



The European Health Data Space legislation: Cancer community advice

November 2022

The European Cancer Organisation applauds the initiative of the European Commission to bring forward a legislative proposal to create a European Health Data Space (EHDS).

The European Health Data Space Regulation, published in May 2022 by the European Commission, is expected to support a successful digital health transition by promoting better exchange and access to health data, not only to support healthcare delivery, but also for research, regulatory, and policy-making purposes.

Moreover, the implementation of the EHDS can have positive implications for strengthening research and innovation in cancer care and should actively complement Europe's Beating Cancer Plan and Cancer Mission.

The EHDS should allow researchers to collect significant amount of data related to quality of life (QoL), survivorship, and follow-up.

With the expansion of data repositories and AI, such information raises the possibility of further improvements to treatment strategies, including better understanding of late effects and treatment burden.



SUMMARY OF OUR EHDS AMENDMENT PROPOSALS

November 2022

The European Cancer Organisation provides the following key headline recommendations to Members of the European Parliament and national representatives currently conducting scrutiny of the European Health Data Space legislative proposal:

1. Ensure that the legislation mandates that the European Health Data Space Board includes stakeholder representation, including for patients and healthcare professionals.
2. Require the European Commission to conduct a study on the impact of the General Data Protection Regulation upon cancer research in Europe, including the divergence of implementation approaches, and with provision of remedial recommendations.
3. Require explicit time-based targets for implementation and progress on cross-border health data interoperability, including for cancer registry interoperability.
4. Include in the legislation understanding that EU funding support, from a range of sources, will be made available to assist all health data systems in the EU prepare and be in a state of readiness for the introduction of the European Health Data Space
5. Make clear in the legislation that the European Health Data Space Board has mandate to explore connections with health systems outside of the EU for the purposes of creating and maintaining a highly effective health data space with maximised benefits for patients.
6. Ensure that lessons are learned from implementation difficulties associated with other legislative initiatives, such as GDPR. This includes ensuring that terms and definitions within the legislation are appropriately and tightly described. The risk of 27 interpretations of the legislation must be mitigated against.

The remainder of this document provides some further contextual background to these recommendations, and some suggested amendments to the legal text that could support bringing the above recommendations into being.

We would be delighted to discuss the background and reasoning for the proposed amendments with Members of the European Parliament and national representatives further. For further information please contact silvia.romeo@europeancancer.org.



EUROPEAN CANCER ORGANISATION - PROPOSED AMENDMENTS TO THE PROPOSAL FOR A REGULATION - THE EUROPEAN HEALTH DATA SPACE

1. EHDS BOARD

Preamble – recitals

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<i>New recital 65</i>	<i>The EHDS Board should operate transparently with open publication of meeting dates and minutes of the discussion as well as an annual report. Moreover, impacted stakeholders, and those for whom the EHDS is designed, such as healthcare professionals, patients and other stakeholders, should be involved as members of the EHDS Board with voting rights.</i>	In view of the key need of establishing an environment of trust during the implementation of the European Health Data Space, transparency and inclusiveness must be key principles adhered to throughout its governance approach.

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<i>Article 64.1</i>	<i>A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high-level representatives of digital health authorities and health data access bodies of all the Member States, as well as not less than one representative from a European level patient organisation, and not less than one representative of a European level healthcare professional organisation.</i>	Patients and healthcare professionals are critical end users of the European Health Data Space. Ensuring their active participation in the governance of the European Health Data is critical to ensuring trust, improving implementation and achieving a continuously improving European Health Data Space.



2. GDPR AND CANCER

Preamble – recitals

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<i>New recital 27</i>	<i>In order to alleviate reported difficulties associated with implementation of GDPR regulation and its impact upon cancer research, the European Commission shall conduct an official study to examine the impact of the General Data Protection Regulation on cancer research. The study shall be completed and published by not later than December 2024. The study shall examine divergence of implementation approaches and the impacts upon different areas of cancer research, including Europe’s participation in international cancer trials. The study shall include remedial recommendations.</i>	European cancer stakeholders have repeatedly raised concerns about the impacts that poorly harmonized implementation of the General Data Protection Regulation has had on cancer research in Europe. These concerns should be investigated, reported on, and where solutions are identified, acted upon.

