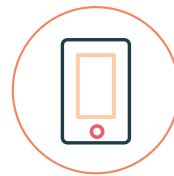


Position paper on digital health from a patient perspective



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Foreward



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Established in 2016, the European Patient Innovation Summit (EPIS) is a platform for patient advocates from across Europe to discuss all aspects of digital health and to achieve consensus on the patients' position on different issues relating to the digital world. EPIS is an event organized by Novartis together with a Steering Committee, representing the patient community that uses an innovative multi-site and multi-lingual format to enable patient advocates to learn more about developments in digital health and discuss how to embed a stronger patient voice within the digital health ecosystem. When planning EPIS 2018, the Steering Committee decided to directly address some of the key factors that have prevented patients from truly benefitting from digital health solutions.

EPIS 2018, which took place on 15th November 2018, was attended by over 270 patient advocates, spread out across thirteen hubs in different European countries and linked through 2-way connectivity* and livestream†. The Summit consisted of presentations and consensus-building sessions. Voting technology was used to ensure that all participants contributed to the recommendations that were formulated during the meeting. These recommendations, which are summarized in this position paper, represent a clear call to action on patient-relevant aspects of digital health, not only for patient advocates, but also for technology developers, policy makers, payers and healthcare professionals.

Ultimately, our goal is to improve the health and well-being of the millions of people living with a chronic condition in Europe today. We hope that these recommendations will be used by patient advocates to push for the changes needed to transform how digital health solutions are developed and to increase the uptake of impactful technologies. Concerted action today will mean that more and more patients will benefit from the digital health revolution and we believe that this will translate into improved patient outcomes.

*France, Germany, Ireland, Italy, Portugal, Spain, Switzerland, Central European Cluster, Serbia.
†Austria, Bulgaria, Czech Republic & Slovakia, Hungary, Slovenia.

Executive summary

Digital solutions have the potential to increase the health of millions of European patients and radically change the way health services are delivered in different European countries.¹ However, as the uptake of digital solutions remains slow and varies greatly across different European countries, patients are still not benefitting from the digital solutions that could empower them to take control of their lives and improve their overall well-being.¹ This is a situation that European patient advocates want to change and was the focus of discussion during EPIS 2018.

A huge number of digital health solutions are available today – from cutting edge artificial intelligence (AI) and robotics in the operating room, through diagnostic algorithms that use big data in primary care and products for the engaged consumer – and it is difficult to know which ones actually have a clear benefit for patients.^{2,3} For this reason, there is a need to build an evidence base to demonstrate the value of digital tools prior to their widespread adoption by patients.³ It was acknowledged that digital solutions are not without concern for patients and issues such as data privacy, ownership and protection need to be addressed to encourage greater use of the most impactful technologies.^{1,4} Many healthcare professionals are wary of using digital solutions and this represents an important barrier to the widespread use of digital solutions in daily clinical practice.^{4,5,6} For this reason significant efforts are required to increase awareness among healthcare professionals about the value of different technologies for patients.^{4,5} Digital solutions that are “made by patients” are more likely to address these barriers and to be used by patients and therefore it makes sense to involve patients early and in a systematic manner in the development of digital technologies.⁶

In the light of this discussion, EPIS 2018 participants voted on a series of recommendations that form the basis of this position paper.

There was overwhelming agreement on the following recommendations:

- There is a need to build an evidence base to demonstrate the impact of new technologies on patients' health and well-being.
- Patients should be involved in all stages of the development of digital technology, aimed at empowering patients.
- All patients with chronic conditions, regardless of their digital literacy, economic level, education or disabilities, should have access to technologies that have been shown to improve their health and well-being.
- Patients' concerns about digital technologies (e.g. security, data protection and ownership) need to be addressed so that they will be more likely to use impactful technologies.
- Healthcare professionals need to be aware of digital technologies and see their value as tools to empower patients and encouraged to use them as part of their daily practice.
- Multi-stakeholder and industry alliances should be established to avoid duplication of effort and ensure that patient-relevant digital technologies are developed in the most efficient and effective way possible.

At the close of EPIS 2018 participants were asked if they would be willing to take action to push for more wide-scale adoption of the most impactful digital technologies and there was widespread agreement that they were willing to do this. This overwhelming commitment to take action, in addition to patient advocates' interest to get involved in the development of digital health solutions, will help ensure that the technologies, which become available over the coming years, will be much more relevant and user-friendly than those that are in use today and, hopefully, result in a more rapid adoption of valuable patient-centric technologies.

