Circulation of personal data and non-personal data within the European Research Area for research and health purposes

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Abstract. The availability and circulation of data, information, knowledge and materials are essential in all fields of research, but they are particularly important in a period in which it is necessary to tackle a global phenomenon like the COVID-19 pandemic. Awareness of the importance of the circulation of information derived from data, the European Commission has been elaborating a strategy for the circulation and sharing of personal and non-personal data. The European strategy needs the data to circulate and be shared in the economic, academic, and social environments. To achieve those objectives, EU documents use the metaphor of building a 'European Data Area', that is to say, legal, economic, and cultural frameworks governed at the continental and national levels, such as European Research Area ('ERA', see Article 179 TFEU) and the proposed European Health Data Space ('EHDS'). An analysis of the current legislation seems to indicate several legal constraints on the circulation of data (information, knowledge and material), able to affect the building of an effective European Data Area. These limitations aim at protecting individual rights, such as privacy or other interests. However, such limitations to the circulation of data may affect other relevant rights and interests such as freedom of research and health. For this reason, this paper intends to show what are the legal means to find the points of equilibrium between the different viewpoints and allow the sustainable function of the European Data Area. Because proper global governance of health data and materials is required, the paper tries to the analysis of the main EU instruments which at this moment are able to regulate it, in order to implement an effective system for the exchange of data, in the meantime that the scientific community is waiting for the European Data Protection Board (EDPB) guidance on the processing health data for research purposes, still pending.[1]

Keywords: GDPR, Freedom of research, Open Data, personal data, non-personal data, reuse data in public sector information

[1] This paper is a collaboration between the authors. In any case, paragraphs 1, 2, 3 and 3.1 are attributable to Valentina Colcelli and the paragraphs 3.2, 4, 5, 6 and 7 to Roberto Cippitani. The conclusions are common.

1. Background: the EU Strategy for data

The accessibility and flow of data, information, knowledge, and materials are crucial in all domains of research[1]. We know very well as the exchange of data and information was crucial during a time when it was essential to address a worldwide issue like the COVID-19 pandemic (Colcelli, 2021). Sharing of health data could play an essential role in addressing important individual and societal problems when accompanied by appropriate data protection safeguards. The outbreak of COVID-19, which has affected our lives in an unprecedented way, has very convincingly underlined that. Data sharing could substantially contribute to managing the current crisis and its long-term consequences, help the EU prepare for possible future emergencies of a similar nature (Taylor, 2012), as well as to reach the goal to become a Common European data space.

Awareness of the importance of the circulation of information derived from data, the European Commission (EC) published on 19 February 2020 a Communication called 'A European strategy for data' that is part of a more comprehensive package of strategic documents, including also a 'Communication on Shaping Europe's digital future' and a 'White Paper on Artificial Intelligence' as the European approach to excellence and trust. The starting point of these documents is the indisputable fact that over the last few years, digital technologies have transformed the economy and society, affecting all sectors of activity and the daily lives of all Europeans. Because data is now at the centre of

[1] To guide the readers through the paper, we underline that during the analysis we used concepts such as data, information and knowledge in the following manner: Knowledge is the thorough, complete, and intimate comprehension of something or someone. This knowledge is attained by training, research, experience, or even familiarity. Frequently, knowledge is awareness. The Latin word *cognoscere*, which derives from the words *cum* and *(g)noscere*, is known to have given rise to the term *knowledge* as the faculty of understanding. In Indo-European languages, knowledge is known by the names *gnas* in Sanskrit and *gnósis* in Greek. The present participle of the Latin verb *cognoscere*, which means 'to know', is where the word *cognoscentia*, a late Latin word, derives. In linguistic terms, knowledge can refer to education, awareness, consciousness developed over time and space, and learning based on reasoning or experience. Additionally, it is the very ability to perceive or to learn. Therefore, 'knowledge' is also realised through the deliberate layering of data and information (Colcelli, 2010). Data doesn't represent knowledge. Data serve as the foundation for new understanding. Data doesn't come with any intrinsic meaning. Information's foundational component is data. Data is changed into information by adding value, and information has meaning, significance, and purpose. Data is defined as information-as-a-thing processed in some way for use (Davenport and Prusak, 1998). From the Latin in and form, the word 'information' derives its etymological meaning of moulding and instructing. In any case, sometimes we use data as all comprehensive word that include information, knowledge, and material.

this transformation and more is to come, the EU decided to delineate a path for creating a Common European data space in strategic economic sectors and domains of public interest – such as e.g. the Common European health data space (see par. 1.1.) – to enable the EU will become the 'most attractive, most secure and most dynamic data economy in the world' to face China ad USA which is emerging as two data and Artificial Intelligence (AI) superpowers. The above-mentioned strategic path can support the EC's idea that data sources could be limited to concentrations in a few places as we have with an oil-driven economy such as the USA or as we have in states with democratic limitations, such as China. Starting from the beginning, the EU legal system has been described using new ways for governing its market integration, as complementary or alternative answers to legislative harmonisation realised and implemented with institutional instruments (Colcelli and Arnold, 2016).

