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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

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To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND  
SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on  
enabling the digital transformation of health and care in the Digital Single  
Market; empowering citizens and building a healthier society

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Delegations will find attached document COM(2018) 233 final.

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Brussels, 25.4.2018  
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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE AND THE COMMITTEE OF THE REGIONS**

**on enabling the digital transformation of health and care in the Digital Single Market;  
empowering citizens and building a healthier society**

{SWD(2018) 126 final}

## 1. POLICY CONTEXT: HEALTH AND CARE IN A DIGITISING WORLD

The recent report on the State of Health in the EU<sup>1</sup> concluded that only by fundamentally rethinking our health and care systems<sup>2</sup> can we ensure that they remain fit-for-purpose. This means systems which aim to continue to promote health, prevent disease and provide patient-centred care that meets citizens' needs. Health and care systems require reforms and innovative solutions to become more resilient, accessible and effective in providing quality care to European citizens<sup>3</sup>.

Europe's health and care systems face serious challenges. These are ageing, multi-morbidity<sup>4</sup>, health workforce shortages, and the rising burden of preventable non-communicable diseases caused by risk factors such as tobacco, alcohol, and obesity, and other diseases including neuro-degenerative and rare diseases. We are also seeing a growing threat from infectious diseases due to increased resistance to antibiotics and new or re-emerging pathogens<sup>5</sup>. Public spending on health and long-term care is steadily rising in EU Member States and is expected to continue to do so<sup>6</sup>.

Digital solutions for health and care can increase the well-being of millions of citizens and radically change the way health and care services are delivered to patients, if designed purposefully and implemented in a cost-effective way. Digitisation can support the continuity of care across borders, an important aspect for those who spend time abroad for business or leisure purposes. Digitisation can also help to promote health and prevent disease, including in the work place. It can support the reform of health systems and their transition to new care models, centred on people's needs and enable a shift from hospital-centred systems to more community-based and integrated care structures<sup>7</sup>. Digital tools can translate scientific knowledge into helping citizens remain in good health, thus helping to ensure that they do not turn into patients. They also have the potential to enable a better use of health data in research and innovation to support personalised healthcare, better health interventions and more effective health and social care systems.

Data is a key enabler for digital transformation. Health data may be available in various forms; it is not managed in the same way in all EU Member States or within national health systems. It is often not even available to the patients themselves or to public authorities, medical professionals or researchers to help them develop and deliver better diagnosis, treatment or personalised care. Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide use.

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<sup>1</sup> State of Health in the EU "Companion Report 2017", <https://ec.europa.eu/health/state>

<sup>2</sup> The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems", notably encompassing public health and social care.

<sup>3</sup> Communication from the Commission "On effective, accessible and resilient health systems", COM(2014) 215 final

<sup>4</sup> Multiple chronic conditions or illnesses

<sup>5</sup> [http://reports.weforum.org/global-risks-2016/global-disease-outbreaks/?doing\\_wp\\_cron=1516386480.4622519016265869140625](http://reports.weforum.org/global-risks-2016/global-disease-outbreaks/?doing_wp_cron=1516386480.4622519016265869140625)

<sup>6</sup> Joint Report by the Commission services and the Economic Policy Committee on Health Care and Long-term Care Systems and Fiscal Sustainability, European Commission and Economic Policy Committee, October 2016, [https://ec.europa.eu/info/publications/economy-finance/joint-report-health-care-and-long-term-care-systems-fiscal-sustainability-0\\_en](https://ec.europa.eu/info/publications/economy-finance/joint-report-health-care-and-long-term-care-systems-fiscal-sustainability-0_en)

<sup>7</sup> Ministerial Statement, Organisation for Economic Co-Operation and Development Health Ministerial Meeting, "The next generation of health reforms", 2017, <http://www.oecd.org/health/ministerial/ministerial-statement-2017.pdf> & WHO global strategy on people-centred and integrated health services, World Health Organisation, 2015

Because of this, health systems lack key information to optimise their services, and providers find it hard to build economies of scale to offer efficient digital health and care solutions<sup>8</sup> and to support cross-border use of health services. As a result, citizens cannot yet fully benefit from the digital single market in this area. Market fragmentation and lack of interoperability across health systems stand in the way of an integrated approach to disease prevention, care and cure better geared to people's needs.

