

## EASL's Response to European Health Data Space Consultation

Geneva, 26 July 2021

The European Association for the Study of the Liver (EASL) welcomes the European Commission's initiative to establish a European Health Data Space (EHDS) and looks forward to future consultation activities.

The European Institutions and Member States should support research projects and cross-country collaboration by setting up EU-wide platforms with the aim of sharing data and closing the gap between medical knowledge and clinical practice. Sourcing and maintaining good quality data concerning the diagnosis and treatment pathways of patients with liver diseases, including liver cancer, remain crucial.

EASL addresses the three areas investigated by the European Commission, namely:

### Section 1: Access and use of personal health data for healthcare, research and innovation, policy-making, and regulatory decision-making.

- ❖ **Education, awareness, and transparency:** There is a critical need to educate people, to demonstrate how valuable health data is for research, and to improve understanding and thereby generate enthusiasm among citizens towards the sharing and using of their data. There is a real need to increase literacy on data. Education will be of paramount importance, not only to facilitating trust in the system, but also to catalysing patients to ask for their own health data. **Medical associations play a central role in training – and thus influencing the education of – future physicians and to enabling them to proactively confront the imminent changes in the practice of medicine.**
- ❖ **Building trust in the system:** Trust is crucial for data-sharing and trust in the system must be built from the beginning. Specific questions should be asked such as: how much will industry have access to the given data? Transparency and accountability are required. There is a need to ensure that people are informed as to how their data is going to be used (including transparency or consent required should data be subsequently shared with the industry).
- ❖ **Patients' access to their data:** Portals will need to be created to give access to patients to their own data, especially for patients with rare diseases who can seek answers by accessing their own data.
- ❖ **GDPR application in health research:** Since the processing of personal health data across Member States is fragmented, it leads to challenges and limited access to the data for researchers and public institutions. Furthermore, this reduces cooperation and consequently competitiveness in the research sector.
- ❖ **Medical associations** must play a leading role in national and European agreements on all aspects of digital health. They can facilitate understanding, including from the hospital-level up to the

national level, on diverse matters, such as of electronic medical records, electronic health records, and data storage.

## Section 2: Digital health services and products

- ❖ **Concerns about ethical and equitable access use:** The uneven access to digital technologies (“digital divide”) impacts negatively on equity. Nowadays, the uptake of healthcare apps is predominantly among people aged 20 to 40. This must be taken into consideration, as well as unequal access to telecommunications, internet services, communications, and computing equipment. It will be crucial for people to gain digital access in languages they are comfortable using, requiring translations into those languages.
- ❖ **Workforce:** Medical associations play an essential role in training, and thereby in ensuring that the health workforce is open to change and appropriately trained.

## Section 3: Artificial Intelligence (AI) in healthcare

- ❖ **When using AI for decision-making processes,** it is key to ensure that the data is accurate and representative.
- ❖ **Ethical concerns about data protection:** Digital health tools and healthcare apps, AI, and big data can allow a swifter connection between people’s lifestyles and their related conditions, and in the process, help them ascertain how their chances of having or developing a specific medical condition can be influenced by engaging in certain activities or abstaining from them. However, the impact on people’s related rights – including fundamental, economic, environmental, and social rights – must be considered and accommodated. Fears prevail among certain segments of the population about using apps and about digital health in general, such as how data will be stored, accessed, etc. Structural inequities persist in healthcare systems, including in datasets that incorporate past biases, so there is a dire need to mitigate those adverse effects.
- ❖ **Community organisations,** especially those representing marginalised groups, should be engaged in the discussion on AI design and use in healthcare. By consulting with physicians, medical associations, and patient groups, stakeholders can gain a broader understanding of the role AI can play in healthcare and, importantly, a realistic sense of what AI can and cannot do. AI technology should not become a complementary tool or a replacement for a physician. Anticipating potential ethical pitfalls, identifying possible solutions, and offering policy recommendations will be of benefit to physicians adopting AI technology in their practice as well as the patients who receive their care.



*The mission of the European Association for the Study of the Liver is to be the Home of Hepatology so that everyone involved in treating patients with liver disease can realise their full potential to cure and prevent it.*

*We promote communication among all professionals, in Europe and beyond, interested in the liver and its disorders, particularly by:*

- *promoting liver research and facilitating scientific exchange*
- *fostering research interactions across Europe and beyond*
- *supporting the next generation of researchers, including Young Investigators, as they develop through involvement in EASL activities*
- *promoting education of physicians, scientists, allied health professionals, other medical professionals, and patients*
- *promoting public awareness of liver diseases and their management acting as an advisor to European and national health authorities concerning liver diseases, the provision of clinical services, and the need for research funding*
- *working with patient groups to ensure their perspectives and views are represented in our work*

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