'Data Strategy should be to prove the viability and sustainability of an alternative data economy model - open, fair and democratic. Unlike the current predominant business model, characterised by unprecedented concentration of data in a handful of powerful players, as well as pervasive tracking, the European data space should serve as an example of transparency, effective accountability and proper balance between the interests of the individual data subjects and the shared interest of the society as a whole (EDPS, 2020).

Data value chains are built on different data activities: data creation and collection; data aggregation and organisation; data processing; data analysis, marketing, and distribution; use and re-use of data[2]. The collections of materials are the fundamental 'infrastructures' for scientific research, as underlined by the documents of international organisations (OECD, 2007). Among today's most important research tools are datasets, collections of materials[3]. Biological materials and the data related to, them are invaluable resources for biomedical research as pointed out by EU and International sources. The issue of the sharing of data and personal data is crucial, in particular, in biobanking activities also for research. A biobank is 'any collection of biological materials, whether the source be human, plant, or animal, fungi, bacteria, microorganisms or other living families, as well as bioinformatic data on such organic materials' (Perry, 2013). In the field of medicine, biobanks

[2] 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 (Text with EEA relevance.) PE/53/2018/REV/1.

[3] See, e.g., Article 2 of the International Treaty on Plant Genetic Resources for Food and Agriculture of FAO of November 2001 and Article 2 of the Convention on Biological Diversity approved by the United Nations in 1992).

are the basis of translational biomedical research, a relevant component of personalised medicine and a pillar of disruptive medical innovations in precision medicine (EC and EXPH, 2021) and because they allow to re-analyse and share human samples and derived health personal data between clinical and biomedical experts.

2. Free circulation within European Data Area(s)

The European strategy needs that the data may circulate and may be shared in the economic, academic, and social environments.

To achieve those objectives, EU documents use the metaphor of building a 'European Data Areas' or 'spaces', that is to say, European legal frameworks taking into consideration the multiple dimensions in the circulation of data, such as economic, professional, cultural, scientific, educational ones, and considering that the movement of data is realised through several levels of governance (at International, EU, National levels)[4].

The EU approach devote to capturing the benefits of better use of data, is based on the creation of dedicated areas for the circulation of data. According to the Communication 'A European strategy for data', EU is expected to build several European common spaces: a Common European industrial (manufacturing) data space; a Common European Green Deal data space; a Common European mobility data space; a Common European financial data space; Common European agriculture data space; Common European data spaces for public administration; Common European skills data space and a Common European health data space.

In addition, according to EU legislation, the circulation of data for tasks in the public interest, such as health and research, is one of the primary characteristics of the European Research Area (ERA) in which researchers, technology, moreover, knowledge can circulate freely (see Article 179, para 1, Treaty on Functioning of the European Union) (Admunno, 2012).

[4] The metaphor of 'space' or 'area' is used also in other fields, such as the 'internal market', i.e. 'The internal market shall comprise an area without internal frontiers in which the free movement of goods, persons, services and capital is ensured in accordance with the provisions of the Treaties' (Article 26 TFEU); 'area of freedom, security and justice without internal fronteers' (see Articles 3 (2), 67 ff. TFEU); the 'monetary area' (cf. Article 48 (3) TFUE); the trans-European networks (see Article 170 TFEU); the documents of the 'Bologna Process' to build an European Higher Education Area.

Furthermore, the European legislature is discussing on a proposal for a regulation establishing an European Health Data Space (EHDS)[5].

EHDS proposal is the first example of how the EU wants to implement its Data Strategy. EHDS will help to prevent, detect, and rapidly respond to health emergencies; to improve understanding, prevention, early detection, diagnosis, treatment, and monitoring of cancer as well as of many diseases through the EU cross-border secure access[6] and sharing between healthcare providers of health[7].

This could mean safe access to public health and healthcare data and the wide availability of electronic health data. European space of personal data shall influence health policies and the well-being of citizens.

Moreover, it could also touch on research and innovation. EHDS aims to open datasets or platforms collecting data.

EHDS is aimed at improving individuals' access to and control over their electronic personal health data in the context of healthcare (primary use of electronic health data[8]) and increasing the well-being of society by stimulating research, innovation, policymaking, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data)[9].

To establish the Data Areas is crucial to recognise the freedom of circulation of data. As matter of fact, all legal sources concerning data establish this principle right from their title. This is the case of the

[5] Proposal for a regulation - The European Health Data Space, (EHDS) COM(2022) 197/2.

[6] Currently, the cross-border exchange of data is regulated by Directive 2011/24/EU on the application of patient's rights in cross-border healthcare. The directive sets out the conditions under which a patient may travel to another European Union (EU) country to receive safe, high-quality medical care that can be reimbursed by their health insurance scheme. It also encourages cooperation between national healthcare systems.

[7] Explanatory Memorandum of the Proposal for a Regulation on the European Health Data Space (COM(2022) 197 final.

[8] 'Primary use of electronic health data' means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services (see art. 2, lett. d, Proposal for a regulation - The European Health Data Space EHDS).

[9] 'Secondary use of electronic health data' means the processing of electronic health data for purposes set out in Chapter IV of this Regulation. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for secondary use (see art. 2, lett. e, Proposal for a regulation - The European Health Data Space EHDS). Chapter IV facilitates the secondary use of electronic health data, e.g. for research, innovation, policy-making, patient safety or regulatory activities.

Regulation (EU) 2018/1807 about a framework for the free flow of non-personal data in the European Union; the Regulation (EU) 2016/679 (GDPR) on the protection of natural persons regarding the processing of personal data and the free movement of such data; the Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information about the re-use of data.

3. Limitations on the circulation of data for scientific purposes

An analysis of the current legislation seems to indicate several legal constraints on the circulation of data (information, knowledge, and material), able to affect the building of an effective European Data Area.

In particular, such limitations are laid down by the discipline of protection of personal data and by other legal sources: the normative concerning clinical trials (see, for example, Regulation (EU) no. 536/2014) and the use of biological material (see Directive 2004/23/EC); as well as the discipline of 'intellectual property rights'; security reasons concerning the 'sensitive information', etc.

We summarise in the following paragraphs the main actual limitation of the existing legislation able to reduce the circulation of the information and data (personal and non-personal).

3.1. GDPR application in the research activity: the lack of harmonisation of data protection rules across Europe. Focusing on Health data governance.

The General Data Protection Regulation (GDPR) is the European regulation, on the protection of natural persons through the processing of personal data and the free movement of such data. It contains several provisions that give EU member states the authority to develop and adapt the GDPR at the national level, including the adoption of provisions to cover the processing of health data for scientific research (Recital 159 GDPR).

GDPR, also outside the EU, constitutes the benchmarking legal standard in regulating the use of personal data and in the protection of the rights linked to the processing of information of individuals.

In addition, GDPR is built on the idea that research activities are in the collective interests and, therefore, that the processing of personal data in scientific fields may benefit from special rules or derogations, as

it happens also in other EU legal sources (e.g. in public procurements, in the discipline of State aid, etc.)[10].

The GDPR, Article 89, establishes that when "personal data are processed for scientific or historical research purposes or statistical purposes", European and national laws may provide derogations from the rights normally belonging to data subjects, such as the right of access (Article 15), the right to rectification (Article 16), the right to restriction of processing (Article 18), and the right to object (Article 21). Laws may also establish a derogation from the right to erasure (the right to be forgotten), established by Article 17(1), GDPR[11].

However, from the application of the GDPR to the setting-up and functioning of research activities may arise some issues.

While it is true that Regulation (EU) 2016/679 (GDPR) is a wide-ranging piece of legislation that includes several provisions which favour scientific research – or rather, favour an understanding of its specific needs – its application is not always easy in the research context. This is mainly due to the vast discretion the GDPR grants to the Member States in this regard. This situation produces fragmentation of the application of GDPR at national levels that impact research activity in several ways.

'The national legislator of each Member State may enact specific laws under Article (9) (2) (i) and (j) GDPR to enable the processing of health data for scientific research purposes. The processing of health data for scientific research must also be covered by one of the legal bases in Article 6 (1) GDPR. Therefore, the conditions and the extent for such processing varies depending on the enacted laws of the particular member state'[12].

According to Article 89(2) of the GDPR, the derogations in the context of research exemptions in the GPDR are related to (a) the rights of data subjects or (b) the so-called secondary use for further processing of personal data:

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[10] See Commission, Open innovation, open science, open to the world – a vision for Europe, note 10 above.

[11] Derogations from the individual rights usually accorded to data subjects are also recognised in documents issued by the Council of Europe's bodies. For instance, Article 8(2)(d), Recommendation R(97) 5 Recommendation R(97) states that access to medical data (including genetic data) and the right of rectification may be refused when "the data are used for statistical or for scientific research purposes where there is no risk of an infringement of the privacy of the data subject, notably the possibility of using the data collected in support of decisions or measures regarding any particular individual".

[12] Guidelines on the processing of data concerning health for scientific research in the context of the COVID-19 outbreak.

a. The derogations for the rights of data subjects in the context of the research exemptions of the GPDR are:

- Article 14(5) GDPR: requirement to inform data subjects about data processing when their data was collected from other sources.
- Article 17 GDPR: 'right to be forgotten'.
- Article 20 GDPR: data portability rights.
- Article 21 GDPR: right to object at any time to the processing of their data.
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- Article 20 of GDPR is also worth mentioning – it provides individuals with data portability rights.

b. Derogations from the general prohibition on further processing of personal data due to Article 5(1)(b) which states that 'further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, under Article 89(1), not be considered to be incompatible with the initial purposes'.

At the same time, Member State (MS) and/or European Union law is needed regarding the legal basis under Article 9 GDPR to stipulate:

- a. a legal obligation and/or a task carried out in the public interest under Article 6 GDPR;
- b. reasons of substantial public interest; and
- c. reasons of public interest in the area of public health and/or scientific research purpose.

'This implies that choices made in MS laws can have a considerable impact both on the legal basis (Article 6) and on the exemption for processing of health data (Article 9) that must be relied on when processing personal (health) data for scientific research purposes [...] 'In addition, the possibility foreseen in Article 9(4) GDPR for MS to maintain or introduce further conditions, including limitations, concerning the processing of genetic data, biometric data or data concerning

health'[13] must be taken into account in analysing the possible conflict of laws in the case of cross-border data sharing'[14].

The issue of the sharing of personal data also commonly arises in situations in which data processing takes place in an intragroup context for research purposes. Examples include collaboration agreements for scientific research activities between several entities dedicated to the performance of a project that uses personal data for research activities, biobanks that collect the personal health data of donors from hospitals, and companies that jointly manage personnel and support activities.

The GDPR enables data flows for research cooperation in the EU, but the rules at the national level regarding research exemptions create a hurdle for cross-border research by ignoring the intra-EU conflict of laws that inevitably arise in a fragmented regulatory framework.

Problems may arise in the management of supranational research consortia when data collected in a Member State are made available to researchers in one or more European states other than the one where the data were collected or when the data is stored in a cloud which is hosted in a Member State other than the State where the personal data were collected. The question arises as to which national law is applicable because there can be different legal bases for that of the Member State where the data subject is located and that of the State(s) where the data can be processed. This is the case, for example, when the country of destination lays down rules on the secondary use of data that are more extensive than those laid down by the country in which the data were collected and in which the basis of the rules on information notice to the data subject was drawn up; or if it provides for a secondary use that is based on a different legal basis from the consent that may have been used to collect the data in the specific research project for which the processing is carried out; or if there are differences between the two countries in the rules governing the exercise of the right of access or rectification. Article 20 of GDPR which provides individuals with the right to data portability is also worth mentioning. However, it only applies if the data subject provided the personal data based on his or her consent or if the processing was necessary for the performance of a contract. Therefore, if the research was carried out on another legal basis in another Member State, this right would not be available to data subjects.

Concerning Article 21 GDPR, the right to object at any time to the processing of personal data can only be overridden when a task is

[13] EDPB Document in response to the request from the European Commission for clarifications on the consistent application of the GDPR focusing on health research – EDPB 02-02-2021

[14] *Ibid.*

carried out for reasons of public interest. For this task to be valid, it must be established by the Member State or EU law. Even if the data controller can invoke the research exemption of the GDPR, processing for research purposes could still be impeded as the data subject retains the right to object to the processing ('right to object') under Article 21 of the GDPR.

'The lack of harmonisation of data protection rules across Europe must [...] be kept in mind, as said rules may influence data processing for scientific research purposes, such as determining conditions under which processing personal data can generally be lawful. Many member states have written their own rules on the role of consent—especially broad consent—for the processing of genetic and health data or may in the future specifically define what exactly constitutes "public interest", which could also influence the lawfulness of processing for scientific research purposes. If multiple research stakeholders within the EU work together to process data, or a single stakeholder operates in multiple EU countries, identifying a (common) justification for processing personal or even sensitive data is challenging' (Molnár-Gábor, Korbel, 2020).

We are going to approach the GDPR applies to research activities with specific attention to biomedical fields, because the application in this area of knowledge is particularly tough. For this reason, this analysis could be our benchmark for the application of GDPR in the whole area of research activities.

Most of our current knowledge in biomedical fields arises from the systematic investigation of human biological samples - also stored in biobanks containing biological materials such as blood, cells, tissues, and DNA - associated with information on the samples and the sample donors. (Vivas Tesón, 2013) (Scaffardi, 2008) (Godard, et al., 2003).

According to the European Union law, in addition to constitutional provisions (see Article 3 of the Charter of Fundamental Rights), other legislative legal sources regulate the collection and storage of biological materials such as Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and the other related dispositions at EU and national levels.

Moreover, human tissues contain "personal data", i.e. information able to identify a natural person and then they are subject to the EU legal sources concerning the protection of personal information, especially Article 8 of the Charter of Fundamental Rights and GDPR. Health data governance remains fragmented at national and regional levels, hindering any effort to scale up research and healthcare solutions. The coordination of national efforts is also fragmented as is the

harmonisation of the treatment of personal health data considering the GDPR.

Dealing with these situations in a research consortium context opens the classic private international law problem of conflict of laws. This situation could have an impact on individuals that decide to participate in a study/research activity in terms of equal treatment for the participants/patients involved.

The EDPB is very clear about this situation, especially that considerable differences in Member State laws can be found in the legal bases for processing health data for scientific research purposes. To avoid the problem of the violation of equal treatment for the participants, the EDPB underlines: 'When conducting a health research project in multiple Member States, it is recommended to use, whenever possible, the same legal basis in the project. However, it is foreseeable that in research projects in multiple MS, there might be a need for using a heterogeneous legal basis for processing the health data of the participants in a single research project in several Member States, due to MS law'.

The EDPB's position on how to avoid the potential negative impact of such a heterogeneous legal basis for the processing of health data in one research project in multiple Member States will support us in trying to answer our burning question.

Under the EDPB, 'it is advisable that controllers should as far as possible make an effort to limit the consequences of different Member States' legal regimes for processing health data for scientific research purposes, for instance by optimising and thus harmonising the rights of data subjects irrespective of the Member State they live in'.

