Calls to Action on Health Data Ecosystems

RECOMMENDATIONS FROM
MULTI-STAKEHOLDER ROUND TABLES

Digital Health Society & the European Institute for Innovation Through Health Data Calls to Action on Health Data Ecosystems

This contribution summarises the outcomes of two recent multi-stakeholder consultations to examine the acceptance criteria for societal trust in the use of health data and a recipe for trustworthy digital health: standards, architecture and value.

The Round Tables were developed and convened by DHS and i~HD neutrally and independently from the event sponsors, Johnson & Johnson and Microsoft. Each meeting was attended by around 27 online participants from EU institutions, national governments, industry, academia, hospital management,, healthcare professionals, regulators and patient representatives. DG Sante and Connect officials contributed to both events.

The recommendations and calls to action arising from these events were presented to a large online audience at the Digital Health Society Summit in November 2020 and discussed by a multi-stakeholder panel.

The recommendations cover the following key themes.

Please find the full report here:
https://echalliance.com/wp-content/uploads/2021/02/210201-CTA-Health-Data-Report.pdf

1 Raise the digital, literacy & skills of all stakeholders

2 Generate and value trustworthy Real World Evidence

3 Accelerate interoperability across Europe and globally

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

5 Adopt a risk stratification approach

6 Build a trustworthy framework for data access and use

7 Adopt a transformational approach to health data

Raise the digital, literacy & skills of all stakeholders

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.

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.

Education providers targeting public and health professional education should be required to share digital health curricula and learning objectives (not course delivery materials). Equally these points should be applied to curricula for health and data literacy for the education of children.

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

02

Generate and value trustworthy Real World Evidence

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
- improving data quality, starting with facilitating a more motivating culture within healthcare professionals and better EHR system user interfaces
- 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
- audit processes and traceability of the sources of data must be embedded into policies and architectures to ensure transparency.

3

Accelerate inter-operability across Europe and globally

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.

Future standards development strategies should involve representative data creators and users, especially health professionals and patients.

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.

Member States and the EC must support patients and citizens to become strong advocates of joined up (interoperable) health data balancing illness and wellbeing (prevention) needs.

The **EC** should more strongly encourage health data generated through its funded projects to be more widely reusable via the EHDS.
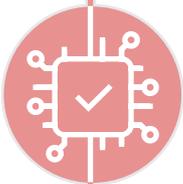
Interoperability between consumer devices which generate health data and EHRs will become increasingly important as this type of data grows in volume and relevance and must therefore be ensured through regulation or soft law.

04

Demonstrate benefits to society from data access, use and reuse

Data Permit Authorities and data sharing intermediaries should:

- publish 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
- define the terms and conditions they will require from data users
- publish annually the benefits they have enabled, and lessons learned from reusing health data
- consult with the public to define societal benefits and value
- involve patients and citizens at decision making (board) levels
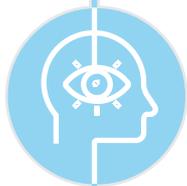- promote and oversee good models of data altruism.

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

05

Adopt a risk stratification approach

The GDPR places too strong an emphasis on the identifiability of individuals from data through explicit attributes and does not give adequate recognition to unique data patterns that may enable data subject identification.

At an EU level a specific health scientific and research basis for reuse is needed.

Pseudonymisation should not always be considered as personal data without taking into account the safeguards including the protection of linkage keys.

EU and national research funders 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 and can be applied consistently according to purpose and risk and not, as at present, in a piecemeal way.

Data Protection Authorities and the European Data Protection Board should indicate willingness to develop and adopt risk stratification guidance on the use of data protection safeguards.

Member States and the EC should balance risks with the opportunity costs of not sharing health data.

06 Build a trustworthy framework for data access and use

Data Permit Authorities should:

- promote the development and adoption of multi-stakeholder Compacts 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)
- 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 themselves
- publish inventories of data use requests received, accepted, declined and of any investigations into misconduct
- conduct public awareness campaigns to explain to the public the research uses and benefits of using health data.

All public and private stakeholder should support the adoption of standards and Compacts for how data access requests are formulated and transparently reported on.

07

Adopt a transformational approach to health data

All stakeholders should support and promote treating repositories of pooled anonymised health data as a societal good.

Investments should promote the uptake of federated data models to facilitate interoperability, connectivity and FAIR data access while upholding GDPR compliance.

Europe should now 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.

Stakeholders should focus eHealth governance models, trust mechanisms and research infrastructures to contribute data to large-scale independent health data repositories that provide real-time continuity of data access for individuals, healthcare delivery and for population level analysis, with appropriate governance.
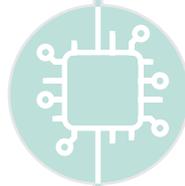
Synthetic data sandboxes should be developed to enable research into novel security approaches and the training of AI algorithms.

A transformation towards cross-organisational and independently run health data repositories will require radical change in ICT products and procurement, for which policy enablers must now be enacted.

Regional and national early adopters should be encouraged to collaborate across borders to develop best practices, lessons learned and accelerate the reuse of data and the development of benefits from it, sharing with other Member States and stimulating European competitiveness.

DHS Summit Feedback

The above calls to action were presented and discussed by an expert panel which comprised Nicola Bedlington, Chair of Data Saves Lives, Jesper Kjaer, Danish Medicines Agency and Nigel Hughes Project Lead EHDEN & Janssen and Ioana-Marie Gligor, Head of Unit DG Sante. They agreed the two most important calls **were upskilling digital, data and health literacy, and generating and valuing trustworthy Real World Evidence.**
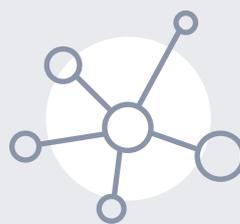
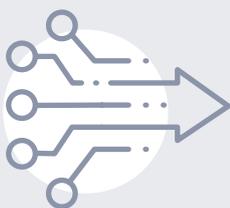We conducted a poll of Summit attendees and the results were:

50% thought the most important call was adopting a transformational approach to health data.

82% thought if health data is to be a societal good it should be defined by a group formed of multiple stakeholders.

72% thought a list of data uses that would normally be supported and those that would not be supported should be developed by a group formed of multiple stakeholders.

73% thought that, to develop trust in data access and use, they would prefer to see a combination of written laws/ regulations and multi-stakeholder codes of conduct.

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THIS INITIATIVE IS SUPPORTED BY

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