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Secondary use of health data in the EU: Exploring the legal challenges of the upcoming European Health Data Space Regulation in light of the findings of the TEHDAS project

Az egészségügyi adatok másodlagos használata az EU-ban: Az európai egészségügyi adattér rendelet kapcsán felmerülő jogi kihívások a TEHDAS közös fellépés eredményeinek tükrében

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Since the end of the 2010s, the use of advanced ICT solutions, the analysis of big data and advanced algorithm-based data processing have become dominant technologies in almost every domain. In the health sector, this process was also fuelled by the COVID-19 pandemic. The fast proliferation of digital solutions and the efforts to regulate their development and application regulations, draw the attention to the problems raised by both the primary and the secondary use of electronic health data. There is an ongoing comprehensive regulatory effort in the European Union to address these challenges. Regarding the health sector, the European Health Data Space Regulation can be considered a flagship legislation. The main ambition of the European Commission is, on the one hand, to create a common space where natural persons can easily control their electronic health data and, on the other hand, to make it possible for researchers, innovators and policymakers to use these health data sets for common societal purposes in a trusted and secure way, based on a specific cross-border digital infrastructure. With 25 participating countries, a European Union project, the Joint Action Towards the European Health Data Space (TEHDAS) has been initiated to support the establishment of the EHDS regarding the secondary use of data.

On the basis of the analysis of the outputs of the TEHDAS project and the available regulatory documents and legislative proposals, our study identified and addressed two important topics: legislative barriers to the secondary use of health data and challenges for citizens' empowerment, including data altruism. The legal complexity of the ongoing strategic legislative initiatives in the EU poses several challenges for future application. Firstly, there can be a terminological problem due to the lack of a common definition of secondary use of data. Secondly, the regulation of the Member States adjusted to their national health and data utilisation systems can be diverse. Both of these may hinder the desired EU-level harmonisation regarding data-sharing. In this context, the division of regulatory competencies related to health care and the chosen legal basis can be decisive. Overall, the EHDS might be a regulation that can challenge the current legal paradigm of competence distribution among the EU and the Member States regarding digital transition, including data usage in health care. As for the citizens' empowerment, the goal of an EU-wide ecosystem of health data utilisation requires individuals who are aware of the economic value of their health data and, via practising altruism, want to share these data also to be used for the common good. Specific provisions of the EHDS, such as the right to data portability or the option for opt-out, are definitely for the empowerment of citizens, but can also reduce the potential health care-related benefits of data utilisation at both individual and population level. Altogether, a concert of requirements should be fulfilled for meaningful citizens' participation, engagement, and practice of data altruism, supported by the complex interplay of the relevant regulations.

Keywords: European Health Data Space Regulation, secondary use of data, legal barriers, citizens' empowerment, data altruism

A 2010-es évek vége óta szinte minden területen meghatározóvá vált a fejlett ICT-megoldások használata, a nagy adatok (big data) feldolgozásával, illetve az algoritmusok bevonásával megvalósuló adatelemzés. A COVID-19 pandémia – minden negatívuma mellett – az egészségügyben a digitális megoldások és szabályozások egyik jelentős motorjává vált, ami ráirányította a figyelmet az elsődleges és másodlagos adathasználat problematikájára. Az Európai Unió szabályozási válasza ezen kihívások kezelésére egy átfogó jogalkotási csomag kidolgozása lett, a digitalizáció és az adathasznosítás stratégiai megközelítésének szellemében. Az egészségügyi ágazatot illetően az előkészítés alatt álló európai egészségügyi adattér rendelet (EHDS) tekinthető kiemelt jelentőségű jogszabálynak. Az Európai Bizottság fő törekvése ezen új ágazatspecifikus szabályozással összetett. Egy olyan közös keretrendszer létrehozását tervezi, amely lehetővé teszi az egyének (páciensek) számára az

elektronikus egészségügyi adataik kezelésének kontrollálását. A szabályozás további kiemelt célja, hogy a kutatási projektek, innovációs törekvések és a szakpolitikai programalkotás számára hozzáférhetővé tegye az egészségügyi adatkészleteket. Ezen célok megbízható megvalósítását, a tervezet szerint, egy speciális, biztonságos és uniós szinten egységes digitális infrastruktúra kialakítása hivatott szavatolni, amelynek megvalósítását egy 25 ország részvételével zajló uniós projekt, az európai egészségügyi adattér felé irányuló közös fellépés (TEHDAS) is támogatja a másodlagos adathasználat tekintetében.

A TEHDAS projekt eredményeinek és az elérhető jogszabálytervezetek szövegének elemzésén alapuló tanulmányunkban az egészségügyi adatok másodlagos felhasználásának jogszabályi akadályait, valamint az állampolgárok szerepének erősítését - beleértve az adataltruizmust - vettük górcső alá. Az EU-n belül folyamatban lévő stratégiai jogalkotási kezdeményezések összetettsége számos kihívás elé állítja a jövőbeni jogalkalmazást. Először is terminológiai jogértelmezési kérdések vetődhetnek fel az adatok másodlagos felhasználására vonatkozó egységes fogalommeghatározás hiánya okán. Másodszor, a tagállamok nemzeti egészségügyi és adathasznosítási rendszereihez igazodó szabályozása sokrétű lehet. Mindkét jelenség akadályozhatja az adatmegosztás vonatkozásában megcélzott uniós szintű jogharmonizációt. Ezzel összefüggésben meghatározó lehet az egészségüggyel kapcsolatos jogalkotási hatáskörök megosztása és a szabályozás választott jogalapja. Összességében a digitális átállással kapcsolatban - beleértve az egészségügyi adathasználatot is - az EHDS hozzájárulhat az EU és a tagállamok közötti kompetenciamegosztás jelenlegi jogi paradigmájának újrafogalmazásához. Az állampolgárok szerepének erősítését illetően az egészségügyi adathasznosítás uniós szinten megvalósítani célzott ökoszisztémája feltételezi, hogy az egyének tisztában legyenek egészségügyi adataik gazdasági értékével, és az adataltruizmus révén ezen adatokat a közjó érdekében is fel kívánják használni. Az EHDS egyes rendelkezései, mint például az adathordozhatósághoz való jog vagy az adatmegosztási rendszerből való kimaradás lehetősége, határozottan az állampolgárok szerepének erősítését szolgálják. Ezek azonban egyéni és lakossági szinten egyaránt csökkenthetik az adathasznosítás egészségügyi ellátással összefüggő előnyeit. Végső soron a polgárok valódi részvételéhez, elköteleződéséhez és az adataltruizmus megvalósulásához az érintett szabályozások kapcsolódó rendelkezéseinek összessége által meghatározott követelmények együttesének teljesülése szükséges.

Kulcsszavak: *európai egészségügyi adattér rendelet, másodlagos adathasznosítás, jogi akadályok, polgárok szerepének erősítése, adataltruizmus*

INTRODUCTION

The secondary analysis of routinely generated data is a well-established research method to implement studies with relatively low cost. The fast pace development of information and communication technologies (ICT) has triggered the digitalisation of virtually all aspects of our modern life, which in turn has started to generate oceans of a wide variety of data with the potential for secondary analysis to fuel technological and societal innovation and development at a cost and scale, never seen before in human history. The emergence of artificial intelligence applications is one example of this new innovation age. Arguably, the data available for secondary use have become the most important new and invaluable resource in all sectors of the economy, and health care is no exception.

The secondary use (or reuse) of data in health care has great potential to improve the performance of health systems, which is underlined by the large number of recent publications addressing the topic [1]. The key to unlocking this potential is to make these data, generated by the routine operation of health services, available for research and policy making, including technological and societal innovations, but the secondary use of health data also exemplifies its main difficulty. Patient (and as a matter of fact any other personal) data are sensitive by nature, and their 'owners' i.e. data subjects, are entitled for the protection of their privacy, so access to them could not be granted for third parties without restrictions. Responding to this challenge, more and more countries are realizing the need for a data strategy to frame the actions to be taken to give way to secondary data-based innovations without sacrificing the fundamental human right to privacy.

"The European data strategy aims to make the EU a leader in a data-driven society" [2, no page number] by creating a single market for data to "benefit businesses, researchers, and public administrations" [2, no page number]. The strategy proposed "the establishment of domain-specific common European data spaces", among which "the European Health Data Space (EHDS) is the first proposal" [3, p. 2], adopted by the European Commission on 3 May 2022 [3]. "EHDS will create a common space where natural persons can easily control their electronic health data. It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy" [3, p. 2]. The EHDS will regulate the secondary use of health data and establish cooperation among Member States on a specific cross-border digital infrastructure, which enables data sharing. According to the European Commission's plans, it will establish common rules of access to electronic health data for secondary use based on a permit issued by a data access body, while safeguarding the rights and interests of individuals concerning their data [4]. The negotiations on the regulatory proposal between the co-legislators are ongoing, the Council of the European Union (Council) adopted its mandate for negotiation with the European Parliament on 6 December

2023 [5], while the European Parliament voted on its amendments in first reading on 13 December 2023 [6]. Despite concerns and doubts of stakeholders expressed during the negotiations that the Commission's original intention to complete the legislative process by the end of its current mandate on 31 October 2024 and to launch the operation of EHDS in 2025 is not feasible because of the large number of issues still to be addressed [7], recent developments offer reason for optimism.

