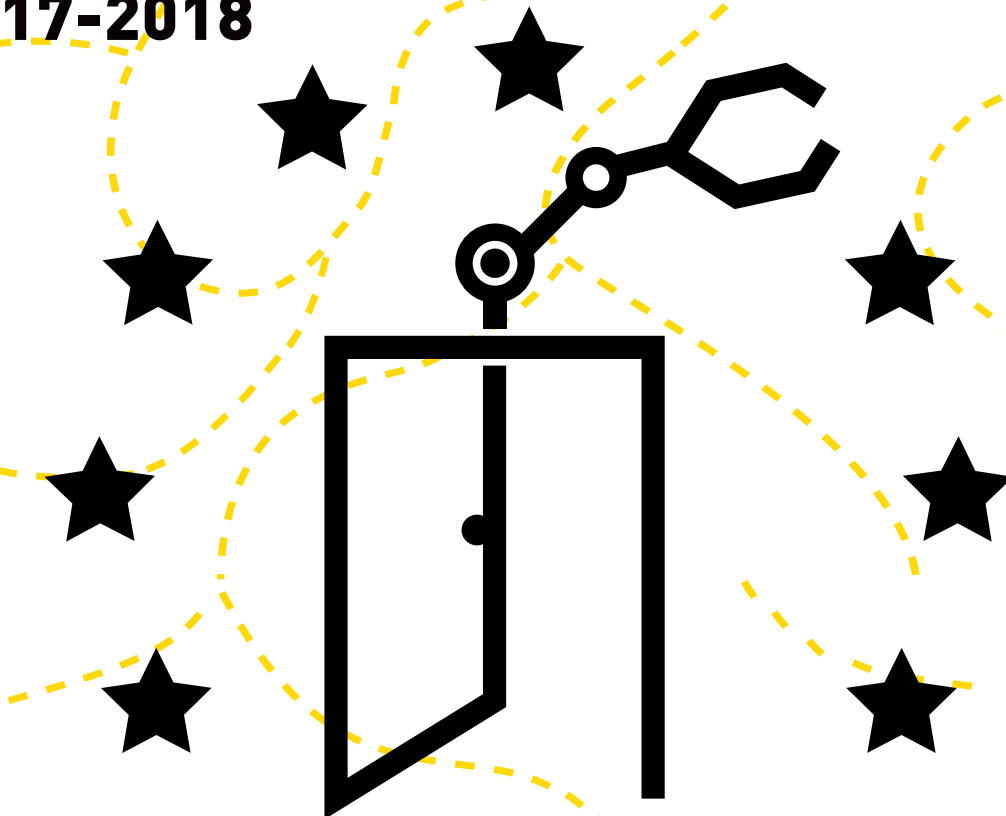# COMMITTEE ON ROBOTICS, AI & PRECISION MEDICINE

Breaking down barriers to digital health in Europe

2017-2018

COMMITTEE ON ROBOTICS, AI & PRECISION MEDICINE

Joep Roet (Chair)

Eric Felli (Vice-Chair)

Evelien De Greef

Claudia Gherman

Annamaria Metz

Elin Mignérus

Arantxa Mugica

Larysa Nykolyn

Mickaël Pinson

Thomas Smith

DISCLAIMER

Serge Bernasconi
Chief Executive Officer at MedTech Europe

*T*he European Health Parliament inspires not only its members but also us, who have worked in healthcare for many years. Innovative thinking is what drives forward the fields of robotics, AI and precision medicine. And I see the same kind of innovation coming from the members of this committee. By making digital health available, affordable and acceptable, we can ensure a healthy Europe for years to come.

To say that I enjoyed working with the young minds of this committee would not be enough. We will continue to work together long after this session of the EHP has ended. I'm confident that not only will they make health great again, they will also make it digital.

Michał Boni
Member of the European Parliament (EPP, Poland)

I fully agree with the submitted strategies to implement digital solutions in European health systems. True digital transformation requires a sharp break with past practices, legacy systems and even long-standing partners. To make that possible, Europe needs to map out how it intends to migrate from the past to the future. We need to be in a state of constant #Digitalhealth revolution. Thank you for your thorough work.

