European Commission

Cybersecurity and eHealth

The MedTech Forum 2019

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1

Digital Health and Care

TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET – Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals

Potential of digital applications and data to improve health

- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

What EU citizens expect...

90% agree
To access their own health data
(requiring interoperable and quality health data)

80% agree
To share their health data
(if privacy and security are ensured)

80% agree
To provide feedback on quality of treatments

Support European Commission:

1 Secure access and exchange of health data

Ambition:
Citizens can securely access and share (e.g. with doctors or pharmacies) their health data anywhere in the EU.

Actions:
- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition:
Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:
- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:
Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:
- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.

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#DigitalSingleMarket   #DigitalHealth   @eHealth_EU   @EU_Health

Updated 07/06/2018

Key challenges

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STATE OF THE UNION 2018

Building strong cybersecurity in Europe

#SOTEU

'Cyber-attacks know no borders, but our response capacity differs very much from one country to the other, creating loopholes where vulnerabilities attract even more the attacks. The EU needs more robust and effective structures to ensure strong cyber resilience and respond to cyber-attacks. We do not want to be the weakest links in this global threat.'

Jean-Claude Juncker, Tallinn Digital Summit, 29 September 2017

Putting people at the centre of **health and care**

Enabling secure access to health data across the EU

Data sharing for better research and personalised healthcare

Empowering patients with digital tools

Trust

#DigitalSingleMarket
#DigitalHealth

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4

Recommendation on a Electronic Health Record exchange format

Guiding principles

- ❑ Citizen centric
- ❑ Comprehensiveness and machine readability
- ❑ Data protection and confidentiality
- ❑ Consent or other lawful basis
- ❑ Auditability
- ❑ Security
- ❑ Identification and authentication
- ❑ Continuity of service

Security and Data Protection

GDPR

NIS Directive

Set up National Digital Health Networks

Recommendation on a Electronic Health Record exchange format

Common technical specifications (baseline)

❑ Initial set **of health information domains**: patient summaries, ePrescriptions, laboratory reports, medical images and reports, and hospital discharge reports

❑ Common list of **interoperability specifications** (existing standards and profiles)

❑ **Incremental and selective approach** for adopting, refining, and maintaining the specifications of the European EHR exchange format

Pooling health data for research and personalised medicine

Declaration for delivering cross-border access to genomic database

- 1 million **genomes accessible** in the EU by 2022
- **Linking access** to existing and future genomic database across the EU
- Providing a sufficient scale for **new clinically impactful** associations in research

Cybersecurity

General Data Protection Regulation

Directive on the Security of Network and Information Systems across the Union (NIS Directive)

Medical Device regulation

EU Cybersecurity Act (EP voted 12.03.2019)

ePrivacy

eIDAS

The EU CYBERSECURITY ACT – ENISA Objectives

Centre of expertise on cybersecurity

Assisting the Union institutions, bodies, offices and agencies, as well as Member States, in developing and implementing Union policies related to cybersecurity

Supporting capacity-building and preparedness across the Union

Promoting cooperation, including information sharing and coordination at Union level

Contributing to increasing cybersecurity capabilities at Union level

Promoting the use of European cybersecurity certification, and a high level of cybersecurity awareness

9

The EU Cybersecurity Certification Framework

Cybersecurity certification plays an important role in increasing **trust in digital products and services**.

A **common European approach** to cybersecurity certification is an important part of the Digital Single Market.

The Cybersecurity Act establishes the European cybersecurity certification framework.

The Framework enables the creation of **tailored**, **voluntary** European Cybersecurity **Certification Schemes** for ICT products, services and processes.

10

NIS Directive – Affected Sectors & Services

Essential Services & Sectors

- Energy
- Transport
- Banking
- Financial market infrastructures
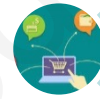- Health Sector
- Drinking Water supply and distribution
- Digital Infrastructure

Digital Services

- Online Marketplace
- Online search engine
- Cloud Computing

The NIS Directive does NOT apply to micro and small enterprises as defined in EC Recommendation 2003/361/EC

Horizon 2020 eHealth Cybersecurity R&I

*Horizon 2020 Societal Challenge 1 **Work Programme** – Health, Demographic Change and Wellbeing*

*2018 **Call for Proposals** on TRUSTED DIGITAL SOLUTIONS AND CYBERSECURITY IN HEALTH AND CARE*

***8** proposals retained for funding, and projects started early 2019*

*The EC funding of the retained proposals is about **35M EUR***

Expected impact:

- Reduced cybersecurity vulnerability of health and care services, data and infrastructures
- Less risk of data privacy breaches
- Increased patient trust and safety
- Less human errors causing cybersecurity threats

Some R&I projects ....

CUREX *aims at developing a platform that allows a healthcare provider to assess the realistic cybersecurity and privacy risks they are exposed to and suggest mathematically optimal strategies for addressing these risks with safeguards tailored specifically for each business case and application.*

- A decentralised architecture enhanced with a **blockchain infrastructure** ensures the integrity of the risk assessment process and of all data transactions that occur between the diverse range of stakeholders.

ProTego will develop a toolkit and guidelines to help health care systems users address cybersecurity risks by extensive use of AI, advanced encryption and access control techniques to protect data.

The toolkit will be integrated and validated in IoT and BYOD-based case studies at two hospitals

MyHealthMyData – use blockchain technology to enable medical data to be stored and transmitted safely and effectively. It encourages hospitals to start making anonymised data available for open research while prompting citizens to become the ultimate owners and controllers of their health data.
http://www.myhealthmydata.eu

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13

Funding opportunities for eHealth 2021-27

Digital Europe Programme and Connecting Europe Facility

Horizon Europe

European Social Fund + and European Globalisation Adjustment Fund

European Regional Development Fund

InvestEU Programme

Digital Europe Programme & Cybersecurity

Investing in the future:
Digital Europe Programme

€2 billion for **Cybersecurity** to:

Support **procurement** of advanced equipment, tools & data infrastructures

Support the best use of **European** knowledge, capacity and skills

Ensure wide deployment of **latest solutions** across the economy

Reinforce **capabilities** for high level of network & information systems

#EUBudget
#DigitalEurope

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16