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"The power of health data: benefits and challenges for the European Health Data Space in Italy"

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Background

In 2021, **EIT Health** published a report, "Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS" (chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://eithealth.eu/wp-content/uploads/2021/11/EHDS_report.pdf). This aimed to serve as supplementary insight, aimed at decision-makers at the European Commission involved in the development of the legislative framework for the European Health Data Space (EHDS). This report produced an overview of challenges in roles, regulations, policies and practices.

Since that time, there has been a substantial publication of positions, thoughts, considerations and opinions from other organisations and individuals on the EHDS. **As we approach the finalisation of the process of legislating the EHDS, expected mid-2024, it is a useful exercise to reflect upon the more practical aspects of the implementation of the EHDS within the existing national healthcare system infrastructure**. How is each Member State preparing for this outcome? What steps must be taken to ensure meaningful and valuable integration of the EHDS into existing systems and processes? What is the level of readiness of Member States to implement the EHDS? What actions must be taken, and who is in charge of them? How feasible is the implementation of the EHDS given the existing status of individual national healthcare systems to incorporate and deploy it?

To answer these questions, it was decided to dedicate the **EIT Health Roundtable Series 2023** to **'Implementation of European Health Data Space across Member States: is it really feasible?'**. In the specific case of Italy, EIT Health InnoStars and Italian partners promoted a round table entitled **'The power of health data: benefits and challenges for the European Health Data Space in Italy'**, held in Bologna on 18 May 2023, in a hybrid format. The roundtable was attended by various experts from a multidisciplinary point of view who mainly discussed the problems and prospects of **Governance**, without forgetting other dimensions such as **Capacity and Skills**, **Education, awareness and communication**, as well as incidentally the **Quality of Data**.

The round table was opened by **Cecilia Maini**, Strategic Development in Life Sciences and Health area - ART-ER and by **Alessio Smeraldo**, Interim Ecosystem Lead for Italy – EIT Health InnoStars and coordinated by **Emanuele Perugini**, editorial director of Trenta Science communication Srl. The participants were: **Marco Aiello**, Medical Imaging Researcher – IRCCS Synlab SDN and Supervisory Board member – EIT Health InnoStars; **Lorenzo Chiari**, Professor of Bioengineering, Alma Mater Studiorum - University of Bologna and President of DARE Foundation - Digital Lifelong Prevention; **Matilde Ratti**, Senior researcher of private law and internet law, Alma Mater Studiorum - University of Bologna, DARE - Digital Lifelong Prevention; **Francesco Gabbrielli**, Director of the National Center for Telemedicine & New Healthcare Technologies, Italian National Institute of Health (Istituto Superiore di Sanità ISS).

The discussion started from the rapidly evolving panorama of the health data sector in Italy, both from a technical-scientific and a regulatory point of view. In fact, if on the one hand, thanks to the pandemic, the strengthening of digital technologies and artificial intelligence and greater availability of data, we find ourselves having a decisive push forward in the country for the secondary use of health data; on the other hand, the fragmentation of the European legal landscape, a non-widespread culture of the quality of data, as well as legitimate requests for the protection of the personal sphere are forcing us to review the balances previously achieved on the subject in view also of the implementation of the European Data Strategy (https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy_it).

Particularly, with regard to Governance, the reflection started from the regulatory data of the GDPR as applied in Italy and as interpreted by the Italian Agency for the Protection of Personal Data (Garante italiano per la Protezione dei Dati Personali). In Italy, although a (primary or further) treatment of health data can be lawfully carried out, according to Italian legislation, this treatment still requires the consent of the interested party, based on what is defined by the "Ethical rules for treatments for statistical or scientific research", compliance with which "constitutes an essential condition for the lawfulness and correctness of the processing of personal data" (https://www.cyberlaws.it/2018/articolo-2-quater-nuovo-codice-privacy-d-lgs-196-2003-agg-d-lgs-101-2018/).

In such situations, the Italian legislator, using the power conferred on the Member States by par. 4 of the art. 9 of the GDPR, **requires consent as a "further condition of lawfulness" for secondary data processing**. In order that this further condition does not constitute a brake on scientific and biomedical research, the legislator with articles 110 and 110-bis of the Code on personal data (https://www.brocardi.it/codice-della-privacy/parte-ii/titolo-vii/capo-iii/art110.html?utm_source=internal&utm_medium=link&utm_campaign=articolo&utm_content=nav_art_prec_top and https://www.brocardi.it/codice-della-privacy/parte-ii/titolo-vii/capo-iii/art110bis.html?utm_source=internal&utm_medium=link&utm_campaign=articolo&utm_content=nav_art_succ_top) has provided for a solution: in situations where the collection of consent involves a disproportionate effort, due to the particularly high number of interested parties and/or their unavailability, and once every reasonable effort has been made to contact them, , it is possible to make up for the absence of consent by consulting the Garante (subject to a favourable opinion of the competent Ethics Committee. In addition, this is applicable even when the request for consent risks of making the achievement of the research purposes impossible or seriously jeopardizing them. Instead, if the data are obtained from third parties experiencing the same difficulties as obtaining direct consent from the interested party, it is allowed to ask for Garante's authorization.

