



# Summary of the Recommendations from Round Tables 1 to 6 and comparison with the European Health Data Space Regulation

OCTOBER 2024

# Calls to Action on Health Data Ecosystems & the European Health Data Space

## CTA V4 Introduction

When the proposal to create a European Health Data System was first announced EHCAlliance 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 as follows:

**RT1:** Acceptance Criteria for societal trust in the use of health data.

**RT2:** A recipe for Trustworthy digital health: standards, architecture and value.

**RT3:** Proposing a common basis for health data access across Europe.

**RT4:** Scaling up the availability and reusability of big health data.

**RT5:** Immunisation information systems: Making interoperable data systems for vaccination a reality in Europe.

**RT6:** Proposal for a Societal Compact for the Secondary use of health data.

If you wish to read the RT published report they are available [here](#).

### RTs 1 & 2 together created 7 Calls to Action:

**CTA 1** Raise the Digital literacy & skills of all stakeholders.

**CTA 2** Generate and value trustworthy Real World Evidence.

**CTA 3** Accelerate interoperability across Europe and globally.

**CTA 4** Demonstrate benefits to society from data access, use and reuse.

**CTA 5** Adopt a risk stratification approach.

**CTA 6** Build a trustworthy framework for data access and use.

**CTA 7** Adopt a transformational approach to health data.



We would like to acknowledge the substantial contributions of a) over [ ] individuals and organisations representing patients, regulators, policy makers, academics, health care professionals and providers, civil society and industry b) the support of J&J, Microsoft and MSD. Please note the published reports are the independent work of ECHAAlliance and I~HD.

This report has reviewed the recommendations of the 6 RTs against the published final draft of the EHDS Regulation and listed in:

- **Green text** those recommendations fully included in the EHDS Regulation and/or intended implementing acts and/or by recently started EC projects to develop the needed solutions.
- **Blue text** those recommendations partially included in the EHDS Regulation but not the full aspiration of the recommendation.
- **Purple text** those recommendations that have not been included in the EHDS Regulation.
- **Black text** recommendations that were probably not reasonable to expect in the EHDS Regulation.

These recommendations have been extracted, consolidated and mapped to the final EHDS compromise text of March 2024. In order to confirm those consensus views across our RTs and participants that have largely been incorporated, and others that might be appropriate to promote again towards MEPs and legislators who are developing the secondary legislation (Implementing Acts) that will be necessary to formalise the adoption of the Regulation.

Please note the recommendations below were created between 2020 and 2023 and we have not attempted to update them to reflect any developments since they were published.

DHS and i~HD will convene a webinar to present these findings, and raise discussion about the outstanding areas and what proposals we should now make to ensure the greatest value and success of the secondary legislation.

Please note the recommendations below were created between 2020 and 2023 and we have not attempted to update them to reflect any developments since they were published.

# Scale up data availability and access

## Actions for the EC

- The European Commission should undertake and publish a survey of the data and infrastructure capability of Member States to inform policy and investment by the EC and Member States.
- Investments in the EHDS should promote the uptake of federated data models to facilitate interoperability, connectivity and FAIR data access while upholding GDPR compliance.
- 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.
- The European Commission should extend the EU Digital COVID Certificate into an EU Health Card in a staged process e.g. incorporate all routine vaccinations, e-Prescriptions and patient summaries.
- The European Commission should incorporate into the EU Health Card the ability for citizens and patients to give informed consent to the access to and use of their health data and its portability into the EHDS and approved federated networks.
- The European Commission should undertake an audit of completed EU funded projects (including the Recovery and Resilience Facility and EU- 4Health program) to determine what data sources could be made available (in compliance with GDPR and ethics) for the EHDS and all future funded projects should have a contractual condition to supply this data to the EHDS.
- The EC should boost research into synthetic data sandboxes to enable research into novel security approaches and the training of AI algorithms.
- The European Commission must ensure that custodianship and governance of future health data sets must uphold the perspectives of citizens and patients, reflect common European values and principles, be 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 European Commission should recognise that the distinction between primary and secondary uses of health data may not be sustainable and is neither representative of what happens in health care practice or conducive to protecting rights, reaping benefits or improving health expediently.