The EU is developing strong approaches in high performance computing, data analytics and artificial intelligence, which can help design and test new healthcare products<sup>9</sup>, provide faster diagnosis and better treatments. But succeeding in these endeavours depends on the availability of vast amounts of high quality data and appropriate regulatory frameworks that will safeguard the rights of the individual and society as well as stimulating innovation. As the report on the State of Health in the EU concluded, the use of patient-centred health data is still under-developed across the EU<sup>10</sup>.

The organisation and delivery of health and social care are the responsibility of the Member States. In some Member States, particularly those with (federal) regional systems, regional authorities are responsible for financing and providing healthcare. Nevertheless, in accordance with the Treaty on the Functioning of the European Union<sup>11</sup>, the Commission can promote public health and the prevention of disease and support cooperation between the Member States, for example, to improve the complementarity of their health services cross-border. The Commission can also take action to stimulate innovation, economic growth and the development of the Single Market in close coordination with Member States.

Health and care authorities across Europe face common challenges, which can be best addressed jointly. To this end, the Commission has been working with the Member States, regional authorities and other stakeholders to tap into the potential of innovative solutions, such as digital technologies and data analytics, and in doing so assist Member States in pursuing the reforms of their health and care systems. The Commission provides its support through funding and actions that promote policy cooperation and exchange of good practice.

EU funding supports research and innovation in digital health and care solutions, notably through the Horizon 2020 programme. It also supports the building of infrastructure for cross-border exchange of patient summaries and electronic prescriptions, with funding from the Connecting Europe Facility programme<sup>12</sup>.

The Directive on patients' rights in cross-border healthcare<sup>13</sup> established the eHealth network to advance the interoperability of eHealth solutions. EU legislation on medical

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<sup>8</sup> Commission Staff Working Document "A Digital Single Market Strategy for Europe - Analysis and Evidence", SWD(2015) 100 final, Section 5.6 Digitisation in Basic Sectors; eHealth and eCare, pages 79-81

<sup>9</sup> Drugs, devices, advanced therapy medicinal products etc.

<sup>10</sup> See page 37 of the "State of Health in the EU "Companion Report 2017", referred above.

<sup>11</sup> Article 168, Treaty on the Functioning of the European Union

<sup>12</sup> eHealth actions are financed from the telecommunications sector of the Connecting Europe Facility under the annual work programmes.

<sup>13</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88 of 4.4.2011

devices<sup>14</sup>, data protection<sup>15</sup>, electronic identification<sup>16</sup> and security of network and information systems<sup>17</sup> offers a range of opportunities to facilitate the responsible use of digital technologies in health and care.

Cooperation structures have also been developed; for example, the European Innovation Partnership on Active and Healthy Ageing<sup>18</sup>, the Active and Assisted Living Joint Programme<sup>19</sup>, and public-private partnerships such as the Innovative Medicines Initiative<sup>20</sup> and the Electronic Components and Systems for European Leadership<sup>21</sup>. Regional and national smart specialisation strategies also play a central role in the development of stronger regional ecosystems around the healthcare domain. Since 2004, two eHealth Action Plans<sup>22</sup> have provided a framework for policy action for the Member States and the Commission, and the eHealth Stakeholders Group<sup>23</sup> has played an important role.

## 2. NEED FOR FURTHER EU ACTION

To date, the uptake of digital solutions for health and care remains slow and varies greatly across Member States and regions. Further action at EU level is crucial to accelerate the meaningful use of digital solutions in public health and healthcare in Europe. In its mid-term review on the implementation of the digital single market strategy<sup>24</sup> the Commission set out its intention to take further action in three areas:

- *citizens' secure access to and sharing of health data across borders;*
- *better data to advance research, disease prevention and personalised health and care;*
- *digital tools for citizen empowerment and person-centred care.*

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<sup>14</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, OJ L 117 of 5.5.2017; Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices, OJ L 117 of 5.05.2017

<sup>15</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119/1 of 4.05.2016

<sup>16</sup> Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257 of 28.8.2014

<sup>17</sup> Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union, OJ L 194 of 19.7.2016

<sup>18</sup> [https://ec.europa.eu/eip/ageing/home\\_en](https://ec.europa.eu/eip/ageing/home_en)

<sup>19</sup> <http://www.aal-europe.eu/>

<sup>20</sup> Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking, OJ L 169 of 7.6.2014

<sup>21</sup> Council Regulation (EU) No 561/2014 of 6 May 2014 establishing the Electronic Components and Systems for European Leadership Joint Undertaking, OJ L 169 of 7.6.2014

<sup>22</sup> COM(2004) 356 final & COM(2012) 736 final

<sup>23</sup> <http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2769>

<sup>24</sup> COM(2017) 228 final

For this purpose, the Commission carried out a public consultation<sup>25</sup>. The responses to the consultation largely recognised the need for further work, identifying important challenges that prevent digital health and care solutions from being adopted across the EU and underserve people's needs. These refer to areas such as access to health data, diversity of Electronic Health Records, lack of technical interoperability and access to digital health services. The consultation also identified concerns specific to the electronic sharing of data, namely the risk of privacy breaches, cybersecurity risks and the quality and reliability of data.

