Public consultation on European Health Data Space – EPF accompanying paper

26 July 2021

The European Patients' Forum (EPF) is an umbrella organisation of patients' organisations across Europe and across disease-areas. EPF represents the interests of over 150 million patients with chronic conditions across the EU who expect and rely on European cooperation to improve healthcare delivery and quality for all. In concert with its 77 members, EPF ensures the patient perspective in European key health debates, including digital health and health data. To achieve this goal, over the past years EPF has been particularly active in these fields through both its policy work[1] and several projects[2].

This statement is an addition to the EPF's response to the European Health Data Space (EHDS) Public Consultation, submitted through the EU Consultation portal. The response and this statement have been developed in a consultative process with our members and our EPF Digital Health Working Group. In this accompanying statement, we further elaborate on some of the key elements included in our response and summarise our views on the EHDS.

NOTE – the responses included in the Consultation and in this accompanying paper are based on the current understanding of the European Health Data Space proposal development and on the interpretation of the questions included in the questionnaire. On this point, several of the questions have been identified quite broad and unclear, at least in some of their elements, in particular in terms of prioritisation and identification of what should constitute a precondition for the EHDS design and implementation. For instance, it is essential to note that ***many of the proposed options, tools, platforms, and policies mentioned in the questionnaire as ways to facilitate health data sharing, can be considered viable choices only if patients are first ensured proper access and control over their health data with a transparent and trustworthy framework****. Furthermore, EPF's responses might not entirely reflect individual organisations views or precisely capture national or disease-specific challenges and suggestions. They should be therefore considered in parallel with the inputs shared by our members, both patients' national coalitions and European disease-specific organisations*

Introduction

Health is an area where Europe can undoubtedly benefit from the data revolution. Proper use of health data can improve health systems' sustainability, increase the quality, safety and patient-centredness of healthcare, decrease costs and transform care into a more participatory process.[3] Health data can support the work of regulatory bodies, facilitating the assessment of medical products and demonstration of their safety and efficacy. Furthermore, the COVID-19 pandemic has demonstrated how accurate and quickly accessible data is also fundamental in the management of cross-border public health emergencies. Nevertheless, the road to fully exploit the potential benefits

[1] EPF policy and advocacy work related to digital health and data includes our position paper on eHealth (2016), GDPR guide for patients and patients' organisations (2016), Data and Artificial Intelligence EU Policy Briefing for Patient Organisations (2020) and a brief summary of our recent EPF survey on Electronic Healthcare Records (2020). Furthermore, EPF responded to the EC Consultations on the Data Strategy and AI White Paper (2020), European Health Data Space roadmap and Data Governance Act (2021).

[2] EPF recent projects related to digital health and data include: Digital Health Europe, EHDEN – The European Health Data and Evidence Network, and Data Saves Lives.

[3] Europe for patients Manifesto, https://www.europeforpatients.eu/

of data in health is only partially built, still extremely fragmented and not yet developed with the patients' views at the centre.

Given this context, the **EHDS can be considered as a welcome exercise to better harmonise and clarify the health data panorama in Europe, while also having a potential positive impact on digital health in more general terms** (e.g., digital health services, Artificial Intelligence, etc.). If shaped and implemented in the right way, the EHDS can become a crucial pillar of the 'European Health Union', and ultimately improve citizens and patients' lives.

At the same time, **its broad scope makes prioritisation and planning efforts a necessity in order to ensure that all the elements of the EHDS will be enshrined on a series of principles based on citizens and patients' needs, to be considered essential preconditions**.

Indeed, the EHDS must overall:

- be shaped to ensure barrier-free access and control of health data in an easy and transparent way, with the highest possible level of data protection and based on consent;
- ensure patient safety at all levels;
- deliver harmonisation while keeping in mind the differences between different health systems;
- take into consideration and tackle current and potential inequalities and gaps in health literacy and access to digital;
- tackle the ethical and practical challenges linked to current and future digital health transformation;
- foster a digital transformation of healthcare that delivers added value for patients and responds to their true needs and concerns;
- concretely and meaningfully involve patients in its shaping, governance and implementation.

