MULTILEVEL HEALTH DATA MANAGEMENT IN EU, BETWEEN RESEARCH, HEALTH NATIONAL SYSTEM EFFECTIVENESS, AND DIGITAL PLATFORMS*

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SUMMARY: 1.- Introductory remarks about the integrated governance of health data in the European Union: the role of the European Health Data Space between innovation, privacy and subsidiarity; 2.- The vertical subsidiarity perspective: digital tools for the management of Italian health data; 3.- The horizontal subsidiarity perspective: contribution of Article 40 of Digital Services Act (DSA) and its delegated regulation in health data management; 4.- Conclusions.

1.- **Introductory remarks about the integrated governance of health data in the European Union: the role of the European Health Data Space between innovation, privacy, and subsidiarity.**

The need of coordinated and integrated governance framework for health data in the European Union has become increasingly urgent, particularly considering the establishment of the European Health Union[1] in response to the COVID-19 pandemic. In this context, the European Health Data Space (EHDS)[2] represents a significant step forward, aiming at improving individuals' access to their electronic health data and to optimise data secondary use for research and development purposes[3].

The EHDS has a dual objective. On the one hand, it aims to improve the common infrastructure for the cross-border health data, thereby promoting interoperability between Member States[4]. On the other hand, it introduces an innovative legal framework for the secondary use of such data to generate public benefits, support policy and regulatory decision[5], and stimulate the development of artificial intelligence systems applied to the health sector[6].

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[1] Regulation (EU) 2021/522 establishing a programme for the EU's action in the field of health (EU4Health programme) for the period 2021-2027.

[2] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive (EU) 2011/24 and Regulation (EU) 2024/2847 (EHDS).

[3] See Recital no. 1 EHDS.

[4] A goal that the European Union tried to achieve through art. 14 of Directive (EU) 2011/24 of European Parliament and of the Council of 9 March 2011 on the application of patient's rights in cross-border healthcare, but without the desired success.

[5] See Recital no. 53 EHDS.

[6] See Recital no. 61 EHDS on the interconnection with the provisions of Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending

Although the GDPR[7] is the main legal reference for data protection in the EU, it does not comprehensively address all aspects of electronic health data governance. In particular, it does not provide specific solutions for cross-border data sharing, secondary use of data for research purposes, and the processing of *post-mortem* data[8], and is limited to defining «biometric data means personal data resulting from specific technical processing relating to the physical, physiological or behavioural characteristics of a natural person, which allow or confirm the unique identification of that natural person such as facial images or dactyloscopic data»[9]. In this context, the EHDS introduces the definition of «personal electronic health data»[10] by including personal health data processed in electronic format[11].

The EHDS thus faces a double hurdle. From the perspective of vertical subsidiarity, the persistence of regulatory differences between Member States regarding data retention periods, access rights, standardisation criteria, and interoperability requirements for electronic health data collection tools has long prevented the creation of a single interoperable system, thus restricting the free movement of health data within the European Union. Therefore, the EHDS aims to harmonise the systems for collecting, exchanging, and processing health data in a cross-border perspective, and to establish a common technical and legal framework to ensure data accessibility and protection, privacy and security, but above all to promote their primary use[12]. In this context, the success of the EHDS will depend on the ability of Member States to align their national health data systems with European standards, a process that will require significant investment in digital infrastructure and the adoption of regulatory and governance frameworks in line with EU requirements[13].

The second critical profile concerns the secondary use of health data for scientific research, public policy, and regulatory decision-making. The strategic value of such data for medical innovation, the efficiency of health systems, and the strengthening of public health responses is undisputed[14], but must be appropriately balanced with guarantees of data protection and respect for ethical principles. In this context, and with a view to horizontal subsidiarity, the EHDS is an essential tool for creating a more interoperable European health data ecosystem and for defining a more stable legal framework for their secondary use. Responsible data management requires the involvement of a wide range of stakeholders, including public institutions, healthcare professionals, researchers, healthcare

Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) and Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13/06/2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act).

[7] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27/04/2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive (EC) 95/46 (GDPR).

[8] *Amplius infra.*

[9] See art. 4, n. 14 GDPR.

[10] See art. 2, §2, l. a) EHDS.

[11] It then defines non-personal health data as personal health data that has been properly anonymised so that it no longer relates to an identified or identifiable natural person.