On the scope of future EU actions, respondents gave priority to:

- the development of EU-wide standards for data quality, reliability and cybersecurity;
- EU-wide standardisation of electronic health records; and
- better interoperability through open exchange formats.

On 8 December 2017, the Council adopted Conclusions<sup>26</sup>, inviting Member States and the Commission to work together on a range of issues and seize the potential of digital technologies in health and care. The Conclusions also call specifically for the implementation in the health sector of existing EU legislation on the protection of personal data, electronic identification and information security.

The present Communication sets out how the EU can help meet the objectives of these Council Conclusions. It proposes to build the necessary cooperation and infrastructure across the EU and in doing so help Member States to fulfil their political commitment in these areas. The proposed actions also support the Commission's commitment to deliver on the Sustainable Development Goals on healthy lives and well-being for all at all ages<sup>27</sup> and the principles of the European Pillar of Social Rights<sup>28</sup>.

The vision outlined in this Communication is to promote health, prevent and control disease, help address patients' unmet needs and make it easier for citizens to have equal access to high quality care through the meaningful use of digital innovations. It will also strengthen the resilience and sustainability of Europe's health and care systems. By helping to maximise the potential of the digital internal market with a wider deployment of digital products and services in health and care, the proposed actions also aim to stimulate growth and promote the European industry in the domain.

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<sup>25</sup> Public Consultation on Transformation of Health and Care in the Digital Single Market, carried out between July and October 2017 ([https://ec.europa.eu/info/consultations/public-consultation-transformation-health-and-care-digital-single-market\\_en](https://ec.europa.eu/info/consultations/public-consultation-transformation-health-and-care-digital-single-market_en))

<sup>26</sup> Council conclusions 2017/C 440/05 on Health in the Digital Society — making progress in data-driven innovation in the field of health, OJ C 440 of 21.12.2017

<sup>27</sup> COM(2016) 739 final and <https://www.un.org/sustainabledevelopment/health/>

<sup>28</sup> COM/2017/0250 final

### 3. CITIZENS' SECURE ACCESS TO AND SHARING OF HEALTH DATA

Citizens have the right to access and share their health data. When it enters into application on 25 May 2018, the General Data Protection Regulation<sup>29</sup> will put citizens in control of the use of their personal data including health data. The public consultation confirmed that a majority of respondents would like to have more access to their health data. They would also like to share the data for their treatment or for research, if appropriate guarantees are in place. Technology should ensure that this is the case with infrastructure that is built in conformity with data protection rules.

However, at present, many citizens in Europe have limited electronic access to data about their own health. The data is often untraceable and scattered in different places. This may impact adversely on diagnosis, treatment and follow-up; for example, when a person is abroad and their medical information is not accessible. Moreover, incompatible formats and standards in electronic health record systems continue to be used across the EU.

In essence, citizens should have secure access, anywhere in the EU, to a comprehensive electronic record of their health data. Citizens should remain in control of and be able to share their health data securely with authorised parties (for medical treatment, preventive services, research or for any other purpose they deem appropriate). This should be irrespective of where the data is located and in line with data protection legislation. Unauthorised access should be prevented.

Current efforts to exchange patient data across borders in the EU rely on the voluntary cooperation of health authorities to connect to the eHealth digital service infrastructure<sup>30</sup>, which is supported by the Connecting Europe Facility (Broadband and Information and Communication Technologies) programme and uses the guidelines agreed by the eHealth network<sup>31</sup> for the governance, establishment and operation of the eHealth digital service infrastructure<sup>32</sup>.

Currently, this exchange is limited to patient summaries and ePrescriptions, and does not cover electronic health records. These two use cases of patient data exchanges are planned to start in 2018 between 8 - 9 Member States, with around 22 Member States expected to join the exchange by 2020.

