RESPONSE BY BBMRI-ERIC to

"EUROPEAN HEALTH DATA SPACE" (EHDS) Questionnaire

(PUBLIC CONSULTATION)

BBMRI-ERIC[1] is one of the largest Research Infrastructures for health research in Europe providing a gateway for access to biobanks and biomolecular resources coordinated by the National Nodes across 21 Member States and IARC/WHO as International Organisation. BBMRI-ERIC aims at improving the accessibility and interoperability of the existing comprehensive collections, either population-based or clinical-oriented, of biological samples from different (sub-) populations of Europe including rare diseases. These collections also include sample associated data with parameters such as health status, nutrition, lifestyle, and environmental exposure of patients and probands.

BBMRI-ERIC welcomes the public consultation launched by the European Commission, in order to involve the public, stakeholders and organisations in the design of a legal framework for a European Health Data Space.

BBMRI-ERIC has filled in the online questionnaire; however, we would like to insist on specific items through the present statement, which constitute additional information to the answers provided.

Moreover, BBMRI-ERIC would like to point out that, considering its expertise and focus on biomedical research, we have provided **answers regarding questions focusing on research only**, **keeping aside the issues related to healthcare**. Indeed, even if BMMRI-ERIC is convinced that the line between healthcare and health/biomedical research is often blurry in practice, its mission is to collect here researchers' and research organisations' views only. Thus, the following

[1] https://www.BBMRI-ERIC-eric.eu/ accessed 14 July 2021.

statements reflect not any other position but BBMRI-ERIC and researchers' view, leaving out all questions about healthcare and cross-border exchange or questions addressed to healthcare professionals, healthcare providers, citizens (patients and data subjects) and policy makers.

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With reference to question Q2 "Should a European framework on the access and exchange of personal health data aim at achieving the following objectives?", we underline the following:

1. **Division between primary use and secondary use of health data cannot be strictly upheld in practice**

BBMRI-ERIC answers with reference to the point about research, namely "Support and accelerate research in health". BBMRI-ERIC considers that a European framework on the access and exchange of health data should take into account that the line between healthcare and health research is often blurry in practice and a division between primary use and secondary use of health data cannot be strictly upheld. It is therefore critical to conceptualize the legislation with the multitude of health data usage in mind.

A legislative framework should equally consider both the healthcare purposes and the research one, in order to set up healthcare systems, from the start, in a compatible way with the needs of research. Indeed, health data and digital workflows are at the intersection of primary care and research and need to be conceptualized from the beginning as complementary to reduce errors, avoid duplication of procedures and allow for innovative digital health solutions in the sector of health, since healthcare and research are intertwined in practice. Research is at the basis of an efficient healthcare, and, in turn, healthcare can offer challenging paths to research. In the field of health research, health data stem from the health care context, but equally from clinical studies, cohorts, and biobanks and increasingly from patient/citizen owned initiatives or connecting wearable data.

We therefore insist that the legislative framework should take into account the use of health data in its different aspects, understanding health care and health research as Siamese twins that cannot and should not be separated.

2. **A new legislation might lead to even more complexity if it does not serve one feasible purpose across Europe**

Harmonised legal basis for processing, harmonised principles of transparency, data integrity, fairness and respect of data subjects' rights are relevant to be drawn. The subsidiarity principle and the space of national legislation should also be taken into account, but also common bases among Member States that need to be achieved across Europe are important. However, we must also underline that we are doubtful that one piece of legislation could be comprehensive enough to include both mentioned aspects. We consider that there is no need for another layer of rules, but we argue for more clarity about the existing ones, such as the General Data Protection Regulation (GDPR), whose implementation in Member States is still fragmented.

Another piece of legislation, even though intended to generate clarity, would add another layer of complexity and issues of compatibility. The use and sharing of health data for research purposes needs to be clarified, rather than being the object of a separate and specific legislation.

3. **Federated versus centralised is irrelevant. Technical compatibility of federated and centralised models across Europe is key**

Along with the legal clarity, the operational harmonization is essential. From the operational viewpoint, it must be considered that infrastructures differ within Member States.

To ensure data access and data exchange for research purposes, and to build sustainable, solid and interoperable infrastructures, such infrastructures should follow shared, standardised and common rules and practices.

BBRMI-ERIC has a preference for a federated model (having operated with it since 2014), where databases in Member States process and store data (at the local level), and they transmit to a central authority metadata only (i.e., data that accompany and describe data).