[12] See Chapter II EHDS.

[13] It should be recalled that the European Union's competence in the field of health protection and improvement is to support, coordinate, and complement national policies.

[14] On this point see K.L. Sterling, *The European Health Data Space (EHDS): The Promise of Secondary Use of Data for Healthcare Innovation*, in *MedTech Europe* (2023); and A. Ruediger, J. Clark, *EU:EHDS – Access to health data for secondary use under the European Health Data Space*, in *DLA Piper's Global Privacy and Data Protection Resource* (2024).

companies and research institutes, as well as the adoption of advanced technological solutions such as blockchain, federated learning, and decentralised architectures. However, achieving these objectives requires close cooperation between the European and national levels, the harmonisation of regulations, the implementation of advanced technological solutions, and the economic actors active in the field of data management, as, for example, online platforms.

In this scenario, an important role could be played by Article 40 DSA[15]. Due to their transnational reach, online platforms have increasingly established themselves as "gatekeepers" of personal data, including health data. It is therefore crucial to understand how the EHDS can be integrated with the DSA and the delegated regulation[16], which foresees the possibility for authorised researchers to request access to data held by large online platforms of search engines to conduct studies on systemic risks in the EU[17]. Synergy between these regulatory instruments could promote safer and more responsible use of health data, while ensuring transparency and protection of fundamental rights[18].

However, significant regulatory fragmentation remains regarding health data, in particular *post-mortem* data. Although such data containing information of potential relevance for the development of treatment, cure and diagnoses, they remain in a state of legal uncertainly. Indeed, the GDPR states in Recital 27 that its provisions do not apply to personal data of deceased persons, providing a safeguard clause and leaving it to the Member States to adopt specific provisions on the matter.

In Italy, Article 2-*terdecies* of the Privacy Code[19] regulates access to the health data of a deceased person, allowing access only to persons who have an interest of their own, act in defence of the person concerned or assert family reasons worthy of protection. This provision assumes that access to the data of a deceased person does not undermine the protection of his or her privacy. Consequently, in the event of the death of a patient, the patient's representative or next of kin may request access to personal data and health records and exercise the rights inherent in the processing of the data would have accrued to the patient, provided that a family reason deserving of protection can be established. On the public side, on the other hand, a request for access to such data is not admissible because of the express prohibition on the disclosure of sensitive and health-related information[20].

However, regarding the use of health data for the purposes of scientific research in the medical, biomedical, and epidemiological fields, Article 110 Privacy Code states that the consent of data subject is not required if the processing is carried out based on specific national laws, regulations or

[15] Regulation (EU) 2022/2065 on a single market for digital services and amending Directive (EC) 2000/31 (Digital Services Ac).

[16] C(2025) 4340 final 1.7.2025, Commission Delegated Regulation (EU) …/... of 1.7.2025 supplementing Regulation (EU) 2022/2065 of the European Parliament and of the Council by laying down the technical conditions and procedures under which providers of very large online platforms and of very large online search engines are to share data with vetted researchers.

[17] On this point, for more details, see *amplius* S. Pugliese, A. Pietracupa, *EU Health Union in digital environment, between fight against fake medicines, shortage prevention, and data protection*, in *Corti supreme e salute* (2024) 429ff.

[18] The relationship between personal digital data and digital platforms, in particular search engines, has already been examined by the Court of Justice of the European Union in the judgment of 24/09/2019, Case C-136/17, *GC e a.* c. *Commission nationale de l'informatique et des libertés (CNIL)*, points 38ff. In this judgment, which predates both the DSA and EHDS, the Court jointly interpreted the GDPR and Directive 95/46, stating that search engines are obliged to assess de-referencing requests concerning link to webpages containing information relating to the personal data of the data subject.

[19] D.Lgs. 196 of 30/06/2003, which was last updated by D. L. 19 of 02/03/2024, subsequently converted with amendments by L. 56 of 29/04/2024, known as the Privacy Code.

[20] See Garante per la protezione dei dati personali, *Parere su istanza di accesso civico – n. 2* del 10/01/2019 [9084520].