## **Actions for the EC and Member States**

- The European Commission and Member States using EHDS should provide for a plan to create combined health and social care EHR.
- The European Commission and Member States should ensure that incentives for digitalisation and infrastructure do not increase the health inequalities and in turn reduces and not increases the digital divide.
- The European Commission and Member States should develop a clear communication campaign for citizens explaining the “jargon” e.g. federated networks so that they are able to understand the various components of the EHDS including the infrastructure concepts as well as what an EU health learning system is and what benefits it would bring citizens and patients.

## **Actions for the EC and EMA**

- The European Commission and the European Medicines Agency should together develop a communication plan and map to explain the roles of GAIA-X, DARWIN EU and EHDEN and how collaboration between them will be assured and duplication of effort and resources avoided.

# Assure public trust and transparency

## Actions for the EC and Member States

- The European Commission and Member States should consult with the public to agree the societal benefits that health data users should be required to target, and how population and personal preferences for data reuse should be reflected through policies, rules and decisions.
- The European Commission and Member States should conduct public awareness campaigns to explain to the public the research uses and benefits of using health data.
- 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). [Round Table developed an operational draft for how such a Compact could work and it is summarised on page [ ]. This was developed to demonstrated how the EHDS concept could be implemented in a practical way.]
- The European Commission and Member States should adopt the following principles when developing or promoting a European Societal Compact
  - Require open, transparent, responsible, inclusive and accountable use of health data
  - Using health data only to improve the health, care and wellbeing of citizens and contribute to improving health and care inequalities.
  - Oversee fair and equitable value exchange between signatories respecting the requirement for society and common benefits from individual and organisation giving access/data altruism
  - Compliance with all national and European laws e.g. GDPR and ethics to ensure data privacy, good data management and governance
  - Fees should be charged on a cost recovery basis
  - Require clarity of purpose and transparency about how health data will be used
  - Require compliance with the FAIR principles for scientific data management
  - Ensure transparent communication by and to signatories on the use of health data, the social benefits realised, and lessons learned.

- o Promote a “Data culture for Society” building upon the Data Saves Lives initiative.

## **Actions for Health Data Access Bodies and data intermediaries**

- Hold open public consultation when developing governance frameworks and decision-making rules for health data uses and reuses.
- Include members of the public in the constitution of the European, national or regional decision making bodies and boards.
- 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.
- Publish illustrative lists of data uses they will normally support, and those they would not.
- Require the intended benefit of data use to be stated with each data request.
- Publish inventories of data use requests received, accepted, declined and of any investigations into misconduct.
- Publish the benefits they have enabled, and lessons learned from reusing health data.
- Promote and oversee good models of data altruism.

## **Actions for industry sectors that use health data**

- Industry should support and then adopt consensus practices on how best to communicate the benefits to society from their use of health data.

# Accelerate interoperability standards adoption across europe

## Actions for the EC

- The EC must require that all health data feeds into the European Health Data Space, to support cross-border care to individuals or for large scale data analysis, conform to a specified portfolio of international interoperability standards, profiles, clinical models, terminology value sets and interfaces, which should build on the European Electronic Health Record Exchange Format (EEHRxF).
- The EC and the eHealth Network should consult stakeholders on high priority (high value / high unmet need / high volume / low complexity) health data sets to prioritise for pan-European interoperability standards adoption and information sharing. These could include the International Patient Summary, immunisation data, the core data sets enabling patient recruitment for clinical research, and rare disease diagnostic and clinical care data sets.
- The EC and the eHealth Network should establish mechanisms for sharing their learning, approaches and benefits from scaling up standards adoption. This includes the sharing of methods, tools and developed semantic resources that connect structural standards and terminological standards (i.e. clinical models, EHR archetypes, FHIR profiles).
- The EC must negotiate with the relevant Standards Development Organisations (SDOs) to procure an open access licence to all of the standards included in the portfolio.
- 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.

## Actions for Member States

- Member States must specify a portfolio of interoperability standards for national eHealth and research infrastructures that aligns with the European standards portfolio, whilst accommodating national priorities and specificities.

