

UEG statement on the European Health Data Space (EHDS) Regulation

Contributions of digestive disease healthcare professionals and researchers on the successful implementation of the EHDS regulation

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As the leading non-profit organisation for excellence in digestive health in Europe and beyond, United European Gastroenterology [UEG](#), welcomes the recent publication of the **European Health Data Space (EHDS) Regulation** in the [European Official Journal](#) and its entering into force.

This landmark initiative by the European Commission enables the creation of a secure and trusted environment for the use and exchange of electronic health data across the European Union (EU). It will enhance the primary use of health data, boosting individuals' access to and control over their electronic health data, allowing them to securely share information with healthcare providers across EU member states. With patient consent, it will enable the secure reuse of anonymized or pseudonymized electronic health data. This secondary use holds enormous potential to advance research (including digestive diseases and oncology), improve clinical care, support evidence-based policymaking, improve regulatory processes, ultimately empowering patients whilst addressing the needs of healthcare professionals.

The Regulation establishes common standards and infrastructures to ensure interoperability and secure data exchange across healthcare systems within the EU. It also requires Member States to implement training initiatives that equip healthcare professionals with the necessary digital skills and competencies.

UEG recognises the enormous value of health data in enhancing healthcare delivery and advancing scientific research. The new digital framework will significantly impact healthcare professionals in their roles as clinicians and researchers, positioning them as crucial actors in its implementation. **To help realize the full potential of the EHDS, we call on the European Commission to take the following recommendations into account:**

- **Stakeholder Forum:** UEG welcomes the creation of the Stakeholder Forum as the formal platform representing stakeholders, aimed at fostering collaboration with health professionals and supporting the implementation of the Regulation. To ensure its effective operation, we recommend that it be provided with sufficient resources, established as a strong voice within the EHDS governance framework, launched without delay, and composed of a diverse range of stakeholders with substantial involvement and meaningful representation of healthcare professionals.

- **Regulatory consistency:** The implementation of the EHDS should be undertaken in a manner that ensures full consistency and interoperability with existing regulatory regimes, most notably the General Data Protection Regulation (GDPR) and the Clinical Trials Regulation (CTR). It is essential that any overlaps between these regimes are addressed proactively to avoid legal uncertainties, regulatory fragmentation, or conflicting obligations for stakeholders.
- **Fee structures:** With respect to the provisions on fees for making electronic health data available for secondary use, it is essential that the fee policies and structures established by the European Commission ensure that academic institutions and non-commercial research entities are not subject to excessive financial burdens.
- **Standardised data sets:** We strongly support the objective of establishing a consistent framework to facilitate the re-use of electronic health data for the advancement of scientific research, the development of evidence-based policymaking, and the enhancement of regulatory activities. To ensure the effective implementation of this framework, we propose the creation of standardised minimum data sets with clearly defined structures for each disease area. This process should be undertaken in close collaboration with relevant medical societies to guarantee clinical relevance, interoperability, and quality of the data made available for secondary use.
- **Involvement of medical societies:** UEG and other medical societies are well positioned to play a critical role in supporting the harmonisation of health data. We advocate for the early and structured involvement of scientific societies in this process. Furthermore, we recommend that the templates to be developed by the European Commission for data access be designed to minimise the administrative burden on data users to the greatest extent possible.
- **Funding:** We also call for dedicated funding for the effective implementation of the EHDS regulation, and to ensure sustained financial support for related EU research initiatives such as Horizon Europe, the European Strategy for Data, and the EU4Health programme, which are essential for advancing health innovation, data interoperability, and evidence-based policymaking across Europe.

As emphasised by Professor Patrizia Burra, Chair of the UEG Public Affairs Group:

“Unlocking the full potential of the EHDS regulation to advance research in gastroenterology requires ensuring that researchers can access health data seamlessly, without being hindered by excessive bureaucracy or costs. UEG is committed to helping to achieve this goal and stands ready to serve as an active and engaged partner, working alongside the European Commission and other stakeholders to address critical elements of the EHDS initiative. Our shared goal is to advance research in digestive diseases and cancer across Europe, ultimately improving patient outcomes and quality of life for European citizens and patients”.

We thank all our Specialist Member Societies



About UEG

Founded in 1992 United European Gastroenterology (UEG) is the leading non-profit organisation for excellence in digestive health in Europe and beyond with its headquarters in Vienna. We improve the prevention and care of digestive diseases in Europe through providing top tier education, supporting research and advancing clinical standards.

As Europe's home for multidisciplinary gastroenterology, we unite over 50,000 engaged professionals from national and specialist societies, individual digestive health experts and related scientists from all fields and career stages.

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