Feedback on the proposal for a Regulation on the European Health Data Space

Instrat Foundation and Open Future welcome the publication of the proposal for a regulation of the European Health Data Space (EHDS regulation) and appreciate the opportunity to provide comments on the topic.

As progressive organizations working to maximize societal benefits of shared data by, for instance, being actively involved in discussion on the shape of the Data Act (DA) proposal or data opening in the energy sector, we focus exclusively on Chapter IV of the proposal.

Given the broad scope of secondary use of electronic data outlined in the proposed EHDS regulation, we acknowledge the value of the proposal in the process of unlocking the potential of data and enhancing the management of health data as a shared resource. As such, the framework for secondary use proposed by the EHDS regulation can maximize and redistribute societal value stemming from access to and sharing of electronic health data by functioning as a commons.

Given this objective, we believe that certain aspects of Chapter IV related to public trust and collective governance of Health Data Access Bodies (HDABs) must be strengthened. This can be achieved by maximizing community participation in governing the data held by HDABs while building appropriate trust-by-design mechanisms.

The most recent version of the Eurobarometer shows that the level of trust in the Member States (MS) public institutions is considerably lower than that which citizens hold for EU institutions. Almost half of Europeans have confidence in the European Union (49%), while trust in national governments (36%) and national parliaments (35%) has lost ground (Eurobarometer, 2021).

One of the most important factors determining the trust in institutions is the level of rule of law in a country – thus, the accountability of public office holders to the laws and promises made to citizens (Postema, 2020). As a crucial component of rule of law safeguards, democratic governance implies the enforcement of public accountability through society-wide participation.

Institutional legitimacy is a crucial factor for the implementation of the legislation itself, for the fulfillment of the goals set out in the proposed EHDS regulation and for the promotion of the development of prosocial innovation in medicine. The legitimacy of an institution emerging under a newly enacted law should come primarily from the people it will concern.

To achieve this, it is essential to make sure that all actors - both those who create the institution and those who will be its beneficiaries (patients and health professionals, as well as researchers, policy makers, innovators and industry representatives), can actively participate, not solely cooperate, in the governance of HDABs.

As a result of unequal levels of citizens' trust in public national institutions across MS, it is predictable that introducing initiatives such as the proposed EHDS regulation in those MS with lower confidence in public institutions will be more burdensome than in those with a higher confidence. This is due to the risk that democratic governance of secondary use of electronic health data might be sabotaged via their political or corporate capture. The lack of institutional legitimacy and safeguards over access to and sharing of electronic health data in the EU may result in ineffective enforcement and, consequently, in the failure of the EHDS to deliver on its expectations.

Therefore, HDABs would benefit from a structure building societal trust in data permit authorities via collective data governance mechanisms. As elaborated in our Data Commons Primer[1], Europe needs a data governance framework that fosters a collective and democratic approach to data as a common resource, that is generative and serves to create public value. In the proposed EHDS regulation, this can be achieved by strengthening societal control via third parties' involvement while locating HDABs' conduct under the supervision of the Commission.

In light of this objective, the remainder of this submission comments on Chapter IV of the Commission's proposal from four different points:

1. Collective data governance of Health Data Access Bodies via independent supervisory panels;
2. Trust-by-design and societal control of Health Data Access Bodies;
3. Access fees for public institutions; and
4. Business-to-Government (B2G) data sharing rules.

1. Collective data governance of Health Data Access Bodies via independent supervisory panels

Despite being crucial to foster the governance of electronic health data as a commons, HDABs, as conceived in the current proposal, lack appropriate safeguards related to democratic control and public accountability. If not tackled, these shortcomings can lead to corporate, public, and political capture of independent institutions, whose mandate includes the advancements of public interest goals related to access to and sharing of electronic health data.

[1] This is a pre-publication version of the Data Commons Primer, which will be published In early September 2022 by Open Future. The Data Commons Primer translates conceptualizations of governance of data as a commons into a framework for designs that bring this idea to life through public policies.

In our Data Commons Primer, under the "collective governance pillar", we have identified characteristics of commons-based governance structures that can prevent such capture by leveraging the role of existing trusted or newly established entities to become the institutional vehicles for the data commons. In particular, within this objective, we notice that the HDABs lack important venues where the community can enjoy greater autonomy and decision-making on the shared data.

For this to occur, it is important to safeguard HDABs' independence while creating the conditions to instate a collective layer of democratic control and accountability. As such, article 36(3) must be expanded to crystallize a permanent and structured venue for third parties' engagement. Hence, we propose extending the article with a provision concerning an independent supervisory panel, acting as the governance centerpiece of HDABs through society-wide participation. In its current form, the proposed text vaguely foresees "*cooperation with stakeholders' representatives, especially with representatives of patients, data holders and data users*", but does not go far enough in providing a framework that can leverage the role of third parties in taking part to democratic decision-making while overseeing HDABs' conduct.

The independent supervisory panel should offer a democratic framework for third parties' engagement to embody a collective data governance layer in HDABs' institutional design. Such involvement must be as representative of society-wide interests as possible and shall take place in a balanced configuration in relation to professional expertise, gender diversity, and geographical provenance. More stakeholders from civil society, health professional researchers, ethical committees, and patients' rights ombudspersons should sit on the panel.

To maximize public accountability and societal supervision, the panel's internal deliberations and documents should be made public. Equally, members of the independent supervisory board should have the possibility of reporting potential misconduct airing from HDABs' conduct under the obligations laid out in Chapter IV. These should be addressed to the Commission in the form of ad-hoc or joint complaints. This is crucial to prevent situations where the HDABs – being the sole entity tasked with monitoring and supervising compliance of data users and data holders in Chapter IV – might abuse from their central position.