- Member States should embrace an alignment of standards adoption with other countries, such as on the EEHRxF, and reflect those as strong interoperability demands within national and regional procurement policy and specifications.
- Member States health policymakers must prioritise resource allocation to the procurement of electronic health systems in hospitals and primary care that have been certified to comply with its national standards portfolio.
- Member States and healthcare providers should collectively ensure that procurement officers for EHR systems and platforms are sufficiently educated about standards and interoperability, including what evidence of standards conformance they should require within tenders, to ensure that procurements result in genuinely interoperable and co-operating health ICT solutions.
- Member States must support patients and citizens to become strong advocates of joined up (interoperable) health data balancing illness and wellbeing (prevention) needs.
- Member States must ensure interoperability between consumer devices (which will become increasingly important as this type of data grows in volume and relevance) through regulation or soft law.
- Member States, health policymakers must ensure that the approval and reimbursement process for digital health tools (e.g. apps, wearable sensors) used by citizens under clinical supervision comply with relevant sections of the national standards portfolio.
- Member States must 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.

## **Actions for standards development organisations**

- SDOs must work together with clinical and patient communities in the development of interoperability specifications (e.g. clinical models, profiles) to ensure these have clinical validity and utility, such as effectiveness at the point of care (and to avoid fragmentation).
- SDOs, their end user communities and health ICT vendors must work more closely together to ensure standards are well aligned to needs and are practical to adopt (especially, that multiple standards can be used together smoothly).
- Future standards development should involve representative data creators and users, especially health professionals and patients.

## **Actions for healthcare providers**

- Healthcare providers should demand, from their EHR suppliers, explicit and independently verified interoperability against prescribed standards through procurement specifications and renewal contracts.
- The extent of the interoperability a healthcare organisation and its supplier can deliver should be measured and made public.

## **Actions for all stakeholders**

- All stakeholders must collaborate to raise awareness within healthcare professional societies and patient organisations, and their members, about the benefits of creating more interoperable (i.e. structured, coded, complete, timely) records, of trusting the data professionals use from other sources and be more convinced about why their investment in creating better data brings societal value. This should be promoted through funded awareness-raising campaigns and demonstrators.

# Measure and improve data quality

## Actions for the EC and Member States

- The European Commission and Member States should prioritise use cases to showcase shared data quality specifications, shared efforts for conformant data generation and shared benefits.
- The European Commission and Member States should prioritise use cases for the European Health Data Space not only as an interoperability specification but also a data quality specification (data quality requirements), with data flows, intended data uses and standardised workflows for the generation of high quality, re-usable data sets.
- The European Commission and Member States must label health data sets in a standardised way with provenance metadata so everybody can trust its origins and safely interpret data from its original context. This metadata must be efficiently incorporated automatically by EHR and PHR systems, not by adding to the data entry burden.
- The European Commission and Member States should provide incentives and assessment and certification frameworks for digital therapeutics and data collected from medical devices, as well as for EHR tools to facilitate collection of high-quality data.
- The European Commission and Member States, along with other stakeholders, should leverage citizen/ patient agency to complement the validation of data in EHRs.

## Actions for healthcare payers and providers

- Health Authorities and health care managers must view investments in data quality as part of their core strategy, create awareness and an understanding of how high quality and trustworthy data will impact all levels of care, including return on investment.
- Health authorities and health care managers must use buying power to encourage the incorporation of tools supporting the capture of high-quality data and interaction with the users, aiming to optimise the collection of data against predefined quality specifications.
- Healthcare provider organisations should invest in improving the quality and interoperability of their routinely collected data. This may mean investing in training,

upgrading their electronic health record systems and paying for new interoperability interfaces, appointing data quality managers, data quality assessment and benchmarking.

## Actions for all stakeholders

- Stakeholders across the health system, industry and innovators need to design new models for the data continuum from care to research and innovation, starting from properly articulating the value propositions, the needed investments, potential savings and the benefits to patients, professionals and health systems from better data, across the value chain.
- All Stakeholders must focus efforts on optimising data quality and re-usability at source.
- All stakeholders should agree on a Data Quality and Trust framework that includes
  - Quality principles (dimensions of data quality)
  - Process criteria for data provenance.
  - Quality Information for the data consumer to assess the suitability of the data against the intended use.
- All stakeholders should agree on 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.
- All stakeholders should promote awareness of the importance of generating high and trustworthy data and promote a data quality culture as an integral part of contributing to and using the EHDS.