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<i>New article 64.9</i>	<i>The EHDS board shall be empowered to commission studies and other initiatives in order to support the implementation and development of the EHDS.</i>	In a fast-evolving landscape like health data, the EHDS Board must have flexibility and an ability to adapt approaches and horizon scan. The Board should also have an ability to respond meaningfully to issues of high concern to stakeholders in connection to EHDS implementation. Examples include user-friendly and intuitive interfaces, accessibility standards, privacy by design, distributed data governance, eHR standards, and actions to be taken in scenarios of data misuse. Reducing the ecological impact of the EHDS is another matter that the Board should be able to respond to.

3. TARGETS FOR IMPLEMENTATION

Preamble – recitals

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<p>Recital 16</p>	<p><i>Timely and full access of health professionals to the medical records of patients is fundamental for ensuring continuity of care and avoiding duplications and errors. However, due to a lack of interoperability, in many cases, health professionals cannot access the complete medical records of their patients and cannot make optimal medical decisions for their diagnosis and treatment, which adds considerable costs for both health systems and natural persons and may lead to worse health outcomes for natural persons. Electronic health data made available in interoperable format, which can be transmitted between healthcare providers can also reduce the administrative burden on health professionals of manually entering or copying health data between electronic systems. Therefore, health professionals should be provided with appropriate electronic means, such as health professional portals, to use personal electronic health data for the exercise of their duties. Moreover, the European Commission and Member States should agree on time-based targets to implement improved health data interoperability across Europe, including in respect to cancer registry interoperability (by 2023, by 2024, by 2025 etc).</i></p>	<p>For too long calls for fuller interoperability of approaches by European cancer registries have not been acted upon. An example is a failure of most cancer registries to collect quality information on cancer recurrence and cancer metastasis or information relating to race/ethnicity and cancer.</p>
<p>Recital 19</p>	<p><i>...The use of European electronic health record exchange format should become more generalised at EU and national level. While the eHealth Network under Article 14 of Directive 2011/24/EU of the European Parliament and of the Council recommended Member States to use the European electronic health record exchange format in procurements, in order to improve interoperability, uptake was limited in practice, resulting in fragmented landscape and uneven access to and portability of electronic health data. Moreover, consideration should be made to the agreement of time-based EU level targets for implementation of health data interoperability, including in respect to cancer registry interoperability.</i></p>	<p>For too long calls for fuller interoperability of approaches by European cancer registries have not been acted upon. An example is a failure of most cancer registries to collect quality information on cancer recurrence and cancer metastasis or information relating to race/ethnicity and cancer.</p>
<p>Recital 25</p>	<p><i>In the context of MyHealth@EU, a central platform should provide a common infrastructure for the Member States to ensure connectivity and interoperability in an efficient and secure way. In order to guarantee compliance with data protection rules and to provide a risk management framework for the transmission of personal electronic health data, the Commission should, by means of implementing acts, allocate specific responsibilities among the Member States, as joint controllers, and prescribe its</i></p>	<p>Political accountability is required to ensure that progress on cross-border health data interoperability is achieved. Without this, the overall aspirations of the European Health Data Space will be threatened.</p>

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	<i>own obligations, as processor. Moreover, time-based targets in support of this objective should be developed.</i>	
<i>New recital 19</i>	<i>In order to support the successful implementation of the EHDS and the execution of an effective landscape of European health data cooperation, the European Commission shall agree with Member States a range of targets for health data interoperability milestones, including in respect to cancer registry interoperability.</i>	Political accountability is required to ensure that progress on cross-border health data interoperability is achieved. Without this, the overall aspirations of the European Health Data Space will be threatened.
<i>New recital 73</i>	<i>In order to mitigate against risks of delay in implementation, a range of time-based targets for EHDS should be agreed and published by the European Commission and Member States including in respect to health data interoperability.</i>	Political accountability is required to ensure that progress on cross-border health data interoperability is achieved. Without this, the overall aspirations of the European Health Data Space will be threatened.

