



The digital transformation of healthcare

Brussels, 25 April 2018

Questions and Answers

1. What is the Commission proposing today?

The Commission has adopted today a communication setting out a plan of action that puts citizens at the centre of the healthcare system in three ways:

- by enabling citizens' secure, cross-border access to their electronic health records and the possibility of sharing their records across borders;
- by facilitating the use of larger data sets through a shared European data infrastructure to prevent diseases, determine personalised medical treatment and better anticipate epidemics;
- and by providing digital tools that enable citizens to manage their health more actively within integrated care systems.

This approach will provide the basis for EU action in digital health over the next years, such as support for the exchange of e-prescriptions and electronic patient summaries, enabling the cross-border exchange of full electronic health records, voluntary coordination in sharing data and resources for disease prevention and research, and capacity building and the exchange of innovation and best practices for healthcare authorities.

2. How do you plan on making sure that citizens' access to their health data across Europe is secure?

First, the Commission will review the Implementing Decision of the [Directive on patients' rights in cross-border healthcare](#) (Article 14). Revised rules will define the role of the eHealth Network in the governance of the eHealth Digital Service Infrastructure (eHDSI) and clarify the rules applicable to cross-border data transfers. The eHealth Network, which is composed of members from 28 Member States, will soon start discussions on this.

Secondly, the Commission will make a Recommendation on technical specifications about how citizens' electronic health records can be exchanged across the EU. The cross-border accessibility of electronic health records will help citizens to access and manage their health data within the EU.

Thirdly, the Commission will further mobilise investments in order to expand the scope of the programme to include the eHDSI, meaning that it will finance the introduction of the exchange of electronic national health records between participating Member States.

3. What should be done at the European level to personalise diagnosis and treatment?

National authorities and other stakeholders, notably researchers, are encouraged to share data and infrastructure. This will allow for a better understanding and prevention of diseases and will improve personalised medical research, diagnosis and treatment. One of the initial targets is to provide access to at least 1 million sequenced genomes in the European Union by 2022. 14 Member States recently committed to this target.

Secondly, the Commission will draw up a catalogue of common technical specifications to support secure cross-border access to genomic and other health data for research purposes.

Furthermore, the Commission will implement pilot projects based on 'real world data' (data after clinical trials, data gathered from real patients after the medicine or products are released in the market) to meet patients' needs with medicines or therapies. Starting with rare diseases, via the European Reference Networks, these projects will look into providing treatment for patients with such diseases, and how to help anticipate epidemics. The aim of these pilot projects will be to demonstrate the benefits of pooling resources and expertise.

4. How can the use of digital tools benefit people?

Digital tools such as mobile health applications or personal devices to monitor blood or sugar, will empower people to look after their health, improving disease prevention, and enabling feedback and

interaction between users and healthcare providers.

EU countries and regions will be supported in investing in large-scale deployment of integrated care models centred in the needs of the person (to explain: the different services of the hospital, the treatments at home are based on different care models), through the exchange of innovative and best practices, capacity building and technical assistance.

The Commission will raise awareness on innovative procurement and investment possibilities, including by mobilising relevant European Union programmes and other financial instruments.

5. What will the Member States have to do?

The Commission is calling for the collaboration of Member States and relevant stakeholders.

Member States (14 EU countries) will follow up on the recent [Declaration](#) in linking genomic databases across borders.

The Commission is supporting voluntary cooperation among Member States, such as the cross-border exchange of e-prescriptions and patient summaries and the collaboration on genomic data for research and personalised health and care. With the support of the Connecting Europe Facility (CEF) Programme, we expect the first exchanges of e-prescriptions and patient summaries to take place in 8 Member States later this year, and other Member States to follow by 2020.

Member States also play a key role when it comes to cooperation on common principles for validating health technology to stimulate the supply and uptake of digital health and in the exchange of innovative and best practices, capacity building and technical assistance.

6. How will today's approach Does the Communication help protect citizens' health data?

Data protection principles are core elements of the Commission's proposals. Compliance with EU data protection rules and adequate security measures are essential to achieve the goals of this communication: enabling secure access to health data across the EU, data sharing for better research and personalised healthcare and empowering patients with digital tools.

7. Will there be a follow-up?

All relevant stakeholders are invited to contribute to the main objectives of the communication, and the Commission will actively contribute and facilitate to their implementation. In addition, digital healthcare is part of the Digital Single Market Strategy, and the Commission will continuously monitor progress and review the Strategy and decide what follow up is needed.

For More Information

[Press release: Data in the EU: Commission steps up efforts to increase availability and boost healthcare data sharing](#)

[Synopsis report of the public consultation on building a European data economy](#)

[Public Consultation on Health and Care in the Digital Single Market](#)

[European Reference Networks](#) on rare and complex diseases

[EU countries will cooperate in linking genomic databases across borders](#)

[Open Access to scientific information](#)

[Directive 2003/98/EC on the re-use of public sector information](#)

[General Data Protection Regulation](#)

[ePrivacy rules](#)

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