well as different sectorial spaces, which aim to create secure and reliable processing environments, guaranteeing the rights of data subjects, intellectual property, confidentiality, integrity and accessibility, in addition to the fact that the download, export of data, as well as the calculation of data derived through computational algorithms must be guaranteed (Art. 2.20 Data Law); in fact, one of the greatest challenges is undoubtedly to provide trust in such spaces, which requires understanding data protection regulations as a working tool to ensure trust in the design, the necessary transparency and respect for the ethical and social values of the rule of law[22].

The 14 Common Data Spaces under development include: 1) the European Health Data Space (EEDS)[23-25], 2) the European Industrial Data Space; 3) the European Green Pact Data Space (Environment); 4) the European Space concerning mobility data (transport); 5) the European Financial Data Space (finance); 6) the European Energy Data Space; 7) the European Agricultural Data Space (agriculture, sustainability, production patterns); 8) the European Public Administrations Data Space (improving transparency, public spending, regulatory compliance, reducing (and fighting) corruption, etc.); 9) the European Data Space on qualifications in the education and vocational training system; 10) the European Research Data Space; 11) the European Tourism Data Space; 12) the European Construction Data Space; 13) the European Communication Data Space; and 14) the European Cultural Heritage Data Space.

The European Health Data Space (EEDS), which is the one of interest here, is also the one with the most developed legal framework to date. The European Commission's proposal was dated May 3, 2022, and the European Parliament and the Council reached an agreement on March 15, 2024, with formal publication of the regulation expected during the fall of 2024[26-28].

The objectives are to help people to control their own health data, supporting its use for the improvement of health care delivery, research, innovation, public policy making in the field of health data (health data). It is the most advanced in terms of the development of the applicable legal regime.

We are therefore at a good time, taking into consideration the development of the regulatory framework. In addition, the digital transformation and the scientific-technological progress we are experiencing, with scientific and technological research in a process of progressive acceleration , is going to pose increasingly greater ethical and legal challenges, as the massive use of data (big data) and the development of biometric recognition systems, automated decision-making and, in general, those that incorporate elements of Artificial Intelligence (AI), which constitute a reality that in turn poses its own specific challenges, as evidenced by the very regulation of Artificial Intelligence in the European Union.

(iv) Regulation (EU) 2024/1689 of the European Parliament and of the Council of June, 13, 2024 laying down harmonized rules in the field of artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Regulation).

Figure 1. Regulation of Artificial Intelligence

Source: European Commission.

This Regulation on Artificial Intelligence has the following fundamental characteristics: it places the human being at the center, it is a regulation based on the risk of AI systems, from the perspective of the protection of the rights and freedoms of individuals, including data protection, and it handles a broad concept of "Artificial Intelligence systems".

Undoubtedly, as has already been pointed out by numerous authors, we are witnessing, as far as the issue of scientific research with data is concerned, a certain tendency to call for a new paradigm (or new paradigms) that would go beyond the traditional model of data protection, replacing the cornerstone of the consent of the source subject - and the individual interest - with a system based on general principles and guarantees, in the interest of public health and collective interests (solidarity in public health), with due guarantees of confidentiality, pseudonymization and, in general, of the rights of individuals, even sponsoring a greater development of self-regulation, which would form part of

what has been called, since the approval of the GDPR, a new European model of privacy; and perhaps we should say, a new model of data regulation, which would weigh up the interests and legal assets at stake.[27-29]

Thus, the new regulatory instruments, regulating and weighing the interests at stake, are opening the doors to a new model that would be in full construction, but which involves both the consolidation of the objectives already set in the GDPR, which already hinged on the dual purpose of, firstly, protecting individuals with regard to data processing (art. 1 paragraphs 1 and 2 GDPR); as well as the free movement of personal data within the Union (art. 1.3 GDPR), and the correction of its limits, which allowed excessive fragmentation through the development and adaptation by internal rules of the Member States.

As we have argued, this model should guarantee a (European) data research area, or even, we could say, seek a global data research area, governed by common principles that guarantee the efficiency of quality scientific research as well as information and transparency in the use of data, confidentiality and minimization in the use of data, with adequate ethical and legal control, in particular through Research Ethics Committees, and the complementary development of self-regulation, without ignoring the person from whom the data initially originate, even incorporating the possibility of his/her participation in the benefits of the results of the research with his/her data[29].

Conclusions

As we have seen, we live in a digital era that requires us to rethink the current legal paradigms in which we are settled, and to face the challenges, but also opportunities, that arise for the regulation and governance of research with data, particularly taking into consideration the possibilities of using massive amounts of data (big data) for research, especially biomedical research.

The European Union is aware of the challenges, and is working on changing the model, through legislative initiatives that, within the framework of the European Data Strategy, aim to make Europe a preferential place for research with data, through European data spaces, and this with the greatest guarantees of both the rights and freedoms of individuals, as well as security.

The opportunities posed by data spaces for research, and the possibility of building or developing a data space that allows adequate research, either at European or even global level, is fascinating; but lawyers must work, from the Law, so that the emerging (European) Law of Science and Technology does not forget the rights and freedoms of individuals, so that the regulation and governance follow a series of appropriate ethical and legal principles, a work that, being pending, opens the door to new studies, from different disciplines, including constitutional law.

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Conflict of interest

The author declares that there is no conflict of interest.

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