Introduction: Patients in the digital world

Whether it's through the increasing use of medical devices and systems that support clinical decision making and patient care, or technologies that empower patients to take control of their condition, there is no doubt that digitalization is rapidly changing the healthcare landscape (see glossary in appendix 1).^{2,7} Many patients like digital solutions because of their ease of accessibility as they can be accessed anytime, anywhere, and with minimal waiting time.⁷ While there is widespread consensus that digital technologies have an increasingly important role to play in healthcare,^{2,7} questions remain about how to ensure that digital health solutions provide meaningful benefits for patients.^{4,5}

There are concerns about how patients can have access to technologies that have been shown to actually improve their lives and well-being.² To address these concerns it has been argued that patients should be systematically involved in the design of digital health solutions. Unfortunately, this does not happen routinely,^{4,5} which means that many digital health solutions do not solve the problems patients face in their daily life and are, therefore, not used by patients. Additional barriers might be posed by the regulations that govern the use of medical devices.

“There is widespread consensus that digital technologies have an increasingly important role to play in healthcare”

If an App is a medical device, it can take up to three years for it to be approved. Not only does this result in the App being out of date by the time it is approved, but it slows down the uptake of digital tools. However, as it affects many different aspects of digital healthcare, the issue of regulation is far from straightforward.⁸

In order to maximize the potential of digitalization for patients, there is a need to tackle the barriers faced

to the widespread uptake of impactful digital solutions.² This will require a collective effort by all those involved in the digital health ecosystem.¹

Digital health solutions – ranging from electronic health records accessible throughout the spectrum of care, wellness apps, and wearable devices with sensors that track a host of functions and parameters to robotic aids for high-precision surgery – are potentially valuable for patients as they can improve the way health and care services are delivered.¹

“To maximize the potential of digitalization for patients, there is a need to tackle the barriers faced to the widespread uptake of impactful digital solutions”

Electronic health records (EHR) are viewed as tools with high potential value for improving care⁶ and their standardization is viewed as a key priority for the EU.¹ The key benefit of an EHR is that it provides easy access to a comprehensive record of a patient's health history and means that dots can be connected more quickly and patients are less likely to fall between gaps in care provision.⁹ Equally important for patients is access to their personal health records.^{9,10} It has been estimated that 90% of EU citizens want to have access to their own health data to make sure they receive the best possible treatment and care.^{7,10} Digitalisation makes this much easier to achieve.

Apps and wearables can facilitate communications between patients and healthcare professionals are also valuable as they can empower patients and help them take back control over the health.⁷ Big data and artificial intelligence (AI) also represent important means to transform the lives of patients with chronic conditions because of the potential of data-driven technologies to improve the early diagnosis of diseases and improve clinical decision making, especially

Introduction: Patients in the digital world

for patients with more complex needs.¹¹ In addition to technologies that can support clinicians to make better decisions or assist them in practice,^{11,12} there are numerous smart algorithm-powered, text- or voice-based interfaces that are emerging that can guide patients and help them learn to take better care of their health.² Apps and wearables become increasingly valuable as patients become more and more willing to share the collected data with healthcare professionals.⁷ On one hand, these technologies can encourage treatment adherence, and on the other, they provide the means to collect real-time information about symptoms which can be shared directly with health professionals.^{7,13} As adherence determines effectiveness and data from smart devices can facilitate care and accurate treatment services and strategies, these can result in more rapid resolution of disease- and treatment-related problems that can be highly burdensome for patients.^{13,14}

As digital technologies are shown to have clinically relevant effects for patients, the World Economic Forum anticipates that broader usage of digital health technologies will bring two significant shifts to the healthcare system.

The first will be disruption to the location of care (for instance, moving care out of the hospital and closer to home) and the second will be a change from 'diagnose and treat' to 'prevent and manage'.¹⁵ This has the potential to transform the patient journey and help improve patients' health outcomes.¹⁵ However, despite this keen interest in digital health and widespread access to internet within the home (installed in approx. 86% of European dwellings¹⁶) and high interest and demand for digital health solutions, medical and fitness apps have a 90-day user retention rate

of only 27–30% and 50% of apps are downloaded less than 500 times.¹⁷

“The World Economic Forum anticipates that broader usage of digital health technologies will bring two significant shifts to the healthcare system”

While good health behaviors and lifestyle choices are key to preventing the progression of chronic conditions, there are significant challenges faced in encouraging people, living with these diseases, to change their behaviors and improve their overall well-being.^{18,19} Digital solutions can help address these barriers.¹

However, EPIS 2018 speaker Dr David Ebert (Faculty of Behavioural and Movement Sciences, Clinical, Neuro- & Developmental Psychology, Vrije Universiteit Amsterdam) pointed to the fact that there are many barriers to the use of digital technologies. These include:

- A lack of evidence-based treatments or resources with proven positive outcomes;
- Attitudinal barriers to behavior change (e.g. instinctively handle problems alone and avoid proactively seeking help);
- There is a sense that health systems could provide more resources or data to help patients feel they are in charge of their own care.



