Ensuring the full potential of EHDS: Stakeholders' recommendations on how to make the digital transformation a success across Europe

We, the stakeholders of this joint statement, welcome the proposal for a Regulation on the European Health Data Space (COM 197/2022). Its adoption will accelerate the appropriate availability and improve the quality of electronic health data to support safe continuity of care across borders and empower patients to have greater access to, and control over, their own health data across Europe.

The Regulation has the potential to harness the benefits of the digital age for better health outcomes. It can bring important European alignment to, and rapidly scale up, well-governed access to health data sets for the delivery of healthcare services but also for a wide range of secondary use purposes for better health outcomes. This will increase Europe's capability and global competitiveness for research and innovation, as well as strengthen its health systems and public health resilience. It will be an essential enabler of European health initiatives such as the Beating Cancer Plan and the Non-Communicable Diseases initiative. This statement is signed by such a representative group because the EHDS will have a significant and broad impact. However, there are important details in such a broad-sweeping proposal which need to be addressed to ensure that it will meet its objectives. **We, therefore, petition all Member State and European decision-makers to strongly support this Regulation and to engage with the broad group of stakeholders to ensure the final Regulation optimises its potential.**

With this in mind, we would like to recommend several considerations be taken into account when developing the more specific implementation plans to put this Regulation into practice across the Member States.

1. **A broad range of stakeholders must be strongly involved from the outset of the process to guarantee the success of the EHDS.** This will depend upon the buy-in, expertise, investment and support of many stakeholder groups. These will therefore need to be strongly involved from the outset of the process for each of the aspects, including prioritisation, scoping and timing of the new obligations, through to the implementation phase, including in the technical operationalisation and the setting of relevant standards. This means citizens, patient representatives, clinicians, scientists, healthcare providers and industry stakeholders. Winning trust and broad engagement will be essential for the general acceptance, effectiveness, endorsement, and rapid adoption of the EHDS.
2. **The EHDS must align with all relevant horizontal and sectoral European laws**. The regulatory framework should form an enabler for innovation to take place in Europe by providing regulatory certainty, and not eroding relevant, already established legal rights and concepts, attracting much-needed investment by aligning with relevant horizontal and sectoral legislation. Alignment with all applicable European laws on data governance and data protection must be ensured, including the General Data Protection Regulation, Data Governance Act, Data Act, AI Act and Regulations on cybersecurity. For instance, further clarity is needed on the definition of personal data in the context of the EHDS. Furthermore, alignment with existing European sectoral legislation such as the Clinical Trial Regulation, Medical Devices Regulation, *In vitro* Diagnostic Medical Devices Regulation is a must. These alignments should not only be ensured at an instrument level, but also at the level of European and Member State-nominated authorities and bodies responsible for their enforcement.

3. **There must be harmonised interpretation and implementation of the Regulation across the EU**. For the vision of a European Health Data Space to be achieved, harmonised interpretation and implementation of the Regulation will be crucial. Additionally, clearer descriptions of the data in scope will avoid ending up with 27 fundamentally different data spaces. Whilst respecting Member State autonomy, the implementation of the EHDS Regulation must maximise this alignment and cross-recognition.
4. **Approvals for secondary use of health data must be consistent and harmonised across Europe**. The Regulation proposes that national Health Data Access Bodies establish secure processing environments, primarily for anonymised data sets to be analysed for approved purposes by authorised parties. Pseudonymised data is often valuable to enable data linkage for longitudinal analysis, which is recognised in the Regulation, but we recommend that legal and ethical criteria for approving pseudonymised data use and data linkage be more formally specified at a European level to encourage a more harmonised and consistent approach, while ensuring genuine input from patient representatives and citizens. If applied, ethical approvals for data access should be clearly defined and consistently used across the EU and provide timely and consistent decisions on secondary use of electronic health data. In implementation, the expectations on data users and holders should be more formally specified and harmonised across Europe, in order to better enable multi-country longitudinal data access and use in a streamlined and consistent way.
5. **The scope of EHR systems must be defined clearly within the Regulation**. The Regulation importantly emphasises the interoperability and reliability of EHR systems through mandatory self-certification. Therefore, it is important to define the of scope of "EHR systems" more specifically to ensure application to relevant systems. A definition that focuses on systems intended to share patient information with authorised providers, healthcare professionals or patients and to a data flow between healthcare facilities, may be more in line with the intended aim of the EHDS. The quality criteria and assessment schemes used should reflect state of the art by adopting relevant international standards and should benefit from existing European expertise in EHR system certification.
6. **The successful implementation of the EHDS must be adequately resourced**. This will require significant new funding to be injected throughout the health, health ICT and research ecosystems at European and Member State levels. It is vital that this initiative is adequately resourced, including appropriate investments in capacity building and training, particularly of smaller and non-profit organisations, and that there is a strong, well-funded commitment to public consultation and engagement.
7. **Existing health data infrastructures must be leveraged to allow continuity and build on existing expertise**. The European Commission, Member States and other stakeholders have in recent years invested considerable finance and resources in many health and research data infrastructures and registries that have established data flows, technical architectures, governance models and data access rules that could helpfully inform the detailing and implementation of the EHDS Regulation. To avoid unnecessary bottlenecks, we strongly recommend that a level of continuity be maintained with initiatives where data collaboration is working today. This will allow for communities of practice that already have this relevant expertise and experience, and the methodologies that have already been proven to be utilised when implementing the EHDS.

The signatory organisations of this position statement are actively engaged in European and Member State initiatives relating to the primary use and secondary use of health data at scale and have areas of expertise together with established methods and tools that could facilitate the high quality adoption and rapid benefits realisation from the EHDS Regulation. We would welcome the opportunity to contribute to its success and to discuss further with co-legislators.

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