The specific criteria of a common legal basis cannot be found at the EU level or in the GDPR because 'as for relevant Union law, until now, only the Clinical Trial Regulation (CTR) can be identified as Union law in which a uniform legal basis for controllers can be found in the stipulated legal obligation for controllers (Articles 41-43 CTR) to process personal data in clinical trials for reliability and safety related purposes. However, this legal obligation for controllers does not cover all (other) purposes for which personal data are processed in a clinical trial. Therefore, the controller will have to rely on another legal basis Article 6 GDPR for processing personal data for such other research purposes'.

The point that the EDPB underlines is that the 'potential lack of homogeneity cannot be solved in the EDPB guidelines or using Codes of conduct'. If this is true for the heterogeneous/different legal basis for processing health data, it is also true for the other questions which arise from the lack of harmonization.

The EU institutions and bodies have adopted several documents to apply the principles of the GDPR to the health emergency[15] (such as minimisation and security, see Article 5 GDPR) (Kędzior, 2020). As above mentioned, GDPR shows several shortcomings in regulating the activities carried out by biobanks, especially those for research purposes. GDPR has still brought a big advantage since it has offered the EU and national legislations the opportunity to reconsider the entire system and design a more complete protection framework for scientific research (Slokenberga, Tzortzatou, Reichel, 2021), but the reality is that the rules are not clear, nor when they have to apply to research activity.

3.2. Other limitations to the circulation of data

Some limitations on the circulation of data for scientific purposes arise also from the discipline of 'intellectual property rights' which attributes to authors of works or inventions the exclusive right to exploit those works or inventions (see the definitions provided by the Paris Convention for the Protection of Industrial Property of 20 March 1883, as last amended on 28 September 1979, and the Berne Convention for the Protection of Literary and Artistic Works of 9 September 1886, last amended on 28 September 1979).

Other important norms lead to a restriction on the sharing of information, such as legislation on the protection of personal data, the discipline for clinical trials (see, for example, Regulation (EU) no. 536/2014), and the use of genetic information (see Article 2 of the International Declaration on Human Genetic Data adopted by UNESCO in 2003). Such norms put information under the control of the 'data subject' who is entitled to give his/her consent for all uses of personal data (Cippitani, R., 2014).

International Treaties concerning biodiversity may also prevent the sharing of information and biological materials, that is, genetic resources from plants and animals. This is the approach of the CBD (see Article 15, para. 1) as well as of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA, see Article 10.1) and of the Convention on Access to genetic resources and the fair and equitable sharing of benefits arising from their use of the Convention on Biological Diversity of 2014 (hereinafter referred to as the Nagoya

[15] Among the others: Statement on the processing of personal data in the context of the COVID-19 outbreak. Adopted on 19 March 2020.Guidelines 04/2020 on the use of location data and contact tracing tools in the context of the COVID-19 outbreak. Adopted on 21 April 2020. Guidelines 03/2020 on the processing of data concerning health for scientific research in the context of the COVID-19 outbreak. Adopted on 21 April 2020. Statement on restrictions on data subject rights in connection to the state of emergency1 in Member States, adopted on 2 June 2020.

Protocol; see within EU law, Regulation no. 514/2014 of the European Parliament and of the Council of 16 April 2014).

In particular, Article 15, para. 1, CBD states that 'Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'.

In addition, the preamble to the United Nations Framework Convention on Climate Change recalled that the 'States have, by the Charter of the United Nations and the principles of international law, the sovereign right to exploit their resources according to their own environmental and developmental policies' and reaffirmed 'the principle of sovereignty of States in international cooperation to address climate change.

The assertion of sovereignty is consistent with the approach of international law governing relations between autonomous and independent states (Conforti B., 2010) that have the ultimate power to implement transnational rules (Henkin L., 2008).

These rules are based on the idea that information[16] and material are forms of 'property' held by individuals (de Witte, Have, 1997) or by the states[17], depending on the situation. According to the traditional idea of property, the owner has a sort of absolute power over the res and is entitled to exclude the rights of third parties.

This property scheme may be useful to protect some relevant interests. The discipline on privacy tries to protect individuals from the enormous risks derived from the use of personal data. In the case of natural genetic resources, the affirmation of state sovereignty has been a response to the depredation of natural resources to the detriment of developing countries.

However, the 'proprietary paradigm' may lead to effects on important interests that are different from those of the owners.

For example, the consent provided by the discipline governing personal data derives from an individualistic logic[18] which, if applied in an absolute way, can prevent other individual or collective interests from being satisfied (e.g., the use of personal data to protect the health of other individuals).

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[16] The famous work by Samuel Warren and Louis Brandeis, 'The Right to Privacy' published in the Harvard Law Review in 1890, constructs the notion of 'privacy' as the right of the individual to exclude others from invading his/her sphere. In practice, privacy was born as an extension of the logic of property (originating in Roman law) from the physical to the 'spiritual' sphere.

[17] Sovereignty was considered as a sort of 'property' by Grotius in De iure belli ac pacis.

[18] Article 29 Data Protection Working Party, Working Document on Genetic Data, Adopted on 17 March 2004, p. 8.