# Generate trustworthy real-world evidence

## **Actions for health ministries and healthcare authorities**

- National and Regional Health data infrastructure providers and coordinators, the research community, public health agencies and European data infrastructure programmes should increase and co-ordinate investments in:
  - education to raise the skills of those who need to generate real-world evidence, so they ask the right questions and generate comparable answers
  - the kinds of research questions can be answered by distributed analytics, and which ones need to work on a dedicated patient level data extract
  - research into errors and statistical corrections for low quality data, and the generation of synthetic data e.g. for the training and validation of AI
  - ensuring that audit processes and traceability of the sources of data are embedded into policies and architectures to ensure transparency.

# Provide greater clarity on data protection and GDPR compliance

## Actions for the EC and Member States

- The European Commission and Member States should invest in further research on risk stratification methods for health data sets so that proportionate protections such as appropriate codes of conduct and suitable information security measures can be applied consistently according to purpose and risk and not, as at present, in a piecemeal way.
- 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 encourage 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 do often need fine-grained, close to real-time, data including longitudinal histories and increasingly including specialised data types such as genomics.
- The European Commission and Member States should encourage the European Data Protection Board and Data Protection Authorities to identify acceptable standards for the anonymisation of health data, given the challenges with anonymising genomics, fine grained location data, rich clinical profiles, rare diseases etc.
- The European Commission and Member States should increase investments into research on strong risk management and assurance safeguards that can ensure GDPR compliant and transparent data use whilst maximising the opportunities from diverse categories of data.

# Skills and training for stakeholder groups

## Actions for Member States

- Member States should set target standards for population and professional digital, health and data literacy and openly share these targets at a European 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.
- Researchers, regulators, public health and political decision makers also need to be health data science literate.

## Actions for healthcare funders

- Healthcare funders (ministries, regions, insurers) should publicly declare an annual budget they will invest in patient/citizen literacy resources and initiatives, and how they will cover age ranges, ethnicities and other population subgroups and leave no one behind.

## Actions for education providers

- Education providers targeting public and health professional education should be required to share digital health curricula and learning objectives (not course delivery

materials). Equally sharing should extend to curricula for health and data literacy for the education of children.

### **Actions for industry**

- Industry should contribute to this mission by sharing educational resources and the selective sponsorship of training places on literacy programmes.

# Prioritise immunisation information and systems

## Actions for the EC, WHO and Member States

- Immunisation should be a focus for the EC One Health mission.
- 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
- 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
  - academic and industry research
  - industry research into new or improved vaccines and other prevention measures
  - comparisons of vaccination programmes and delivery models
- Each Member State holding the EU Presidency should help to accelerate Europe-wide alignment on data sets and data standards.
- The EC and Member States should hold consultations with key stakeholders to determine what incentives might persuade countries to increase their adoption and use of immunisation information systems, such as funding support, piloting support,

expertise, mentoring from another country, some centralised computing power, sharing technology solutions.

- The EC, WHO and Member States should define core data sets along with their interoperability and data quality specifications, recognising the data sets will be use case specific and might have vaccine specific elements.
- Member States should strengthen coordination across sectors and organisations on shared immunisation records, which might be contained within a health, school or occupational record, requiring inter-agency and sector alignment within as well as between regions and countries.
- The European Commission should prioritise an immunisation data space within the EHDS.
- The European Commission should convene further multi-stakeholder round tables to determine the best ways to accelerate immunisation information systems and sharing within and between Member States.
- The European Commission should fund large scale demonstrators on models and tools that enable individuals to exercise control over their personal vaccination and immunisation data, as an implementation of self-sovereignty.

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

A voluntary agreement between a range of stakeholders who co-operate to achieve social benefits by granting access to and reuse of health data.

The Compact aims to provide an assurance to all stakeholders in the health data ecosystem, especially the public, that organisations and individuals reuse health data in legal, ethical and secure ways and in society's interests

## Ethical principles

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.

6. Organisations that reuse health and health related data must make every effort to be as transparent as possible to the public about their use of health data and the outcomes of each data use.
7. 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.