European patients' position on digital health



EPIS recommendations

There is a need to build an evidence base to demonstrate the impact of digital solutions



One of the primary reasons for the potential of digital health solutions to have not been realized yet is the difficulty of generating an evidence base for guiding decisions around their use.^{3,5} The importance of building an evidence base to demonstrate the impact of a technology cannot be underestimated.^{3,4,5} As David Ebert, one of the EPIS 2018 keynote speakers pointed out: “Just because a pill is white or blue does not mean it works, so in the same way that we need to test a medicine to make sure that it works and is safe, we need to test digital technologies to make sure that they are effective. Otherwise, we risk spending a lot of money on something that looks great

but has no real benefits for patients”. Discussions at EPIS 2018 revealed that patient groups have an important role to play to ensure that consistent evidence is provided to show the safety and effectiveness of a digital health solution before it is made more widely available and reimbursed by healthcare systems. On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

There is a need to build an evidence base to demonstrate the impact of new technologies on patients' health and well-being

Patients want to be involved in the development of digital health solutions



The consensus from the EPIS 2018 participants was that patient involvement in the development of digital tools is critical to the success of any digital health project. By placing patients and patient groups at the core of the ideation, creation and testing process, many of the challenges to widespread uptake of digital health solutions could be combatted.^{4,17} Involvement of patients at the earliest stage of ideation can help ensure that digital solutions reflect patients' preferences.⁹ Rooted in a true knowledge of the daily problems faced by patients, digital solutions should be precisely targeted at solving the most pressing real-life needs, rather than the demands of the market.^{6,20} This is crucial because if a digital technology does not solve an important real-life problem, and only increases the time and investment patients have to make in their healthcare, it's highly unlikely to be used.⁹ It is, therefore, clear that

developing technologies for patients without input from patients is a waste of resource for the developer.^{6,9} Developers need to think how to avoid a tokenistic approach and engage patients in a purposeful way in the development of their products.⁹ Establishing contact with a patient group in the relevant disease area is a good first step in the engagement process.⁹ Careful insight gathering and regular engagement at different points throughout the development process can help ensure that the digital health solution provides real added value for patients and is, therefore, more likely to be used.⁹ On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

Patients should be involved in all stages of the development of digital technology, aimed at empowering patients

EPIS recommendations

Patients should have timely access to impactful digital solutions



Despite the huge potential of digital technologies to improve the health and well-being of patients with chronic conditions there are numerous barriers to the uptake and utilization

of impactful digital health solutions. Two barriers have been especially highlighted as key: Uptake of solutions is low⁵ and the overwhelming number of digital health solutions available today makes it difficult for healthcare professionals and patients to identify which digital solution is most applicable to their care and help them to adopt healthier behaviours.³ EPIS 2018 participants felt that patient groups should play a key role in addressing this problem and in educating patients about the pros and cons of different digital solutions. Another barrier to access is that healthcare systems do not routinely reimburse the use of digital health solutions,^{3,4} which means that patients may have to fund the use of these tools by themselves.²¹

This can be expensive at a time when patients are often facing significant financial difficulties as a result of their condition.²¹ One of the problems is that there is often a limited evidence base of the added value to patients' health outcomes that the digital solutions are providing.³ This highlights the importance of building an evidence base to support the use of different digital technologies,³ an issue which is covered in greater depth below. On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

All patients with chronic conditions, regardless of their digital literacy, economic level, education or disabilities, should have access to technologies that have been shown to improve their health and well-being

Patients' concerns about digital solutions should be addressed in order to increase the uptake of impactful solutions



Patients have a number of concerns about digitalization and digital health solutions.⁹ A huge concern for many patients is the question of data ownership and data privacy.^{5,9,20}