Without building on these elements, the EHDS might not be able to deliver on its promises independently of the choice on specific options, tools, platforms, or guidelines. On the contrary, it might further exacerbate existing inequalities within Europe, potentially increase mistrust and, ultimately, not be accepted by the very individuals that should be at the centre of this initiative.

For the European Health Data Space to work, it will have to be more than a large-scale flagship European project. It must reach patients and citizens, be shaped with them, be accepted by them, respond to their needs, and ultimately ensure that health data and the digital transformation of health and care will help delivering better care and increase quality of life.

EPF's recommendations
SHAPING A EUROPEAN HEALTH DATA SPACE FOR AND WITH PATIENTS

In this section of the EPF EHDS consultation accompanying paper, we will focus on the most important elements of our responses to the four pillars of the questionnaire, covering: access to and exchange of health data for healthcare; access and use of personal health data for research and innovation, policy-making and regulatory decision; digital health services and products; Artificial Intelligence (AI) in healthcare.

➢ IMPROVING ACCESS AND CONTROL OF HEALTH DATA WHILE ENSURING THE HIGHEST POSSIBLE LEVEL OF DATA PROTECTION – THE KEY TO A PATIENT-CENTRED EUROPEAN HEALTH DATA SPACE

In EPF's view, a European framework on the access and exchange of personal data should have the ultimate goal in improving healthcare delivery for all Europeans, both within and across borders, while ensuring the highest level possible of interoperability, safety, data protection while avoiding the potential misuse of data.

To achieve better and more trustworthy use of personal data in the field of healthcare, **patients must be in control of their data**. They should be able to freely access it, decide who to share it with, and on what conditions. As identified by the EPF community and confirmed by the Inception Impact Assessment (IIA), exercising barrier-free access and control over their own health data is often difficult for patients. For example, electronic health records (EHRs) are not yet a reality across the whole EU, and many patients cannot easily access, understand and use the information they contain, or transfer them between healthcare providers, including when they move across borders. **Achieving a higher level of barrier-free[4] access and control should therefore be considered as the key priority of the EHDS, and subject to prioritisation when developing such European framework.**

Access should also be linked to measures ensuring that failures in providing access and control to patients' health data, or the eventual unwanted use and sharing of patients' data, would be linked to sanctions or fines. These measures should be seen as a way to increase **patients' trust in health data**, safeguarding their essential rights and they should be based on a clear framework, easy for patients to exercise. **Transparency is also key**, in particular with regards to how handling and processing of the data will be organised and through which platforms/providers (e.g., if not located in Europe).

Furthermore, it is essential to **avoid patients' data being leaked or misused** as it can have a dramatic impact on the life of individuals. Instances such as the mental health data leak in Finland (2020) or more recent leaks occurred in France, United Kingdom, and Ireland (2021) must not happen under the European Health Data Space.

Once the precondition of secure and protected access and control to health data is enshrined and prioritised, it will be important to set a clear framework granting the needed options to patients to

[4] Barrier-free access for patients to control and administer their own healthcare data is essential, especially patients with sensory or cognitive impairment. For instance, the healthcare data for visually impaired patients should be accessible via acoustics and screen reader.

exercise their essential rights related to health data while ensuring the highest possible level of protection. These should include decisions on **how to access such data** in the easiest way possible and for the broadest spectrum of the population (e.g., considering different levels of health literacy or access to digital means), **how to share it and with whom**, for **which purposes**, how to **ensure that such decisions are respected[5], and, eventually, how to withdraw access.**

Patients should also be able to feed information and corrections to their health data. Out of date, incomplete or incorrect information has the potential to lead to mistakes and errors, both in care, but also for planning care, policy, and research.[6] This is essential to improve **quality of data**.

Fundamentally, the **EU framework should firstly support and enable barrier-free access for patients to their healthcare data, granting control in the most secure environment possible.** The EU should investigate carefully driving **minimum standards to ensure that such possibility is granted across Europe**, while taking into consideration the existing difference between health systems and ensuring that no one is left behind.