EU law. This provision makes it possible to overcome the limitations resulting from the absence of explicit consent and guarantees the use of health data for purposes of collective interest, while respecting the principles of personal data protection. However, in cases where consent is required, the adoption of EHDS-compliant tools by the National Health Service could prove strategic in reconciling the need to protect privacy with the promotion of scientific research and innovation in health care, facilitating the collection of the necessary informed consent before death[21].

2.- **The vertical subsidiarity perspective: digital tools for the management of Italian health data.**
From the perspective of vertical subsidiarity, the Italian National Recovery and Resilience Plan (NRRP)[22] allocated a significant investment to the Italian health sector, even though the latter was not subject to a minimum allocation constraint at European level. Specifically, Mission 6 – Health received funding of 15,63 billion euros, 8,16% of the total amount of the plan, with the aim of implementing a structural reform of the National Health Services (SSN) to be completed by 2026[23].
One of the priority objectives of the NRRP is strengthening the management and use of health data, considered as a strategic lever for effective health planning and improved epidemiological surveillance. To this end, the plan provides for an investment of 1,67 billion euros to strengthen technological infrastructures and develop advanced tools for collecting, processing, and analysing health data.
In particular, the NRRP foresees the consolidation of the "Nuovo Sistema Informativo Sanitario" (NSIS)[24] to improve monitoring and predictive analysis capabilities. This measure will make it possible to develop advanced epidemiological scenarios and improve the planning capacity of health services, thus enabling new health emergencies to be identified more quickly.
A key element of this transformation is the "Fascicolo Sanitario Elettronico" (FSE), for which the NRRP has allocated 1,38 billion euros to promote its expansion, standardisation, and accessibility throughout the country, guaranteeing citizens and health professionals single, integrated system for managing clinical information.
Introduced into the Italian legal system by D. L. n. 179/20012, converted with amendments by law no. 221/2012, the FSE represents a significant advance in the digitalisation of health documentation[25].
In the doctrine, this tool has been defined as a computer system intended for the collection, storage, and management of personal data of an administrative, social and health nature, with the aim of providing a complete and dynamic representation of the state of health of an individual. This tool is

[21] *Amplius infra.*
[22] Italy's NRRP (Italia Domani) was approved on 13/07/2021 with the Council Implementing Decision on the approval of the assessment of recovery and resilience plan for Italy, in accordance with the Regulation (EU) 2021/241 of the European Parliament and of the Council of 12/02/2021 establishing the Recovery and Resilience Facility, art. 7.
[23] To this amount must be added the resources allocated through the National Plan for Complementary Investments (PNC), which earmarked an additional 2,89 billion euros for the health sector. To pursue the objectives, set out in the NRRP, Italy adopted the PNC by D. L. 59 of 6/05/2021, converted with amendments by L. 101 of 2021. The resources and programmes provided for by the PNC were specified in the Ministerial Decree of the Ministry of the Economy and Finance of 15/07/2021.
[24] Established by art. 87 L. 388 of 2000, it is the reference tool for monitoring the quality, efficiency and appropriateness of the SSN, with the aim of collecting and managing data, rules, and methodologies at national and regional level.
[25] The art. 12, co. 1, of D. L. 179 of 2012, as amended by D.Lgs. 34 of 2020 define the FSE like a digital repository that systematically collects health and social care data and documents related to each patient, generated in the context of past end current clinical events, including services provided outside the SSN.

therefore configured as an innovative way of organising and using the patient's health information, allowing the centralisation of data in a single digital archive, thus facilitating not only the continuity of care and the efficiency of healthcare processes (primary use), but also ensuring timely and structured access to information by authorised parties, in compliance with current regulations on the protection of personal data (secondary use)[26].

The impact of the NRRP on the FSE has been particularly significant, leading to a structural transformation of the system with the introduction of FSE 2.0[27]; the evolution of the system has involved the implementation of innovative functionalities aimed at improving the accessibility, efficiency, and integration of digital health services[28].

Although the system being already operational in several Italian Regions, the primary objective remains to ensure its uniform implementation throughout the country by 2026, in accordance with the provisions of the NRRP. At the same time, it is essential to establish the FSE as a strategic infrastructure for the future of the Italian healthcare system. This means not only facilitating faster, more efficient, and secure access to digital health services, but also laying the groundwork for its integration with European initiatives, including the EHDS[29].

