



EFN Policy Statement on the European Health Data Space (EHDS)

The EFN welcomes the European Commission proposal for a Regulation on the European Health Data Space (EHDS) ([COM/2022/197](#)) and its key objectives as a next step in the digital transformation of health and care ecosystems. 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 citizens/patients to have greater access to, and control over, their own health data across the EU and 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 research. This will increase Europe's research and innovation capability, as well as strengthen its health systems and public health resilience.

However, the EHDS will have a significant and broad impact on nurses' daily workload if not governed well. The EHDS will be a success only if Member States dedicate sufficient resources to the development of infrastructures able to establish a true interoperability between different national data and digital frameworks. The interoperability challenge is not only between countries but also within countries.

The EHDS will be unsuccessful if, during the implementation phase, the role and workload of nurses are not taken into consideration. Nurses play a central role in ensuring that EHR data are collected in a coherent and timely way without adding further administrative burden. New IT solutions (e.g., sensors, platforms, AI applications, etc.) should therefore be co-created with nurses to take into account the constraints and burden of their daily practices. The implementation of the EHDS cannot create major disruption in nursing practice and place an additional burden on

their shoulders. We need to take into consideration the difference between the healthcare services in the member states and ensure that common nursing language and deontology is in place to provide safe patient care.

With this in mind, the EFN highlights the importance of developing specific implementation plans to put this Regulation into practice across the Member States.

1. A broad range of stakeholders, including the National Nurses' Associations, 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 nurses to the EHDS implementation plan. Frontline nurses 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, to the implementation phase, including the technical operationalisation. Winning trust and broad engagement of frontline nurses will be essential for the general acceptance, effectiveness, endorsement, and rapid adoption of the EHDS.
2. The EHDS must align with all relevant existing horizontal and sectoral European laws and be supported to the national regulation in the member states. The regulatory framework should form an enabler for innovation to take place in the EU and Europe by providing regulatory certainty. 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. It is key that we achieve with EHDS a harmonised interpretation and implementation of the EHDS Regulation across the EU.
3. Approvals for secondary use of health data must be consistent and harmonised across Europe. EFN highlights 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 patients and citizens. 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.
4. The successful implementation of the EHDS must be adequately resourced. This will require significant new funding to be injected throughout the healthcare, health ICT and research ecosystems at EU level. There needs to be appropriate investments in capacity building and education & training for

nurses. To avoid unnecessary bottlenecks, the EFN strongly recommends that a level of continuity is maintained building on nurses' expertise and experience, with methodologies that have already been proven to be utilised when implementing the EHDS.

The Europe's digital decade for 2030 targets state that, by 2030, 100% of the European citizens should have access to their digital health records. The EHDS, intended as a key pillar of the European Health Union and aiming to facilitate and enhance access to and use of health data for citizens, health professionals and researchers across the EU, is a key pillar in achieving this ambitious target. To attain a high level of trust and uptake by the end-user, the EHDS should support frontline to deliver high quality and safe services and improved health outcomes for citizens/patients. The envisaged end-user of the EHDS Regulation should have a central role to increase the EHDS exploitation and its impact. Tangible benefits can only be achieved when the end-users will use the EHDS infrastructure to lower down the workload and deliver better healthcare outcomes.

Further readings:

- [European Health Data Space](#)
- [Impact Assessment on the European Health Data Space](#)
- EFN Policy Statement on [End-user co-designing EU digital health systems](#)

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