Gino Gumirato
Former Member of the American PPACA Commission

*F*or many years we have been focused on identifying excellent governance models, often losing ourselves in demagogic clashes on public health systems versus private ones. The merit of this report lies in how it shows that the 'future is already here (see Peter Durcker)', which, between the Internet of Things, robotics, infrastructure and digital health technologies, identifies a revolution that brings an unprecedented value creation.

Executive summary

The promise of digital health in Europe is undeniable. But to make this promise a reality, it is necessary to break down several barriers to make digital health technologies available, affordable and acceptable.

Available

1. Create a Connected European Health Area, which acts as a long-term vision on the required digital health infrastructure in Europe.
2. Establish a Digital Health Investment Fund, to support the creation of the CEHA.
3. Promote pilot projects to make Europe the world's frontrunner in digital health.

Removing the structural barriers to digital health by establishing a Connected European Health Area would reliably deliver digital health services to European citizens.

Affordable

4. Adapt health systems to incentivise the use of digital health technologies, by developing appropriate reimbursement models.
5. Ensure digital health in all policies, starting with the next MFF.

Adapting health systems to integrate digital health technologies would accelerate R&D as well as manufacturing, thus driving down the cost of new discoveries. This speeds up access for patients and will ease the burden on our health systems.
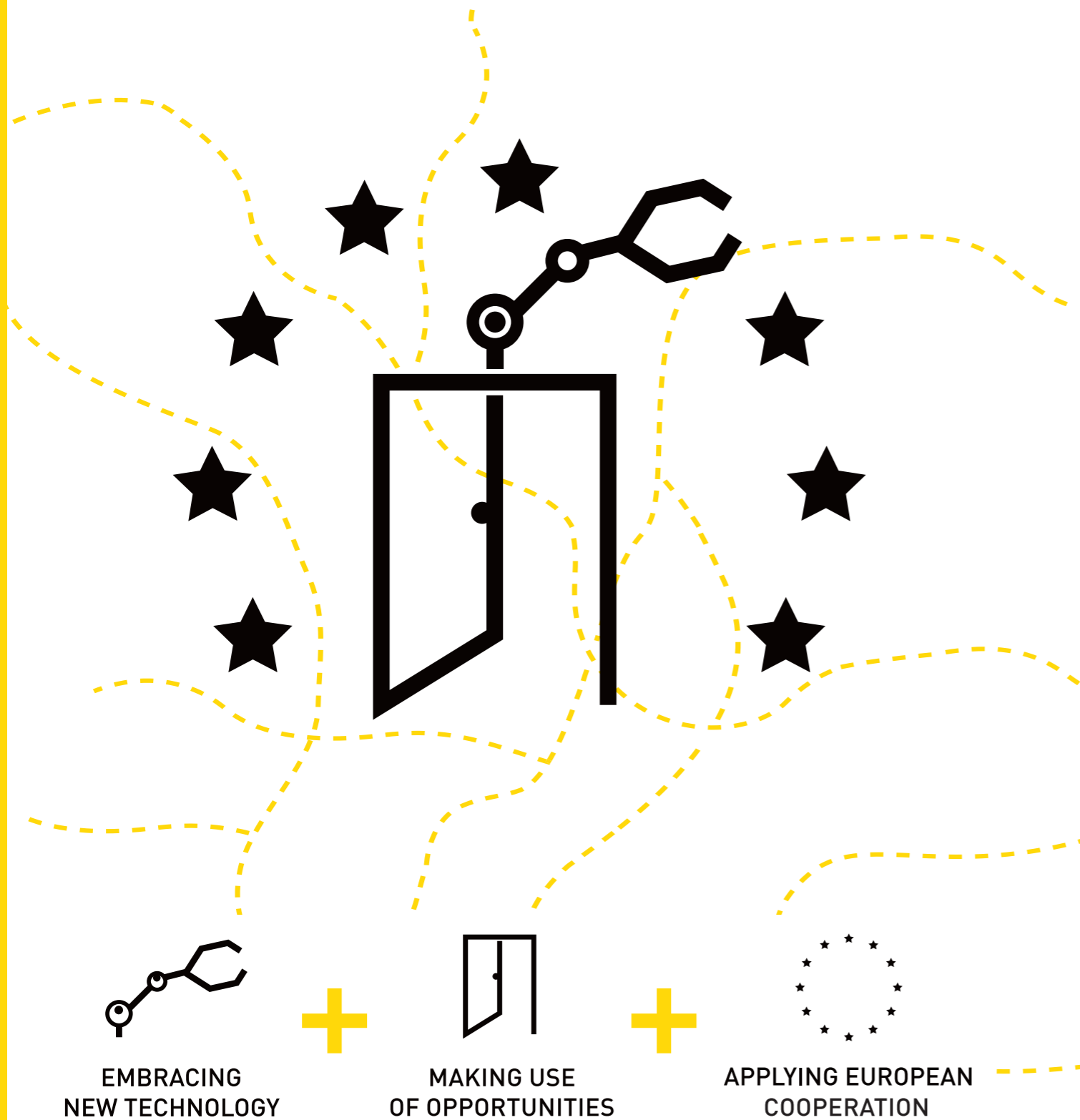
Acceptable