To date, the new architecture of the Italian digital health system rests on two main pillars. Firstly, it is based on the FSE 2.0 as a central archive, it serves as the Italian core of "MyHealth@EU" portal[30], facilitating cross-border healthcare. Secondly, FSE 2.0 will be a cornerstone of the "Ecosistema dei Dati Sanitari" (EDS)[31] and the "HealthData@EU" platform[32], ensuring effective and secure use of health data for research and policy-making purposes.

However, there are still many unresolved issues: in a context where digital (health) data are becoming increasingly important, especially about their secondary use.

In this scenario, Italy stands out for a still backward approach, as it has allowed citizens to oppose the retroactive collection of health data. Indeed, to facilitate the feeding of the FSE, Article 11 of D. L. n.

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[26] On this point, for more details, see *amplius* S. Corso, *Sanità digitale e riservatezza. Interpretazioni sul Fascicolo Sanitario Elettronico*, in S. Corso, A. Thiene (curr.), *La protezione dei dati sanitari Privacy e innovazione tecnologica tra salute pubblica e diritto alla riservatezza*, Atti del convegno di Rovigo del 4/11/2022, Napoli 2023, 91ff.

[27] Formalised by the Decreto del Ministero della Salute of 7/11/2023, published in the Gazzetta Ufficiale Serie Generale of 24/10/2023, in implementation of the provisions of paragraph 7 of art. 12 of D. L. 179 of 2012.

[28] The main innovations introduced are: telematic management of health card payments; automated booking of specialist visits and diagnostic tests; the possibility of choosing or changing general practitioners via digital platforms; and direct access to digital medical reports, including diagnostic tests and images.

[29] Other Member States are also developing their own Electronic Health Record Systems, including France with "Mon espace santé", Spain with "Historia Clínica Digital del Sistema Nacional de Salud" and Germany with the ePA – Die elektronische Patientenakte".

[30] MyHealth@EU is the European Union's digital infrastructure designed to give citizens of the Member States secure, controlled and interoperable access to their health information. It facilitates the cross-border exchange of health data, while respecting the principles of personal data protection and cybersecurity and contributes to improving the continuity of medical care in the European Health Data Area.

[31] The "Ecosistema dei Dati Sanitari" (EDS), established by the Ministerial Decree of the Ministry of Health of 31/12/2024, is configured as an interoperability infrastructure designed to interact with other digital health tools, including the FSE 2.0, the "Sistema Tessera Sanitaria" (Sistema TS) and the "Anagrafe Nazionale Assistiti" (ANA). Through the centralised collection of health data, the EDS aims to optimise health information management process and contribute to improving the efficiency and quality of healthcare at national level.

[32] The HealthData@EU platform is a digital infrastructure developed by the European Commission to ensure compliance with the EHDS. The platform serves as a repository for the Data Set Catalogue, which aggregates metadata from Member States, European institutions, third countries and research infrastructures, facilitating the secure and standardised exchange of health data across jurisdictions.

34/2020 had established that, from the publication of the decree, the uploading of data to the FSE would be automatic, thus eliminating the explicit consent previously required.
However, for health data and documents created before 19 May 2020, patients had the opportunity to exercise their right to object through the online service "FSE – Opposition to the past"[33]. In this perspective, it is significant to point out that the use of the FSE, both before and after the pandemic, did not show encouraging data[34].
The Italian reality and, consequently, the Italian SSN still seems to diverge from the direction taken at the European level, which almost represents another missed opportunity, especially in view of the fragmentary legislation on the secondary use of *post-mortem* health data. In this scenario, the FSE could be transformed into a regulatory and technical instrument to collet informed consent for secondary use of (anonymised) personal health data during life, even after death, proposing a model like that adopted for organ donation.

3.- **The horizontal subsidiarity perspective: contribution of Article 40 of Digital Services Act (DSA) and its delegated regulation in health data management.**

In a vision of horizontal subsidiarity, health data management is a responsibility not only charged on the Public Authorities but also on the private actors that operates with data. Among the actors more engaged in this activity, an important role is played by providers of intermediary services[35], and by the online platforms[36]. Indeed, both marketplaces, social networks and research engines manage several data concerning the health status of their users, as, for example, eating habits, well-being, side effects of drugs or medical devices, and treatment effectiveness. All these data could be useful to develop new products and services and for the planning of sanitary public policies[37]. Their sharing and management are disciplined by several EU acts, between which the afore-mentioned DSA is acquiring a prominent role. As is well-known, the DSA is devoted to assuring the online platform transparency and liability and, with this aim, it establishes rules that are appliable to all the intermediary service providers and specific rules for the very large platforms and service engines