In the case of genetic resources, the national sovereignty ensured by international law may conflict with other legitimate purposes, such as the protection of the rights of indigenous communities present in particular territories. Those rights are also recognised by international instruments (see, for example, Article 2 of the Nagoya Protocol) (Pacheco Cornejo, 2013) but it is not clear how they may be protected from the actions of the states. In addition, sovereignty fails when it is necessary to safeguard the environment, which does not belong to a specific state but is a common asset of humankind[19].

4. Issues arising from the limitations in the circulation of data

The limitations in the circulation of data may represent an obstacle to carrying out activities in the common interest, such as scientific research or the protection of public health. Some rules recognise those interests in the processing and circulation of data and materials. For example, research on the genetic makeup and/or biochemical composition of genetic resources is considered particularly relevant in the Nagoya Protocol. Article 8 provides that each state shall 'create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research' (see also recitals 6, 18, 27 and 28 and Article 13 of Regulation (EU) No 511/2014).

However, the states have the last word in determining the measures which would allow scientists to use genetic resources. In particular, each legal system gives its interpretation of concepts such as research and non-commercial research (according to EU law, for example, see the definitions provided by the European Commission, Communication, Framework for state aid for research and development and innovation, C(2014) 3282 of 21 May 2014).

This can constitute an obstacle to the circulation of materials and information in a field such as science in which national interests are often considered to take precedence over benefits to the international community.

[19] See the case of the President of Brazil, Bolsonaro, who affirmed national sovereignty over the Amazon forest to exclude any intervention of the international community. See his speech at the General Assembly of the United Nations on 24 September 2019.

Article 7 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended by the 2005 Protocol Amending the TRIPS Agreement) provides that 'The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations'.

Any decision is subject to the discretional power of the states as provided by Article 8 of the same agreement. The Member States 'may' 'adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development' and to 'prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology'.

Although the legal sources concerning the circulation of information, especially the international instruments, still depend on the property paradigm, it is possible to observe some paradigm shifts which may allow a different interpretation of the present rules and other future regulations.

5. Open science and Freedom of Knowledge within EU law

In order to avoid the limitations in the circulation of data may affect relevant interests, EU legal sources propose to 'open' the science. 'Open science' implies moving from the mainstream approach, based on the protection of information, towards a collaborative system based on the actual possibility to share scientific data. This would take advantage of possibilities within information and communication technologies.

The first popular application of the open approach to research was the international Human Genome Project started in the early 1990s and allowed the decoding of the human genome in a period of fewer than 15 years and the worldwide sharing of the knowledge.

In addition, many of the research initiatives carried out to fight the COVID-19 pandemic represent examples of open science (see, for example, the European COVID-19 Data Platform, available at `https://www.covid19dataportal.org/`).

In brief, open science may be defined as an approach to scientific activities based on open and cooperative work, as well as on tools and the diffusion of knowledge (see Article 2, n. 5, Regulation (EU)

2021/695 of the European Parliament and of the Council of 28 April 2021 establishing the programme Horizon Europe) (Rentier, 2019).

This openness may be useful for scientific research and also innovation, that is, the transformation of knowledge into economic and social development (Chesbrough, 2015).

In addition, Open Science has an impact on the entire research cycle, from the inception of research to its publication, and on how this cycle is organized' (see the communication of the European Commission, 'Open innovation, open science, open to the world. A vision for Europe', 2016).

Within the EU law, the objective to open science and innovation has implied the adoption of the legislation on free circulation (see 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) and re-use of data (see the Directive (EU) 2019/1024 of the European Parliament and of the Council of 20 June 2019 on open data and the re-use of public sector information), as well as the creation of specific infrastructures focused on data (see European Commission, European Cloud Initiative – Building a competitive data and knowledge economy in Europe, COM/2016/0178 final).

Furthermore, the legal base of the EU Programmes, in particular 'Horizon Europe', provide the obligation for the beneficiaries to publish in open access and to deposit the data in repositories freely accessible by the scientific community and by the public (Article 14, para. 1, Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe).

Those legal sources constitute the implementation of the objective of the overall governance of data (see the Proposal for a Regulation of the European Parliament and of the Council on European Data Governance [Data Governance Act] COM/2020/767), especially to build a European health data space (see recitals no. 3 and 19 of the Proposal of Regulation; see Annexes to the Communication of the European Commission, Commission Work Programme 2021, COM(2020) 690 final) and to stimulate research and innovation (see recital no. 20 of the Data Governance Act).

The documents of the European institutions affirm based on Article 179 TFEU that the Union and the Member States must guarantee and promote 'freedom of knowledge', which is considered the fifth freedom granted by the Treaties of the European Union[20] in conjunction with the free movement of persons, goods, services and capital.

[20] See the communication of the European Commission, 'Better careers and more mobility: A European partnership for researchers', 23 May 2008, COM(2008) 317 final.

Furthermore, freedom of research is a fundamental right (Article 13 Charter of Fundamental Rights of the European Union) (Cippitani, 2015).