6. Establish grounds for trust in digital health, starting with GDPR and a review of the Liability Directive.
7. Help healthcare practitioners prepare for the future of healthcare.
8. Engage citizens through access to electronic health records and an awareness campaign.

Ensuring that healthcare practitioners and patients are willing and able to use digital health technologies to improve prevention, diagnosis, intervention and treatment is essential.

Digital health has incredible potential, but this is meaningless if it is not available, affordable and acceptable...

Breaking down barriers to digital health in Europe

EMBRACING NEW TECHNOLOGY + **MAKING USE OF OPPORTUNITIES** + **APPLYING EUROPEAN COOPERATION**

Introduction

European health systems are under stress. An ageing population, changes in societal behaviour and the rise of chronic diseases increase the long-term cost of healthcare. Together with budgetary constraints, this puts immense pressure on the sustainability of our healthcare systems that cannot be solved by merely throwing more money at them.

Fortunately, digital health technologies can improve our health services, as is shown in Figure 1. Advances in robotics, AI and precision medicine mean patients can benefit from improved health outcomes and a higher quality of life. Health systems see a reduction of healthcare costs, improved quality of services and overall more effectiveness. Indeed, as Commissioner Andriukaitis recently noted, digital tools can be used to improve health in Europe through promotion, prevention and protection.

However, the success of this digital transformation of health depends on how we embrace it in the years to come.[2] Access to quality and affordable healthcare for all citizens should be the ultimate goal for each and every society. The Committee on Robotics, AI & Precision Medicine, therefore, proposes a set of recommendations to ensure that digital health is **available**, **affordable** and **acceptable**.
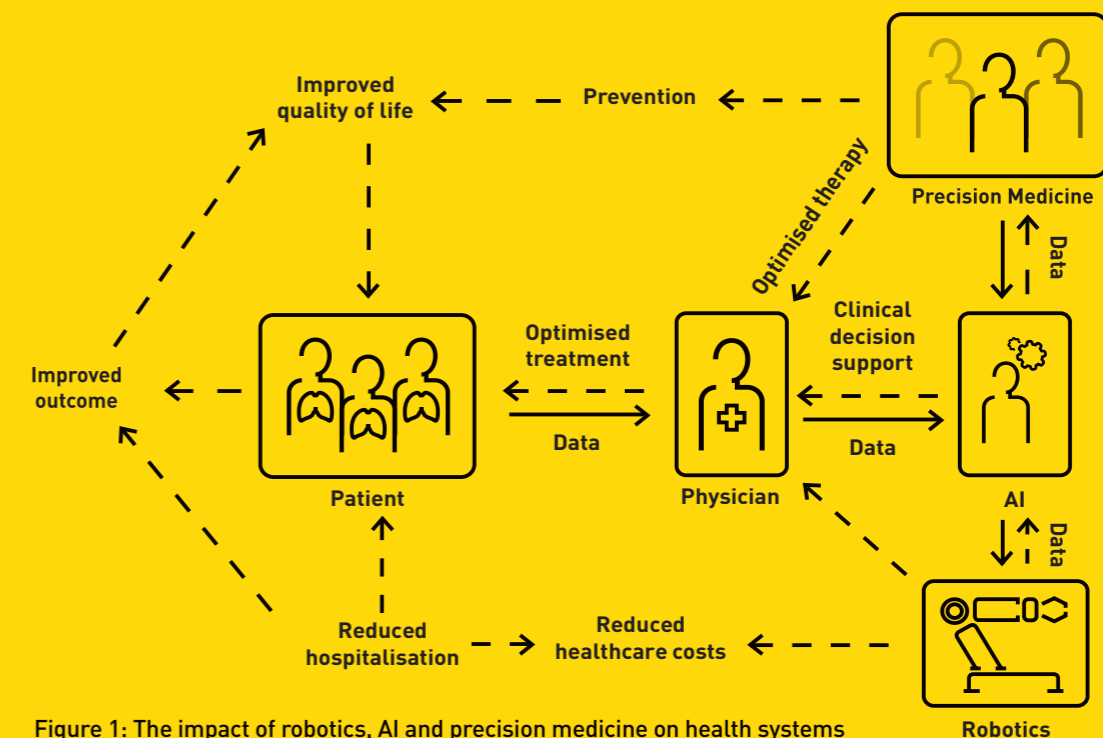