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<i>Article 12.4</i>	<i>The Commission shall, by means of implementing acts, adopt the necessary measures for the technical development of MyHealth@EU, detailed rules concerning the security, confidentiality and protection of electronic health data and the conditions and compliance checks necessary to join and remain connected to MyHealth@EU and conditions for temporary or definitive exclusion from MyHealth@EU. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 68(2). The implementing act should include the agreement of target implementation dates, including for improved cross border health data interoperability, in consultation with the EHDS board.</i>	Political accountability is required to help progress cross-border health data interoperability.
<i>Article 65.1. New point (f)</i>	<i>(f) to advise the European Commission and Member States on the current status of cross-border health data interoperability in respect to the primary use of electronic health data.</i>	The EHDS Board should have clear mandate to be active in progressing cross border health data interoperability.
<i>Article 65.2 New point (f)</i>	<i>(f) to advise the European Commission and Member States on the current status of cross-border health data interoperability in respect to the secondary use of electronic health data.</i>	The EHDS Board should have clear mandate to be active in progressing cross border health data interoperability.

4. SUPPORT FOR HEALTH DATA INFRASTRUCTURE IMPROVEMENT

Preamble – recitals

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<p><i>Recital 3</i></p>	<p><i>The COVID-19 crisis strongly anchored the work of the eHealth Network, a voluntary network of digital health authorities, as the main pillar for the development of mobile contact tracing and warning applications and the technical aspects of the EU Digital COVID Certificates. Moreover, real time access to data was also highly valuable in directing appropriate policy responses. It also highlighted the need for sharing electronic health data that are findable, accessible, interoperable and reusable ('FAIR principles'), and ensuring that electronic health data are as open as possible and as closed as necessary. Synergies between the EHDS, the European Open Science Cloud and the European Research Infrastructures should be ensured, as well as lessons learned from data sharing solutions developed under the European COVID-19 Data Platform.</i></p>	<p>Improving real time access to data during periods of health emergency, and in normal periods, is a key ask of the European Cancer Organisation's Special Network on the impact of Covid-19 on cancer. More here: https://www.europeancancer.org/resources/165:build-back-smarter-from-covid-19-the-european-cancer-community-speaks-out.html</p>
<p><i>Recital 7</i></p>	<p><i>In health systems, personal electronic health data is usually gathered in electronic health records, which typically contain a natural person's medical history, diagnoses and treatment, medications, allergies, immunisations, as well as radiology images and laboratory results, spread between different entities from the health system (general practitioners, hospitals, pharmacies, care services). In order to enable that electronic health data to be accessed, shared and changed by the natural persons or health professionals, some Member States have taken the necessary legal and technical measures and set up centralised infrastructures connecting EHR systems used by healthcare providers and natural persons. Alternatively, some Member States support public and private healthcare providers to set up personal health data spaces to enable interoperability between different healthcare providers. Several Member States have also supported or provided health data access services for patients and health professionals (for instance through patients or health professional portals). They have also taken measures to ensure that EHR systems or wellness applications are able to transmit electronic health data with the central EHR system (some Member States do this by ensuring, for instance, a system of certification). However, not all Member States have put in place such systems, and the Member States that have implemented them have done so in a fragmented</i></p>	<p>The European Commission should be given a clear understanding of a political expectation for funding to be made available to support all countries meet the health data needs raised by the creation of a European Health Data Space.</p> <p>Creation of a user-friendly and intuitive system should be a guiding principle of implementation.</p>