## Purposes for which EHDS will permit secondary health data use

- activities for reasons of **public interest in the area of public and occupational health**, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices
- to support **public sector bodies** or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates
- to produce national, multi-national and Union level official **statistics related to health or care sectors**
- **education or teaching** activities in health or care sectors
- **scientific research** related to health or care sectors
- development and **innovation activities for products or services contributing to public health or social security**, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices
- **training, testing and evaluating of algorithms**, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices
- **providing personalised healthcare** consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons

## Expansion of research purposes (examples)

- Epidemiology and observational research studies
- Disease understanding, disease burden, unmet need and stratification

- Outcomes research, comparative effectiveness research
- Predictive analytics and identify patient sub-groups that respond better to certain treatment
- Digital innovation: devices, sensors, apps (including understanding patient experience and PROs)
- AI development conforming to the new AI Regulation
- Quantify deeply stratified populations, for targeted therapies and personalised medicine
- Biomarker discovery and validation
- Diagnostics development
- Accelerate the conduct of clinical trials
- New treatment indication areas
- Adaptive trials and licensing
- Patient characterisation and optimal treatment sequencing
- Testing and improving outcome sets
- Assessing the feasibility of planned research and implementation

### Prohibited secondary uses of health data

- taking decisions detrimental to a natural person based on their electronic health data; in order to qualify as “decisions”, they must produce legal effects or similarly significantly affect those natural persons
- taking decisions in relation to a natural person or groups of natural persons to exclude them from the benefit of an insurance contract or to modify their contributions and insurance premiums
- advertising or marketing activities towards health professionals, organisations in health or natural persons
- providing access to, or otherwise making available, the electronic health data to third parties not mentioned in the data permit
- developing products or services that may harm individuals and societies at large, including, but not limited to illicit drugs, alcoholic beverages, tobacco products, or goods or services which are designed or modified in such a way that they contravene public order or morality

An organisation adopting this Compact additionally declares that it will not reuse health or health related data for purposes that would violate the European Convention on Human Rights.

### Further prohibited purposes

- Research uses of data that would require but have failed to apply for or obtain ethical approval
- Development and uses of new technologies that would not be permissible in the EU
- Weapons development and research, including development of biological weapons (excluding research into protection against or treatment for the effects of biological weapons)
- Drugs for use in capital punishment, interrogation or torture
- Eugenics
- Political projects where there is party political gain motivating the research
- Discrimination and profiling of persons using data to develop profiles intended for marketing, service access or financial purposes,
  - e.g. the exclusion of guarantees from insurance contracts and the modification of insurance contributions or premiums of an individual or group of individuals presenting the same risk - unless the population profiling is solely to target appropriate therapies and to assess health risks
- Marketing or endorsement of an existing product
  - the competitive promotion of the products towards health professionals or health establishments, or towards patients or the public
  - except to conduct usability testing of devices, to uncover unmet treatment needs, new uses of existing solutions, or to provide factual education on new uses of diagnostics and treatments
- Research where the sole outcome is a financial benefit, i.e. exclusion of societal benefit
- Research which would be deemed illegal in the country in which the data user organisation is based, the country of data processing or the country from which the data originates

## **Data use commitments**

- Declared purpose
- Legal basis
- Permission
- Data protection
- Data handling
- Analysis and results handling
- Transparency of use
- Intended societal benefit
- Access to results

# Glossary

**CTA:** The 7 Calls to Action created by the Round Tables.

**DARWIN EU:**

**DPIA:** Data Protection Impact Assessment.

**EC:** European Commission.

**EHDS:** European Health Data Space.

**EHR:** Electronic Health Record

**EHDEN:**

**EHRxF:** European Electronic Health Record eXchange Format.

**FAIR:** Findable Accessible Interoperable Reuseable.

**GAIA-X:**

**GDPR:** The General Data Protection Regulation [ ]

**HDAB:** Health Data Access Body.

**HTA:**

**ICT:** Information and Communications Technology.

**I ~HD:** The European Institute for Innovation through Health Data.

**The Regulation or EHDS Regulation:**

**Round Tables:** The 6 Round Tables created by ECHAlliance and I~HD and listed in the introduction to this report.

**SDOs:** Standard Development Organisations.

**TEHDAS:**

**WHO:** World Health Organisation



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THIS INITIATIVE IS SUPPORTED BY