Figure 1: The impact of robotics, AI and precision medicine on health systems

For Europe to embrace digital health, it must be available, affordable and acceptable to all Europeans.

Policy Environment

The **European Commission** adopted its first eHealth Action Plan in 2004,[3] followed by a second action plan in 2012.[4] Several initiatives and legislative texts have supported these plans, including the 2011 Cross-Border Healthcare Directive,[5] the Commission green paper on mobile health[6] and the Commission staff working document on telemedicine.[7]

Under the current Commission, promoting digital health became a goal of the Digital Single Market Strategy (DSM). The 2017 mid-term review of said strategy and an internal task force also looked at how the DSM can benefit European citizens, healthcare systems and the European economy at large.[8] The ensuing public consultation on health and care in the DSM sought to collect input for a forthcoming Communication on eHealth,[9] which will focus on three pillars:

1. Citizens' secure access to health data and sharing of their health data across borders.
2. Connecting health data to advance research, disease prevention, treatment and personalised health and care.
3. Using digital tools to foster citizen empowerment and person-centred care.

Meanwhile, the **Estonian Presidency of the Council** launched the Digital Health Society in July 2017,[10] which eventually led to the adoption of the Council conclusions on health in the digital society.[11] The **European Parliament** has also adopted a resolution on Civil Law Rules on Robotics, among others.[12]

Momentum for digital health in Europe is clearly building, but for the EU to take on a leading position in the future health technologies, we need to take action now. We hope that, together with the Commission's upcoming Communications on eHealth and AI, our recommendations set out a plan to realise the potential of digital health and, ultimately, advance our common goal: better health for all Europeans.

I. Available

Digital health has incredible potential, but this is meaningless if it is not available.

Despite proof of the benefits that digital health technologies offer, structural barriers hinder their availability to patients. The lack of infrastructure and long-term planning are two barriers that we need to break down in the years to come. On the one hand, proper infrastructure can make health digital. On the other hand, a long-term vision will rally round all partners, public or private, to make our healthcare systems fit for the future. To ensure that digital health is available, the European Commission, together with the Member States and the European Parliament, should:

Recommendation #1

Create a Connected European Health Area

• **Formulate a vision on the required European digital health infrastructure**, based on criteria, such as connectivity, interoperability, and safety. The Connected European Health Area could follow the models of the Trans-European Transportation and Energy Networks. The Commission should translate the second priority in its upcoming Communication on eHealth, namely to connect health data to advance research, disease prevention, treatment and personalised health, into a concrete infrastructure investment plan, akin to the present Investment Plan for Europe.

• **Support individual actors to build digital capabilities**, such as hospitals, clinics, SMEs and research institutes, both physically (by linking up Europe's regions, boosting connectivity, expanding facilities) and in terms of human capital (technical skills & know-how).

Recommendation #2

Establish a Digital Health Investment Fund

• **The Digital Health Investment Fund will support the creation of the Connected European Health area**. It should invest in both the development and implementation of digital health technologies. The Fund should be one of the instruments to address strategic infrastructure in Europe considered for the next Multiannual Financial Framework.

• **Public-Private Partnerships can leverage alternative sources of funding**. Similar to the European Fund for Strategic Investment, private investments can be redirected to strategically important projects. Horizon 2020 partnerships, like the Partnership for Robotics in Europe (SPARC), the Human Brain Project or Big Data, already demonstrate that collaboration between EU institutions, industry and academia can drive results.