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	<p><i>manner. In order to facilitate the free movement of personal health data across the Union and avoid negative consequences for patients when receiving healthcare in cross-border context, Union action is needed in order to ensure individuals have improved access to their own personal electronic health data and are empowered to share it. In this respect, appropriate funding and appropriate support at EU level should be considered as means to reduce fragmentation, heterogeneity, and division and to achieve a system that is user-friendly and intuitive in all countries.</i></p>	
<p><i>Recital 24</i></p>	<p><i>Access to and transmission of electronic health data is relevant in cross-border healthcare situations, as it may support continuity of healthcare when natural persons travel to other Member States or change their place of residence. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to get health care. In many border regions, some specialised health care services may be available closer across the border rather than in the same Member State. An infrastructure is needed for the transmission of personal electronic health data across borders, in situations where a natural person is using services of a healthcare provider established in another Member State. A voluntary infrastructure for that purpose, MyHealth@EU, has been established as part of the actions provided for in Article 14 of Directive 2011/24/EU. Through MyHealth@EU, Member States started to provide natural persons with the possibility to share their personal electronic health data with healthcare providers when travelling abroad. To further support such possibilities, the participation of Member States in the digital infrastructure MyHealth@EU should become mandatory. All Member States should join the infrastructure and connect healthcare providers and pharmacies to it, as this is necessary for the implementation of the rights of natural persons to access and make use of their personal electronic health data regardless of the Member State. The infrastructure should be gradually expanded to support further categories of electronic health data, and funding as well as other means of European level support should be considered.</i></p>	<p>The European Commission should be given a clear understanding of a political expectation for funding to be made available to support all countries meet the health data needs raised by the creation of a European Health Data Space.</p>

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
Article 65. New paragraph 3.	<i>The EHDS Board shall also provide advice to the European Commission and Member States on matters relevant for the implementation and development of the European Health Data Space, including cross-border interoperability of health data, and potential mechanisms of funding support to ensure equal development of health data systems across Europe.</i>	As the key governance body of the EHDS, the EHDS Board should take an active role in identifying challenges to implementation as well as associated recommendations.

5. OPEN THE EHDS FOR PARTICIPATION BEYOND THE EU

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
Article 64.1	<i>A European Health Data Space Board (EHDS Board) is hereby established to facilitate cooperation and the exchange of information among Member States. The EHDS Board shall be composed of the high-level representatives of digital health authorities and health data access bodies of all the Member States. Other national authorities, including market surveillance authorities referred to in Article 28, European Data Protection Board and European Data Protection Supervisor may be invited to the meetings, where the issues discussed are of relevance for them. The Board may also invite experts and observers to attend its meetings, and may cooperate with other external experts as appropriate. The EHDS Board may also explore with digital health authorities and health data access bodies outside of the EU potential means of their connection to the European Health Data Space. Other Union institutions, bodies, offices and agencies, research infrastructures and other similar structures shall have an observer role.</i>	The ultimate test of the European Health Data Space's value will be in achieving improvements to the care and outcomes of patients. If expanded connection of the EHDS to other countries can support this goal, undue impediment should not be raised.

6. HARMONISED IMPLEMENTATION

Legal text

ORIGINAL TEXT	SUGGESTED AMENDMENT	JUSTIFICATION
<p>Article 10.1</p>	<p><i>Each Member State shall designate a digital health authority responsible for the implementation and enforcement of this Chapter at national level. Implementation should be harmonised at national level and across Member States with the EHDS Board conducting an oversight and leadership role in achieving this. The Member State shall communicate the identity of the digital health authority to the Commission by the date of application of this Regulation. Where a designated digital health authority is an entity consisting of multiple organisations, the Member State shall communicate to the Commission a description of the separation of tasks between the organisations. The Commission shall make this information publicly available.</i></p>	<p>As the key governance body of the EHDS, the EHDS Board should take an active role in identifying challenges to implementation as well as associated recommendations. As an example, challenges are likely to include the governance and guidance for national authorities in respect to patient consent procedures, and the interpretation of regulator definitions in the legal text of the regulation e.g., ‘data holder’ and the scope of data sources listed in the Annex.</p>
<p>Article 64. New paragraph 5.</p>	<p><i>The EHDS Board shall publish an annual report to include the implementation status of the European Health Data Space and other relevant points of development, including in respect to cross-border health data interoperability, and arising implementation challenges.</i></p>	<p>Accountability should be a fundamental principle in implementation of the European Health Data Space.</p>



ANNEX: Hearing all voices. Convening the European cancer community on the opportunities of digital healthcare. Arriving to our 6 recommendations.

