Policies to promote a digital infrastructure that supports Digital Health Innovations

Silvia VICECONTE

EUROPEAN COMMISSION
DG CONNECT

Setting the framework

The EU : *An integrated digital market: the DSM*

The Digital Single Market Strategy

European Commission

THE STRATEGY AT A GLANCE

1 — **Better access for consumers and businesses**

2 — **An environment where digital networks and services can prosper**

3 — **Maximise the growth potential of the digital economy**

- Geo-blocking
- E-commerce (digital contracts, consumer protection)
- Copyright
- Parcel delivery
- VAT
- Telecoms market
- Media services
- Platforms and intermediaries
- Trust and security (e-privacy, cybersecurity cPPP)
- Data Economy
- Inclusive digital society
- Interoperability and Standardisation
- Digitisation of European industry

European Council implementation deadline: 2018

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Digital Single Market Mid-term Review (2017)

I. Taking stock of what has been achieved since 2015

II. Future Agenda

- **Ensuring a fair, open and secure digital environment**: online platforms, data economy, cybersecurity

- **Managing the digital transformation**: Digital Skills, Digitisation of industry, eHealth, eGovernment, Connected mobility, High Performance Computing (HPC), Investment

- **International Dimension**

Some basic conditions for innovation in e-health

(1) A data economy

(2) Security of the networks: trust is a must

(3) Government and industry need to be aligned in managing the digital transformation

Unlocking the DATA ECONOMY

- The EU data economy grew by **21.53%** from 2013 to 2016
- The data economy can reach **€739bn by 2020** (4% of EU GDP)

  ✓ **Cross-border free flow of non-personal data** (*legislation proposed in September 2017*)

  - **Removing data localisation restrictions in the EU** (one of the most important **factors for the data economy to double its value to 4% of GDP in 2020**) **... balanced by a principle of data availability for regulatory control**

  - **Enhancing legal certainty for businesses on storing and processing data in other EU Member States**

Yet to come:
➢ An initiative on accessibility and reuse of public and publicly funded data (*April 25 2018*)

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Boosting CYBERSECURITY

- **6 billion** household devices will be connected to the internet by 2020 in the EU
- More than **4,000 ransomware attacks** have occurred every day since the beginning of 2016 (a 300% increase over 2015)

  ✓ Review of **European Union Agency for Network and Information Security** (ENISA)
    - greater operational responsibilities and a stable footing for the future to reflect the new reality and needs in cybersecurity

  ✓ A **European Cybersecurity Certification Framework:**
    - to avoid the fragmentation of cybersecurity market, and
    - to make it easier for purchasers to understand the security features of the ICT products and services

  ✓ A **Blueprint for a coordinated response to large scale cybersecurity incident and crises**

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E-GOVERNMENT

- Digital technologies allow public authorities to deliver services more quickly, more precisely and more efficiently

- **EU eGovernment Action Plan 2016-2020:** aims to accelerate and broaden the scope of digitisation of public administrations

DIGITISING EUROPEAN INDUSTRY

- The process of boosting digital skills must go hand in hand with the up-take of digital technologies by companies of all sizes and industries.

- **Digitising European Industry Commission:** adopted in April 2016 to help European businesses reap the full benefits of digital technology

Patient health data and e-health services

Open Public Consultation run in 2017

"What are the major barriers to electronic sharing of health data?"

Risk of privacy breaches	65.89%
Heterogeneity electronic health records	58.24%
Cybersecurity risks	54.41%
Data quality and reliability	48.46%
Lack of infrastructure	45.32%
Legal restrictions in member states	44.02%
Lack of awareness	41.35%
Lack of interest	28.37%