Recommendation #3

Promote pilot projects to make Europe the world's frontrunner in digital health

• **Foster cooperation in digital health across Europe's regions through pilot projects**. This can be done both physically by creating health tech test beds within identified areas to test implementation in practice as well as by providing digital platforms. The European Commission can facilitate such projects and establish an expert committee to identify projects that can be scaled up and promote uptake of proven innovation.

• **Frontrunner Member States and regions can provide leadership and guidance** to the other Member States, as is currently done with the eHealth Digital Services Infrastructure for sharing patient summaries and ePrescriptions across borders.[13]

• **Explore programmes to fast-track digital health innovations for timely access**, such as the US FD Software Precertification (Pre-Vert) Programmes.

Removing the structural barriers to digital health by establishing a Connected European Health Area would reliably deliver digital health services to European citizens.

II. Affordable

Digital health has incredible potential,
but this is meaningless if it is not affordable

Health systems are currently not ready to adopt digital health. The pace of innovation outstrips the pace of changing legislation and allocating funding necessary for integration. The start-up costs of digital health can be high. Regional differences in terms of economic development, knowledge and infrastructure also hamper adoption. To ensure that digital health is affordable, the European Commission, together with the Member States and the European Parliament, should:

Recommendation #4

Adapt health systems to incentivise the use of digital health technologies

• **Develop appropriate models for the reimbursement of digital health technologies**. Current models do not adequately cover digital health innovation, limiting widespread adoption of digital health by providers. Some Member States have taken first steps in this direction, such as Belgium, which is preparing to reimburse health apps based on three criteria. Reimbursement models could shape the health environment, for instance by requiring interoperability or the publishing of health-economic outcomes in incremental reimbursement schemes.

• **European cooperation on HTA should take into account digital health technologies.** To be effective- and to avoid revisions in the near future – the potential regulation to strengthen EU cooperation on health technology assessment beyond 2020 should include provisions for the assessment of digital health technologies.[14] Phasing out health technologies that are no longer cost-effective will also help improve the sustainability of our health systems.

Recommendation #5

Ensure digital health in all policies, starting with the next MFF

• **Health in all policies should specifically include digital health in all policies**. The discussions on the next Multiannual Financial Framework present the first opportunity to enshrine this principle as an allocation priority for each of the relevant instruments in the next budgetary framework, including those for Strategic Infrastructure, the European Structural and Investment Funds, the apparent Framework Programme for Research and Innovation and an independent Health Programme.

• **These instruments should support the creation of the Connected European Health Area**, in addition to realising the priorities for EU actions in health identified in the Digital Single Market mid-term review and the Commission's forthcoming Communications on eHealth and AI.

Adapting health systems to accommodate digital health technologies would accelerate R&D as well as manufacturing, thus driving down the cost of new discoveries. This speeds up access for patients and will ease the burden on our health systems.

III. Acceptable

Digital health has incredible potential,
but this is meaningless if it is not acceptable.

Widespread adoption of digital health technologies requires society to accept them, which is currently not self-evident. Perennial privacy and safety concerns and fear of abuse leave many individuals apprehensive about sharing personal health data. Legal measures to address these concerns are only partly in place and do not answer all questions. Knowledge gaps and the digital divide also slow adoption; although healthcare practitioners believe that digital technologies will trigger a new healthcare paradigm, many feel equally unprepared to keep up with the pace of change.[15] To ensure that digital health is acceptable, the European Commission, the Member States and the European Parliament, should:

Recommendation #6

Establish grounds for trust in digital health

• **Use of digital health technologies should be based on consent**. The General Data Protection Regulation (GDPR) is a major step forward in the protection of personal data, including data concerning health. However, inconsistent legislation between the Member States should be avoided where possible in order to improve clarity for patients and HCPs and increase the willingness to invest in digital health.

• **Involve patients as well HCPs from the start** to ensure effectiveness and desirability, for instance in the aforementioned pilot projects. Medical programmes, products and services should only be developed if desired – and hence accepted – by the people that will use and benefit from them.

• **Review the Liability Directive from 1985 to see which aspects are still fit today**. The work of the recently announced High-Level Expert Group on Artificial Intelligence, which will also propose AI ethics guidelines to the Commission, may feed into this.[16]

Recommendation #7

Help healthcare practitioners prepare for the future of healthcare

• **Help HCPs prepare for the future of healthcare** by integrating computing, ethical and practical skills into medical curricula, as well as through continued professional development programmes that equip practitioners with the latest know-how. This should address concerns that digital health technologies may one day replace physical HCPs, which is neither needed nor wanted.