Therefore, as the system is now moving into the operational phase, the Commission sees a need to gradually extend these two use cases to also cover the interoperability of Member states' electronic health record systems by supporting the development and adoption of a European electronic health record exchange format. There is also a clear case to develop further effective methods for enabling the use of medical information for public health and research and to develop common identification and authentication measures, as laid down in Article 14(2) of Directive 2011/24/EU. Such changes will require reviewing the management and functioning of the eHealth network to ensure appropriate governance of the eHealth digital service infrastructure and its financial basis.

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<sup>29</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC, OJ L 119/1 of 4.05.2016, particularly Article 15 (right of access) and Article 20 (right to data portability)

<sup>30</sup> <https://ec.europa.eu/cefdigital/wiki/display/CEFDISIS/eHealth+2.0>

<sup>31</sup> [https://ec.europa.eu/health/ehealth/policy/network/guidance\\_ehealthgenericservices\\_en](https://ec.europa.eu/health/ehealth/policy/network/guidance_ehealthgenericservices_en)

<sup>32</sup> [https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev\\_20151123\\_co01\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co01_en.pdf)



It will also necessitate, in agreement with the eHealth network, extending the current scope of the eHealth digital service infrastructure itself.

Developing specifications for a European electronic health record exchange format should be based on open standards and build on appropriate technical expertise, taking into account the potential use of data for research and other purposes. Additionally, the Commission intends to monitor the cross-border interoperability of electronic health record systems and, once in place, the adoption of the European electronic health record exchange format across the EU.

Moreover, the Commission intends to identify incentives for adopting the open European electronic health record exchange format widely across the EU and explore other measures to tackle any practices that result in the lack of interoperability, thus hindering the digital single market in this area. The Commission also plans to encourage approaches already developed in some Member States and regions to establish interoperable systems.

The Commission will monitor the implementation of the General Data Protection Regulation and the Regulation on electronic identification and trust services for electronic transactions in the internal market<sup>33</sup> with regard to health. The recently proposed rules on certification for cybersecurity requirements<sup>34</sup> may, once adopted, also be factored in the system. Here, account should be taken of emerging technologies such as blockchain, innovative identity management mechanisms, and certification mechanism for secure solutions in line with the cybersecurity Communication<sup>35</sup> and the provisions of the General Data Protection Regulation, in particular, on security, data breach and notification requirements<sup>36</sup>.

The Commission intends to mobilise funding from the Connecting Europe Facility and Horizon 2020 programmes for the European electronic health record exchange format and the further development of the eHealth digital service infrastructure. Health authorities can explore a targeted use of EU financing instruments, such as the European Structural and Investment Funds and the European Fund for Strategic Investments, for the deployment of interoperable electronic health records at national and regional level which enable citizens (and authorised third parties) to access their personal health data. Additional funding for this might also be considered under the next EU multi-annual financial framework.

The Commission will:

- Review Commission Implementing Decision 2011/890<sup>37</sup> pursuant to Article 14 of the Directive on patients' rights in cross-border healthcare<sup>38</sup>, in order to clarify

<sup>33</sup> Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257 of 28.8.2014

<sup>34</sup> COM(2017)477, [https://ec.europa.eu/info/law/better-regulation/initiatives/com-2017-477\\_en](https://ec.europa.eu/info/law/better-regulation/initiatives/com-2017-477_en)

<sup>35</sup> Joint Communication to the European Parliament and the Council Resilience, Deterrence and Defence: Building strong cybersecurity for the EU, JOIN/2017/0450 final

<sup>36</sup> General Data Protection Regulation Article 32 on security requirements; Articles 33 and 34 on data breach and notification requirements

<sup>37</sup> Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth. OJ L 344, 28.12.2011, p. 48–50



the role of the eHealth Network in the governance of the eHealth digital service infrastructure and its operational requirements, as well as to improve the interoperability of patient data and access by the citizen.

- Adopt a **Commission recommendation** on the technical specifications for a European electronic health record exchange format, while monitoring implementation of relevant EU legislation and considering other measures in the future if needed. Such specifications should also address citizens' access to electronic health records and aspects related to the implementation of appropriate data protection safeguards and security of patient health data in compliance with the General Data Protection Regulation.
- Further support the eHealth Digital Service Infrastructure to enable new services for people, such as exchange of electronic health records using the specifications of the European electronic health record exchange format, and the use of the data for public health and research.
- Mobilise funds from the Connecting Europe Facility (Broadband and Information and Communication Technologies) and Horizon 2020 programmes within the current envelopes, and consider further support from the next multi-annual financial framework, to encourage further collaboration between **Member States and between regions** on the cross-border exchange of health data and its possible expansion (notably to full electronic health records and other new services).