- ## The EHDS as a unique chance to shed light on health data complexity

One of the central questions of the EHDS consultation (Question 11) refers to **whether additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decisions are needed at EU level**. As this is an example of a very broad question with equally broader multiple choices offered within the questionnaire, further clarification on EPF's position and responses is needed.

While in the questionnaire response we have identified how 'additional rules in all cases' would be EPF's preferred option, **our position does not intend to call for new, overly burdensome or duplicating efforts not taking into consideration the already available rules and initiatives** (e.g., GDPR, guidelines by the European Data Protection Supervisor, European Data Protection Board and national data protection authorities, EU-funded projects). In our view, **the EHDS has the chance to set up a framework that sheds light, clarity, and transparency on the complex panorama of health data sharing, addressing the peculiarity of health data, ensuring security and privacy but without creating additional unnecessary hurdles to use data in the public interest**. The EHDS should help streamline and navigate health data, in particular for patients, clinicians, and researchers. This could be done through **guidance, clarification of rules, better tackling known gaps and in silos approaches, and developing dedicated code of conducts**. Of course, particular attention should be dedicated to areas where the EHDS will bring particular innovation in procedures, access and data sharing.

On the specific issue concerns **data sharing outside of the EU**. On this point, rules should be shaped to avoid jeopardising research happening beyond our borders, if health data is shared under clear and transparent circumstances, with a specific focus for data protection. Particular attention must be dedicated to ensuring secure access to health data, in particular if not anonymised or pseudonymised.

Independently of the rules/guidelines adopted in shaping the European Health Data Space, the primary focus should always be on ensuring safe, clear, protected and transparent patients' access and control to their health data.

[5] As indicated in our response to Q3 and Q4 of the EHDS 2021 Public Consultation questionnaire
[6] This was identified as a key ask in our recent EPF survey on EHRs

- **Defining frameworks and mechanisms within the EHDS**

Several questions of the EHDS consultation concern the definition of possible mechanisms of collaboration between Member States and the EU-level, including the development of standards and technical requirements or their application.

In EPF's view, the choices related to **developing standards and technical requirements should be taken in strong collaboration between national digital health bodies** and possibly coordinated through a dedicated EU structure/body in charge of overseeing the process and ensuring a **harmonised approach as well as the involvement of patients in the governance**.

Furthermore, better **coordination and harmonisation of national approaches on health data exchanges across the EU to build a less fragmented, more accessible and trustworthy framework should be the ultimate goal of the European Health Data Space**. This is important, in particular in light of the current implementation challenges of the GDPR. Such approach should also build on common principles such as the **FAIR** pillars:[7] data should be findable, accessible, interoperable, and reusable. Building on this, in EPF's view, a coordinated authorisation scheme managed by national bodies, taking into consideration the specificity of the healthcare sector and the specific risks linked to health data, could be the best option to ensure safe exchanges of data. At the same time, while avoiding too much complexity, it could be interesting to explore the option of a **labelling system for interoperability** as part of the mandatory prior approval, which may be useful for identifying good practices, increasing trust, transparency, and understandability of the process.

In terms of defining possible mechanisms, a key question revolves around the choice of the **most appropriate option to facilitate access to health data for research, innovation, policy-making and regulatory decision (Question 10). In EPF's view,** once again, independently of the body selected to handle access to health data, it will be fundamental to ensure full independence and accountability. It should be built on transparent processes and with the inclusion of patients' representatives in its governance/decision-making structures.

Public body and mandatory-based options should be the preferred ways to reduce fragmentation and increase clarity. Private not-for-profit entities, as presented in the Consultation, have been defined as the least preferred option, mainly due to additional questions concerning the nature of such entities, their affiliation and governance.

The Consultation also discusses the issue of **voluntary data sharing** and the 'data altruism' term. Concerning 'data altruism', as identified in our Data Governance Act[8] response and considering the importance granted to it within the DGA and in the EHDS, it is necessary to ensure a harmonised and clear definition of the term to ensure that patients are fully aware of its meaning and impact.

