

JOINT STATEMENT ON THE EUROPEAN HEALTH DATA SPACE DRAFT PROPOSAL

A call for society-centred digitalisation of healthcare

We, the undersigned not-for-profit organisations, representing patients, healthcare professionals, hospital pharmacists, payers, and healthcare institutions call on European policy-makers to ensure a more coherent, fair and society-centred approach to the European Health Data Space (EHDS).

We strongly believe that when it comes to healthcare, research and sensitivities linked with health data, the interest of society must prevail over the market. To ensure that public needs are prioritised over profit, we urge you:

- **Not to support strengthened provisions for IP rights and trade secrets.** Data carries great value. Data generated by individuals and shared through the EHDS must be considered a public investment. While IP rights and trade secrets are essential to stimulate the development and distribution of new products and services, we need to ensure that they do not hinder access to important data and information that could benefit society as a whole. In any event, the result of secondary health data processing should be the subject of strong data protection obligations. The EHDS proposal must ensure that the benefits of data are widely shared and used to advance scientific knowledge and improve health outcomes while also protecting the rights of data subjects and data holders.
- **To include provisions on public return on data investment.** Given the high value of health data, which would be increasingly shared by individuals, it is important not to reduce the fundamental right to privacy to a commodity that does not bring a societal benefit. While direct payments to individuals raise several ethical concerns and may lead to unfair practices, it is also problematic not to have any ‘public return’ of investment on the commercialised gains of data usage. One of the options to guarantee such a return would be to include a return value to society, instead of an individual gain. For instance, if due to the EHDS research area medicine and/or treatments are developed and used commercially, conditionalities should apply, such as:
 - a requirement to make use of research results public and license them freely to enable other parties and not ‘lock in’ the acquired knowledge within one entity, regardless of whether or not the research led to the desired outcome;
 - a requirement to accept accessible price caps for those medicines, thus acknowledging the societal contribution of data as valuable input into the research outcome.
- **To incorporate a wider range of civil society representatives into EHDS governance.** The established European Health Data Space will have an impact on a diverse range of stakeholders and not only patient organisations, healthcare professionals and the healthcare industry. To ensure the smooth functioning of the new system, we call on the co-legislators to include in the EHDS governance mechanism all relevant representatives of civil society such as patients, consumers, citizens, healthcare professionals, payers, public health representatives, healthcare institutions, as well as digital rights advocates. To safeguard the transparency, the representatives must be chosen based on the absence of conflict of interest.
- **To foresee sufficient time to develop and implement the EHDS.** The timeline anticipated in Article 72 of the EHDS proposal does not create the circumstances to work with care and precision needed to ensure successful EHDS. More time is needed to realise a project of such scale. This also means respect for the principles of the GDPR and attention to the need for robust cybersecurity. Those are success factors which are needed to guarantee the trust of individuals and other stakeholders.

All in all, the European Health Data Space proposal is set to bring an enormous change to the way European healthcare systems are organised and how health data is processed. We, therefore, ask policy-makers not to take this task lightly and discuss the EHDS proposal thoroughly, as well as foresee an adequate timeline and resources for its implementation.

SIGNATORIES:

