the digital health society
The data arm of ECHAlliance Group

iHD

Targeting the Calls to Action and Recommendations towards EHDS secondary legislation

DECEMBER 2024

Round Table 8

Targeting the Calls to Action and Recommendations towards EHDS secondary legislation

When the proposal to create a *European Health Data System* was first announced ECHAlliance and I~HD created in 2020 a virtual multi-stakeholder Round Table Programme on Calls to Action on Health Data Ecosystems. The purpose was to help the European Union design the EHDS and the enabling regulation. There were 6 Round Tables held between 2020 and 2023, and published as reports that can be downloaded **here**.

Now that the regulation has been formally adopted, an ambitious program is underway to develop the implementing acts (secondary legislation) that provides the legal details necessary for putting the measures of the regulation into practice including conformance details and enforcement measures. These implementing acts will involve legislation from both the European Commission and Member States. This is an important window of opportunity to influence that secondary legislation so that it drives the best possible implemented European Health Data Space for the benefit of all stakeholders. Whether you are a patient, healthcare professional, citizen, healthcare provider or researcher or work in medtech, pharma or technology it is in the interests of all stakeholders for EHDS to be as successful as possible.

In order to inform our stakeholders about the possible areas to promote to the attention of the legislators, ECHA and I~HD have revisited all seven reports to map these sets of recommendations to the EHDS Regulation, in particular which recommendations have been incorporated, and which recommendations should be re-emphasised to the legislators. We were pleased to see that 28 and 16 of our recommendations were respectively fully and partially incorporated into the EHDS regulation and only two not included.

All the participants to our previous round tables, and some additional stakeholders, were invited to a webinar on 5th December 2024, to review and discuss these recommendations. The webinar discussed the enabling measures that could scale up data availability and access for secondary use including interoperability and quality, measures that can strengthen public trust and transparency, and from a primary use perspective enabler to accelerating the adoption of interoperability standards focusing on the European EHR exchange format. The webinar attracted one hundred participants. This report follows on from our Round Table Webinar on the 5th of December 2024 when we presented our Summary of the Recommendations from Round Tables 1 to 6 and a comparison with the then latest draft EHDS Regulation and that Summary is **here**.

Scale up data availability and access

EHDS for Primary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- Mandatory Member State participation in MyHealth@EU
- Mandatory capability for EHR systems to be able to import and export EEHRxF data categories, to make these available cross-border and to enable patients to access this data or direct it to another provider.
- Mitigation of the risk that increased digitalisation of healthcare increases health inequalities, reducing the digital divide by requiring Member States to invest in digital and data literacy for health professionals and the public.

Recommendations to secondary legislators

- Legislation should embed the use of the EEHRxF (presently focused on its use in MyHealth@EU) also within Member States, accessible via authorisation as an extension of the EU Digital COVID Certificate, using the EU Digital Wallet.
- Legislation should enable a formal but agile method for extending the EEHRxF data categories, aligned across Member States, to include long term condition status and monitoring, the data needed in rare diseases and for children, social care and health needs.
- Although the opt out of primary use will be implemented at Member State level, the choices made by each citizen should be aligned across borders and be incorporated into the EU Digital Wallet.
- Legislation should set minimum levels of investment and activity to increase the digital and data literacy of health professionals and the public and enable Member State co-operation in the development and use of resources and educational programmes.

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- Ensure that custodianship and governance of future health data sets reflects common European values and principles, and is independent of the EHR system vendors, of the companies that collect data via apps and sensors and of the companies that make use of data. The role of HDABs including their transparency obligations and the proposals for a secondary use opt out contribute to this, although their rules and criteria for issuing permits need to make this explicit.

Recommendations to secondary legislators

- The decision-making policies of HDABs regarding data access decision making and transparency should visibly uphold the perspectives of citizens and patients, EU societal ethical principles and values, in enabling the appropriate use of data as well as preventing misuse.
- The EHDS methods for making data sets available should consolidate efforts on one or a small number of common data models so that data harmonisation methods, tools and skills can be scaled up to become a readily available and affordable resource. Secondary legislation should define preferred common data models for shared data sets, whilst recognising it may not be feasible to impose this on legacy data sets and ongoing data collections.
- Investments in the EHDS should promote the uptake of federated data models to facilitate interoperability and FAIR data set access while upholding GDPR compliance. The preamble text mentions the ideal situation of bringing questions to the data, but this is not reflected in the Regulation. It should be endorsed and encouraged for data access for secondary purposes by HDABs. A governance model, interoperability specifications and minimum security standards should be defined in secondary legislation for HDAB-mediated federated analysis at a European level.
- All future funded EC projects should have a contractual condition to supply suitable data sets to the EHDS.

Assure public trust and transparency

EHDS for Primary Use

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- Requires open, transparent, responsible, inclusive and accountable use of health data.
- Requires clarity of purpose and transparency about how health data will be used. Publishes lists of data uses that will normally be supported and those that will not. Use of health data may only be to improve the health, care and wellbeing of citizens and contribute to improving health and care inequalities.
- Complies with and aligns with other relevant European Regulations e.g. GDPR to ensure data privacy, good data management and governance.

- Requires compliance with the FAIR principles for scientific data management.
- Charges data access fees on a cost recovery basis.
- Ensures transparent communication by and with signatories on the use of health data, the social benefits realised, and lessons learned.
- Includes members of the public in the constitution of the European, national or regional decision making bodies and boards.
- Publishes via HDABs inventories of data use requests received, accepted, declined and of any investigations into misconduct.
- Publishes via HDABs the benefits data use has enabled.

Recommendations to secondary legislators

- The European Commission and Member States should promote the development and adoption of a multi-stakeholder Compact regarding responsible data use, transparency, accountability, communication, by including the public (patient and civil society organisations) health funders, providers and health data organisations (public bodies and industry).
- Secondary legislation should clarify in greater detail how population and personal preferences for data reuse should be reflected through policies, rules and decisions offered by Member States, and how preference choices should be communicated through public outreach activities and channels.
- Ensure that the policies and rules developed for data access decision making adequately reflect public preferences and optimally balance differing public viewpoints.
- Specify and publish the data processing conduct expected from all data users, including how this will be monitored and enforced.
- Establish mechanisms to publish the learning and good practices across Member States through reusing health data.

Accelerate interoperability standards adoption across Europe

EHDS for Primary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- Member States required to align on standards adoption, initially on the EEHRxF, to reflect those as strong interoperability drivers within national and regional policy and specifications.
- All primary use health data flows into the European Health Data Space are required to support cross-border care to individuals by conforming to a specified portfolio of international interoperability standards, profiles, clinical models, terminology value sets and interfaces: the European Electronic Health Record Exchange Format (EEHRxF).
- Member States health policymakers expected to prioritise resource allocation to the procurement of electronic health systems in hospitals and primary care that have been certified to comply with the EHDS EEHRxF standards.

Recommendations to secondary legislators

- The EC should negotiate with the relevant Standards Development Organisations (SDOs) to secure an open access licence to all of the standards included in the portfolio.
- The EEHRxF should have a rout map to extend the priority health data categories for primary use, to include immunisation data, rare disease diagnostic and long-term condition monitoring data sets.
- Member States should ensure interoperability between consumer devices (which will become increasingly important as this type of data grows in volume and relevance), and not only with EHR systems, through regulation or soft law.
- Member States should work towards the cross-country recognition of conformance testing and certification and approval of standards implementation by health ICT systems, platforms, mobile health apps and near patient devices to drive a strong and single European market for interoperable products.
- The extent of the interoperability a healthcare organisation and its supplier can deliver should be measured and made public.

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Recommendations to secondary legislators

- The EC should require that all health data flows into the European Health Data Space for large scale data analysis conform to a specified portfolio of international interoperability standards, profiles, clinical models, terminology value sets and interfaces.

- The EC and the eHealth Network should consult stakeholders on high priority secondary use data sets for European interoperability standards adoption and information sharing terms, including the core data sets enabling patient recruitment for clinical research.
- The EC should require that public and private organisations show commitment to standards adoption themselves before they are permitted to access data via the EHDS for research.
- The EC should more strongly encourage health data generated through its funded projects to be more widely reusable via the EHDS, in particular on evidence for the benefits case for greater investments in standards adoption and interoperable interfaces.

Measure and improve data quality

EHDS for Primary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- The European Commission and Member States are required to label health data in a standardised way with provenance metadata so all primary users can trust its origins and safely interpret data from its original context. (The EEHRxF will include such metadata for the priority categories.)

Recommendations to secondary legislators

- The European Commission and Member States should provide an aligned EU wide assessment and certification frameworks for digital therapeutics and data collected from medical devices, as well as for EHR tools, to facilitate the collection of high-quality and interoperable data.
- Member States should use policy levers to mandate and incentivise improving the quality and interoperability of routinely collected EHR data. This may mean investing in training, upgrading electronic health record systems and for new interoperability interfaces, appointing data quality managers, data quality assessment and benchmarking.
- Member States should use policy levers to mandate and incentivise the incorporation of features supporting the capture of high-quality data EHR and medical device data.

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- The European Commission and Member States requires the labelling and cataloguing of health data sets in a standardised way with provenance metadata so users can trust its origins and safely interpret data from its original context. (The requirement to adopt FAIR principles, to populate data catalogues and the option to incorporate the data quality and utility label will be enforced by HDABs.)

Recommendations to secondary legislators

- Secondary legislation should specify a Data Quality and trust framework that includes
    - process criteria for data provenance
    - dimensions of data quality
    - quality Information for the data consumer to assess the suitability of the data against the intended use.
- Secondary legislation should specify core data quality metadata to be made available by the provider of shared data sets, at minimum:
    - the data pipeline i.e., collection process, controls applied, any further processing such as mapping or transcoding
    - the original purpose for which the data was collected
    - who collected the data (i.e. patient, GP, hospital) and how was data extracted from which sources
    - internal quality assessment mechanisms and assessment reports.