However, for the purpose of the EHDS, we believe that a decision for or against a federated or centralised model is not necessary. What is important is that responsibilities and a clear allocation of local versus central bodies is essential. Each repository of health data for research in each Member State should have certified and high-quality standards and follow harmonised and shared data integrity principles. Then, the infrastructure should be designed in a manner to fit all relevant use cases and according to the necessary flexibility to cover these different use cases and building on complementarity. This approach does justice to the different healthcare systems in the Member States that will continue to exist (e.g., federated in Germany vs centralised in France).

We argue that intermediaries and providers of data-sharing services shall assist both data holders, such as hospitals and research institutions, and data subjects (patients and research participants) with sharing their data for altruistic purposes. Such data-sharing infrastructure should also be compatible with the GDPR, namely ensuring that databases can only be accessed by authorized users for authorized purposes.

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Concerning question Q11 "In your opinion, would additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decision be needed at EU level?", we stress the following:

1. **Bottom-up approaches building on existing legislation**

Considering the complexity of the GDPR and the open questions and shortcomings that it shows, meaningful use cases and examples provided by soft law instruments such as Codes of Conduct should be encouraged, promoted, drafted, and enacted according to Art. 41 and 41 GDPR. It is

necessary to complete the EU regulatory panorama to fill the gaps left in the GDPR concerning the use of health data.

In the area of health research, in particular, a code of conduct, drafted through the involvement of the research community and different stakeholders, could be very useful for suggesting harmonized understandings of how to read basic terms and implement requirements following practical standards. The Code cannot prevent Member States from adopting specific rules, but it can provide models for how to balance conflicting interests in the field of health research and thus contribute to a more aligned legislation and interpretation. It can also help institutions to develop wide policies and guidelines and be a basis and a means to educate researchers to learn about, and follow, institution rules. Some organisations, among which there is BBMRI-ERIC, are already working on codes of conduct, by gathering different partners and stakeholders comprising representatives from academia and industry concerned with human research data and patient advocacy groups. Some code initiatives already collaborate with each other in order to achieve complementarity to one another.

Ultimately, BBMRI-ERIC considers that there is no need for another layer of rules, but for more clarity about the existing ones, such as the General Data Protection Regulation (GDPR).

2. **Clear Governance Rules and Rules for Access and Sharing**

Considering the points that need better clarification and following the indications of the questionnaire, a clear **governance and rules** for access and sharing of "health data from medical records" and "genetic and genomic data" for research purposes is needed.

As regards the **format**, we think that the "pseudonymization format" balancing the re-identification risk with the research purpose is clearly preferred in practice for health data for research purposes.

Anonymisation should not be the standard for data minimization in biomedical research and it is not the proper format for health data for research purposes. When data are anonymous, individual research participants or third persons cannot be identified anymore and thus their

engagement in research with decisions around how the data are being used is undermined, as well as their insights, control, and oversight of their data.

Then, in health research, data belonging to research participants is broader than a normal data set: data include contact information (name, surname, address), but also patient level data (patient identifier, date of birth, gender, sex, age, efficacy outcomes, side effects, laboratory test results, etc.). Whereas direct identifiers can easily be taken out, the latter category of data is harder to anonymise, since this is the information needed for research.

Even more important, the possibility of contacting patients and of re-identifying them through the health care provider (in case, in collaboration with Trusted Third Parties) remains crucial not only for the purposes of research, but also in order to allow research participants exercise their rights. Indeed, anonymization makes feeding back research results or incidental findings impossible, it deprives the patient of the option to withdraw consent and it often makes data useless for analysis.

Moreover, the research community is currently elaborating on the concept of 'anonymized use of data' for certain research scenarios done within federated networks: it means that the analysis/processing of personal data on site should be encouraged, giving back anonymous results. Especially in federated systems, the fact of bringing the algorithms to the data with anonymous results is an effective means to protect participants' interests. This allows for dynamic anonymization along the research question.

As regards **eligibility**, BBMRI-ERIC considers that "Safeguards for the access to health data for the purpose of reuse, in line with ethical and data protection requirements" have to be drawn for research purposes. Safeguards are the base for the trust of citizens and in research, they mean to grant access to health data to those who are permitted, and to specified / limited health data in a safe and secure environment.

As regards **security**, "conditions for the secure access to health data for research purposes" is also another point to be defined: responsible access to health data is essential for maintaining

citizens' trust. Health data processed and stored in secure systems need specific (cyber) security management.

