Position Paper

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Proposals for the European Health Data Space

The Guild
of European Research-Intensive Universities

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The Guild's proposals for improved access to health data for research purposes

Introduction

In February 2020, the European Commission presented the European Data Strategy.[1] Its ambition is to give a strong impetus to the emergence of a single market for data and data-driven society and economy in Europe. The strategy calls, to that end, for the creation of "common data spaces in strategic sectors and domains of public interest". The European Commission's proposal for a Digital Governance Act[2] published in November 2020 fleshes out this idea. The common data spaces aim to increase the availability of data for reuse by removing barriers to data exchange and encouraging data sharing notably on altruistic ground. Both the European Data Strategy and the proposal for a Digital Governance Act recognize the importance of dedicating one of these common data spaces to health data.

The European Commission's proposal for a European Health Data Space pursues three objectives: to facilitate (cross-border) sharing of health data either for improving health care (primary purpose) or for research and policy purposes (secondary purposes); to remove obstacles to the free movement of digital health services; and to support the development and deployment of artificial intelligence services. In its proposals for the Pharmaceutical Strategy for Europe,[3] The Guild has already acknowledged the idea of a European Health Data Space (EHDS) and recommends that this space should provide a "clear legal framework for enabling cross-border sharing of sensitive data, and the merging of data from multiple countries". The present paper further elaborates on this recommendation. First, it reminds us of the importance of access to health data for medical research. It then describes the main challenges that impede the reuse of health data for research purposes. Finally, it formulates recommendations for the European Health Data Space and other EU actions.

[1] "A European strategy for Data", COM(2020) 66 final.
[2] Proposal for a regulation on European data governance (Data Governance Act), COM(2020) 767 final.
[3] The Guild (2020) *Proposal for the Pharmaceutical Strategy for Europe*. The Guild of European Research-Intensive Universities and Bern Open Publishing. DOI: 10.7892/boris.146527

1. The importance of access to health data for research purposes

Access to health data is crucial for medical research. A large volume of data is more likely to provide compelling and robust evidence. The improvement of disease diagnostic techniques and treatments and of preventive and health promoting strategies also relies on the combination of diverse data. The cross-border exchange of data in the context of multi-national clinical trials ensures that conclusions are valid for different groups of people, and avoids any misleading focus on the idiosyncrasies of specific populations, e.g. in terms of genetics and of social and environmental determinants.[4] Researchers must be allowed also to tap into non-clinical and non-health data. The combination of diverse data is essential to enable researchers better to elucidate the determinants of health, and may therefore make a significant contribution to the development of more effective health diagnostics and treatment, to the reduction of health inequalities, and to shifting society towards prevention.

2. Challenges facing the (re)use of health data for research purposes

The General Data Protection Regulation (GDPR)[5] and the interpretation of some of its provisions impose limitations on the sharing and reuse of health data for research purposes.

The GDPR provides a regulatory framework for the protection of personal data. It prohibits the processing of sensitive data, whose misuse may affect individuals. Some exemptions to these rules were intended to avoid any stifling of research and innovation activities, especially in health. However, the European Parliamentary Research Service acknowledged that the (medical) research community still viewed the GDPR as a barrier to research in 2019.[6]

The Guild similarly notes that it is still unclear how and to what extent the exemptions for research in the GDPR apply to health research, as there has so far been little case law on this topic. For instance, since it is uncertain how cloud-based infrastructures such as the EHDS and cloud providers could ensure compliance with GDPR, the potential of the cloud for the storage and sharing of health data is not yet fully exploited. Moreover, the Member States do not share the same interpretation of the GDPR rules and their applications, hence there is high heterogeneity across EU and EEA Member States in their policies for reuse and sharing of data.[7] Because of these uncertainties and the lack of cross-border harmonization, research actors avoid sharing health data across borders and/or reusing health data for research purposes in order to ensure their compliance with GDPR rules.

Some provisions in the GDPR create obstacles to health research too. It is, for instance, widely understood that data subjects must give, in some instances, their explicit consent to the transfer of their personal data. As this consent must be given for specific research projects, it

[4] ALLEA, EASAC & FEAM (2021) *International Sharing of Personal Health Data for Research*. DOI: 10.26356/IHDT.

[5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

[6] European Parliamentary Research Service (2019) *How the General Data Protection Regulation changes the rule for scientific research*, Scientific Foresight Unit (STOA) of the European Parliament. DOI: 10.2861/17421

[7] European Commission (2021) *Assessment of the EU Member States' rules on health data in the light of GDPR*. Luxembourg: Publications Office of the European Union. DOI: 10.2818/546193

does not allow for the reuse of the data in other – even relevant – research projects. The Guild notes that the GDPR rules are interpreted as introducing the obligation to provide separate and specific consent for each data processing operation. This requirement, although understandable and desirable in many respects, is not practical to implement in many cases. The result is that data reuse is not allowed, not even for public health reasons or in presence of clear social benefits.

In contrast with pseudonymized data, anonymized data do not relate to identified or identifiable natural people and do not therefore need to comply with the GDPR data protection rules. However, health data such as genome sequences are impossible or very difficult to anonymize. The combination of health data also increases the possibility of tracing back to the individual subjects. Therefore, their anonymization is not a sensible solution for allowing the (cross-border) exchange of health data. It is also worth noting that anonymization reduces the value of data in the context of medical research, as it would imply removing some variables that could potentially offer useful insights.