The development of protocols or procedures for the practical exercise of such voluntary transfer of data should also be considered and **patients should be able to check information on who has had access to their data, on what basis and for what purpose**. Furthermore, while many patients are willing to make their healthcare data available to foster new therapies and treatments on a voluntary

[7] https://www.go-fair.org/fair-principles/

[8] EPF, Response to Data Governance Act Consultation (2021), https://www.eu-patient.eu/news/latest-epf-news/2021/shaping-a-patient-centred-european-health-data-environment/

basis, those who are not able nor willing to share their data should still be granted full access to high-quality care.[9]

- ## Facilitating access to health data for research, innovation, policy-making and regulatory decision

Access to data must be subject to the consent of patients, especially where third parties are using data for "innovation" or commercial purposes. Many patients will agree to their data being used for research, policy, and public services, in particular where they believe there is public benefit in doing so. They are in general less inclined to share for the purposes of vaguely defined innovation.

There are numerous examples of patients opting out of their data being used, especially because of concerns of these external organisations being involved and because of poor communication around projects or how data will be used, etc.

Furthermore, access to data held by private stakeholders should be facilitated for research, innovation, policy-making and regulatory decisions in accordance with existing legal frameworks and based on the initial consent by data subjects. The **consent frameworks should be shaped keeping into consideration the potential unwanted impact of data use** for research, innovation, policy-making and regulatory decision, for instance taking into consideration broad or dynamic consent.

The Consultation also mentions the possibility for the **establishment of an EU body governing access to health data for research, innovation, policy making and regulatory decisions (Question 14)**. Such a body could, for instance, bring together national bodies dealing with secondary use of health data, setting interoperability standards, act as technical intermediary, facilitate cross-border health data sharing. In EPF's view, this could potentially help harmonise the currently fragmented health data panorama in the European Union.

At the same time, such an EU body should be built on enhanced cooperation between national bodies and ensure the inclusion of patient representatives in its governance structure to ensure that patients' needs are fully taken into consideration. It is also noteworthy to mention that, when adopting an EU pathway, it will be necessary to shape it in a considerate way to **avoid more regulatory obstacles and increase the burden of administration, potentially impeding rather than facilitating progress.**

- ## Potential benefits and expected impacts of the EHDS

Ensuring **efficient, safe, and affordable care** for patients should be considered as a key goal of the European Health Data Space framework to improve access to health data. Concerning **innovation**, it will be particularly important that the data used to drive advancements in treatments, medicines, devices, and services will lead to innovation answering the patients' unmet needs.

The EHDS Consultation foresees six (6) potential main benefits from the EHDS:

- Availability of new treatments and medicines;
- Increased safety of health care and of medicinal products or medical devices;
- Faster innovation in health;
- Better informed decision-making (including risks and errors);

[9] As concerns the data altruism term, as identified in our Data Governance Act response[9] and considering the importance granted to it within the DGA and in the EHDS, it is necessary to ensure a harmonised and clear definition of the term to ensure that patients are fully aware of its meaning and impact.

- Reduced administrative burden in accessing health data;
- Technological progress.

While all these benefits can have a considerable potential high impact, their short to medium term actual impact might be rather moderate if we consider a more realistic forecast for the deployment of the EHDS. As it concerns **administrative burdens**, it is noteworthy to mention that additional rules, complexity, and processes introduced by the EHDS could potentially have a negative/limited impact, especially if not carefully deployed and implemented at the national level with all stakeholders fully on board, the right platforms and development of skills and literacy.

In addition, the availability of new treatments, medicines, etc., is affected by a range of factors well beyond the scope of the EHDS. While the delivery of efficient, safe, and affordable care for patients is a laudable goal for the EHDS, simply increasing the access to (and sharing of) data is only the first step towards this goal.

In terms of potential additional impacts, EPF recognises that the **increased availability of data can help policy makers and regulators to make better and more effective evidence-based decisions** while facilitating research and innovation based on outcomes that really matter to people. However, this must go **hand in hand with providing patients with clear assurance on how the data is used and that it is used in line with the purposes for which the personal data were initially collected**. Patients should also be made aware of the possible consequences of the intended further processing of data subjects. Adequate safeguards must be ensured (encryption, anonymisation and pseudonymisation). Patients should be also granted opt-out possibility if they believe that their data is used beyond the agreed use.