#### **4. BETTER DATA TO PROMOTE RESEARCH, DISEASE PREVENTION AND PERSONALISED HEALTH AND CARE**

Personalised medicine is an emerging approach that uses data generated by new technologies to better understand the characteristics of an individual and deliver the right care to the right person at the right time. New technologies enable a wider use of genomic and other information (such as molecular profiling, diagnostic imaging, environmental and lifestyle data) to help doctors and scientists better understand disease and how to better predict, prevent, diagnose and treat.

Several national and regional initiatives already support the pooling of genomic and other health data to advance research and personalised medicine. We need to better coordinate these existing initiatives to reach the necessary critical mass at EU level and match similar initiatives in other world regions. Significant breakthroughs can be achieved by linking Europe's fragmented resources through secure cross-border digital infrastructures, while ensuring full compliance with data protection legislation and ethical principles. Ensuring interoperable standards for genomic and other data is also critical for an effective sharing of datasets.

Linking resources and using common standards will improve the accessibility, sharing and use of health data to improve understanding of health and disease. This will also make it possible to better anticipate disease outbreaks, speed up diagnosis and develop better preventive and treatment measures, and monitor the effectiveness and possible undesired effects of such measures. European coordinated action in this field can bring tangible benefits for citizens and health systems in the EU, making it possible to tackle major health challenges such as cancer or brain disease, epidemics of infectious disease, or rare diseases (where half the new cases are found in children). Coordinated EU action

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<sup>38</sup> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 088, p.45

in this area also responds to the Council Conclusions on personalised medicine<sup>39</sup>, which called on the Commission to help achieve the potential of "Big Data".

The Commission intends to support the pooling of the EU's data resources and to facilitate their use for research and health policy. It will do this in line with data protection requirements, and building on the European High Performance Computing initiative<sup>40</sup> and the European Open Science Cloud<sup>41</sup> infrastructure. The aim is to connect national initiatives with European networks of scientific and clinical expertise, such as the International Consortium for Personalised Medicine, the European Reference Networks, the European Research Infrastructures, the Human Brain Project and other relevant initiatives. This will help European research and industry remain at the forefront, bringing new personalised medical solutions to the market. Any initiatives in this area should take full account of EU policy and technological developments in the field of cybersecurity, 5G<sup>42</sup>, the Internet of Things, the European Cloud Initiative<sup>43</sup> and EU policy on healthcare products, i.e. pharmaceuticals, medical devices, advanced therapies and health technology assessments.

The Commission intends step up coordination between authorities across the EU to implement the secure exchange of genomic and other health data in order to advance research and personalised medicine. By combining sequenced genomic data and other medical data, physicians and researchers can get a better picture of disease in a particular individual and determine the most appropriate treatment for that individual. This should be based on a transparent system of governance, with the aim of linking national and regional banks of "-omics"<sup>44</sup> data, biobanks and other registries across the EU. The initial goal of this coordination is to provide access to at least 1 million sequenced genomes in the EU by 2022<sup>45</sup>, and then to a larger prospective population-based cohort (beyond sequenced genomes) of at least 10 million people by 2025. This will integrate molecular profiling, diagnostic imaging, lifestyle (in particular risk factors); microbiological genomics and environmental data as well as links to electronic health records. It will also build on "digital patient" predictive approaches based on computer modelling, simulations and artificial intelligence. Ultimately, it will help to lay the foundation for developing a reference map (atlas) of all human cells, with a view to analyse human tissues and organs by state-of-the-art methodologies, and to compare and understand changes during disease.

It is paramount to agree on technical specifications for access and exchange of health data for research and public health purposes, addressing, for example, health data collection, storage, compression, processing and access across the EU. This effort will build upon the ongoing work of standardisation bodies, national initiatives and initiatives by health

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<sup>39</sup> Personalised Medicine for Patients, Council Conclusions (7 December 2015) 15054/15

<sup>40</sup> [http://europa.eu/rapid/press-release\\_IP-18-64\\_en.htm](http://europa.eu/rapid/press-release_IP-18-64_en.htm)

<sup>41</sup> <https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud>

<sup>42</sup> <https://ec.europa.eu/digital-single-market/en/5g-europe-action-plan>