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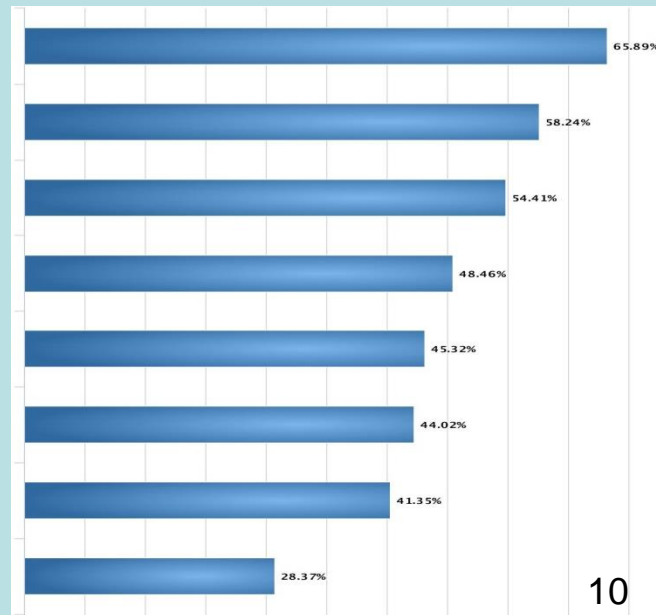
Open Public Consultation

Transformation of Health and Care in the Digital Single Market

What the EU should do to overcome barriers to access and sharing of health data?

Develop standards for data quality and reliability (#1) and *Standardise EHRs (#2)* are the top EU actions supported by the majority of respondents when asked *"What should the EU do to overcome barriers to access and sharing of data"*.

This is followed by *"health-related cybersecurity standards" (#3)* and *"support interoperability through open exchange formats" (#4)*.

DIGITAL HEALTH CHALLENGES IN THE EU

Limited access to health records across borders (citizens and professionals)

- 52% of European citizens wish to have online access to their health records (incl. health data, prescriptions and medical records)

- Only 9% of hospitals in Europe allow citizens to access online their own medical records (and most only give partial access)

- <u>Exchange between professionals and health care organisations</u>: The percentage of hospitals exchanging clinical care information about patients electronically with other health care organisations remains low. Exchange of care information within the same country ranges from 33% to 39%, whereas exchange with health and care providers in another EU country is only 4%.

DIGITAL HEALTH CHALLENGES IN THE EU (2)

No secure infrastructure to exchange health data across borders to advance research and personalised medicine.

- **Citizen's willingness to share personal health data: Overall, seven in ten (70%) would be willing to give their health and personal wellbeing data to others through a secure infrastructure.**

Low integration of digital health tools with health & care services

- **Citizen's use of digital health and care tools / services: Only 18% of citizens have used health and care services provided online without having to go to the hospital or doctor's surgery, in the last 12 months**

Policy needs

- ✓ secure **cross-border access to electronic health records** and use of **e-prescriptions**
- ✓ supporting **high-performance computing** capacity to unlock the potential of **big data for health** through advanced data analytics
- ✓ facilitating **feedback and interaction** between patients and healthcare providers

3 priorities identified in the DSM mid-term review:

Give citizens **better access** to their **health data**, everywhere in the EU

Use **digital** services for citizen empowerment and person-centred care

Connect and **share** health data for research, faster diagnosis and better health outcomes

Upcoming policy EC Communication

PILLARS	OBJECTIVES

PILLAR 1
Citizens' secure access to electronic health records and the possibility to use it across borders

PILLAR 2
Accelerate personalised medicine through a decentralised European data infrastructure for genomic data

PILLAR 3
Foster citizen empowerment and person-centred care with the use of digital tools supporting user feedback and interaction

Citizens can exercise their right to access, manage and use their health data across the EU though an interoperable European Electronic Health Record exchange format.

Researchers and professionals can pool resources (data-sets, scientific expertise and HPC) across the EU, leading to better health prevention, faster and more personalised diagnosis and treatment

