The Guild
of European Research-Intensive Universities

The Guild's reaction to the European Commission's proposal for the European Health Data Space

The Guild welcomes the publication, on Tuesday 3rd May, of the European Commission's proposal for a regulation on the European Health Data Space (EHDS). While contributing to the building of the European Health Union, the proposal recognises the particular sensitivities of health data and the ethics of its use. The Guild fully underlines the urgency of finding solutions to unleash the full potential of shared health data to help scientists develop new treatments for patients and improve the wellbeing of citizens in Europe.

We acknowledge the ambition of the European Commission to develop an EU-level framework which aims to facilitate, through the EHDS, the reuse of data for research purposes. In September 2020, The Guild articulated its views on the Pharmaceutical Strategy for Europe, calling for a "legal framework for enabling cross-border sharing of sensitive data and the merging of data from multiple countries". In our proposals for improved access to health data for research purposes published in June 2021, we voiced our concern that uneven implementation of GDPR across countries impedes data exchanges. This limits research collaboration on health in Europe, putting universities' capacities to answer health threats at risk. It also disadvantages European research in relation to scientists with access to larger shared datasets worldwide.

The European Commission frames the EHDS in the overall framework of the General Data Protection Regulation (GDPR). It nevertheless acknowledges that obstacles to health data reuse come from various (and often conflicting) interpretations of GDPR. The EHDS proposal lays down general rules for processing personal data in health and care contexts and establishing national competent authorities whose mission will be to ensure that requested health data are used for defined purposes, including "education and teaching activities" and "scientific research related to health and care sectors".

The Guild highlights that the collaboration between these national competent authorities will be crucial for a harmonised interpretation and implementation of EHDS rules on the processing of personal data. We support the creation of an EHDS Board to facilitate cooperation and exchange of information among the EU member states and to promote the elaboration of common standards and requirements for the interoperability of health data sets. The Guild encourages the participation of research organisations in the EHDS Board to ensure that the appropriate enabling conditions for cutting-edge health research are in place. The success of the EHDS will depend on its effectiveness in addressing legal uncertainties created by the uneven implementation of GDPR and in convincing researchers that they can reuse and share health data in a safe and legally compliant environment.

The most ambitious endeavour of the EHDS is to empower the European citizens to exercise their rights over their health data while creating the conditions for increased public trust in the reuse of health data for research purposes. The Guild welcomes the objectives of the European Commission to encourage data altruism in the health sector, of citizens and organisations voluntarily providing data for the public good. We also highlight the urgent need to facilitate the obtention of patients' consent to process their data for research purposes. Dynamic consent systems, whereby patients give their

informed consent to the use of their data for research activities not foreseen in the original consent, should be a crucial building block of the EHDS. This must be supported further.

Indeed, The Guild argues that if individuals are to be empowered to have control over their data, they should be able to choose the degree of protection they wish for their data. This degree of protection could also be commensurate to the sensitivity of health data.

By contrast, the systemic anonymisation of health data proposed as a safeguard of individuals' privacy in the European Commission's proposal will reduce the value of the data in the context of medical research, because anonymisation implies removing variables which potentially offer useful insights. Moreover, it does not give citizens the option to have their data used in a way that maximises its potential for research, without anonymisation.

To be sure, the European Commission envisages a derogation of this rule: data could be shared in a pseudonymised form if its anonymised format would deter the achievement of the purpose for which it is requested. The Guild warns against any extra administrative burdens that the request for this derogation may induce, especially if anonymisation would constrain most health research.

The Guild calls for more ambition in the European Health Data Space. We must maximise the potential of collaboration and the exchange of patient data for research purposes if the patients consent to it. Collaboration across borders brings one of the greatest opportunities for health research requiring large patient data sets. The European Health Data Space must ensure this is realised across borders, for the benefit of all citizens eager for new treatments.

Jan Palmowski, Secretary-General of The Guild for European Research-intensive Universities, said: "European science, and the development of new treatments, is held back by a plethora of national rules as well as different interpretations of GDPR requirements. We strongly support the development of a European Health Data Space, but urge the EU to go further. Patients and clinicians must be put in the driving seat of determining how their data is used, for the benefit of collaborative, ground-breaking research".