[33] Available from 18 Nov. to 17 Dec. 2024.
[34] According to the latest analysis available at the time of writing, covering the period Jun.-Aug. 2024, the average percentage of citizens who had used the FSE was 18% nationally. In addition, only 41% of users had given consent for their clinical records to be accessed by doctors and SSN professionals in line with the purposes set out in the Ministerial Order of 7/09/2023. Data updated to 31/08/2024 and published on the Department of Health and Department for Digital Transformation website under the section "Use of the electronic health record", available online at https://monitopen.fse.salute.gov.it/usage#citizens.
[35] The definition of intermediary services has been firstly given by the Directive (EC) 2000/31 of the European Parliament and of the Council of 8/06/2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market ('Directive on electronic commerce'), Arts 12-14.
[36] According to art. 2, l. i), DSA, «online platform means a hosting service that, at the request of a recipient of the service, stores and disseminates information to the public, unless that activity is a minor and purely ancillary feature of another service or a minor functionality of the principal service and, for objective and technical reasons, cannot be used without that other service, and the integration of the feature or functionality into the other service is not a means to circumvent the applicability of this Regulation».
[37] J. Greser, *Access to health data for scientific research. Remarks in the light of Art. 40 DSA*, in *Prawo Mediów Elektronicznych. Kwartalnik Naukowy* (2024) 34ff.; A. Värri, *The impact of EU Digital Services Act and Digital Markets Act on health information systems*, in *Finnish Journal of eHealth and eWelfare* 15 (2023) 67ff.

(vlops/vloses)[38]. More specifically, the Article 40 DSA disciplines the general access to data in this kind of platforms and establishes specific rules for the researchers' access and sharing. As it concerns the first issue, vlops/vloses shall provide the Digital Services Coordinator (DSC) of establishment[39] or the Commission, at their reasoned request and within a reasonable period specified in that request, access to data that are necessary to monitor and assess compliance with this Regulation. As it concerns the second issue, upon a reasoned request from the national DSC, vlops/vloses shall, within a reasonable period, provide access to data to the so called "vetted researchers" for the sole purpose of conducting research that contributes to the detection, identification, and understanding of systemic risks in the Union[40] and to the assessment of the adequacy, efficiency, and impacts of the risk mitigation measures[41]. The Article 40, §5, DSA establishes a specific procedure to allow the vloses/vlops to request the national DSC to be exempted from giving access to the data[42]. The researchers admitted to access the data shall meet the criteria to be appointed as "vetted researchers"[43]. The appointment as "vetted researcher" is subordinated to an assessment by the national DSC[44]. As a part of the risk assessment and management method established for vlops/vloses by the DSA, Article 40 is powerful tool to contrast infringements of health data privacy as well as sanitary disinformation and misinformation[45]. In this perspective, il should be read in connection with the Article 36, which provides for a crisis response mechanism in the event of serious threats to public safety or health in the EU, and Article 48, which provides for the development of voluntary crisis protocols by the European Commission with the involvement of stakeholders.

According to Article 40, §13, the Commission shall adopt delegated acts supplementing this Regulation by laying down the technical conditions under which providers of vlops/vloses are to share data and the purposes for which the data may be used.

[38] According to art. 33, §1, DSA, «online platforms and online search engines which have a number of average monthly active recipients of the service in the Union equal to or higher than 45 million (…) are designated as very large online platforms or very large online search engines».

[39] According to the art. 49, §2, DSA, Member State must designate a competent authority as the Digital Service Coordinator (DSC), responsible for monitoring and enforcing the regulation, unless specific responsibilities are assigned to other authorities. The DSC ensures national coordination and contributes to the effective and consistent application of the Regulation across the EU.

[40] According to art. 34 DSA.

[41] According to art. 35 DSA.

