Calls to Action on Health Data Ecosystems

RECOMMENDATIONS FROM
MULTI-STAKEHOLDER ROUND TABLES

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The big health data opportunity

- Growing need for large scale access to health data
  - from conventional healthcare sources (e.g. detailed EHRs), patient and citizen generated, medical devices and non-health sources such as pollution
  - for this to be fine grained, individual level (not only aggregated), close to real time
  - for this to be longitudinal, reflecting health, wellness, disease trajectories and outcomes
- Growth of large scale data resources that offer these opportunities
  - a mixture of regional, national and cross-border data initiatives
  - a mixture of eHealth services and research infrastructures
  - a mixture of centralised and federated architectures

Need for alignment

- The growing European data infrastructures are set up quite differently
  - different kinds of data offerings
  - adopting different data standards
  - different permitted uses and users
  - different access terms
  - different approaches to GDPR compliance
- Europe is revealing variable interpretations of GDPR compliance when it comes to health data use and reuse e.g. legal basis, pseudonymisation safeguards
- COVID-19 has highlighted the value of sharing intelligence across countries, but introduced approaches that might only be temporarily acceptable e.g. location tracking
- Multiple public attitude surveys are generating mixed messages (not all surveys are framed well), perhaps confusing public opinion, and with mixed findings

Our stakeholder engagements

- Two Round Tables, held in autumn 2020
  - Acceptance criteria for societal trust in the use of health data
  - A recipe for trustworthy digital health: standards, architecture and value

- Developed and run by DHS and i~HD - neutral and independent
- Sponsored by Johnson & Johnson and Microsoft

- Each attended by ~27 invited participants from industry, academia, health systems, healthcare professionals, patient representatives
- DG Sante and Connect officials contributed to both events.

- The recommendations and calls to action were presented to a large online audience at the Digital Health Society Summit in November 2020

Core themes explored

Acceptance criteria for societal trust

- The who, what and why of data use and reuse
- Technical and organisational safeguards
- Transparency and trust about use and value

Standards, architecture and value

- Improving the (re)usability of data through standards
- Architectures enabling large scale, secure and timely data access
- Sustaining data sharing and access by demonstrating value and trustworthy decision-making

Multi-stakeholder consensus recommendations

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**

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Raise the digital, literacy & skills of all stakeholders

- Citizens, health professionals, researchers and decision makers all need higher levels of health data literacy
- Member States, healthcare funders and research sponsors all need to invest more in educational programmes and their delivery, ensuring equity of access to literacy services

Generate and value trustworthy Real World Evidence

- All of those connected with building, operating and making use of health data infrastructures must ensure staff understand
  - the nature, strengths and limitations of real world data
  - how to analyse it appropriately to generate trustworthy insights
  - how to appraise the quality of the data they are using

Accelerate interoperability across Europe and globally

- Member States should embrace an alignment of standards adoption with other countries, such as on the EEHRxF
- They must reflect those as strong interoperability demands within national and regional procurement policy and specifications
- Healthcare providers should demand, from their EHR suppliers, explicit and independently verified interoperability against prescribed standards through procurement specifications and renewal contracts

Demonstrate benefits to society from data access, use and reuse

- Data Permit Authorities and data sharing intermediaries should
  - make transparent
    - the purposes and kinds of organisation they will allow to use health data
    - what terms and conditions they will require for use
  - publish regularly their access decision and benefits emerging from data use

Adopt a risk stratification approach

- When applying the GDPR to research data use, a risk stratification approach should be adopted, and guidance developed, so that
  - proportionate protection measures are applied
  - data uses are appropriately enabled

Build a trustworthy framework for data access and use

- Data Permit Authorities should promote the development and adoption of multi-stakeholder Compacts/codes of conduct regarding
  - responsible data use and re-use
  - transparency, accountability
  - communication
- All public and private stakeholder should support
  - the adoption of these Compacts
  - standards for how data access requests are formulated and transparently reported

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

Taking a deeper dive in 2021

- The acceptance criteria for societal trust in the use of health data
  - Transparency and trustworthy decision-making
  - Societal compact and returning value from data use
  - Risk and reward

- Scaling up the availability and reusability of big health data
  - Interoperability, standards alignment and adoption
  - Data quality, benchmarking and improvement
  - Designing health data infrastructures for large scale data reuse