<sup>43</sup> European Cloud Initiative - Building a competitive data and knowledge economy in Europe. COM(2016) 178 final

<sup>44</sup> 'Omics' technology is a general term for a broad discipline in science and engineering for analysing the interactions of biological information objects in various 'omes' that include the genome, proteome, metabolome, transcriptome etc. Its main focus is on developing technologies and tools for gathering information on various classes of biomolecules and their ligands, and understanding relationships among them, including the related regulatory mechanisms. (SWD(2013) 436)

<sup>45</sup> In April 2018, 14 Member States signed a joint declaration on cooperation "Towards access to at least 1 million sequenced genomes in the European Union by 2022", <https://ec.europa.eu/digital-single-market/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders>

professional societies, considering, among other things, the link with electronic health records.

The Commission also intends to test specific practical applications of cross-border health data exchange for research and health policy to improve treatment, diagnosis and prevention of diseases, initially focusing on the following pilot areas:

- faster diagnosis and better treatment of rare diseases for the almost 30 million people in the EU affected by one of the 5000-8000 life threatening or chronically debilitating rare diseases;
- better anticipation of epidemics and EU-wide identification of cross-border infectious threats; and
- use of "real world data"<sup>46</sup> (collected outside formal clinical trials) by healthcare professionals, public authorities and industry to ensure that healthcare products, innovative technologies and therapies meet patient's needs and lead to favourable health outcomes.

These pilot actions will aim to bring together appropriate programmes, initiatives and actors, both at EU and national level. This includes research programmes, the European Surveillance System for infectious disease surveillance<sup>47</sup>, medical expertise and work of the European Reference Networks, the European Platform for Rare Diseases Registration, and the global rare diseases information repository (Orphanet) within the framework of the planned European Joint Programme Co-fund on Rare Diseases. The pilot actions will be developed with clinical associations, national competent authorities, health technology assessment bodies, research infrastructures, industry, the Innovative Medicines Initiative and relevant EU agencies<sup>48</sup>.

Beyond these initial pilot areas, others may also be considered, notably focusing on cancer or neurodegenerative diseases (establishing links with appropriate initiatives such as the Human Brain Project).

These activities will increase the quality of data, standardise data collection, promote interoperability of European disease registries (such as the cancer and rare disease registries supported by the Joint Research Centre) and advance the analysis of data using of high performance computing and modelling. In this way, a critical mass of usable data will support vital knowledge generation and help improve prevention, diagnosis and treatment of patients. Furthermore, the Commission will explore with scientific representatives and clinical groups how best to stimulate demand for data aggregation, addressing incentives and concerns, such as safeguarding data protection compliance, for the further processing of health data.

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<sup>46</sup> Real world data is big data, referring specifically to any type of data not collected in a randomised clinical trial. This data can complement randomised clinical trial data to fill the knowledge gap between clinical trials and clinical practice, provide new insights into disease patterns and help improve the safety and effectiveness of health interventions.

<sup>47</sup> Decision 1082/2013/EU on serious cross-border threats to health

<sup>48</sup> Such as the European Centre for Disease Prevention, the European Food Safety Authority and the European Medicines Agency

Resources will be mobilised through the EU research programme Horizon 2020<sup>49</sup>, including the Innovative Medicines Initiative, the third "Health" programme<sup>50</sup>, and the Connecting Europe Facility<sup>51</sup> (Broadband and Information and Communication Technologies). Additional support from the Member States will be encouraged to allow the pilots to reach their full potential. Additional funding for this might be considered also under the next EU multi-annual financial framework to more closely link existing European resources to a world-leading health data and computation infrastructure able to effectively support scientific research and personalised medicine.

The Commission will, while ensuring full compliance with data protection legislation and ethical principles:

- Set up a **mechanism for the voluntary coordination** of authorities and other stakeholders to share data and infrastructure for prevention and personalised medicine research. This includes a European network on genomics, and seeking to link also with ongoing '-omics' and human cell mapping initiatives.
- Support the development of **technical specifications for secure access and cross-border exchange of genomic and other health datasets** within the internal market for research purposes. This is to facilitate interoperability of relevant registries and databases in support of personalised medicine research.
- Launch **pilot actions**, pooling data and resources across the EU, to demonstrate the benefits of advancing research, disease prevention, personalised medicine, health technology assessment, as well as clinical and regulatory decision making; and
- Support all the above by **mobilising funds** from Horizon 2020 and the Connecting Europe Facility (Broadband and Information and Communication Technologies,) within the current envelopes, and consider further support from the next multi-annual financial framework.