Joint Actions (JA) are a special type of EU funded policy projects, where authorities of Member States and associated countries participating in the health programme of the EU (currently: EU4Health) are offered the opportunity to work together on issues, which can be best addressed at the European level, on a voluntary basis [8]. The EHDS legislative process has also been supported by a JA, the so-called "Joint Action towards the European Health Data Space", or TEHDAS for short, under the third Health Programme of the EU [9]. The number of countries involved, and the work accomplished within the framework of the projects indicate that the secondary use of health data is a priority topic for governments, and there is a willingness for cooperation to make it reality.

Building on the work of previous, digital transformation related JAs, TEHDAS was a consortium of 22 EU Member States and 3 associated countries, working for 30 months, from early 2021 with the aim to help Members States and the Commission in developing and promoting concepts for sharing of data so that "in the future European citizens, organisations, research and innovation, communities and companies will benefit from secure and seamless access to health data regardless of where it is stored" [9, p. 23]. The primary research carried out by the project partners included a thorough analysis of the available literature, the organisation of workshops to collect expert and stakeholder views and semi-structured interviews with key informants. In the frame of the project, 12 Member States – including Hungary – were visited (virtual or face-to-face) to gain insights into their perspectives and expectations regarding the EHDS. Through active dialogue with key stakeholders, the discussions acknowledged the benefits of the EHDS proposal, while also identified practical and legal hurdles that need to be addressed to ensure its successful implementation [9].

The main outputs of TEHDAS addressed a few important themes, including the governance framework, specific national regulations and the state of national implementation of related European directives, data quality and semantic interoperability, technical interoperability of infrastructures, the security of data processing, and data altruism, i.e. the voluntary sharing of data for societal benefit [9,10,11,12,13]. As a result, recommendations concerning Member States regulations were elaborated, a data quality framework was drafted, a pan-European model for health data usage was introduced, and a guideline was developed for encouraging and implementing voluntary data sharing practices that adhere to data protection laws [9,11,13].

Although, the work of the TEHDAS consortia terminated on 31 July 2023, a new Joint Action had already been initiated by the European Commission in the frame of the new health programme, EU4Health [13], in order to ensure the continuity of work and to support the Commission with proposing guidelines for the implementing regulations of the EHDS. The new JA is expected to cover the development of guidelines for Health Data Access Bodies, data holders and users covering aspects such as data categories, compliance, collaboration, altruism, obligations towards people, limitations on data reuse, dataset descriptions, access, secure processing and research outcomes [14]. While TEHDAS aimed to facilitate the development of the regulatory framework, with a particular focus on envisioning the secondary use of health data within the forthcoming EHDS, TEHDAS 2 is set to develop practical tools to ensure that it goes operational.

When analysing the main barriers to the implementation of the EHDS, TEHDAS has pointed out that most of them are related to legal aspects, including the lack of a common European interpretation of "secondary use of data", and the diverse landscape of national legislation and derogations under the General Data Protection Regulation (GDPR) [10]. Further, the study on citizens' perspectives revealed a public interest in sharing health data, provided there are robust privacy and security measures in place [12]. Focussing on the legal challenges of the secondary use of health data, this paper aims to analyse and discuss these findings in the context of the current state of the EHDS legislation.

AIMS

This study had three objectives. Firstly, to examine the role of TEHDAS and the goals and expected outcomes of TEHDAS 2 in the implementation of the EHDS in certain focus areas and provides an interpretation of those results. Secondly, to explore, through the evaluation of the practical experiences of a Hungarian project partner (Semmelweis University), the future possibilities of implementation and development, by analysing potential legal solutions and strategic directions at both national and EU levels. And finally, it aims to support the dissemination of certain results of TEHDAS project to stakeholders, both national and across borders, in order to support to the implementation of a well-established European health data-sharing system.