To build a true European Research Area (Communication of the European Commission, 'Towards a European Research Area', COM [2000] 6 final, 18 January 2000), the Union has to encourage the free circulation of research and cooperation between undertakings, research centres and universities and also remove obstacles to this circulation and cooperation.

6. Equilibrium between individual and collective interests: the case of EHDS

Another approach to benefit of the circulation of data within the European Areas is to find the points of equilibrium between individual rights and collective interests such as health. For sure, the processing of personal electronic health data is subject to the provisions of GDPR (Whereas n. 4 of Proposal for a regulation EHDS)[21].

Nevertheless, the GDPR must be applied in the implementation of European data spaces in terms of transparency, effective accountability, and proper balance between the interests of the data subjects and the shared interests of society, based on European values and fundamental rights with the human being at the centre. This is because the GDPR also takes a technologically neutral approach. Anyway, the EHDS is related also to non-personal electronic health data[22], because of the aim of free circulation.

The development of the European Health Data Space (EHDS) and the reuse of health data for research, innovation, policymaking and regulatory activities means building large-scale infrastructures for the reuse of health data. Such infrastructures should demonstrate the potential to reuse cross-country health data for research, innovation, policymaking, regulatory activities, and possibly personalised medicine. EHDS will promote the development of cloud computing healthcare platforms on which patient data will be shared and stored under secure federated cloud databases which fulfil the data protection requirements (legal or ethical) imposed by the General Data Protection Regulation (GDPR).

[21] The EHDS proposal gets started also from the Communication from the Commission to the European Parliament and the Council Data protection as a pillar of citizens' empowerment and the EU's approach to the digital transition - two years of application of the General Data Protection Regulation (COM/2020/264 final).

[22] See art. 2, lett. b, Proposal for a regulation - The European Health Data Space EHDS.

The existing regulatory framework seems insufficient to deliver on the promises of the EHDS.

To this end, it is necessary to achieve a balanced approach between EU strategies and the protection of fundamental rights and interests when dealing with information involving private life and sensitive aspects of individuals. Improving data access and management is a key issue, but personal data must be accessible in a secure way for legitimate use, under Regulation (EU) 2016/679; also considering collective interests, such as those related to scientific research and health policies. This means that safe access to public health and healthcare data and the wide availability of electronic health data in a European space of personal data shall influence health policies and the well-being of citizens. Moreover, it could also affect research and innovation.

The integration of health data in the European space shall also be a priority for research and innovation purposes since it should allow the re-use of quality data, with reliable governance, for secure research, with reduced costs.

Once in the EHDS, these data should feed into activities of secondary use. This means that access to electronic health data is provided not for healthcare purposes (for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services), but for secondary use (Article 34 of the EHDS Regulation). This entails that the owners of the data platforms/databases would only confer those data to the European space to ensure access to electronic health data only for secondary use, including research and innovation itself.

Chapter IV of the proposal contains rules on the implementation of so-called 'data altruism', which is defined by another proposal of regulation, that on European data governance ('Data Governance Act' COM/2020/767 final), and which serves to attain a higher level of trust, without unnecessary restrictions, helping to develop an internal market for the exchange of data (cf. Explanatory Memorandum concerning the proposal of Data Governance Act, paragraph 2).

The term 'data altruism', refers to the use of data - following consent by the data subjects or authorisation by the data controllers - free of charge, for purposes of general interest (such as scientific purposes, research, or improvement of public services) (see Article 4 (10) of the proposal on Data Governance Act).

The main issue is regulating and approaching the application of the abovementioned concept in the health scenario of the secondary use of personal data for future research. Given the stringent interpretation of

the EDPB to recital 33 GDPR, this is a very important matter that may present new difficulties. It is yet unclear how this permission may interact with the idea of consent as established in the GDPR.

By the proposed regulation, data controllers must provide access bodies with health data to make it available to third parties granted permission to access the data for secondary purposes. Recital 37 of the Proposal states that the "[...] Regulation provides the legal basis under Article 9(2)(g), (h), and (j) of Regulation (EU) 2016/679 for the secondary use of health data, setting out the safeguards for processing, in terms of lawful purposes, trusted governance to provide access to health data (through health data access bodies), and processing in a secure environment, and how the data is processed."

Although this is not always represented in the proposal's operational section, the same Recital in this situation requires the data requester to demonstrate a legal ground under Article 6 of the GDPR on the basis of which a data access request can be made in light of the proposal. The two authorities, on the other hand, point out that Article 34(1) of the Proposal lists a number of purposes for which electronic health data may be processed for secondary use, including but not limited to the goal of conducting a scientific study in the area of health or care. When a person's consent is required under national law, the authorities in charge of access to health data must adhere to the requirements outlined in the proposal to provide access to electronic health data.

This paper is not the place to analyse the actual limitation of the proposal. We limited ourselves to underline how at this moment, creating EHDS has several critical points in the concrete application, a lot linked to the GDPR. This is a sort of problematic 'fil rouge' among the already existing legal constraints on the circulation of data (information, knowledge and material) in the internal market and the ERA.

7. Human rights and 'Digital Solidarity'

The limitations in the circulation of data should be viewed from the perspective of the human rights and the fundamental principles such as the solidarity.