The question would therefore be resolved, except that, among the opinions expressed by the Garante, **there are some - not many, which concern requests pursuant to art. 110 - while there is none that, pursuant to 110-bis, authorizes further processing for purposes of scientific research by third parties.** (https://www.agendadigitale.eu/sicurezza/privacy/dati-sanitari-perche-sono-cruciali-per-la-ricerca-le-norme-vigenti-e-le-proposte-ue-per-usarli-meglio/)

Governance

Based on these premises, the question of **Governance was central** to all the interlocutors of the Round Table and occupied a large part of the discussion. All the participants recognized that the question of the secondary use of data for research purposes, both from a national and a European perspective, lies at the centre of the tension between two **often conflicting needs**: on the one hand, **the need to feed research** with more and more data and, on the other hand, the protection of **individual confidentiality**, as well as the protection of the individual's dominion over his own data, especially in a sensitive area such as the health sector.

It has been underlined that, in order to set up an adequate analysis of the problem, **a multidisciplinary gaze** is essential which takes into account the voices of healthcare operators, researchers, experts in the technical-legal sector and, last but not least, patients and their representatives with the aim to embrace all the complexity of the issue and to consider as many interests as possible, in search of the right balance.

A balance that cannot only refer to the implementation of the EHDS, but which **regards the GDPR upstream, its national variations and its interpretation by the competent authorities**.

The heart of the discussion was structured precisely on the GDPR, with opinions that were not always unanimous: if on the one hand, the majority of those attending the round table recognized its potential and value as a point of reference for the evolution of global data regulations, there were some interventions that have identified it as a real obstacle to research. However, everyone acknowledged that the **regulation presents critical issues that must be overcome**, starting with an adequate comparison up to the awareness of all the actors involved, first of all, the legislator.

In particular, the following focuses emerged:

1) The question of consent: the query about consent as still an appropriate instrument to respond to the need for personal protection has been generally raised. In fact, the need for a specific consent for every single secondary use of data poses a significant problem that relegates the Italian reality to a disadvantageous position, globally as well as in Europe;

2) The question of regulatory uniformity: taking into consideration the possibility that the GDPR leaves to the individual States of the Union to partially have particular regulations on the processing of data, the issue of being able to operate in **harmony** and to avoid that certain research projects have to deal with legal variations, both at a national level and at a European level, arises;

3) The role of the Garante: the difficulties that the interpretation of the function of the Garante as merely censorial leads to the use of data for research has been underlined from many sides. A revised role of the Garante was hoped for, which lead this authority to intervene not only to sanction the committed errors, but also and above all **to participate in the structuring phase of research projects** to direct them in the correct tracks from the point of view of the GDPR;

4) The question of the subjects identified by the GDPR: the categories of the GDPR to frame those who deal with data, risk to harness complex and dynamic realities in an obsolete manner, attributing responsibilities in a way that does not comply with the objectives of the GDPR itself;

5) The value of data: the legal qualification of health data and the clarification of the interests that underlie this qualification were another central theme. Taking into account the two extremes of data as a public good, i.e. beyond the availability of the individual, and the full monetization of data, it has been tried to understand how to give prominence to the value of the data from the point of view of the **common good**. The debate was around favouring their use for purposes of public interest, but leaving the individual the possibility of choosing, for example, to grant the use of their data pro bono and in what juridical form (for example by **licensing contracts**), up to providing forms of reward, not necessarily economic, for the patient which allows the secondary use of his data;

6) The type of data: the **uniformity of treatment of health data** has emerged as a further **unjustified obstacle** to research. In fact, if certain protections can be considered appreciable in relation to very sensitive data such as a genetic profile, the same cannot be said for other health data which also fall under the stricter rules of the GDPR.

In general, the participants have focused their discussion on the discrepancy between legislation, that is already affected by the wear and tear of time, and the faster times of research and the use of data in it that require a legal framework capable of evolving by adapting to ever-changing circumstances.

Education, awareness and communication

Both in the analysis of Governance and separately, the participants in the Round Table dwelt at length on the role of **data culture** in its various facets. Starting from the consideration that Italy finds itself inserted in a block, the European one, which has chosen a **median position on data management**, compared to the liberal approach of the USA and the statist one of China, it was analyzed how this middle address materialized in Italy. The widespread opinion is that the country still suffers from a **backward culture of data**, very reluctant to share them. A phenomenon aggravated by the rarity of moments of confrontation between operators of different sectors to seek operational solutions for better use of the data assets. In the concrete of research, this aspect intersects with that of **data quality**.