Finally, the creation of a future EHDS may also **help identify and ultimately tackle differences and inequalities between Member States** (and potentially between sectors) in terms of health data digitisation, access and sharing mechanisms. Said differences and inequalities will have to be carefully considered in the deployment of the EHDS to avoid increasing disparity across Europe in the digitalisation of health and care systems.

➢ A FRAMEWORK FOR DIGITAL HEALTH SERVICES AND PRODUCTS WITHIN THE EHDS

Broader deployment and use of digital health products and services can surely benefit patients at different levels. Better communication with healthcare professionals, improving self-management and monitoring of their own condition, easier access to their health records and sharing of their health data within and across-borders, improved access to healthcare for patients in remote areas are only few examples of the main positive impacts of digital health.

However, the deployment and use of digital health products and services must take into a series of current challenges into consideration, including cultural and link to the potential reticence to use digital health.

Digitalisation levels, both in terms of **infrastructures, literacy and access to digital means, are highly unequal across the European Union and even within Member States territories**. The EHDS framework should therefore keep into consideration this divide to avoid further exacerbating already existing inequalities again, within and across Member States. This should be done by targeted work and support to specific Member States, areas and population categories to limit as much as possible the gap in accessing digital health.

We need to keep patient choice and control in primary consideration, as some cannot access these services and even those who can, may not wish to use these products. While digitalisation is extremely important, it should be seen as supplementary/complementary to existing models of healthcare and services.

- ### Access and sharing health data nationally and across borders through digital health services and devices

Accessing and sharing health data through digital health services and devices must go hand in hand with ensuring and safeguarding proper consent coming from the patients. They must be in full control of what kind of data they want to share/transmit. Indeed, patients are generally willing to provide access to their data provided that proper and clear consent is granted and that they have control over how and what kind of the data is accessed and for what purpose. In EPF's view, actions to improve how patients control their data, for instance, granting enhanced possibilities to transmit it from their m-health/tele-health tools into both EHRs and an EU health data exchange infrastructure, are important elements for the development of the EHDS framework.

Once the consent is clearly granted, and the actual use of data is respectful of such consent, data can be considered as a fundamental tool to improve collaboration between HCPs and patients for the delivery of better care.

Furthermore, the relationship between healthcare professionals and patients over health data through digital health services and devices should be integrated in the European Health Data Space as a collaborative interaction to ensure information to patients about the opportunities offered by digital health; exploitation of existing opportunities provided by digital health to improve care and self-management; facilitating control of their data and digital health use.

- ### Minimise risks related to tele-health and improve the relationship between patients and healthcare professionals

While the correct application of tele-health solutions can improve the relationship between patients and healthcare professionals, and access to care, there are some essential elements to be taken into consideration:

- Tele-health should, in normal conditions, not be seen as a replacement for traditional care but rather as an additional tool;
- Increased trust issues from the patients' point of view;
- The correct use of tele-health needs adequate skills and access to digital health solutions, both for healthcare professionals and patients;
- Additional stress for both patients and doctors, from difficulties in accessing and using digital solutions to the de-personalisation of care, and adopting additional tools in already overcrowded schedules;
- Potential risks of misdiagnosis, errors and miscommunication exacerbated by the use of tele-health solutions;
- Tele-health also requires proper access to digital tools. The digital divide currently existing within and across EU-countries should be therefore taken into consideration.
- Patients with hearing, vision or physical impairment, dementia and other conditions are potentially prevented from using technologies related to tele-health.

Given the broad scope of the European Health Data Space, there is a chance to tackle such issues and promote better harmonisation, to drive a higher level of coordinated protection and clarity for both patients and healthcare professionals.

A more coordinated approach could also facilitate patients to travel across the EU without facing too many diverse frameworks that would increase uncertainty and potentially hamper patients' willingness to engage with telehealth solutions. This could also facilitate healthcare professionals to travel across borders, facilitate more coherent training and education on how to use and communicate about telehealth, and ultimately increase safety for patients.

