WEBINAR

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The role of a health Data Space in a pandemic

Moderated by Cecilia Bonefeld-Dahl, Director General of DIGITALEUROPE
Ioana-Maria Gligor
Head of Unit, European Reference Networks and Digital Health
DG SANTE
European Health Data Space & COVID-19

Ioana-Maria Gligor

Head of Unit European Reference Networks and Digital Health, DG SANTE
Content

• Data strategy and European Health Data Space

• Actions against COVID

• Questions
European Strategy for Data

A common European data space, a single market for data

- Data can flow within the EU and across sectors
- Availability of high quality data to create and innovate
- European rules and values are fully respected
- Rules for access and use of data are fair, practical and clear & clear data governance mechanisms are in place
What are the problems?

Lack of European data processing & storage solutions

- Not enough data available for reuse
  - More public sector data can be made available
  - Low uptake of voluntary data sharing among companies
  - No clarity on the use of private sector data for the common good

Absence of comprehensive data governance approaches

- To address legal and technical barriers within and across sectors (e.g. standardisation & interoperability)

Skills shortage and low data literacy

No real user empowerment

- Imperfect data portability mechanisms

Fragmentation of the single market
Deploying the strategy through 4 Pillars

A cross-sectoral governance framework for data access and use
including a legislative framework for the governance of European data spaces and other cross-sectoral measures for data access and use

Enablers
Total investments of €4-6 billion in a High Impact Project on European data spaces and federated cloud infrastructures

Competences
Empowering individuals, investing in digital skills & data literacy and in dedicated capacity building for SMEs.

Rollout of common European data spaces
in crucial economic sectors and domains of public interest, looking at data governance and practical arrangements.

International Aspects
Rich pool of data (varying degree of accessibility)

Free flow of data across sectors and countries

Full respect of GDPR

Horizontal framework for data governance and data access

Common European data spaces

Health
Industrial & Manufacturing
Agriculture
Finance
Mobility
Green Deal
Energy
Public Administration
Skills

- Technical tools for data pooling and sharing
- Standards & interoperability (technical, semantic)
- Sectoral Data Governance (contracts, licenses, access rights, usage rights)
- IT capacity, including cloud storage, processing and services
Public Online Consultation
open until 31 May 2020

“We need to make the most of the potential of e-health to provide high-quality healthcare and reduce inequalities. I want you to work on the creation of a European Health Data Space to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes. As part of this, you should ensure citizens have control over their own personal data.”

Mission letter of Stella Kyrriakides
Commissioner for Health
European Health Data Space

What?

Use of health data for:

- Better healthcare
- Better policy making
- Better research and innovation

How?

3 pillars of action:

- Data governance and rules
- Data quality and interoperability
- Infrastructure and technology
Matrix of the EHDS

**Better Healthcare**
- Legislative and non-legislative measures on governance and rules for primary and secondary use of data, respecting GDPR (data for healthcare, policy making, research and innovation)
- AI framework (incl AI&liability)

**Better Policy Making**
- Uptake and develop the EHRxF
- FAIR-ification of health data for primary and secondary use

**Better Research and Innovation**
- MyHealth@EU ERN-CPMS
- 1+mil genomes
- Access of regulators to data
- Linking repositories in MS, including data permit authorities, registries and other databases
- Images database
- Research infrastructures
Governance – preparatory work

Workshops & study on primary and secondary use of health data (2020: 29 Jan, 16 Mar, 28 Apr) DE EPSCO Council and Council Conclusions

- Mapping of GDPR implementation
  - Access of citizens to health data and portability of data, including rules and governance structures
  - Use of data for policy making and regulatory purposes, access of regulators to health data: rules and governance structures
  - Use of data for research and innovation: rules and governance structures

- What EU action?

Study on regulatory gaps in cross-border digital healthcare – digital healthservices, AI (including AI&liability, evaluation of article 14 of the Directive 2011/24)

Joint Action on European Health Data Space, (to be signed in Q3 2020)

Support for a Code of Conduct on secondary use of health data (to be launched in 2020)

- build upon the workshops
Data quality

- Joint action
- Projects for FAIR-ification of data
  - Electronic health records
  - Data for research
MyHealth@EU enables exchange of patient data across borders

- **Patient Summary** provides access to health professionals to verified key health data of a patient during an unplanned care encounter while abroad

- **ePrescription** enables patients to receive equivalent medication while abroad to what they would receive in their home country

- New services to be added: **images**, results, **laboratory discharge** reports
Infrastructure: ERN- CPMS

- **24 Networks**
- **29 Countries**
- **300 HOSPITALS**
- **900 HEALTHCARE UNITS**
- **Full Member**
2018 Declaration "Towards access to at least 1 million sequenced genomes in the EU by 2020"

- cross-border access to genomic databases in the EU
- for a sufficient scale for clinically impactful research
- in full compliance with data protection rules
- Member States driven initiative
- EC facilitating the progress
**Infrastructure**

- Linking MS data sources cross-border

- Technical interoperability guidelines/agreements to enable European Health Data Space services
COVID activities
COVID-19 communication platforms

- Clinical management
- Research to policy action
- Policy coordination
- Researcher chat
Work on COVID

• Cooperation between clinicians
• Transfer of patients data between hospitals and MS
• COVID registries: Leoss, semantics (eHN)
• Tracing apps (eHN + COM):
  • COM Recommendation
  • Toolbox
  • Interoperability
Questions:

• In the context of COVID, what is your experience with special systems/rules that have been put in place to facilitate patient access to care (eg through telemedicine, telemonitoring), but also to data concerning them and data portability? Did you see any problems in cross-border context in these areas? What action do you believe is needed at EU level in this area?

• Where do you see the main challenges for the use of data that are collected in the context of care provision for secondary purposes of public health management, including the planning of care provision, resources management and the evaluation of care protocols, medicines and devices? Do you see any need for any EU level guidance or legal action could be useful now and in preparing for future epidemics?

• Some MS have created systems for citizens to provide access to their data so that it may be shared for research purposes – this is known variably as data donation, data altruism or data solidarity. We are keen to hear your views about MS who have adopted such systems or a in the process of doing so and if you see any need for action in this area at EU level.

• Where do you see the main challenges for the use of data that are collected in the context of care provision for secondary purposes of scientific research?

• We would like to hear from your experience with countries that have created special systems or organisations for providing access to health data for research purposes (eg data permit authorities, data hubs etc.) We are keen to hear about the governance of such secondary use in 'normal' situations and now in the context of a public health crisis.

• What actions do you believe are necessary at EU level to support access to data for research purposes across EU borders? Should this be addressed through hard law or soft law measures such as a Code of Conduct?
Thank you for your attention!

Questions?

Contact details:

Ioana-Maria Gligor, DG SANTE.B3
Head of Unit European Reference Networks and Digital Health
E-mail: Ioana-Maria.Gligor@ec.europa.eu
Tel: +32 229 85326; +32 460 75 22 46