In fact, it emerged that, in the collection of primary data, also due to the lack of adequate training of professionals in the field, due attention is not paid to the construction of the data as well as for the immediate clinical purpose and for any research purposes too, imposing then a significant additional workload which could be considerably reduced. In this context, reference was made to the **DAVID (Data Value in Integrated Diagnostics) educational program** carried out by EIT Health and IRCCS Synlab SDN among others, aimed at creating "data friend" professionals capable of informing patients and encouraging them to share, aware of the principles of data analytics and of the correct procedures for data collection, also for research purposes. Education, training and updating that must also be aimed at members of **ethics committees** as per objective - among others - of the **DARE Digital Lifelong Prevention initiative** (https://it.linkedin.com/company/dare-foundation-digital-lifelong-prevention) funded under the NPRR and the related Foundation.

In any case, the work of education and awareness must be addressed not only to professionals, but also to the public and especially to **patients**, who must be able to perceive, as already mentioned, a return of their choice to share, even if only in terms of concrete and specific contribution to research. Also in this case, the DARE program is laying the foundations for an initiative in this sense aimed at allowing the individual patient to **trace the use that is made of his data** for the advancement of knowledge in the medical and biological fields.

Capacity and Skills

In view of the implementation of the EHDS, the approach that prevailed in the round table is the one that sees a broad comparison between actors with different experiences as the necessary prerequisite for an adequate decision-making process. Currently, the **players in the data sector need to connect more closely and to better inform the legislator in order to modify a national reality that is still fragmented and not fully ready** - in various aspects - for the arrival of the EHDS. Various experiences, both at the public, public-private and private level, present themselves as **advanced points of excellence** which could represent a model for a fuller transformation. We should consider, for example, the work of the **National Center for Telemedicine and New Assistance Technologies** of the Istituto Superiore di Sanità (ISS) (https://www.iss.it/centro-nazionale-per-la-telemedicina-e-le-nuove-tecnologie-assistenziali) which is working on a national platform for telemedicine which however encounters the difficulty of having to intervene in a context parceled out where the Italian Regions have created their own telemedicine platforms; the **Health Big Data (HBD) project**, financed by the Ministry of Economy and Finance and coordinated by the Ministry of Health, with a ten-year extension, whose objective is to create a technological platform for the management, collection, sharing and analysis of clinical and scientific data (the platform will have to guarantee connectivity between the IRCCS participating in the project, with other Italian and non-Italian research institutes, with the databases of the National Health Service and with international public databases) (https://www.alleanzacontroilcancro.it/en/progetti/health-big-

data/). Another relevant project is the **DARE** programme itself, a four-year initiative financed by the Ministry of University and Research as part of the National Plan Complementary to the NPRR. It involves a large community of partners and stakeholders, including universities, research centers, research hospitals, local health authorities, foundations, and private companies. The initiative aims to create and develop a community of knowledge, connected and distributed, which favours the emergence of models and solutions for surveillance, prevention, health promotion and health security, in the general population and in special populations , such as workers, minors, pregnant women and chronic patients, who best benefit from the potential offered by digital technologies, helping to bridge social and territorial disparities in the offer of integrated social and health services. Finally, it has been underlined the Italian participation in the **European Cancer Imaging Initiative (**https://digital-strategy.ec.europa.eu/en/policies/cancer-imaging), a European initiative that aims to promote innovation and the diffusion of digital technologies in the treatment and cure of cancer, to obtain a clinical, diagnostic, therapeutic and predictive decision-making process more accurate and rapid for cancer patients, and which stands as one of the first pillars of the future EHDS. All these initiatives need to be connected and strengthened also with an adequate regulatory structure in view of the creation of the European health data space.

Proposals

At the end of the round table, the proposals of the experts can be summarized with the following points:

1) **Strengthen the implementation of the knowledge triangle** at the level of discussion of the health data problem, involving experts and stakeholders from all the sectors concerned with particular regard for legal experts who are often not present in the moments of discussion;

2) **Strengthen the culture of data at national level**, both with regard to patients, with adequate forms of incentives and awareness campaigns aimed at increasing the propensity to share; both at the expert level, preparing them for a collection of data that can also be useful for secondary uses;

3) **Sensitize the national legislator**, the Garante and other competent authorities about the need for an update of the privacy legislation that takes into account the dynamic reality of data research and at the same time finds forms of protection of the personal sphere that do not necessarily pass through traditional means such as the request for consent for each individual research use;

4) Always with regard to Governance, **sensitize state and national authorities on the need for regulatory uniformity that data sharing requires**;

5) **Strengthen the initiatives already in place** aimed at collecting and sharing data, linking them more and more and at the same time preparing them for a European perspective where this dimension had not yet been adequately taken into consideration.