[42] Access to data may be denied if the platform does not have the requested data or if granting access would compromise the security of the service or the protection of confidential information, in particular trade secrets. Requests for amendment must propose alternative means of providing access either to the data requested or to equivalent data sufficient for the purpose of the request. The DSC of establishment shall decide on the amendment request within 15 days and shall notify the vlop/vlose of its decision, any amendments and the revised deadline for compliance. Vlops/vloses shall facilitate access to data through designated interfaces, such as online databases or Application Programming Interfaces (APIs).

[43] The criteria are set out in art. 40, §8, DSA

[44] Researchers apply to DSC of their research organisation's Member State, which carries out an initial compliance assessment and forwards the application without delay to the DSC of establishment for a final decision. The DSC of establishment has the final say on the granting of "vetted researcher" status, considering the initial assessment. The granting DSC may revoke this status if an independent investigation or third-party report finds the researcher to be non-compliant, after giving the researcher an opportunity to respond. VLOPs/VLOSEs must provide timely access to data, including real-time data if public, to researchers who meet the requirements and use them exclusively for EU systemic risk studies (art. 34, §1, DSA).

[45] S. Wehrli and oth., *The role of the (in)accessibility of social media data for infodemic management: a public health perspective on the situation in the European Union in March 2024*, in *Frontiers in Public Health* 12 (2024) 1ff.

In April 2023 the European Commission opened a call for evidence to collect the stakeholders' opinions useful to elaborate the delegated regulation draft[46]. Some documents presented by researchers in medical sectors highlighted the importance that a proper Article 40 DSA implementation could have in terms of avoiding disinformation and manipulation in health data management[47].

Based on these results, in October 2024 the European Commission released a draft of delegated regulation[48] and submitted it to consultations. In the explanatory memorandum, the European Commission underlines that the impact of Article 40 DSA is twofold: from a hand, the researchers will benefit from access to previously undisclosed or under-disclosed data, opening new avenues for research, and increasing the potential of generating knowledge for the benefit of all. From another hand, these insights will contribute to regulators' work on their enforcement tasks. In this perspective, the Delegated Regulation Draft (DRD) establishes the creation of a "DSA data access portal"[49]; the procedures and specific technical conditions for the management of the data access process by DSC and data providers; the requirements for the formulation of the reasoned requests and the assessment of amendment requests[50]; the technical and specific conditions for the sharing of the data by the data providers.

From the consultations opened in December 2024, it appeared that the scientific community appreciated the Draft, but proposed some amendments, mainly as it concerns the timeliness and accuracy of data request answering; the DSC obligations, especially in the communication language; the vagueness of certain expressions, as "public data". The more important opinion concerns the absence of an independent mechanism whereby the principal researcher can request the reassessment of their data access request, or the amendment request submitted by the data provider. More in general it has been underlined the risk that domestic authorities be captured by governmental power, and the opportunity that, to protect researchers' academic freedom in pursuing legitimate platform research, the DSC discretionary power during the assessment of research projects should be limited[51]. More specifically, by medical scientists the necessity of standardized protocols for data access requests and

[46] Ref. Ares(2023)2911406 - 25/04/2023, Delegated Regulation on data access provided for in the Digital Services Act, available online. For results, P. Leerssen, *Call for evidence on the Delegated Regulation on data access provided for in the Digital Services Act Summary & analysis.*

[47] See, for example, the Panoptykon Foundation's paper on "Algorithms of Trauma", which analysed health-damaging advertising and the data needs for the future research. In 2021, it examined the Facebook newsfeed of a young mother who was exposed to distressing ads about cancer, genetic disorders and medical crowdfunding. Although she never knowingly shared health-related information, these ads triggered anxiety and past trauma. By replicating her behaviour, the Foundation analysed how Facebook's algorithms amplify anxiety-provoking ads, revealing their disproportionate reach and potential harm. It also highlighted the lack of effective user controls. Existing transparency tools, including those provided by the DSA, were deemed inadequate because they focus on the targeting of ads rather than their delivery. The Foundation called for greater transparency in ad delivery algorithms, particularly in auctions, relevance scoring, and budget allocation.

[48] Draft delegated regulation - Ares(2024)7652659, 29/10/2024.

[49] The Commission will set up the DSA Data Access Portal to streamline the management of data access for researchers, data providers and DSCs, acting as a single digital exchange point. Both researchers and data providers will have to register. The portal will include a public interface and restricted dashboards for applicants and vetted researchers.