Although the Hungarian participation in the project covered all the focus areas, special attention was given to the topic of citizens' rights and data altruism practices because the related activity was led by the Hungarian competent authority, the National Directorate for Hospitals (OKFŐ). The analysis in the frame of this article aims to have a closer look at these areas, with the closely linked legal challenges identified by the project. The paper aims to shed light on how the forthcoming EHDS, with regard to the results of TEHDAS, may influence future national and EU legislative directions. This includes supporting citizens in exercising their rights related to health data and their readiness to voluntarily

donate their data, as well as considering ways to overcome legislative barriers that hinder secondary use.

METHODOLOGY

The main method of the study is documentary analysis. In particular, the publicly available outputs of the TEHDAS project, and the relevant provisions of the draft regulation on European Health Data Space have been reviewed, analysed and discussed. We have also conducted a literature search, and the findings of relevant research papers are also referred to, where appropriate.

As the primary focus of our analysis is the project activities on the legal barriers of data-sharing and citizens' involvement, we systematically gathered publicly available milestones and deliverables of the corresponding thematic activities, the so-called Work Packages (WP) of the TEHDAS project, namely WP 5 (data sharing) and WP 8 (citizen perspectives). Each document related to WP5 and WP8 was meticulously reviewed.

For WP5, we concentrated on identifying and understanding the barriers to health data sharing and use, especially those of legal nature. For WP8, our focus was on the findings related to better understanding of citizens' attitudes towards sharing their health data and the role of data altruism in data sharing within the context of EHDS.

Concurrently, we conducted a thorough analysis of the relevant provisions of the draft regulation on EHDS and a review of relevant academic literature, focusing on provisions that relate directly to the challenges and themes identified in WP5 and WP8.

The information from WP5 and WP8 results, along with EHDS regulations and related literature, formed the basis of our analysis offering insights into the challenges of the currently evolving framework of health data utilization and sharing in the European Union, including implications for policy, practice, and future research. Our analysis also critically evaluates the approaches, results, and recommendations of the TEHDAS project, focusing on the issues and challenges arising from the implementation of EHDS regulations.

RESULTS AND DISCUSSION

The EHDS and, for that matter, any of the WPs in the TEHDAS project cannot be evaluated as a standalone effort to regulate the secondary use of data. In fact, there is a systematic legislative strategy within the EU framed by the digital transition in general [2,15]. The first and most important EU regulation is arguably the GDPR in this realm, which has been the primary building block in ensuring a legally controlled environment for the re-use of data since 2016. However, the goal of GDPR is to use personal data in general, hence its name. Therefore, even if the main requirements are established, its legal instruments are not focused on health data. Furthermore, big data, data processing with advanced ICT solutions (e.g. AI-based algorithms) and data sharing were accelerated during the end of the 2010s, also fuelled by the COVID-19 pandemic. This latter can be reasonably considered a booster of the use of so-called data-driven digital solutions and its regulations, which brought up issues regarding both primary and secondary use of digital (electronic) health data.

One main legal challenge is determining what rules to follow in a certain case. As the explanatory memorandum of the EHDS proposal also emphasises, this new, sector-specific regulation shall be applied in accordance with the other related EU laws. Thus, EHDS 'builds upon' related regulations such as the GDPR, the Data Governance Act [16], the Data Act [17], the Medical Device Regulation (MDR) [18] or the proposed AI Act [19]. Accordingly, the EHDS declared to set a more specific goal with a focus on specific personal, sensitive health data (vs general rules for personal data in GDPR) and on data sharing and processing of a specific domain (vs the horizontal approach of the Data Governance Act and the Data Act) and on electronic health record systems, i.e. EHRs (to find a regulatory gap considering the scope and subject matter of the MDR and the proposed AI Act) [3,20]. This brief summary may already show how a highly complex legal system has evolved within the EU in the last 5-6 years, in which national jurisdictions are also supposed to find their legislative role and position. Notably, despite the harmonisation enabled by EU-level regulations, this area is a matter of complex competence distribution. Member States have the right not only to adopt derogations ensured in EU regulations, but also to establish other rules according to their national legal and health systems (see assessment of legal grounds below). The legal complexity evokes many questions to be addressed concerning implementation, which should be solved partially by the legislator, but partially also by other actors in the field, e.g. the EU and national institutions and organisations. EU-funded projects, like TEHDAS, have also been launched to contribute to this effort. As elaborated above, the aim of TEHDAS was to support the European Commission in the establishment of the regulatory framework, and as a further step forward, the main task of TEHDAS 2 is to make the EHDS operational by proposing implementation guidelines and tools for Health Data Access Bodies, data holders and data users concerning many issues, including legal, semantic, technical and organisational aspects.