Numerous stakeholders, including a significant number of patients, are worried about how data will be protected and used by others.^{5,9,20} Addressing these concerns will be critical in ensuring the widespread usage of digital technologies.^{1,9} EPIS 2018 participants concluded that patient groups can play a role here by clarifying exactly who is able to access patient data that is collected and held digitally (especially employers and insurers), advocating that patients have the right for their data to be deleted,

and communicating to patients the advantages of making their data available. Other actors in the digital health ecosystem also need to take action to address patients' concerns so that they will feel confident to use available technologies.⁹ On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

Patients' concerns about digital technologies (e.g. security, data protection and ownership) need to be addressed so that they will be more likely to use impactful technologies

EPIS recommendations

There is a need to raise healthcare professionals' awareness about the benefits of digital health solutions and find ways to overcome resistance to their use in daily practice



Despite the potential of digital health to improve patient outcomes, healthcare care professionals are often reluctant to use patient-relevant technologies in their daily practice.^{5,6}

Given the importance of healthcare professionals as a source of information for patients and trusted advisors on how to best manage their health and chronic conditions,^{22,23,24} patient advocates at EPIS 2018 were concerned that healthcare professionals are not recommending relevant digital solutions to patients. There is a need to raise healthcare professionals' awareness and knowledge about the potential of digital health solutions to empower

patients and improve their health and well-being.^{4,5,6,20} The potential advantages to healthcare professionals of using digital tools can be further demonstrated and emphasized so that they see digitalization as a solution, rather than a burden.²⁵ On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

Healthcare professionals need to be aware of digital technologies and see their value as tools to empower patients and encouraged to use them as part of their daily practice

Strategic alliances between different interested stakeholders can help accelerate the development of impactful digital health solutions



The current model for providing healthcare in Europe is under enormous strain, largely due to the combination of an ageing population and stretch on healthcare spend across Europe.¹

There is an urgent need for all stakeholders to work together to transform the healthcare system, with digital health solutions playing a key role in moving to 'consumer-centric' healthcare, allowing citizens to have much more responsibility for managing their healthcare and that of their families.¹⁵ There is a need to speed up the development of digital health solutions that can transform patients' lives.¹⁷ Alliance-building between different stakeholders can help break down barriers to accelerating the development of impactful digital solutions and ensure that these solutions are made available to patients in a timely manner.¹⁷ Brian O'Connor from the European Connected Health Alliance, another speaker at EPIS 2018, encouraged patient groups to engage with digital health ecosystems, which have been established in different countries, to ensure that patients have a voice in policy discussions around the

development of digital technologies (<https://echalliance.com/page/EcosystemsOverall>). Discussions at EPIS 2018 made clear that patient groups can also increase their influence in shaping policy around access to digital health solutions by collaborating with each other at a national and European levels. This would not only enable patients to input into policy decisions but also to learn from each other as experiences differ across disease areas. Such cross-fertilization between patient groups could increase awareness about digital solutions that have broad applicability to patients with chronic conditions but also about how to advocate within the digital health setting. On the basis of this discussion, EPIS 2018 participants agreed to the following recommendation:

Multi-stakeholder and industry alliances should be established to avoid duplication of effort and ensure that patient-relevant digital technologies are developed in the most efficient and effective way possible

Appendix 1: Glossary of digital terms

DIGITALISATION

The way in which many domains of public and private life are restructured around the use of computer technology.

Digital technology – The branch of scientific or engineering knowledge that deals with the creation and practical use of digital or computerized devices, methods, systems, etc., or a digital device, method, system, etc., created by using this knowledge.

AI (Artificial Intelligence) – The simulation of human intelligence processes by machines, especially computer systems.

Big data – An umbrella term describing data sets that are too large or complex to be analyzed by traditional data-processing software, and the analysis and systematic extraction of information from such data sets.

Data protection – The process of safeguarding important, often personal or confidential, information from corruption, compromise or loss.

DIGITAL LITERACY

The ability to use computer-enabled information and communication technologies to find, evaluate, create, and communicate information, requiring both cognitive and technical skills.

DIGITAL HEALTH

An overarching term that comprises eHealth (which includes mHealth), and emerging areas, such as the use of computing sciences in the fields of artificial intelligence, big data and genomics.

Digital health architecture – An overview or blueprint used to design and describe how different digital applications (software and ICT systems) and other core functionalities will interact with each other within a given context

Digital health ecosystem – The combined set of digital health components representing the enabling environment, foundational architecture and ICT capabilities available in a given context or country

Digital health solution – Any device, software or other technology that fits into the paradigm of digital health and seeks to solve a problem for a set of actors or stakeholders in the field.