## 5. DIGITAL TOOLS FOR CITIZEN EMPOWERMENT AND FOR PERSON-CENTRED CARE

The ageing of the population together with the growing burden of chronic conditions and multi-morbidity are steadily increasing demand for health and care. This means health and social care systems have to develop a different approach to enable more effective care delivery and to confront the complexity of different services which patients are now expected to navigate. That is why it is widely recognised that health systems need to shift from treatment to health promotion and disease prevention, from a focus on disease to a focus on well-being and individuals, and from service fragmentation to the integration and coordination of services along the continuum of care. Member States and regional

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<sup>49</sup> Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC, OJ L 347 of 20.12.2013

<sup>50</sup> Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC, OJ L 86 of 21.3.2014

<sup>51</sup> Regulation (EU) No 1316/2013 of the European Parliament and of the Council of 11 December 2013 establishing the Connecting Europe Facility, amending Regulation (EU) No 913/2010 and repealing Regulations (EC) No 680/2007 and (EC) No 67/2010, OJ L 348 of 20.12.2013

authorities are already moving forward with such reforms in order to improve the effectiveness, accessibility and resilience of their health systems<sup>52</sup>.

To better advance health promotion, prevent disease and deliver integrated services based on people's needs, health systems have to find innovative solutions through new technologies, products and organisational changes. Central to the success of this transformation are:

- the configuration of new care models,
- the use of health technology assessment for attaining greater quality and sustainability of health services<sup>53</sup>,
- the involvement of multi-disciplinary care teams with new or redesigned roles for care professionals,
- the integration of promotion and prevention into primary care,
- a health workforce of sufficient capacity and appropriate skills,
- the active cooperation between care professionals and patients, and
- the utilisation of digital solutions, all of which provide the necessary means for delivery of efficient and cost-effective care.

Person-centred approaches to organising health and care can allow citizens to assume responsibility for their health, improve their well-being and the quality of care and contribute to sustainable health systems. By using digital solutions, such as wearables and mHealth<sup>54</sup> apps, citizens can actively engage in health promotion and self-management of chronic conditions. This in turn can help control the rising demand for health and care. Digital tools hold great potential to disseminate scientific knowledge in an easily accessible form, so as to help people stay in good health – thus preventing them from turning into patients. Building on scientific information on risk factors, digital solutions can be used across all sectors, including in education, transport, and urban policies to promote information and awareness campaigns on healthy lifestyles. Digital tools also enable citizens to provide feedback and data about their health to their doctors. This can improve the quality of health services and ultimately people's health and well-being.

So far, such new care models have typically been deployed on a small scale, but initial evidence indicates their benefits for both patients and health and care systems. For this

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<sup>52</sup> See footnotes 1, 3, 6, 7 and also:

- Council Conclusions: Towards modern, responsive and sustainable health systems, OJ C 202, 8.7.2011, p. 10–12 &

- Council Conclusions on the EPC - Commission Joint Report on health care and long-term care in the EU, 8 November 2016, <http://data.consilium.europa.eu/doc/document/ST-14182-2016-INIT/en/pdf> &

- Strategic Implementation Plan of the European Innovation Partnership on Active and Healthy Ageing. Examples of implementation can be found in the [Reference Sites](#) of the partnership.

<sup>53</sup> COM(2018) 51 final

<sup>54</sup> Mobile Health (mHealth) is a sub-segment of eHealth and covers medical and public health practice supported by mobile devices. It especially includes the use of mobile communication devices for health and well-being services and information purposes as well as mobile health applications. See COM(2014) 219 Green Paper on mobile health ([http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=5147](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5147))



transformation to truly materialise, there will have to be full-scale deployment of new care models. Only then will it be possible to deliver better health outcomes for people, achieve efficiency gains for health and care systems, reduce the risk of a digital divide and allow equitable and inclusive access to better health services for all segments of the population.

However, this transformation is complex and only possible if the many different actors engage in a joint effort. It requires: (i) significant financial investment at a time when health and social care systems are under financial pressure; (ii) commitment and knowledge of how to ensure such an investment leads to successful and cost-effective implementation of digitally-enabled, person-centred care solutions; and (iii) market conditions that can facilitate economies of scale for the suppliers of technology and services. As these preconditions have not yet been adequately fulfilled, the health and care sector in Europe has so far been relatively slow in implementing and scaling up innovative solutions for person-centred care.