Generate trustworthy real-world evidence

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Provide greater clarity on data protection and gdpr compliance

EHDS for Primary Use

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Recommendations to secondary legislators

- The European Commission and Member States should encourage the European Data Protection Board and Data Protection Authorities to develop and adopt risk stratification guidance on the use of data protection safeguards, to better balance risks with the opportunity costs of not sharing health data.
- The European Commission and Member States should request the European Data Protection Board and Data Protection Authorities to identify acceptable safeguards for pseudonymised data that recognises that many of the reuses of data, especially for research, public health and health service improvement do not need identifiable data, but they often need fine-grained, close to real-time, data including longitudinal histories and increasingly including specialised data types such as genomics.

Skills and training for stakeholder groups

EHDS for Primary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- The Regulation specifies a requirement on Member States to invest in the digital literacy of health care professionals so that they can facilitate patient choices regarding their data within the EHDS.
- The Regulation specifies a requirement on Member States to invest in the digital literacy of the public so that they can exercise choices regarding their data within the EHDS.

Recommendations to secondary legislators

- Legislation should require policy level action by Member States to invest appropriately to their population size in digital and data literacy for citizens, HCPs and healthcare delivery support staff.
- Member States should set target standards for population and professional digital, health and data literacy and openly share these targets at a European level.

- A minimum digital literacy syllabus should be specified at EU level.
- Literacy should cover, for the public:
  - becoming fluent data users for their own health
  - appreciating the importance of the data they create
  - understanding their rights and protections over data held by and used by others
  - understanding the benefits their data can offer to society.
- Literacy should cover, for existing and future health professionals and managers:
  - how to use digital health tools/data science for patients and citizens
  - how to educate and support patient/citizen users of health data and digital health tools
  - how to respond to and escalate issues, readings of concern
  - the importance of RWE and its quality
  - how to understand data science and its contribution to healthcare practice.
- Education providers targeting public and health professional education should be required to share digital health information curricula and learning objectives (not course delivery materials). Equally sharing should extend to curricula for health and data literacy for the education of children.

EHDS for Secondary Use

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Prioritise immunisation information and systems

EHDS for Primary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Recommendations to secondary legislators

- The EC and Member States should collaborate to ensure effective, timely and interoperable information about all vaccine-preventable diseases is available at EU, country and regional levels.
- The EC should leverage the EHDS for:
  - accelerated cross-border access to citizen-level immunisation information
  - aggregated-data intelligence on coverage, outbreaks and the effectiveness of prevention and containment strategies
- The EC, WHO and Member States should define core data sets along with their interoperability and data quality specifications as Europe wide extensions to the EEHRxF, recognising the data sets will be use case specific and might have vaccine specific elements.
- Each Member State holding the EU Presidency should help to accelerate Europe-wide alignment on data sets and data standards.
- Immunisation information systems, linking to public health and healthcare systems, should prioritise:
  - vaccination record access to individuals and families
  - continuity of care across borders
  - tracking complications and adverse events: individuals and populations
  - linking vaccination coverage to disease burden
  - linking outbreaks to vaccination coverage gaps
  - linking campaigns to vaccination uptake

EHDS for Secondary Use

There are no Regulatory provisions or forthcoming secondary legislation on this topic.

Proposal for a societal compact for the secondary use of health data

EHDS for Primary Use

Not applicable

EHDS for Secondary Use

Key provisions in the Regulation that align with the CTA and Round Table recommendations

- The purposes for which secondary use of health data are permitted, and prohibited, within the EHDS must be specified at EU level.
- Health and health related data must only be reused for purposes that aim to directly result in, or contribute to bringing, benefits to society in terms of improved opportunities for better health and care.
- Health and health related data must never be reused for purposes that are unethical, violate human rights, will directly disadvantage or are very likely to directly disadvantage individuals or groups of individuals, or will exclusively further individual or organisational interests without bringing benefits to some parts of society.
- The reuses of health and health related data must always safeguard the privacy of individuals whose data are being reused, by complying with all applicable data protection laws (such as the EU GDPR), by adopting robust information security and privacy preserving measures, and by using aggregated or anonymised data whenever possible. These limits must be balanced against benefits that may be achieved by using identifiable or pseudonymised data.
- The results from reusing health and health related data should be published, or shared in some other way unless the results are (i) personally damaging to identifiable participants, (ii) may be used to discriminate against groups, (iii) subject to commercial use for products and services. In the latter case those products and services should be available to all possible adopters on fair terms such as fair pricing.
- Bodies that make decisions to permit data access must ensure that these principles are upheld when defining decision making rules and be transparent to the public about those rules, the data access decisions that they make and the societal benefits that those data reuses have enabled.

Recommendations to secondary legislators

- The descriptions of each permitted and prohibited purpose should be elaborated with illustrative more detailed lists
- The governance rules regarding terms for health data use including terms for being granted access to pseudonymised data and the safeguards required for its use should be agreed at EU level.
- The reuses of health data must be respectful to the holders of the data being used, and adhere to data use terms agreed with the data holders including the purposes for which their data may be reused.

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