Regarding potential infringements on the side of data users and data holders, the proposed regulation states that any natural or legal person affected by a decision of HDABs concerning fines or data permits shall have the right to an effective judicial remedy against such decision (article 43 (9)). While we welcome this provision, we believe that it may be insufficient to achieve ambitious objectives linked to enhanced supervision resulting from a collective governance layer. Engaging civil society representatives via independent panels will be valueless unless these are equipped with sufficient tools allowing them to influence HDABs' activities. Hence, we suggest designing article 43 in a way that allows the

submission of applications for remedies not only by persons directly affected but also by monitoring bodies – such as independent panels and the European Health Data Space Board – acting on behalf of individuals or society as a whole.

2. Trust-by-design and societal control of Health Data Access Bodies

Article 38(4) imposes the obligation for MS to inform the public at large about the benefits deriving from the existence of HDABs. At the same time, the regulation misses to inform stakeholders on the need to establish these institutions in a way which would consequently increase their trust in HDABs.

Moreover, MS' information obligations expressed in article 38(4) are included in the section on the responsibilities of the HDABs, instead of article 36 of the regulation, which refers to MS' responsibilities towards the HDABs' designation and performance. This evokes a sense of separation between trust-enhancing mechanisms in HDABs' design and legitimacy issues, which are left solely to the matters for which the HDAB was created (its roles and benefits), without answering the question of how it was designed and on the basis of which principles.

It should also be emphasized that the proposed EHDS regulation gives significant discretion to MS' authorities in choosing the appropriate number of HDABs as well as the type of institution (article 36 (1)). Although article 36(3) stipulates that HDABs shall not be bound by any instructions when making their decisions, the regulation leaves its design solely to MS and outside of an effective EU or social control. This poses a risk for HDABs of being prone to influence from national bodies, as those public sector entities might try to overreach their powers.

Therefore, we recommend institutionalizing trust-by-design governance mechanisms in the overall architecture of HDABs. This means, first, to create a resilient regulatory framework granting the European Commission with sufficient tools to execute its competencies. Second, to design the functioning of HDABs in a way that guarantees adequate societal control.

As previously mentioned, the current version of the proposed EHDS regulation gives the MS a wide margin of discretion when designating HDABs. At the same time, the possibility to obtain information on HDABs activities (eg. by civil society organizations) is limited and depends on MS' will to share its insights with the public at large. In this light, we recommend placing article 38(4) under article 36, where it would be linked to the provisions on collective governance over HDAB.

It is also important to highlight the significant differences between the nature of primary and secondary use in the proposed EHDS regulation. The first relates to patient data used by medical professionals for health-related purposes. Their use is therefore limited and the potential variants of abuse is negligible. In such a case, the Commission leaves most of the tasks related to determining specific aspects of the primary use to MS. On the contrary, the

secondary use concerns different types of data from numerous sources. Moreover, the concept of acting in "*general interest of the society*," poses additional dangers for data misuse. For this reason, we believe that the control over the design and operation of HDABs should be strengthened by giving the European Commission the ability to impose penalties for eventual violations of the regulation, as expressed in article 69 of the proposed EHDS regulation.

3. Access fees for public institutions

Article 42 stipulates that HDABs and data holders can charge "access fees" to data users when providing access to electronic health data. These need to be transparent and proportionate at the level of incurred marginal costs and must be derived from the costs related to conducting the procedure for requests. In addition, the specific interests of third parties, including those of public bodies, shall be taken into account when setting the fees by "*reducing them proportionately to their size or budget*".

In light of this provision, it would be contradictory to charge disproportionate fees to public sector bodies when accessing health data for the pursuit of a task in the public interest. This is exactly what happened in 2020 with the Polish Energy Market Agency (ARE) case where access to energy and coal consumption datasets was shielded with extremely high fees, introduced intentionally to prevent access to high-value information relevant for public scrutiny. To avoid similar situations from occuring in the field of electronic health data, there is the need to specify that any fees charged on public institutions when accessing data in the pursuit of the public interest must be strictly limited to the costs related to conducting the procedure for requests.

4. Business-to-Government (B2G) data sharing rules

In article 34, HDABs also have the task to enable data sharing flows between data holders and public sector bodies for electronic health data. In this context, article 34(3) clarifies that access to privately-held data for the purpose of preventing, responding to, or assisting in the recovery from public emergencies shall be ensured in accordance with article 15 DA. However, at the same time, recital 41 also adds that

> "*There is a need for public bodies to go beyond the emergency scope of Chapter V of the Data Act*".

As argued more in-depth in this analysis, this provision might generate legal uncertainty on the overall scope of the B2G data sharing rules proposed by the EHDS regulation and on their intersection with the DA proposal.

Article 15(c) of the proposed Data Act regulates B2G data sharing in situations "*where the lack of available data prevents the public sector body or Union institution, agency or body from fulfilling a specific task in the public interest that has been explicitly provided by law*". Fortunately, this limited scope to B2G data sharing is not echoed in the proposed EHDS

regulation, which actually proposes a much more ambitious public interest framework in the area of public and occupational health.

To prevent legal uncertainty, the European legislator should make sure that the two measures are better aligned by acknowledging in the Data Act the primacy of sectoral rules for B2G data sharing, such as the rules concerning the access to health data in the proposed EHDS regulation, over the baseline scenario offered by the DA.

23-07-2022

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