3. Suggested actions

In light of the aforementioned challenges, The Guild recommends that the European Commission pay attention to the following points when shaping the EHDS:

- Clarify GDPR provisions, especially those introducing exemptions for the use and processing of personal data for the purpose of (medical) research. It is crucial that the European Commission reduces existing uncertainties about the interpretation of GDPR rules. For instance, the European Data Protection Board (EDPB)[8] has already highlighted that the GDPR does not define explicitly what "processing for the purpose of scientific research" entails. The Guild calls, in this respect, for a broad but clear definition encompassing scientific research, technological developments, fundamental research and privately funded research, so that exemptions to the GDPR rules "for scientific research" can apply to them. Overall, clarifications must aim at a harmonized interpretation of the GDPR and its provisions regarding the conditions to be met for the sharing and processing of personal health data at the EU level. It is also important that these clarifications reduce the administrative burdens on researchers and their universities induced by the obligation to demonstrate their compliance with GDPR.
- Adapt the degree of protection to the degree of sensitivity of the data. The concept of health data encompasses different types of data which, even though they are not all sensitive, are all covered by the same level of protection. The GDPR provides a broad definition of "data concerning health" as "personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status" (article 4(15)). In 2020, the EDPB[9] reminded us that data concerning certain aspects of health deserve a higher protection than other types of data, and that data combined with health data should be also considered health data and be equally protected. While acknowledging the need to

[8] European Data Protection Board (2020) *Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak*.

[9] *Ibid.*

protect the privacy of patients and, more broadly, any individual, The Guild contends that all health data – according to the definition above – are not equally sensitive. For instance, the processing of data such as blood pressure, heart rate or haemoglobin levels may not present the same level of threat to individuals as the processing of genetic data. Therefore, the European Commission should consider whether all health data deserve the same level of protection or whether the degree of protection must depend on the sensitivity of the data.

- Revise the rules relative to patients' consent to data processing and transfer.
    - The Guild welcomes the provisions in the European Commission's proposal for a Digital Governance Act introducing the concept of 'data altruism' and the European data altruism consent form (Article 22) for a higher harmonization across Member States. Data altruism must nevertheless have a larger scope and encompass also data transfer in order to facilitate multi-country clinical studies and cross-border data-driven medical research. If adopted, the concept of data altruism may nevertheless apply only to data collected after the entry in force of the Data Governance Act. The Guild is inviting the European Commission to find solutions, e.g. an amnesty, to allow the safe exploitation of data collected before that date.
    - The Guild encourages the European Commission to support the development and uptake of dynamic consent systems. Online platforms could indeed facilitate informed and personalized consent while improving communication between researchers and individual subjects and allowing the latter to give their consent to new research activities that were not foreseen in the original consent.[10]
    - Alternative systems, which offer a safe space for the processing and/or transfer of health data for research purposes without relying on the formal individuals' specific consent, may deserve public support and favourable enabling conditions too. They can build on initiatives such as the Data Safe Havens in Scotland[11] or the citizen cooperatives in Switzerland which allow for the processing of personal data under the control of the subject individuals.[12]
- Consider data federation aspects allowing for federation to different levels: national nodes, individual institutes and individual citizens. The European Health Data Space should support the development of efficient tools for federated analysis, and the implementation of data visiting solutions in which queries and algorithms travel to the data, instead of having a centralized approach where data travels to the algorithm. This will require the development of a legal clarification on how to interpret the GDPR in such a data visiting paradigm.
- Support the development of privacy enhancing technologies. EU funding instruments, such as Horizon Europe or the EU4Health programme, should finance research & development projects aimed at the further development of technologies and methodologies for improving the

[10] Budin-Ljøsne, I., Teare, H.J.A., Kaye, J. et al. (2017) "Dynamic Consent: a potential solution to some of the challenges of modern biomedical research". *BMC Medical Ethics* 18, 4. DOI: 10.1186/s12910-016-0162-9

[11] www.nhsresearchscotland.org.uk/research-in-scotland/data/safe-havens

[12] For instance: www.midata.coop

quality of synthetic data created on the basis of real-world data. Another avenue for technological progress is the development of solutions to enable the export of maintained time-series data. The transfer of data requires better interoperability between data storage infrastructures, hence the need for further support to the creation and implementation of standardized protocols for organizing data in interoperable units (e.g., HL7-FHIR). These technological advancements must nevertheless be coupled with the development of legal clarifications, e.g. on how the GDPR rules are applicable to privacy enhancing technologies (if any).

- Develop an approach based on risk-benefit/value assessment. In the medical device industry, there are tools for value/benefit assessment and others for risk assessment and management. Similarly, the GDPR introduced the concept of Data Protection Impact Assessment (DPIA) to identify and minimize privacy-related risks in data processing activities. Risk analysis is used to identify risks and reduce them to the lowest reasonably practicable level, while considering that the residual risk is never zero. Balancing benefits/values and risks is certainly a complex task. It implies defining criteria and thresholds on the acceptance of the residual risk. Decisions on allowing the processing and transfer of health data should not consider exclusively technical and legal parameters. There is instead the need for a well-defined decision-making process that needs to integrate both tools for risk-benefit/value assessment and tools for data and privacy protection. It should be recognized that the value for individuals and society of (re)using health data for research purposes can be far greater than the residual risk.

- Increase citizens' trust by raising their awareness of the potential benefits of data sharing and being transparent on the reuse of health data. Harmonized awareness campaigns across Europe might contribute to generating the social and political momentum needed to make this a challenge for the whole of European society. In order to ensure adequate engagement and the necessary transparency, it could then be beneficial to notify citizens of all the results obtained in clinical-health research thanks to the contribution of the data they have made available to science. Also, as long as there is public trust in research, it is advisable to give a central role to universities and their researchers in the management of health data storage, quality and interoperability, and transfers.


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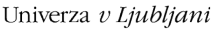
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