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Recommendations on how to engage citizens in the European Health Data Space

Quick facts

What is this document?
This document summarises the results of the Work Package 8 in the TEHDAS Joint Action, focused on citizens, and whose goal is to make recommendations for the Member States and European Commission on how to engage citizens in the coming European Health Data Space. These recommendations are meant to represent citizens' points of view as expressed in the Healthy Data consultation and do not reflect with the point of view of TEHDAS, the authors or their institutions.

How were the recommendations created?
The recommendations are based primarily on the analysis of nearly 6.000 contributions gathered through the Healthy Data consultation, as well as on a broad review of the literature of citizens' values and opinions of the secondary use of health data, 53 stakeholder interviews, and 4 stakeholders workshops conducted at EU and national level in the three participating countries (France, Belgium and the UK).

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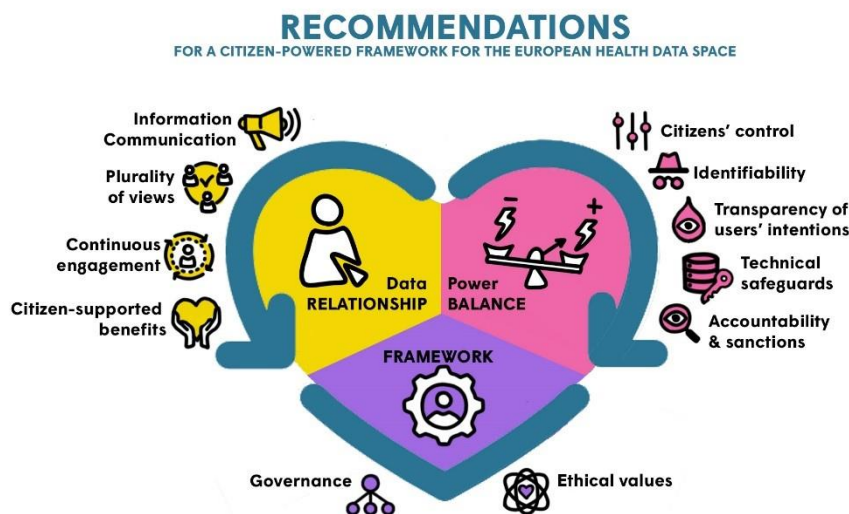**NHS Confederation**: rosie.richards@nhsconfed.org

Figure 1. Infographic on key aspects of recommendations how to engage citizens in the EHDS and promote a citizen-powered framework.

The data relationship
Every time health data is used, citizen perceive that a piece of them, of their identity and history, is being used, including in the case of secondary use. Therefore, anyone using their data is engaged in a relationship with them. They need to be respected as partners in this

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relationship. Every element of this relationship needs to be given proper attention and requires continuous work."

1. Citizens would recommend being able to access information about the secondary use of health data, in an understandable way, allowing them to be more engaged.
2. Citizens would recommend having access to their data and know how they are used for secondary purposes. However, they want to choose how and when they are informed about the uses of their data.
3. Citizens would recommend that their values should inform what is beneficial to individuals and what constitutes the common good.
4. Citizens would recommend that decision-making processes rely on a plurality of views and actors to increase their trustworthiness, as for them the latter depends on who is involved in these instances.
5. Citizens would recommend being given the opportunity to be involved in the lifecycle of health data, as they need to be engaged on a continuous basis. Otherwise, their relationship with data custodians and users can deteriorate.

The power balance

"Data is power: it can be used to greatly benefit everyone, but this power could also be used against citizens. They need a good balance between risk mitigation and benefit maximization to ensure proportional use of health data for purposes we support."

6. Citizens would recommend being provided with the opportunity for meaningful and active decision-making in the secondary use of health data, as they value the ability to exercise control
7. Citizens would recommend to ensure the protection of individuals' identity, which they perceive as one of the best ways to balance the harms and benefits of the secondary use of health data.
8. Citizens would recommend that data users' intentions should be transparent and in line with purposes citizens support, as they think some users might share their values more than others
9. Citizens would recommend that accountability could be enhanced through transparent and stronger mechanisms
10. Citizens would recommend to foster good IT solutions to protect their data, beyond having a strong legal framework in place.

A citizen-powered framework

All the above ideas and concerns should be assembled in a regulatory framework that governs secondary use in actual practice and in a way that is truly supported by citizens. The development of such a citizen powered framework does not only include appropriate governance structures but also respect for central ethical values as they are interpreted by citizens.

11. Citizen would recommend that stakeholders respect principles that align with citizens' ethical values.
12. Citizen would recommend having a framework which facilitates the secondary use of health data for purposes and benefits that they support, while minimising the potential risks they identify.

What could this mean for the EHDS?

It seems the EHDS and its implementation at national level could address more specifically citizens' needs to be informed about the secondary use of health data. It could also push for determining and including the value of the common good in this overarching framework, as well as fostering a plurality of views in decision-making processes and governance. Overall, the proposal and its implementation could push for citizens to be treated as equal partners. This could ensure that key concepts like privacy, consent, control, commercialisation, the

common good, purpose, etc. respect citizens' conceptualisations, values and principles. Special attention could also be given to their concerns regarding identifiability, the establishment of effective sanction mechanisms as well as the guarantee that technical, protective safeguards are in place.