Legislative barriers to the secondary use of health data

Barriers were identified – as mentioned above – by WP5 of TEHDAS, when examining how to facilitate cross-border sharing of data, among which seven were of legal nature (Table 1).

Out of the barriers that were elaborated on, for the sake of this discussion, the following topics are relevant: lack of common definition of secondary use of data; already existing and not harmonised national rules for secondary data usage, including derogations allowed by the GDPR or other EU

Barrier description	Theme
There are differences in governance and health data systems in Europe.	Infrastructure Legal
There is no common European interpretation of what constitutes 'sufficient anonymisation' to transform personal data to non-personal data.	Legal
There is no common European interpretation of what constitutes 'pseudonymisation'.	Legal
There is no common European interpretation of what is, and what is not, 'secondary use' of data.	Legal
European countries have national legislation/rules concerning health and research data in addition to the GDPR.	Legal
European countries have the ability to set their own derogations under the GDPR. This lack of harmonisation may create additional barriers.	Legal
European countries have different preferences as to the choice of legal basis for processing under the GDPR. This impedes the cross-border collaboration and data sharing.	Legal
Health data is considered sensitive data, meaning for example special category data under GDPR, and is treated differently from other types of data when it comes to health data ethics, management and use.	Data
No standardised data sharing agreements exist for products developed by private sector providers using public sector health data to (a) facilitate safe data sharing and (b) protect taxpayers' investment.	Trust and Transparency
Across Europe, different taxonomy and ontology codes are used to label the same health condition, making comparisons between data sets a challenge.	Data
Poor data management procedures reduce the ability to reuse data.	Data

Table 1.
Final list of barriers as selected by participating TEHDAS countries (source: [11])

regulations; and national rules for health data, as a special data category under the GDPR. These are eminent examples of the recent legal challenges. The recommendations of the TEHDAS project can be summarised as the need for more harmonised rules throughout the EU, since, without that, the desired (cross-border) electronic health data sharing, which should not only boost the internal market, but also empower the citizens over their data, will not be possible [11].

An initial issue to consider regarding the evaluation of the EHDS is the discrepancy of the terminology. The GDPR [see Articles 5(1)(b) and 6(4)] does not mention the term 'secondary use of data', and one can rightly wonder about the exact meaning of 're-use' or 'further processing' within the EHDS framework other than use, i.e. processing data for purpose(s) that are different from the original purpose of the data collection (e.g. research). Nonetheless, EHDS builds upon the phrase of 'secondary use of data' in its context. To make a proper distinction and clarification of overlaps in terminology are relevant, since introducing a new legal term without a different meaning is controversial or at least disturbing for any jurists. Historically, the root of this issue might be that the development of data processing has been more technology-driven during the last decade, and tech experts or experts in fields other than law do not pay special attention to the requirements of adequately using legal terms. Moreover, one may find an agreeably fine dichotomy in the pair of primary and secondary use of data. Overall, from a legal point of view, the claims of the TEHDAS project on the need for a common interpretation of these terms in a legal context are valid. Nonetheless, this 'doubled' terminology can have its reasonable legal function. Namely, it emphasises that under the EDHS – and other horizontal regulations, such as the Data Governance Act – the focus is data usage per se and not personal data as in the GDPR. Thus, when defining the primary and secondary use of data, the emphasis is put on the purpose, while the data can or cannot be personal or depersonalised by any means. EHDS clarifies this concerning health data, and the proposal defines the primary and secondary use of health data [5]. Although these definitions do not seem to solve the evoked challenges regarding the overlap in meaning of terminologies of the GDPR and the EHDS; with the detailed legal terms, the European jurisdiction will have a means for reasoning in legal processes. This means, the legal issue may be deemed to be addressed 'only' in a legal manner, since the interconnection between the EHDS and the GDPR and the other mentioned regulations still needs to be found case by case. Thus, there is no clearcut solution, neither for the legal community, nor for the public.