Enable citizens and health care systems benefit from digital tools that empower people to look after their health, stimulating prevention, and enabling feedback and interaction with health care providers.
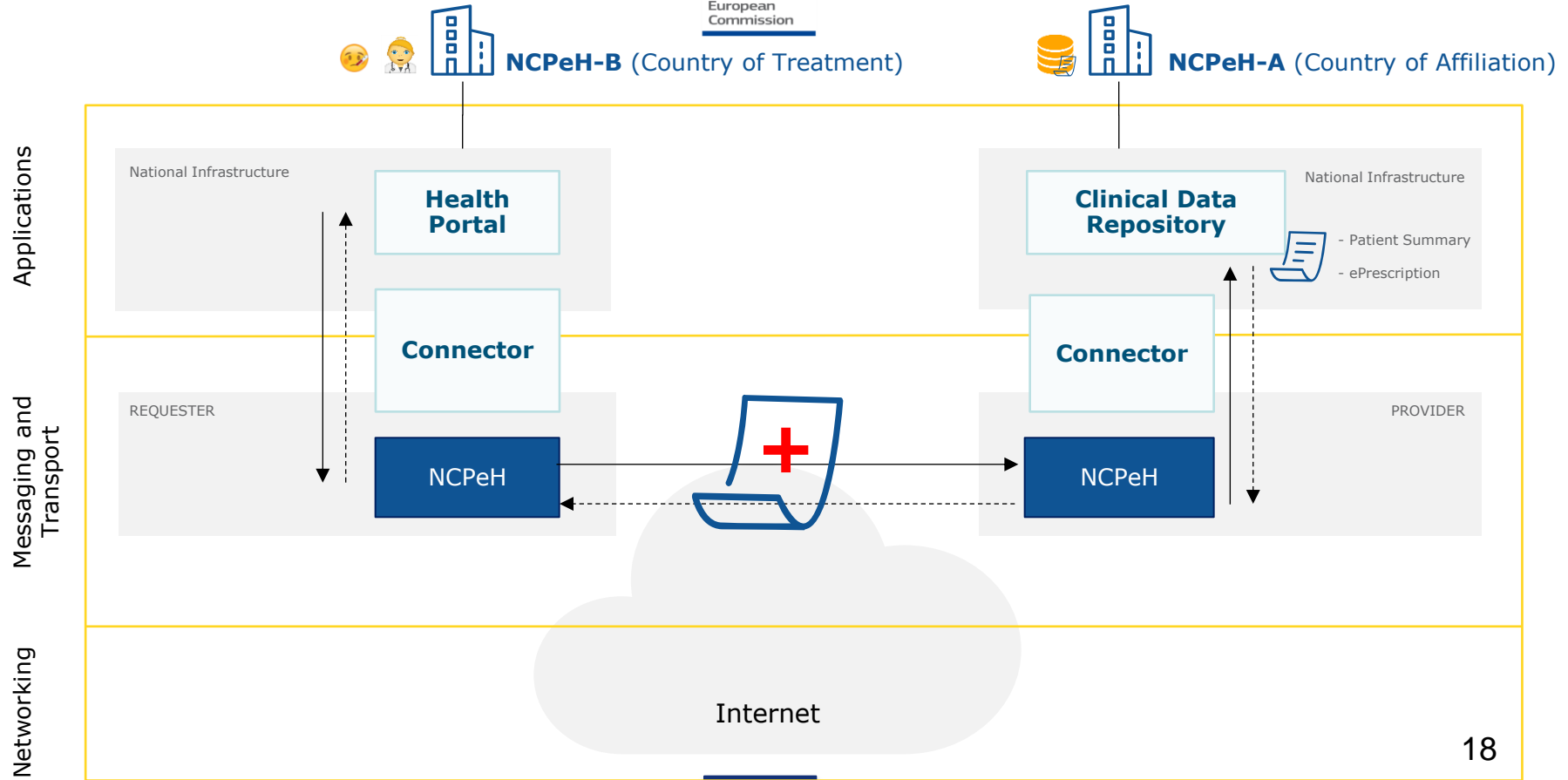
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EU initiatives in practice

The CEF eHealth Digital Service Infrastructure

Research funding- overall Horizon 2020

CEF eHDSI
The interoperability challenge

NCPeH-B (Country of Treatment)

NCPeH-A (Country of Affiliation)

Applications

National Infrastructure

Health Portal

Clinical Data Repository

National Infrastructure

- Patient Summary

- ePrescription

Connector

Connector

Messaging and Transport

REQUESTER

PROVIDER

NCPeH

NCPeH

Networking

Internet

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Horizon2020 draft WP 2018-2020
SC1, Health, demographic change and wellbeing

Call 'Better Health and care, economic growth and sustainable health systems'

Call 'Digital Transformation in Health and Care'

Call 'Trusted digital solutions and Cybersecurity in Health and Care'

approx. € 2 billion

The international dimension

- ➢ **Role of data flows regulation- GDPR and trade agreements**
- ➢ **Possible use of soft instruments-MoUs**
- ➢ **An evidence based discussion- the OECD's Going Digital**

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