

European Health Data Space - proposal for a regulation

EuroHealthNet's vision contributing to the European Commission's public consultation

The **European Health Data Space (EHDS)** aims for “*making the most of the potential of digital health to provide high-quality healthcare and **reduce inequalities***”. EuroHealthNet has supported the establishment of the EHDS as it could improve monitoring and prevention systems, as well as enhance the ability of people to better understand and engage in their own wellbeing via multiple applications and tools.

Throughout the development process of the EHDS, EuroHealthNet has participated in all consultation processes, including public consultations, requests for feedback and the work organised within the eHealth Stakeholder Group.

Digital Health Literacy

The creation and implementation of the European Health Data Space will imply a more widespread use of health data, and associated digital health apps/technologies, across the EU. Along with a multitude of benefits, this could also bring a number of challenges relating to how such health data is managed by those who have access, in terms of trust and safety and whether it is used in an appropriate way. The proposal should give significant importance to the development of digital/data health literacy programmes as integral action targets of the European Health Data Space at both EU and national levels.

Such programmes should be targeted toward the different actors involved:

- **Citizens/patients:** the implementation of the EHDS will imply a more frequent use of digital portfolios, electronic health records, and associated services. People will need to adapt their habits to benefit from such technologies. Improving digital/data literacy across the population will therefore be fundamental to ensure the pick-up and spread of new digital health technologies associated with the EHDS. It would allow people to not only actively manage their personal health and care, but also to increase their understanding of the quality and suitability of apps (including mHealth apps), their marketing, what their data is being used for, how they can control it and other relevant issues. Improved data/digital health literacy would also increase trust in digital innovation in health, care and related sectors.
- **Professionals:** The deployment of the European Health Data Space should go hand in hand with training and capacity building programmes for professionals (including

through up- and re-skilling). The EHDS proposal will require health professionals to adapt their way of working for the use of the new digital infrastructures foreseen in the regulation. At the same time, new non-health professionals will be hired in health settings for the management and treatment of this data. Actions should be put forward to help all these professionals to improve their digital/data health literacy and digital competencies. Due to the sensitive nature of this data, particular attention should be given to trainings focused on how to safely manage health data in the respect of confidentiality and privacy rules. This would help them deliver better quality of care and also create a safer environment. For instance, a large part of cyber threats to health systems begin with phishing events at workstations, which could be prevented using better data and digital literacy.

- **New health authorities:** The EHDS foresees the establishment of several new health authorities in charge for the coordination and management of health data for primary and secondary use as well as for the monitoring and surveillance of the appropriate implementation of the EHDS regulation. Professionals employed in such authorities should have sufficient technical skills, bringing together experts from different organisations. Capacity building activities should be foreseen on a regular basis for continuous training of the employed staff.

Empowering public health

The collection and availability of large volumes of health data under the European Health Data Space infrastructures represent a great opportunity to boost public health, health promotion and disease prevention policies across the European Union. In line with WHO flagship on digital health, the EHDS should support countries to leverage the use of digital health data to improve health system performance and strengthen public health functions including disease surveillance, early warning systems? and risk assessment.

The accessibility to health data at different territorial levels would facilitate close monitoring of population health trends and allow the implementation of tailored public health programmes as well as efficient resource planning.

Secondary use of data data

The secondary use of data can be key in bringing innovation to health settings as well as significant support to policy-making. However, the EHDS Proposal should provide more detailed information regarding the *purposes for which electronic health data can be processed for secondary use*. The *purposes* listed under article 34 are too broad and vague. A more specific definition of what the expected benefits are for citizens and the society as a whole should be provided, ideally backed by studies and sound evidence. The Proposal should also bind the secondary use of health data to principles of inclusivity, equity and anti-discrimination..

Inclusive digital infrastructure and standardisation

The development of sound digital infrastructures should ensure the collection of high-quality data that add value to health systems in a non-discriminatory way. Infrastructure and governance need to be reliable, ethical, safe and inclusive to ensure that data sharing will effectively benefit people's health. This includes ensuring that AI algorithms used in such processes are designed, reflecting the needs, preferences and expectations of people in vulnerable circumstances and priority needs. This means that people with lower digital or health literacy, less education, low income, migrants, disadvantaged older people, people with physical or mental disabilities etc., are systematically and well included in the underpinning research and planning.

In addition to this, standardisation, as a core aspect of the European Health Data Space proposal and its deployment, should ensure high levels of data protection and anti-discriminatory principles. Digital tools collecting this data should also be standardised and regulated to ensure they are safe, comprehensible, easy to use and (therefore) accessible to everyone.

Labelling and certification

The introduction of voluntary labelling of wellness applications should support equitable access and safe use of health apps. The use of health apps is indeed not yet inclusive. The greatest users of such apps are found predominantly among younger, more educated and more digitally literate populations, leaving others underserved and unaware of the benefits they provide.

The use of a trustworthy label would help in fostering quality health apps and ensure that the data these apps produce is well protected and safely managed. As part of the Horizon Europe project "[Label2Enable](#)", EuroHealthNet and other 14 organisations from across the EU joined forces to promote the uptake of the CEN-ISO 82304-2 label that will help understanding levels of *Healthy and safe, Easy to use, Secure data and Robust build* of health apps.