As the TEHDAS WP5 identified, it is also a challenge to have common data-sharing within the EU since there are

quite a few national rules, either based on derogations referred to the special categorisation established by the GDPR [Article 9(4)] for personal health data or just because Member States have already regulated many aspects of the primary and secondary use of health data in general [11]. The main recommendation of the TEHDAS project is that 'legal interoperability' is needed, i.e., Member States should consider compatibility with the laws of other Member States before adopting or amending their national legislation. As the project report emphasises, this concept requires the willingness to adjust national laws to each other, especially in terms of appropriate safeguards [21]. Indeed, "establishing a common mechanism to access electronic health data for secondary use", as stipulated in Recital (37) [5], will be a significant challenge for EHDS. According to the EHDS, the Member States shall or may have different national regulations in relevant topics, such as the mentioned safeguards to enable appropriate protection for natural persons. This can be a significant burden in terms of EU-wide harmonisation and the building of an interoperable system of data usage. Both are important building blocks for data portability, service provision and scientific research. Notably, the legislators also realised this issue regarding the EHDS, as they put effort into finding a balance between the two main objectives: empower natural persons concerning control over their health data and foster the internal market regarding, e.g. data-based research, innovation and policy-making concerning health care. To accomplish these, the EHDS claims to initiate in its Recital (67) [5] more robust and mandatory EU-level harmonised rules without crossing the legally enabled frames of regulatory competencies. This latter, i.e. finding the proper boundary between the EU-level and national-level regulation, can be one of the bottlenecks of the whole idea of the EHDS. The Treaty on the Functioning of the European Union (TFEU), under Article 168 [22], regulates the division of competencies related to health care in a way, where the EU, as a main rule, has a complementary regulatory responsibility to national rules and policies set by the Member States. Interestingly, however, the EHDS proposal, as the legal basis, invokes merely strengthening individuals' right to data protection (TFEU Article 16) and improving the internal market (TFEU Article 114), and Article 168 is only mentioned in the Explanatory Memorandum as to be respected [3]. This hardly can be deemed a coherent domain-specific choice, which could serve well the declared aims of the EHDS [23]. It is, however, considerable that the negotiations between the Council and the European Parliament resulted in an emphasis on national competencies (e.g. allowing patients to opt out of the new data-sharing system) [24], which can be understood as an implied strengthening of the regulatory role of Member States, in the spirit of Article 168.

Although the EU-level rules leave room for interpretation, it can be claimed with high certainty that the EU has a limited, i.e. mainly internal market-focused, regulatory competence concerning health care. This means that Member States can and do have different rules for health care-related domains, including data sharing [25], adjusted to their institutional and legal systems. In short, if there is a legal possibility and/or duty to have derogations and national-level rules on their own rights, then there will be such laws, and these laws can help, but can also hinder EU-level harmonisation efforts. Again, the conundrum arises, where the Member States should have different regulations based on underlying differences in their legal systems. From a broader perspective, the EHDS, concerning health care, might challenge the current legal paradigm of competence distribution among the EU and the Member States as part of the ongoing EU-level strategic legislative efforts relating to digital transition, including data usage. An open question is what should be the solution to be supported by the EU and national actors. More harmonisation is a curse or a blessing? Who will be the winner and the loser of these regulatory choices? As always, the devil lies in the details, and there is a long way to go to find the answers concerning this new order, which could be identified as an interconnected EU-wide legal ecosystem.

Citizens' empowerment concerning control over their health data and data altruism

Another focus area of TEHDAS – examined in WP8 – was about the citizens' perception of sharing health data for secondary use [12], and the so-called data altruism [13]. This aspect is important as it involves assessing the views of individuals (data subjects/natural persons) regarding the secondary use of their health data. As it turned out, according to studies and consultations made by the experts of WP8, citizens have a strong relationship towards the use of their data, and "they feel that a piece of them, their identity and history, is being used" [12, p. 9]. However, for further consideration, limitations of data altruism as a form of data sharing have also been identified [12,13]. Nonetheless, the consultations showed that citizens want to take an active part in the processes regulated by EHDS and wish to have a balanced legal framework and a safe infrastructural environment to be able to be real actors and not only the object of others' data processing activity (Figure 1).

Out of the number of recommendations the TEHDAS study provided, the one that people want to be well-informed and gain autonomy and control over their health data seems to be straightforward. In line with this, according to the consultations conducted in Task 8.2 of WP8 [13], citizens "expressed a strong sense of altruism, which included a fair and equitable benefit for all, regardless of the choices of others" [13, p. 29]. This implies that citizens are aware of the economic value of their data and want to use it for the common good, which can involve an implicit tension between the interests of the individuals' rights and benefits at a community level. It is a legitimate question to be addressed whether individuals' health-specific data, i.e. EHRs, are parts of the 'common good' or whether they have full authority to decide on using their data for any primary or secondary purposes [23].