Application (App) – A software application, especially as downloaded by a user to a mobile device, designed to perform a specific function.

Digital health application – The software, information and communication technology (ICT) systems, and communication channels used in the health sector, such as a software being used for health management information systems or an interactive messaging application (App)

eHealth – The use of ICT in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research. mHealth is a component of eHealth

Electronic Health Record – A digital version of a patient's paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users.

eHealth – The use of mobile and wireless technologies to support health objectives

Wearable [technology] – A category of technological or 'smart' devices that can be worn on the body by a patient or a consumer that often include tracking information related to health and fitness.

Appendix 2:

Votes from EPIS 2018

Recommendations for widespread use of digital technologies to transform the lives of patients with chronic conditions

EPIS 2018 participants were given the opportunity to vote on six recommendations that represent calls to action for different stakeholders to ensure that patients with chronic conditions secure full benefit from available digital technologies. EPIS 2018 participants voted on the recommendations and the results were as follows:

Recommendation 1: There is a need to build an evidence base to demonstrate the impact of new technologies on patients' health and well-being - *92% agreed, and 6.1% were willing to go along with the majority decision, despite not totally agreeing [163 voted].*

Recommendation 2: Patients should be involved in all stages of the development of digital technology, aimed at empowering patients – *85.5% agreed, and 10.8% were willing to go along with the majority decision, despite not totally agreeing [166 voted].*

Recommendation 3: All patients with chronic conditions, regardless of their digital literacy, economic level, education or disabilities, should have access to technologies that have been shown to improve their health and well-being - *93% agreed, and 4.5% were willing to go along with the majority decision, despite not totally agreeing [157 voted].*

Recommendation 4: Patients' concerns about digital technologies (e.g. security, data protection and ownership) need to be addressed so that they will be more likely to use impactful technologies - *93% agreed, and 5.7% were willing to go along with the majority decision, despite not totally agreeing [158 voted].*

Recommendation 5: Healthcare professionals need to be aware of digital technologies and see their value as tools to empower patients and encouraged to use them as part of their daily practice – *90.9% agreed, and 6.5% were willing to go along with the majority decision, despite not totally agreeing [154 voted].*

Recommendation 6: Multi-stakeholder and industry alliances should be established to avoid duplication of effort and ensure that patient-relevant digital technologies are developed in the most efficient and effective way possible - *87.2% agreed, and 11% were willing to go along with the majority decision, despite not totally agreeing [172 voted].*

Participants were given the opportunity to vote 'agree', 'do not completely agree but willing to go along with the majority decision', 'disagree and can't support this recommendation' and 'prefer not to vote'.

Votes from EPIS 2018

Recommendations on the most impactful digital technologies and how patient advocates can ensure their widespread adoption

EPIS 2018 participants also voted to identify the following:

1. The most impactful digital technologies with the greatest potential to empower patients [176 voted]

- Electronic health records: 15.9%
- Big data/ Artificial Intelligence: 14.2%
- Devices to support independent living: 12.5%
- Online peer support: 9.7%
- Patient-owned health records (Data box): 9.7%
- Integrated community platform 9.7%
- Apps/Wearables: 9.1%
- Online support from health professionals: 6.8%
- Website/ platform: 6.8%
- Telemedicine: 5.7%

2. Actions that patient advocates should take to ensure widespread adoption of these technologies [154 voted]

- Patients not only users but lead development: 21.4%
- Educate patients how to use technologies: 16.9%
- Sharing best practices among PAGs: 15.6%
- Forming a national patient group alliance: 13%
- Improve patient group digital health literacy: 12.3%
- Identifying and articulating patients' needs to different stakeholders: 9.7%
- Raise patient awareness of available technologies: 7.8%
- Campaign to increase access to digital technologies: 3.2%

3. Success factors to ensure adoption of these technologies [161 voted]

- Ensure technologies provide tangible benefits for patients: 26.1%
- Engagement of patients in co-creation process: 23%
- Availability of user-friendly technologies: 12.4%
- Patients lead the development of technologies: 8.7%
- Break down of access barriers: 7.5%
- Political willingness to provide access to digital technologies: 6.2%
- Mapping of existing technologies: 6.2%
- Clarify data security issues: 4.3%
- Building mutual trust: 3.1%
- Collaboration with innovative ecosystems: 2.5%

Appendix 3:

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