The Commission will therefore work with relevant actors (such as Member States, regions, technology and service providers, health and care professionals, civil society organisations, academia, investors and existing stakeholder platforms) to support more cooperation across borders and enlarge the deployment of digitally-enabled care models.

In particular, the Commission will encourage closer cooperation between regional and national authorities to stimulate the development of the health technology sector. This includes supporting start-ups and small and medium-size enterprises that develop digital solutions for person-centred care and patient-feedback. The cooperation will involve public authorities and other stakeholders committed to promoting shared or mutually recognised principles for validating and certifying digital solutions for adoption in health systems (for instance, mHealth and independent living).

Addressing the demand side of the digital transformation of health and care, the Commission will help Member States and regional authorities develop their capacity to engage in this transformation and receive technical assistance. It will do this by building on the achievements and assets of existing programmes and EU initiatives<sup>55</sup> and by forging synergies between them in order to deliver a range of actions, which will include: (i) provision of knowledge resources such as guidelines, tools, innovative and best practices as well as reference catalogues<sup>56</sup>; (ii) technical support for implementation, twinning actions for mutual learning and transfer of innovative practices between regions and Member States, large-scale pilots and cross-border innovative procurement projects; (iii) development of toolkits with indicators to measure patient-reported outcomes, use of digital technologies in health and care, and evidence of impact; and (iv) protocols to tackle the reliability of health information.

Additionally, it is necessary to facilitate investment opportunities in Member States and regions to leverage public and private investment for the large-scale deployment of digitally-enabled, integrated person-centred care. This will include actions to raise

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<sup>55</sup> Such as: the European Innovation Partnership on Active and Healthy Ageing, the European Institute of Technology's Knowledge and Innovation Community on Health, the Member State Steering Group on Health Promotion and Prevention and Management of Non-Communicable Diseases, the EU Expert Group on Health Systems Performance Assessment, the Active Assisted Living Joint Programme community, as well as the Internet of Things platforms for digital health and care under the Digitising European Industry initiative.

<sup>56</sup> Such as the EU catalogue of ICT Standards for public procurers.



awareness of financing opportunities and innovative procurement, promote the strategic use of EU financing instruments, increase access to multi-source investment opportunities and promote stakeholder collaboration and community building for investments.

The Commission will support actions in the fields described above with funding from Horizon 2020 and the third "Health" programme. Also, the Structural Reform Support Service is available to provide technical support to Member States upon their request and subject to budget availability. The Commission will also promote synergies in this area with the European Structural and Investment Funds and the European Fund for Strategic Investments. Further funding might also be considered under the next EU multi-annual financial framework.

The Commission will:

- Support cooperation to stimulate the supply and uptake of digital health by promoting common principles for validating and certifying health technology.
- Support the **exchange of innovative and best practices, capacity building and technical assistance** for health and care authorities (for using open standards and interoperable digital solutions to promote health, prevent and manage chronic conditions, empower people and centre care on the person), with financial support from Horizon 2020, the Structural Reform Support Programme<sup>57</sup> and the third "Health" programme, within the current budgets, while considering making proposals for further support under the next multi-annual financial framework.
- Raise awareness about **innovative procurement and investment possibilities** for digital transformation in public health and healthcare, mobilising relevant EU programmes and financial instruments, collaborating with the European Investment Bank and investor networks, and considering further support, including possible co-investment approaches, under the next multi-annual financial framework.
- Promote knowledge and **skills of citizens, patients and health and care professionals** in using digital solutions in collaboration with health professional organisations and academia.

## 6. THE WAY FORWARD

Innovative digital solutions can boost people's health and quality of life and enable more efficient ways of organising and delivering health and care services. For this to happen, they must be designed to meet the needs of people and health systems and be thoughtfully implemented to suit the local context. Digital technologies should be seen as an integral part of health and care and geared towards the wider objectives of health systems. The actions put forward in this Communication aim in particular to support the Member States' strategies on reforming health systems.

The swift deployment of innovative digital health solutions can best be achieved by working together at EU level, sharing experiences in deploying, measuring impact and transferring innovation across Member States and regions. The active engagement of all

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<sup>57</sup> This includes informing and encouraging Member States also to explore the possibilities of receiving technical support from the Structural Reform Support Service, with regard to (i) the use of digital solutions for health systems, and (ii) the development of a strong digital governance framework in healthcare.

parties is essential to succeed in creating a “triple win” that benefits people, health systems and the market.