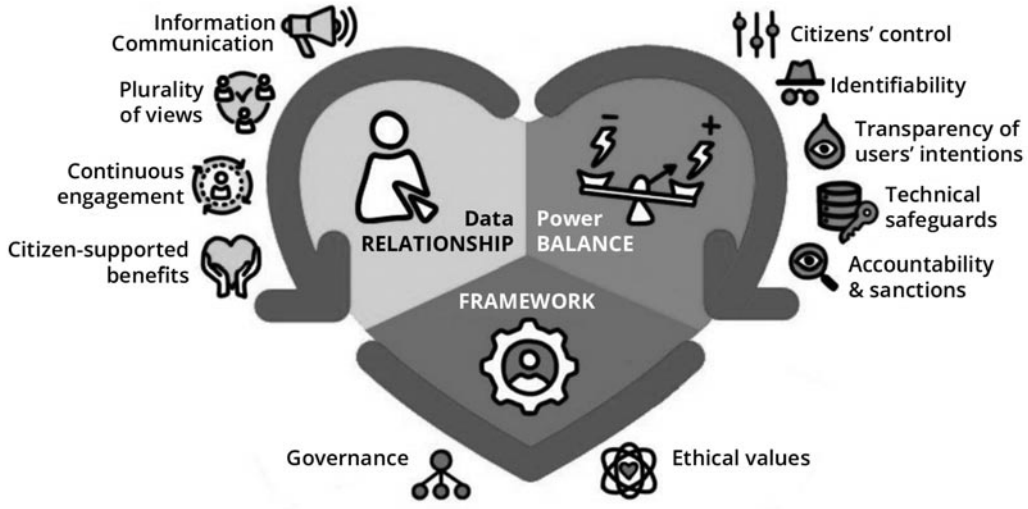

Figure 1.
Recommendations for a citizen-powered framework for the European Health Data Space (source: [12])

As mentioned above, citizens' empowerment is a crucial declared aim of the EHDS. Thus, several provisions aim to strengthen the rights and position of natural persons, e.g., the right to portability [26]. Consent, established by the GDPR, is presumably the most potent means to achieve this on the one hand, but it can also be a considerable burden on the other [27]. For the sake of this discussion, the usually cited argument of how data-protection laws are hindering innovation [28] (including scientific research and substantiated policy-making) will be put aside. Nonetheless, the right to opt-out, e.g. by restricting or objecting to access, can also reduce the potential health care-related benefits for the individual and the whole community. In short, if the individual shares less data, they have less chance to enjoy the positive effects of more precise diagnosis and therapy based on more data. In turn, more opt-outs result in less effectiveness regarding data-driven health care solutions for societies. Nonetheless, there is no place for altruism, if the rules do not ensure individuals' autonomy. Overall, a concert of requirements should be fulfilled for meaningful citizens' participation, engagement, and practice of data altruism [29]. This evokes, again, the legal issues of the complex regulatory approach.

Consent and data altruism are part of the EHDS only via references to other regulations, i.e. it orders to apply the rules of the GDPR and the Data Governance Act. Figure 2 illustrates well the interplay of the three regulations: from a data subject's consent (GDPR) throughout the data processing of a data altruism organisation (Data Governance Act) to the data sharing between a data access body and a data applicant (EHDS).

This is an intriguing lifecycle of health data that should be transparent, secure and well-organised. Thus, proper regulations needs to be established in order to make possible achieving altruism-related goals. In this realm, natural