About the European Cancer Organisation

Our mission is to reduce the burden of cancer, improve outcomes and the quality of care for cancer patients, through multidisciplinary and multi-professionalism.

As the not-for-profit federation of member organisations working in cancer at a European level, we convene oncology professionals and patients to agree policy, advocate for positive change and be the united voice of the European cancer community.

Digital technology continues to revolutionise great areas of our personal, social and work lives, including in health and cancer care. The European Cancer Organisation identifies enormous opportunity for digital healthcare to enhance the provision of cancer care, contribute to the improvement of outcomes and deepen our fundamental understanding of cancer and the responses required to it.

However, many such advances are threatened unless relevant policies are implemented to address critical challenges around accessibility, data interoperability and digital literacy. A successful digital health transition requires empowering patients and rethinking education and life-long training, as well as bringing about strong governance models that inspire and sustain public trust. Since 2020, the European Cancer Organisation (ECO), together with its Digital Health Network, is engaged in the topic of digitalisation in cancer care.

1. [Unlocking the potential of digitalisation in cancer care – No Stopping Us Now!](#)

In November 2021, ECO published the report '[Unlocking the potential of digitalisation in cancer care – No Stopping Us Now!](#)'. Authored in conjunction with the Digital Health Network of the European Cancer Organisation, key recommendations include:

- Addressing known regulatory barriers to the advance of digital healthcare such as cited problems in the application of the General Data Protection Regulation (GDPR).
- Advancing the agenda of digitalisation and data interoperability in cancer care, including by setting strong targets for further alignment and commonality in approach between cancer registries in Europe.
- Supporting the advancement of digital health in cancer care with tailored support to develop the digital literacy of both patients and healthcare professionals.
- Benefitting from the views and contributions of more than 18 organisations, the paper sets out a positive vision of the opportunities to be realised from all major fields of present innovation in digital healthcare and provides a mandate from the European cancer community to secure further action from political decision-makers.

2. [The European Health Data Space and Cancer: Applying Lessons Learnt for Successful Implementation](#)

In September 2022, ECO published an action report: *The European Health Data Space and Cancer: Applying Lessons Learnt for Successful Implementation*. The report provides a detailed account of the presentations and contributions shared during the June 2022 ECO Community 365 Roundtable Meeting on the European Health Data Space and Cancer. This meeting brought together leading policymakers, politicians, oncology experts, and patient advocates to discuss EU policy developments related to the ongoing digital transformation of cancer care, with a special focus on the opportunities and challenges associated to the creation of a European Health Data Space (EHDS), and its potential impact for the improvement of cancer care across Europe.

The main recommendations contained within ‘Applying Lessons Learnt’ included:

- **Data silos:** Data silos should be torn down to improve cancer care, for example, by developing data translators, and taking a citizen-focused data sharing culture.
- **Trust:** Data security, trust, respect for privacy, and transparency of the use and access of health data is key. Citizens and patients need to know how they can engage in the digital transformation of healthcare. There should be a harmonised, fit-for-purpose ethical approval process for secondary use across Europe.
- **Applications for oncology:** The implementation of the EHDS can have positive implications for strengthening research and innovation in cancer care and should actively complement Europe’s Beating Cancer Plan and Cancer Mission.
- **Multi-stakeholder collaboration:** Multi-stakeholder collaboration is key to ensuring the success of the EHDS. Collaboration between different stakeholders, and co-design by end-users will be critical for the successful development and implementation of the EHDS.
- **Applying lessons learnt:** Lessons learnt from pilot projects in the secondary use of health data should be applied to maximise the success of the EHDS. Consideration should be given to deploying Federated Data Spaces using FAIR principles to overcome barriers to access health data. Similarly, experience with real-world data and real-world evidence initiatives point to the need to link data sets with a common data model / format, and thus ensure they are interoperable.
- **Implementation:** Implementation guidelines should be drafted to support the roll-out and implementation of the EHDS at Member State level.