• **Create an interdisciplinary workforce** that transcends the medical profession, for instance through courses on medical ethics for software engineers.

• **Facilitate updating of clinical guidelines to include digital health technologies where appropriate**, so HCPs know how to use them in daily practice.

Recommendation #8

Engage citizens

• **Engage citizens through an awareness campaign: sharing is caring!** The GDPR presents an opportunity to make a persuasive and transparent case for digital health. This could be based on three pillars. First, data sharing will deliver more personalised and hence improved healthcare. Second, while there are serious concerns, a new protection mechanism is now in place. Third, data sharing will benefit the public good, for instance by making clinical data available for research. These pillars should be supported by evidence in the form of case studies.

• **Ensure access to electronic health records.** Individuals should have access to all data related to their health history and, under certain conditions, be able to add information, though never amend or delete medical data entered by a professional. This should drive individual involvement.

Ensuring that healthcare practitioners and patients are willing and able to use digital health technologies to improve prevention, diagnosis, intervention and treatment is essential.

Conclusions

OUR MESSAGE TO EUROPEAN POLITICAL LEADERS

The world is in a digital transition, and the health industry is quickly catching up. The EU must grasp this opportunity to become the world's leading continent in digital health by ensuring that modern and future technologies are available, affordable and acceptable.

Digital health is the means, not the end. Adoption of these technologies will not only benefit the health of all Europeans and guarantee the sustainability of our health systems, but furthermore make Europe attractive for industry, create jobs, and establish the European Union as the leader in digital health innovation.

Our committee, therefore, eagerly awaits the Commission's upcoming Communications on eHealth and AI. We believe that the recommendations set out in this report can add EU value to future undertakings to make health digital.

References

1. Andriukaitis, European Commissioner for Health and Food Safety, Speech on the digital transformation of health and care at the 6th Conference of Partners of the European Innovation Partnership on Active and Healthy Ageing, Brussels, 27 February 2018.

2. PricewaterhouseCoopers, 'What doctor? Why AI and robotics will define New Health', 2017, retrieved 16 February 2018.

3. European Commission, Communication from the Commission on E-Health - 'Making healthcare better for European citizens: An action plan for a European e-Health Area', COM/2004/0356 final, Brussels, 30 April 2004.

4. European Commission, 'Communication from the Commission on E-Health - Action Plan 2012-2020 - Innovative healthcare for the 21st century', COM/2012/0736 final, Brussels, 6 December 2012.

5. European Parliament and the Council, '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', Official Journal of the European Union, L 88/45, Brussels, 4 April 2011.

6. European Commission, Green Paper on mobile health ("mHealth"), COM(2014) 219 final, Brussels, 10 April 2014.

7. European Commission, 'Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services', SWD(2012) 414 final, Brussels, 6 December 2012.

8. European Commission, 'Communication of the Commission on the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All', COM/2017/0228 final, Brussels, 10 May 2017. European Commission, Taskforce to take Health and Digital policies further, 27 February 2017, retrieved 3 March 2018.

9. European Commission, 'Public Consultation on Health and Care in the Digital Single Market, Brussels', 20 July 2017.

10. 'The Digital Health Society', European Connected Health Alliance, retrieved 18 February 2018.

11. Council of the European Union, 'Conclusions on Health in the digital society – making progress in data-driven innovation in the field of health', 14078/17, Brussels, 28 November 2017.

12. European Parliament, Resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)), P8 TA(2017)0051, Strasbourg.

13. European Commission, 'Cross-border digital prescription and patient data exchange are taking off, 21 December 2017', retrieved 3 March 2018.

14. European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU', COM(2018) 51 final, Brussels, 31 January 2018.

15. 2nd European Health Parliament, Committee on Digital Skills for Health Professionals, 'Report on Digital Skills for Healthcare Professionals', 2016

16. European Commission, 'Call for a High-Level Expert Group on Artificial Intelligence', 9 March 2018, retrieved 14 March 2018.

European Health Parliament 2017-2018

**EUROPEAN
HEALTH PARLIAMENT**

www.healthparliament.eu

Supported by

Johnson&Johnson POLITICO eu40® College of Europe / Collège d'Europe Brugge · Natolin Google EPF European Patients Forum