At the same time, stronger harmonisation must take into consideration how the use of tele-health is directly connected and linked to healthcare professionals and to their clinical practice, which operate in very diverse healthcare systems with significant variations. To tackle this while supporting a **progressively less diverse European panorama, guidance, certifications and recommendations be developed at EU level, thereby enabling and supporting integration of telehealth in diverse Member State health systems.**

- ### Fostering uptake of digital health products and services

In EPF's view, ensuring **clear authorisation schemes and the certified interoperability of digital health products and services is essential to foster the uptake of digital health products and services**. It is important to consider how mandatory prior approval by national authorities can increase patients' trust in digital health products and services. Furthermore, assessment of interoperability levels will be essential to drive a true European cross-border adoption of digital health solutions that can help patients travel within the EU.

Concerning **labelling**, especially if voluntary, while it should not be directly preferred to mandatory and prior assessment, it could be already considered as an improvement compared to the current situation. Labelling schemes – when co-developed with patients and clinicians – can help increase the accessibility and understanding of digital health solutions, providing a straightforward means for patients and clinicians to identify solutions that are trustworthy and meet their requirements.

Furthermore, creating a more harmonised **European approach and guidelines towards reimbursement and assessment of digital health** should be seen as an essential building block of the European Health Data Space framework. Such European approach should ensure that all patients in Europe can have the same level of access to digital health services and products, while of course **keeping into consideration the differences between European health systems**. Without such a harmonised approach there is a risk of moving towards a multi-speed system that would ultimately exacerbate the already existing differences in the digitalisation of health and care systems, with a negative impact on patients' lives and hampering European coordination.

EPF also supports the proposal for a **transparent, easy to access and clear repository of digital health products and services** assessed according to EU guidelines to aid national bodies, both to facilitate reimbursement decisions and to increase transparency towards patients. National authorities should also make lists of reimbursable digital health products and services available as an additional transparency measure.

- ### Efficient and coordinated use of EU funds to drive digitalisation

EU funds dedicated to support the adoption and scale-up of digital health services should be conditional to interoperability within and across borders with EHRs and national healthcare

services. Ensuring access and control of patients over their health data, but also patients' involvement in the research and innovation process, should be also considered as an essential condition to access EU funds for digitalisation in healthcare.

Furthermore, **achieving adequate acceptance of the EHDS at a patients' level will be connected to addressing well-known and underlying issues such as the access to digital means and health literacy.** These issues must be tackled through all relevant EU funding programmes, such as the EU4Health Programme to Digital Europe and Horizon Europe, building on pre-existing pilots and ensuring efficient and impactful use of funding responding to the actual needs of patients and health systems.

➢ ARTIFICIAL INTELLIGENCE AND THE EUROPEAN HEALTH DATA SPACE – DEPLOYING AI IN THE BEST INTEREST OF THE PATIENTS

AI, together with big data has the potential to transform care delivery methods and can provide great benefits at several levels of the healthcare value chain. However, as with any new technology, there may also be unrealistic expectations. Artificial intelligence has risks, limitations and concerns including ethical, technical, and legal issues, which are often closely connected.

AI depends on the availability of very large amounts of good/quality data. If the available data are not enough, not good quality, inconsistent, or biased, this limits the potential of AI to be useful. AI also has the potential to make wrong decisions; reliability and safety are particularly critical in healthcare, where errors can have serious consequences. **The EHDS can surely play an important role in making sure that European AI solutions will be built on unbiased and good quality data**. The EHDS framework can facilitate AI manufacturers' access to data in a secure and compliant framework in line with GDPR rules while minimising potential risks in terms of data protection. The EHDS should also ensure that AI is built on good quality and unbiased data: through technical support, the EHDS can ensure that data will be 'by default' suitable for AI purposes.

Furthermore, the development of AI and machine learning also creates significant **ethical risks**, including in relation to the anonymisation and pseudonymisation of data, which poses risks to the privacy of individuals (e.g. through reverse engineering of data to identify individuals). A strong governance approach, that includes patient representation, should be embedded in the EHDS, ensuring that ethical risks are quickly identified and managed.