[50] The DSC of establishment shall: (a) where appropriate, formulate a reasoned request, transmit it to the data provider and inform the principal researcher of its transmission; (b) or inform the principal researcher about the reasons why the reasoned request could not be formulated.

[51] Consortium of Researchers from University of Maastricht, University of Lausanne, University of St. Gallen, University of Oxford, on *the Draft Delegated Act for Article 40 of the Digital Services Act (DSA)* (2024).

of training and capacity building for DSC has been underlined, as well as the need of clear criteria for amendment requests and of assuring the independency of mediation panels. As it concerns the DSA data access portal, the necessity of a user-friendly design for the portal and interoperability with national systems has been emphasized[52]. This issue is important in the perspective of imagining a connection between the portal and national system in the ambit of EHDS[53]. Consequently, it should be desirable that the European Commission takes account these suggestion in the delegated regulation final version.

4.- **Conclusions.**

Considering that the development process of the EHDS has only just begun, it seems reasonable to believe that its adoption, together with a greater openness and availability of digital platforms to researchers in accordance with art. 40 DSA, can contribute to the creation of a system of free circulation of health data for their secondary use.

However, to effectively achieve this objective, it will be essential to ensure first and foremost the interoperability and standardisation of national digital infrastructures, which are essential elements to avoid fragmentation and inhomogeneity in data access. In this direction, Italy has already moved with the FSE 2.0, which, although representing a reference model, still shows criticalities related to social issues among citizens, who sometimes remain doubtful in the discourse related to consent and its use. Therefore, only by striking a good balance between the protection of privacy and other fundamental rights, on the one hand, and access to data or research and innovation purposes, on the other, it will be possible to fully exploit the potential of these tools, while ensuring compliance with the European legal framework.

Another crucial aspect is the coordination between the authorities in charge of managing and supervising the digital ecosystem. In particular, the DSC and the Health Data Access Bodies[54] will play a crucial role in regulating access to data for secondary use, ensuring that they are processed only for purposes specifically provided for in the Regulation and subject to authorisation by the competent bodies.

At present, however, the relationship between these two bodies appears to be unclear. Therefore, intervention by the EU institutions will be necessary to clarify their coordination and respective competences, including through the speed application of a delegated regulation based on Article 40 DSA. Only in this way will it possible to ensure a clear and effective governance model capable of promoting harmonised standardisation of health data at European level, with particular attention to research and secondary use.

Abstract.- La pandemia da COVID-19 ha evidenziato l'urgenza di un quadro unitario di "governance" dei dati sanitari, culminato nel Regolamento sullo Spazio europeo dei dati sanitari (EHDS). Lo studio adotta un duplice approccio: sul piano della sussidiarietà verticale, analizza la necessità di riformare e digitalizzare i sistemi nazionali per garantirne l'interconnessione con

[52] RareGen Youth Network (US), *Delegated Regulation on data access provided for in the Digital Services Act* (2024).

[53] For similarities, see S. Stalla-Bourdillon, *Three key points on the Delegated Act: How to preserve researcher autonomy under Article 40 DSA?*, in *DSA Observatory* (2024).

[54] The Health Data Access Bodies (HDABs-CoP) were established in Jan. 2024 to prepare for the legal requirements for the secondary use of health data within the HDS. It aims to align practices while optimising resource efficiency.

l'EHDS; nella prospettiva della sussidiarietà orizzontale, esamina la responsabilizzazione delle piattaforme digitali attraverso l'art. 40 DSA e il relativo Regolamento delegato sull'accesso dei ricercatori ai dati. Si conclude che interoperabilità, standardizzazione e coordinamento pubblico-privato costituiscono condizioni imprescindibili per un'efficace "governance" multilivello dei dati sanitari.

The urgent need for a unified framework of health data governance was highlighted by the impact o the COVID-19 pandemic, culminating in the Regulation on the European Health Data Space (EHDS). Adopting a twofold approach, from the perspective of vertical subsidiarity, this paper first examines the necessity of reforming and digitalising national health systems to ensure effective interconnection within the EHDS. From the perspective of horizontal subsidiarity, it analyses the responsibility attributed to the digital platforms by Article 40 DSA and the related Delegated Regulation on researchers' access to platform data. It concludes that interoperability, standardisation and coordinated action between public authorities and private operators are indispensable for effective multilevel governance of health data.