LERU Office
Minderbroedersstraat 8
3000 Leuven, Belgium

Key LERU messages on the European Health Data Space (EHDS) for the ongoing trialogue negotiations

As a well-established network of research-intensive universities, the League of European Research Universities (LERU) has substantial experience in developing and disseminating views on research, innovation and higher education and is a valued interlocutor for the European institutions and other policy stakeholders. LERU therefore welcomed the earlier proposal for the European Health Data Space (EHDS) and closely follows the institutional debates since the EHDS aims to open up more data for institutions conducting scientific research across the EU.

As the EHDS regulation is currently in trialogue negotiations, LERU shares its common and grounded concerns and recommendations to contribute to the successful approval and implementation of the regulation. LERU therefore calls upon the EU legislators to take the following key messages into consideration in the negotiations, to safeguard scientific research carried out by universities and university hospitals.

1. Clarify the definition of scientific research

LERU stresses the utmost importance of a clear definition of scientific research for the correct application of the scope of the new regulation. LERU particularly emphasises the following needs:

a. A definition of scientific research should be adopted, which is *consistent with other EU data frameworks* adopted in the context of the European strategy for data, as well as with the GDPR.
b. The definition of scientific research moreover has to ensure that *health-related algorithmic or AI projects* are not exempted from the robust ethical and methodological standards that would apply in scientific research falling within the scope of the regulation. LERU therefore supports the definition suggested by the European Parliament (art. 34e), which includes the training and testing of AI systems.
c. Avoid narrowing the *scope of scientific research* to health and care sectors only. Define scientific research more broadly to include all research projects that require health data (for example, sociology, anthropology, etc.)
d. A clear definition of *public interest* is required to ensure that all scientific research which comes within the scope of the new regulation, is in the public interest (as defined), and that each health data access body (HDAB) tasked with reviewing data users' applications adheres to recognised ethical standards of scientific research and a clear understanding of how to contribute to open science in a standardised way. The EHDS is an opportunity to bring clarity to the concept of public interest, which is under the GDPR essentially left for the member states to define.

2. Clearly define all data categories that will be subject to a sharing mandate

LERU emphasises the importance of a harmonised definition of data categories across the EU Member States. To that end, LERU supports the proposal of the European Parliament on Article 33, whereby,

LERU Office
Minderbroedersstraat 8
3000 Leuven, Belgium

in its understanding, the categories of data are exhaustively enumerated, leaving less opportunity for national fragmentation. However, several concerns remain:

a. The term 'minimum categories' in Article 33 of the Council position, leaves the possibility for further categories to be added or not open.

b. The Parliament and Council text differ in relation to health data related to insurance status, education, lifestyle, wellness, and behaviour (Art. 33(1)(n)). It is deleted in the Parliament document and retained in the Council text. The inclusion of insurance status could lead to risks of insurance discrimination, particularly if incidental findings are shared back to the individual as a result of scientific research being conducted under the EHDS.

3. Ensure consistency with other legislative EU-frameworks

LERU asks to avoid inconsistencies between the EHDS, the GDPR, and the Data Act with regard to the data holders' right to refuse to share their data, as well as contradictions between the EHDS and the AI Act with regard to any use of AI in scientific research projects.

4. Ensure consistency between the opt-out mechanism under the EHDS and the rights of data subjects under the GDPR

LERU asks to align the opt-out mechanism with data subject rights under the GDPR, which permit exemptions in certain situations which could seriously impair the research results (such as if information has been published or is about to be published).

LERU furthermore recommends significant patient involvement in the decision-making of health data access bodies to avoid the risks of under-representation and biased datasets due to certain sub populations opting out because of e.g. public trust. The conditions for valid opt-out identified in the guidelines of the Council for International Organizations of Medical Sciences (CIOMS) might serve as a valuable basis for building it up.

5. Ensure coordination between the national health data access bodies and the EHDS Board

LERU supports the Parliament's version which notes that a standard ethics assessment should be carried out by ethics bodies within health data access bodies. And, moreover, that the health data applicant should make available any previously obtained approval of a competent ethics committee in accordance with their national law, as part of the data access application.

LERU fears that the Council's version will pose challenges, due to the requirement of ethical assessment based on national law. LERU feels this could lead to non-standardisation of ethical review, as at present, ethical review is non-harmonised across the EU.

LERU Office
Minderbroedersstraat 8
3000 Leuven, Belgium

6. Avoid a negative impact of EHDS provisions on technology transfer activities, hampering collaborative research, licensing models, or spin-off creation.

LERU fears that uncertainties in the provisions on the protection of intellectual property (IP) rights and trade secrets create significant challenges to determine the criteria for safeguarding data holders' IP rights effectively, and to predict how IP-protected data will be managed in the future EHDS framework.

Concretely, LERU is of the opinion that the conditions under EHDS for the sharing of data should not mandate the use of shared data obtained under EHDS for unfair commercial use or other unfair competition. Furthermore, the requirement for data users to publish the results of the output should be high level enough not to erode IP rights. Finally, any intention to give the responsibility to the HDAB to act as a gatekeeper for assessing and protecting intellectual property and trade secrets would be inadequate.

As regards IP rights, several provisions are introduced in Article 33 "Minimum categories of electronic data for secondary use", with diverging views between Council and Parliament. LERU supports the Council position on Article 33(1)(l) stating that health data holders shall make data from research cohorts, questionnaires and surveys related to health, available for secondary use *after the first publication of results*, while LERU supports the Parliament's position on Art 33(1)(a), stating that data holders shall make *electronic health data from* EHRs available for secondary use.

Finally, LERU encourages co-legislators to avoid a similar impact to that produced by Regulation (EU) 2017/745 on medical devices, which led to some medtech being withdrawn from the European market.

7. Clarify the legal principles of how to share research results to healthcare purposes

LERU asks the co-legislators to further consider the relationship between primary and secondary use of health data. In this context, LERU notes the differing positions in relation to the requirements of the data user to report back any clinically significant findings (to the HDAB or otherwise).

In the Council text, (in Article 35G), any reporting requirements remain subject to Member State Law. Whereas the Parliament's text imposes a mandatory requirement to inform the HDAB (in Article 38(3)) (which in turn must inform the treating health professional or the natural person), whilst respecting the natural person's right to opt out of the reporting of any such findings. The former is an important caveat.

However, LERU through its engagement with universities partner hospitals, has concerns about how such findings may impact on primary care, and in particular, in relation to any genetic findings, which may require further resources at Member State level (such as genetic counsellors).

LERU Office
Minderbroedersstraat 8
3000 Leuven, Belgium

8. Provide sufficient time, support, and funding for the implementation, considering the inequalities between the countries, and the need to raise awareness among citizens and legal entities on the new regulation.

LERU flags that even digitally mature member states need resources and funding to implement the new rules. In Finland for example, where the legislation of secondary use has been in force for four years now, there are still topics to clarify and processes to develop. In that light, the Council's proposal of 5 and 7 years transition times concerning secondary use seems proportional and needed.

LERU furthermore calls for funding and resources for universities to fulfil the new tasks as data holders and stresses the importance of data quality and invites the legislators to consider international best practices for the implementation of universal data standards.

9. Provide clear guidelines for data holders on what is required of them as data holders

LERU specifically calls for clear timelines for the interaction of data holders with the HDABs, standard operating procedures on data-sharing, and reassurances on the security of the data.

LERU, 15 February 2024