Finally, the EHDS should indeed also serve as a supporting framework to promote a harmonised approach to assess AI products and services for medicines agencies, notified bodies or other competent bodies.

Finally, the EHDS should carefully consider the type of data use and AI, between data used for public good versus commercial benefit. Collaboration within the EHDS for businesses and companies should be therefore guided by criteria of value and legitimacy (e.g. through participation in EU funded research, or return of results/data insights).

For an overview of EPF's broader view on AI in healthcare, it is possible to consult our response to the European Commission White Paper on AI.[10]

[10] EPF, Response and Accompanying Paper - Public consultation on the White Paper on Artificial Intelligence, (2020), https://www.eu-patient.eu/globalassets/documents/1.-ai-white-paper_consultation-response_epf_statement-final.pdf

- ## AI and the EHDS – How to shape the new relationships between patients and healthcare professionals

AI is already creating a new type of relationship between patients and healthcare professionals. AI can be seen as a way to both facilitate healthcare professionals in delivering better care to patients while, at the same time, provide patients with additional tools to have a more informed dialogue with their doctors through enhanced control and monitoring of their medical condition.

However, this potential two-way positive new relationship comes with a series of questions related to human oversight on AI decisions, limiting human autonomy and potentially even issues in terms of increased social isolation and loss of the essential human component in healthcare. In EPF view, the adoption of AI within healthcare should be seen as a support element, and not a replacement, to the traditional way of delivering care. **Professionals must have oversight of decisions, as they should be informed by AI, not directly made by AI**.

This should be supported by ad**equate skills development guaranteed to healthcare professionals to make them able to understand, securely and efficiently exploit the potential of AI** to provide more efficient care to their patients. On the other hand, **digital health literacy for patients** also plays a crucial role to enhance their trust and understanding of the role of AI in their care and to better engage with it in collaboration, where possible, with healthcare professionals.

- ## AI and the EHDS – Addressing key ethical risks

Ethicists have identified a risk of limiting human autonomy if AI were to make a calculation on risk or restrict a patient's right to free, fully informed choice of treatment. An example would be if an AI system made certain decisions based on what it "thinks" is the best for the patient. Maintaining human oversight of AI-based decisions and the decisions flowing from it is thus particularly important in healthcare. When discussing AI in healthcare, it will be fundamental to keep in mind the essential relation between the AI systems, healthcare professionals and patients.

As previously mentioned, **AI must be seen as a support tool to improve care delivered by healthcare professionals (from diagnosis to treatment), but not as a replacement**. Furthermore, AI, if used to replace real human contact, may increase social isolation and additional stress. This approach should clearly apply beyond clinical practice, when AI is used to inform broader delivery of services, public health interventions, and policy making in the field of healthcare.

Biases in data also introduce ethical issues in terms of the potential for AI-enabled decisions themselves to be biased or discriminatory. Biases in data collection can affect the type of patterns AI will identify. This is an issue since, for example, women and ethnic minorities are often underrepresented in clinical trials and large data sets used to train AI. Bias in the data will affect the algorithm that is developed, replicating the bias found in society. Patients with multiple or rare diseases may also be affected by this. This issue should be tackled by making sure that AI is based on good quality and unbiased data.

Transparency is another key issue when it comes to Artificial Intelligence: as previously stated, explainable and ethical AI solutions should be preferred over "black box" methodologies, with rules for transparency and data governance. Clear rules, strategies, risk management and certification mechanisms will also have an impact on user confidence in AI-based products and services.

EPF calls for particular attention in ensuring that AI in healthcare enhances society, and is an enabler of – and not a threat to – patients' rights and wellbeing, guaranteeing that the value of real human contact is not minimised or entirely replaced by technological alternatives.

Finally, a crucial point related to AI in healthcare is linked to the crucial role of **information for patients:** patients have 'the right to be fully informed' about the functionality, consequences, and possible consequences of AI incorporation in e.g., health information, diagnosis and treatment procedures, health monitoring, transactions, and interaction. As matter of prudence, responsible parties (e.g., health professionals, authorities, industry) should follow the existing principles for informed consent and decision making.