STATEMENT BY BBMRI-ERIC ON "A EUROPEAN HEALTH DATA SPACE"

BBMRI 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. It 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 or rare diseases. These collections include the associated data on factors such as health status, nutrition, lifestyle, and environmental exposure of patients and probands.

The roadmap/impact assessment correctly identifies problems hindering the creation of a single European market for data (section "Problems the initiative aims to tackle") and discriminates health data between health care and health research data, including the peculiar issues with data privacy, sharing, and interoperability linked to sensitive data ("Context" and "Evaluation"). This marks a sharp, and very welcome change in approach by the Commission, which rightfully reassesses the large social impact of the European Health Data Space ("Likely social impacts").

The development of the EHDS cannot be timelier, with the launch of groundbreaking initiatives across the competences of the Commission, ranging from health (Beating Cancer Plan, COVID-19 response) to research (Horizon Europe Missions), innovation (AI) that can all tie together under a new European Health Data Space to unlock the full potential of both a single European health data market.

BBMRI-ERIC welcomes the initiative for a European Health Data Space (EHDS). The COVID-19 pandemic has highlighted the importance of having timely access to health data for research and policy-making purposes, and the European Council has recognized the urgency to make progress towards the EHDS.

The European Health Data Space (EHDS) declared goals are to:

- promote safe exchange of patients' data (including when they travel abroad) in order to i.a. avoid duplication of tests and reducing errors and inefficiencies.
- grant citizens control over their health data through facilitating citizens' access to and portability of their own health data
- support research on treatments, including medicines, medical devices and outcomes
- encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules in order to improve cost-effectiveness of health care systems including overcoming staff shortages and reduce inequalities in health care provision
- support digital health services in order to competitiveness of the EU single market
- clarify the safety and liability of artificial intelligence in health.

We believe it is imperative to acknowledge that the line between health care and health research is often blurry in practice and a division between primary use and secondary use of health data cannot be strictly upheld. Personalised medicine is a prominent example where health care and health research go increasingly hand in hand. It is therefore critical to conceptualize possible governance solutions and legislations with the multitude of health data usage in mind. If, for instance, high quality healthcare data systems are set up or fostered that are not compatible and account for the needs of research from the start, then the expected trade-offs between reducing administrative burden for operators and positive health and research benefits will not materialize. Health data and digital workflows are at the intersection of primary care and research and need to be conceptualized from the start as complementary to reduce errors, avoid duplication of procedures and allow for innovative digital health solutions in the sector of health, as care and research are intertwined in practice. We therefore highly welcome the approach of this initiative to address the use of health data in its different aspects. Yet, we have some doubts, whether the legislative programme is in a way comprehensive with respect to the goals pursued. In order to reach the declared goals of the EHDS as well as implement them in due time, it is critical to connect to the achievements of the initiatives or research infrastructures already working towards these joint goals (e.g., 1MGP, ADOPT BBMRI-ERIC, EOSC-Life, AMRI). Especially in the field of health research, there are many actors currently making existing health data from various contexts including health care available for research. But health data being used for research do not solely 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. Consequently, insights are increasingly gained from the combination of these sources with health care data. The upcoming EHDS should take the know-how, tools or full fletched infrastructures of the multiple contexts working with health data into account. In addition, the creation of the EHDS can be built on the experience regarding the collection and use of health data for research purposes in an ethically and legally compliant way.

We strongly believe that groundbreaking achievements in the field of health can only be achieved in a collaboration across sectors, which traditionally have been seen as acting independently and being represented by different advocacy groups, ministries and DGs (, i.e., health care, research and digital innovation).

We also advocate to take the main actors from health research, such as – but not only - the European Research Infrastructures on board while developing the EHDS. Innovation in health care in the EU is always enabled at the cross-section between health care and research, building more and more on big data.

In the following, we would like to draw the attention on some questions being in our view major success factors. We do so by addressing those goal by goal:

1. Promoting safe exchange of patients' data and citizens' (including when they travel abroad) in order to i.a. avoid duplication of tests and reducing errors and inefficiencies.