The core of the EU strategy of data is focused on the respect of European fundamental rights and values, including the right to the protection of personal data provided under Article 8 of the Charter of Fundamental Rights of the EU and Article 16 Treaty on the Functioning of the European Union.

Rules for access and use of data are fair, practical, and clear to make the internal market easier for businesses, public authorities and

researchers to access high-quality data to boost growth and create value, ensuring the proper functioning of internal markets, as it is characterised by the free movement of goods, capital, services and persons.

In the context of a legal system built on the idea of fundamental rights, all rights, also those concerning data, should be considered consistent with other fundamental rights and interests. Therefore, also the fundamental right such as the protection of personal data should be interpreted in the view of the application of other rights, or collective interests, such as freedom of research or individual and collective health.

A fortiori, the limitations to the circulation of data, arising from sovereignty and other interests, should be revaluated in the case they may affect the human rights. Concepts such as sovereignty within the so-called global constitutionalism (Ferrajoli, 2001) have changed in meaning. The exercise and protection of fundamental rights is the present justification for political power (Rawls, 1980).

In addition, sharing of data for collective interests, such as research and health, is also expected to implement the principle of solidarity (Cippitani, 2010) (Stejernø, 2005). Solidarity in its modern meaning (Peces-Barba Martinez, et al., 2001) may be defined as the duty to protect the interests of other persons and vulnerable people. Such a principle is applicable in all social and legal relationships, both vertical (between public authorities and citizens) and horizontal (between individuals, e.g., family and contractual relations).

This principle should be applicable also to the circulation of data, especially for research and the protection of health (see Cippitani, 2022). Indeed, the above-mentioned concept of 'data altruism' can be seen as an application of the general principle of solidarity in the particular field of the circulation of data.

With respect to the necessity of the circulation of data during the pandemic crisis, European Data Protection Supervisor (EDPS)[23] has used the expression 'digital solidarity'. Digital solidarity 'should make data work for all people in Europe and especially for those the most vulnerable'.

On the other hand, EDPS underlines that 'Digital solidarity would refuse to replicate the now tarnished and discredited business models of constant surveillance and targeting that have so damaged trust in the digital society but will allow data protection serve mankind during this extraordinary exam in our knowledge, skills and our human values'.

[23] See the statement of the European Data Protection Supervisor, Wojciech Wiewiórowski, EU Digital Solidarity: A call for a pan-European approach against the pandemic of 6 April 2020.

As matter of fact, the EU and international bodies stress that the sharing of data, even in an emergency, has to respect individual rights and other interests, such as privacy.

The Organisation for Economic Co-operation and Development in its 'Policy Responses to Coronavirus'[24] recommends that policymakers collaborate with privacy enforcement authorities to ensure that any extraordinary measures are proportionate to the risks and are implemented with full transparency and accountability along with a commitment to stop and update those measures when the situation changes.

The Council of Europe in its 'Recommendations on Privacy and Data Protection in the Fight against COVID-19'[25] recalls that 'International and national laws recognize that extraordinary circumstances require extraordinary measures. This means that certain fundamental rights, including the rights to privacy and data protection, may be restricted to address the current health crisis as long as basic democratic principles and a series of safeguards are applied, and the interference is lawful, limited in time, and not arbitrary'.

Those measures have to comply with the principles foreseen in the European system of protection of human rights, that is, 'processing of personal data is carried out only if necessary and proportionate to the explicit, specified and legitimate purpose pursued; an impact assessment is carried out before the processing is started; privacy by design is ensured and appropriate measures are adopted to protect the security of data, in particular when related to special categories of data such as health-related data; data subjects are entitled to exercise their rights'[26].

8. Conclusions

The convergence towards common principles by the European Union is not sufficient to respond to global problems related to the relevance of sharing information and knowledge for research and health purposes, such as the pandemic. To implement an effective system for the exchange of data and for 'developing, enhancing and improving interoperable early warning information, surveillance, and trigger systems

[24] OECD Policy Responses to Coronavirus (COVID-19), Ensuring data privacy as we battle COVID-19, Version of 14 April 2020.

[25] Available at: https://www.accessnow.org/cms/assets/uploads/2020/03/Access-Now-recommendations-on-Covid-and-data-protection-and-privacy.pdf.

[26] See the joint statement of 30 March 2020 on the right to data protection in the context of the COVID-19 pandemic, at https://rm.coe.int/covid19-joint-statement/16809e09f4.

in line with the One Health approach [...] including rapid and transparent cross-sectoral and international information and data sharing' (see Principle 11 of the Declaration of Rome), true global governance of health data and materials is needed, using all instruments which will be able to regulate the transnational relationships, including extensive use of the modern forms of soft law (Schneider, 2021).

For those reasons, EU and international legal sources are aimed at setting up a global system for the sharing of data, biological material, knowledge, and technologies.

To achieve such an important objective, the previous paragraphs show that an adequate legal context must be built. This not only means the elaboration of new legal sources, in particular at the international level but also an interpretative approach which avoids the traditional view based on the proprietary paradigm and is grounded on the protection of human rights and the principle of (transnational) solidarity.

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