BBMRI-ERIC insists, as regards health data category, that clear governance and rules for access and sharing of "health data from medical records" and "genetic and genomic data" for research purposes are needed.

3. **Data Altruism**

An additional aspect that is often neglected in legislation is the concept of "data altruism": many surveys have shown that citizens are willing to share their health data for research purposes in an altruistic manner as long as they trust in the measures to protect their interests. Transparency and accountability are key factors for proofing trustworthiness and ensuring that altruism remains the main motivation for supporting health data sharing. That said, BBMRI-ERIC calls for caution of relying on data altruism as a given and an unshakable constant. In case trust is lost (e.g., due to a lack of transparency, negligence, scandals) it may be impossible to rebuild. Thus, BBMRI-ERIC encourages data altruism forms that may represent an additional legal certainty in the context of scientific research and may contribute to additional transparency for data subjects.

BBMRI-ERIC understands data altruism as a leap of faith by patients, donors and research participants which in return demands accountable practices.

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In relation to question Q14 "Do you agree that an EU body could facilitate access to health data for research, innovation, policy making and regulatory decision with the following functions?", we observe the following:

1. **Central EU Body to Facilitate Access**

BBMRI-ERIC does not agree that one singular central EU body could act as a centralised regulatory agency (bringing together the national bodies that deal with secondary use of health data), which takes decisions in this area. Rather, a central body could help in setting standards on

interoperability together with other national bodies dealing with secondary use of health data, and it could answer researchers'/ stakeholders' queries, instead of them addressing national authorities, with the risk of contradictory answers among Member States. So, a central body could help draw common standards and practices and ensure the correct and consistent application of the rules in individual cases. In our view, it should not act as an authorising body.

It could only be a processor of those metadata that are transmitted by Member States. The Member States' databases are the ones processing, collecting and storing health data at the local / national level.

For biobanks, we believe that a federated system is the most suitable solution: there is a common data model, a common query language and a common protocol between national databases; the central database collects metadata only; between national databases there is exchange of result, exchange of queries/algorithms, exchange of protocols and exchange of data. For EHDS, a mixture of federated and centralised elements can be envisioned to account for the different systems in the Member States.

Facilitating access is key. However, one centralised approach for multiple purposes on data access would not be feasible. Rather a combined federated approach is desired.

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Considering the Section 3 on Artificial Intelligence (AI) in healthcare (Q26-Q30), BBMRI-ERIC underlines the following.

1. **Avoiding Black Box Medicine**

The application of artificial intelligence (AI) brings certainly many opportunities for the improvement of health care and prevention. It, however, raises many ethical concerns ranging from "black box medicine" to discrimination of the sexes, socio-economic groups or minorities by being underrepresented in the data sets. Algorithms are trained and, if not scrutinized appropriately, they threat autonomy and open the doors to new forms of discrimination and

marginalization. AI use, or machine learning, can exacerbate disparity in access to care and attainment of good health outcomes and it can even make disparity less visible because the decision will bear the authoritative objectivity often attributed to algorithms. In addition, AI has the tendency to lead to self-fulfilling prophecies, since outcomes depend on the data input reflecting the – maybe unfair – reality and thus perpetuating it. Thus, it is much more at stake than safety of tools or liability for concrete harms to patients using certain tools or apps. Societal transformation through AI use needs thorough assessment and citizens need to be efficiently protected against unfair results, ideally while the EHDS is in the making.

Ethical and societal considerations are of equal importance as the development of tools and their advancement should go hand in hand from the start to meet the challenges of the complexities of health data use and those who ultimately benefit from them in one as well as across multiple sectors.

About BBMRI-ERIC

BBMRI-ERIC is one of the biggest ERICs in the biomedical field with currently 21 members: 17 Member States and 4 observers, including IARC/WHO. BBMRI-ERIC has its headquarters in Graz, Austria, and a permanent representation at the EU in Brussels, Belgium. As the European research infrastructure for biobanking and biomolecular resources, BBMRI-ERIC is currently active in 20 different EU projects. BBMRI-ERIC brings together all main players from the biobanking field – researchers, biobankers, industry, and patients – to boost biomedical research. To that end, BBMRI-ERIC offers quality management services, supports with ethical, legal and societal issues, and a number of online tools and software solutions for BBMRI-ERIC's ultima goal: Making new treatments possible.

Contacts
Ilaria Colussi, ilaria.colussi@bbmri-eric.eu