The major **success factor** for establishing an EU-wide system of Electronic Health Records (EHS) to enable easy exchange of health data across borders seems to be the **acceptance by citizens and health care professionals (HCPs)**. The loss of privacy, which is unavoidable even under the strictest security regime, needs to correspond to the incentives and long-term benefits for patients and HCPs. It also depends on the costs for setting up, maintaining and being able to use safe exchange platforms. This includes social as well as development costs. Therefore, it is key to identify and promote the benefits for patients and HCPs openly. If they do not see the benefit in sharing and/or providing access, the best technical system is prone to fail due to lack of social acceptance.

2. Grant citizens control over their health data through facilitate citizens' access to and portability of their own health data

Much has been said about **patient empowerment and citizens' control over their health data**. But far less has been concretely proposed to implement this goal. Past and current initiatives show that simply granting citizens access to their own health data is not sufficient, neither is the right to portability, especially because these rights already exist under the GDPR. Having control ultimately means to have the power to exercise it and this requires to know about and to be able to block access if concerns of misuse exist. It is then secondary against whom this access control is exercised, whether towards public or private data users. Control also implies to be appropriately informed about how data are used and for what purpose. In cases where health data are used without the consent of citizens, **a credible concept of information and participation has to be guaranteed.**

3. Supporting research on treatments, including medicines, medical devices and outcomes

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 again key factors for proofing trustworthiness and ensuring that altruism remains the main motivation for supporting health data sharing. In case trust is lost (e.g., due to a lack of transparency) it may be impossible to rebuild.

4. Encourage the access to and use of health data for research, policy-making and regulation, with a trusted governance framework and upholding data-protection rules

Research, policy-making and regulation are critical areas that require access, same as health care, to health data. The purposes for which data is used is, however distinct, especially in contrast to policy making and regulation, and should not be mixed up. Of course, research should inform policy making or regulatory, but the citizens should ideally always have a choice for what purpose they are happy to share their data. At least, **full transparency and the information about the purpose** is again key. Cost effectiveness might be the legitimate goal of policy makers and regulators, but it is clearly not the

only or prominent goal of research. In many cases, research interests are even in conflict with regulators' goals. Citizens might even initiate research in order to challenge regulatory approaches.

5. Supporting digital health services in order to competitiveness of the EU single market

Digital health services such as apps for diagnosis of diseases and treatment are subject to the Medical Devices Regulation providing for harmonized standards throughout the EU. Before adding additional legislative layers, **a gap analysis** should be performed.

6. Clarifying safety and liability of artificial intelligence in health

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 or minorities by being underrepresented in the data sets. Algorithms are trained and, if not scrutinized appropriately threats to autonomy and door openers for new forms of discrimination and marginalization. AI use 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 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 in one as well as across multiple sectors.

Conclusions

In conclusion, the existing regulatory framework is insufficient to deliver on the promises of the EHDS. Health data governance remains fragmented at national and regional level, hindering any effort to scale up research and healthcare solutions.

Most importantly, it is necessary to protect and promote the use of health data, defining clear pan-European rules to overcome the existing gaps in practice.

Therefore, it is necessary to complete the EU regulatory panorama to fill the gaps left in the GDPR concerning the use of health data. The EHDS shall take inspiration and build on existing efforts to provide clarity to the data protection legislation and health research, such as the Code of Conduct for Health Research. Since a mere harmonized implementation of the GDPR will most likely not address all challenges sufficiently (see above), we strongly support policy option A from the roadmap/impact assessment, leading to a new, specific regulatory framework to protect the ethical and safe secondary use of health data.

Finally, the EHDS must be established based on existing European research infrastructures and exploit already developed models for joint services provided by BBMRI-ERIC and other RIs (e.g., via the cluster-projects CORBEL or EOSC-Life) for example, through joint Service Level Agreements. In order to reach the declared goals of the EHDS as well as implement them in due time, it is critical to connect to the achievements of the initiatives or research infrastructures already working towards these joint goals (e.g., 1MGP, ADOPT BBMRI-ERIC, EOSC-Life, AMRI). The upcoming EHDS should take the know-how, tools or full fletched infrastructures of the multiple contexts working with health data into account. In addition, the creation of the EHDS can be built on the experience regarding the collection and use of health data for research purposes in an ethically and legally compliant way. RIs already facilitate access to health data, and have a crucial and well-established harmonization and standardization role within the scientific and health research community.