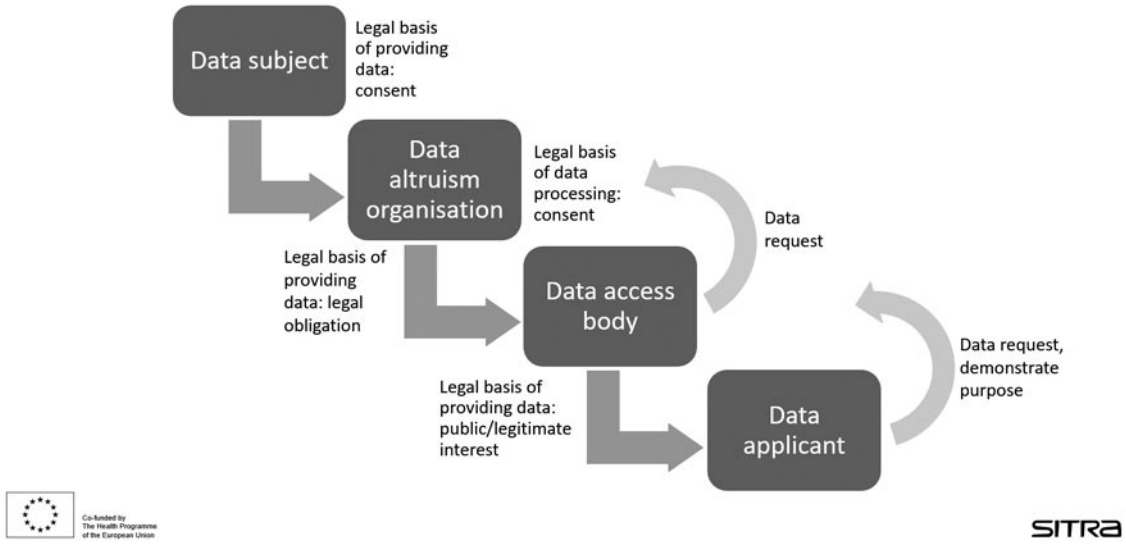

Figure 2.
The interplay between the DGA and the EHDS (source: [13])

persons' right to data portability, i.e. transferring their data from one data holder to another, can be an important means to support data altruism [26]. However, as the TEHDAS report also pointed out, there can be issues in the implementation, e.g. conflict of values and interest, especially between for-profit commercial interests and individual and societal benefits [13]. The power imbalance between actors in the field, indeed, should not be overlooked [30]. There is an ongoing development of data-related services, where the private sector, especially the so-called Big Tech companies, are already challenging the traditional risk-pooling-based public financing schemes. Thus, the questions at stake are whether there is a balanced solution and whether the EHDS-conveyed legal framework will help to find or stifle this.

Limitations

All the legal issues discussed should be assessed in light of the fact the EHDS has not been adopted yet [31]. Furthermore, many other rules are under preparation, e.g., the so-called Rulebook of the Data Governance Act regarding data altruism, which will be relevant for implementing the EHDS. Based on the ongoing legislative procedure between the Council and the European Parliament, there may be relevant changes in the final text, which might address some of the dilemmas evaluated in this article. Overall, EU-funded projects such as TEHDAS can have multifold contributions to the legislation. These projects provide a platform for the Member States to have intense and focused communication and information exchange. Moreover, they provide a framework to elaborate and develop practical details for the implementation and future interpretation of EHDS based on common and coordinated efforts of the Member States. Indirectly, this latter may significantly impact national legislation, which might foster the adoption of more 'compatibility-aware' rules. Overall, the obligatory review and progress report explicitly built into the EHDS (Article 70) opens up a further opportunity for EU projects, namely, even if the recommendations, already available lessons and results of the projects cannot be integrated into the current text of EHDS, those can contribute, at least as starting points to the follow-up regulatory processes.

CONCLUSIONS

The availability of routinely generated health data for secondary use has become a critical success factor of social and technological innovation in health care, but access to these personal data cannot be granted to third parties without safeguarding the patients right to privacy. The cooperation of countries at the European level can have an important added value to the individual country level efforts to unlock the innovation potential of health data, but the European legislation is a complex decision making process, especially in cases involving highly sensitive issues, such as the fundamental right to privacy. In any case, the EHDS is arguably a major regulatory effort to harmonise the use of health data and the protection of the privacy of citizens, and the TEHDAS and TEHDAS 2 projects are valuable tools in supporting the legislative projects of EHDS, by the identification and analysis of key issues, such as the legislative barriers to secondary data use, the empowerment of citizens to have control over their health data, and data altruism, as well as by the elaboration of recommendations on how to solve the identified dilemmas and remove obstacles. However, the success of these projects should not be assumed to be guaranteed; they merely offer opportunities. Ultimately, the practical value of project outputs hinges on the contributions of those involved. To make sense of the solutions offered, individual Member States should interpret the findings in the broader European and national legal context and implement the solution adapted to the local circumstances.

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K.D.&R.K: paper concept and design and drafting of the manuscript: P.G. Critical revision of the manuscript. All authors have read and agreed to the published version of the manuscript.

Competing interests

The authors declare that they have no competing interests.

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A SZERZŐK BEMUTATÁSA

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