Digital health data and services – the European health data space - EPF Internal Consultation

Introduction

The European Health Data Space (EHDS) is a Commission priority that aims at making the most of the potential of digital health to provide high-quality healthcare, reduce inequalities and promote access to health data for research and innovation on new preventive strategies, diagnosis and treatment. At the same time, it should ensure that individuals have control over their own personal data. Innovative solutions that make use of health data and digital technologies, among others digital health solutions based on data analytics and artificial intelligence (AI), can contribute to the transformation and sustainability of healthcare systems, while improving people's health and enabling personalised medicine. The development of these technologies requires access by researchers and innovators to substantial amounts of (health) data.

The Commission announced in the Communication on the European Strategy for Data its intention to deliver concrete results in the area of health data and to tap into the potential created by developments in digital technologies. The collection, access, storage, use and re-use of data in healthcare poses specific challenges that need to be addressed within a regulatory framework that best serves individuals' interests and rights, in particular withregard to the processing of sensitive personal data relating to their health. As a follow up, the Commission adopted its Data Governance Act proposal (2020) laying down conditions around access to certain categories of data, and containing provisions to foster trust in voluntary data sharing. This public consultation will help shape the initiative on the EHDS. It is structured in three sections focusing on:

1. the use of health data for healthcare provision, research and innovation as well as policy-making and regulatory decision;
2. the development and use of digital health services and products;
3. the development and use of Artificial Intelligence systems in healthcare.

Depending on your answers, the questionnaire may take approximately 60-90 minutes.

KEY INFORMATION FOR EPF MEMBERS - BACKGROUND DOCUMENTS AND 'HOW TO FILL' THE CONSULTATION

Background information for EPF members

- **Joint European Commission (EC) - European Patients' Forum (EPF) webinar - Shaping a European Health Data Space for patients and with patients (21 May 2021)** - https://vimeo.com/559010383
- EPF, Response to EHDS feedback consultation (February 2021)
- EPF, Response to Data Governance Act feedback consultation (February 2021)
- EPF, Consultation inputs on AI White Paper and Data Strategy (May-June 2020)
- EPF, EU Policy Briefing for Patient Organisations on Big Data and Artificial Intelligence (April 2020)
- EPF, Electronic Health Records Survey Summary (April 2020)
- European Commission info page on the EHDS, https://ec.europa.eu/health/ehealth/dataspace_en

How to fill the Questionnaire

- In this document you will find all of the 30 questions featured in the European Commission public consultation on the EHDS, which you can find here (webpage) and here (PDF version).
- We invite you to **provide your input to as many answers as possible** using the 'suggesting mode' of Google Docs. The link you have received will have this function automatically switched on.
- **Please provide your input to both multiple choice questions and open text boxes**. To provide your preference for the multiple choice questions, please add your organisation short name or a simple 'x' in the selected table cell.
- Where possible and desired, we invite you to provide additional comments on your answers, also using the '**add comments'** function of Google Docs.
- Feel free to provide inputs on the EPF suggested responses texts
- When providing your text inputs, please **make sure to include the name of your organisation at the beginning of the text.** This will help us identify the different inputs.
- Please check **EPF Secretariat's 'Comments'** to identify where your input is particularly needed.
- If you need any information or clarification, please contact michele.calabro@eu-patient.eu

Section 1: Access and use of personal health data for healthcare, research and innovation, policy-making and regulatory decision-making

Personal health data include a wide range of data on an individual's physical or mental health and information on healthcare received. Health data, including genetic and sometimes biometric data, may reveal information about the health status of a person. Individuals need to have the right tools at hand for managing their health data. These should allow them to consult and share their health data with health professionals or other entities of their choice. This should facilitate receiving adequate healthcare including abroad (doctors, hospitals, pharmacies, etc.).

In addition, sharing personal health data with researchers and innovators could improve health research and innovation in prevention, diagnosis and treatments. Sharing personal health data with policy-makers and regulators such as European and national medicine agencies could facilitate and speed up the approval of new medicines and pass laws that are based on real world data. For this, a mechanism would need to be established that facilitates access to personal health data for further use while protecting the interests and rights of individuals on their health data in compliance with the General Data Protection Regulation (GDPR).

Q1. The cross-border healthcare Directive has established the eHealth Network and an infrastructure to facilitate health data sharing across the EU (Article 14) and includes other aspects with relevance for digital health. In the last five years, are you aware of any changes in the following aspects of health data sharing across border? (one choice each row)

	Greatly reduced	Slightly reduced	No changes	Slightly increased	Greatly increased	I don't know / No opinion
Exchange of health data such as patients' summaries and ePrescriptions						
Continuity and access to safe and high quality healthcare						
Development of methods for enabling the use of medical information for public health and research						

Development of common identification and authentication measures to facilitate transferability of data						
Access of patients to an electronic copy of the electronic health record						
Cross-border provision of telemedicine						

Additional Comments (not included in questionnaire but for reference/accompanying paper)

EPF - Exchange of cross-border health data has improved slightly over the past few years, in particular thanks to collaborative initiatives under myHealth@EU between neighbouring countries facilitating transfer of electronic health records, ePrescriptions and patient summaries. However, it is clear that there is still an unequal advancement and implementation both within (e.g., at regional level, different services implementation) and across countries. For instance, the Report on the implementation of the Cross-border Directive (29/01/2019), states that across the 29 NCPs in Europe, Norway and other EEA countries providing data, 74,589 enquiries were made in 2017, but most Member States received fewer than 1,000 requests. The number of enquiries differs strongly between the different NCPs".Differences have been also highlighted at disease area level, with several EPF members providing very different pictures of how their own communities experienced improvements in terms of cross-border digitalisation of healthcare.

Although many health systems are experiencing an important level of technological improvement and digitalisation, there are still barriers to overcome: from a more harmonised adoption of common standards and inadequate translation of medical documents, to the "digital divide", inequalities in digital health literacy and skills for both patients and professionals. Furthermore, This fragmentation has been highlighted by the COVID-19 crisis, which exposed clear differences within and across national borders. Europe should accelerate the ongoing digitalisation of their healthcare systems in co creation with patients and ensure equity in access to digital services. The delivery of integrated, patient-centred healthcare, for people living with long-term, complex conditions such as dementia, requires the digitalisation and sharing of social care data, alongside data from clinical services.

The European Health Data Space should build on the current initiatives to increase the amount of EU patients that could benefit from more seamless traveling across borders -for themselves and their health data -by accessing a broader range of connected digital health services. Therefore, all aspects listed in Q1 of the EHDS questionnaire should be taken into primary consideration when addressing the cross-border dimension of the Data Space.

Q2. Should a European framework on the access and exchange of personal health data aim at achieving the following objectives? (one choice each row)

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Facilitate delivering healthcare for citizens at national level			■			
Facilitate delivering healthcare for citizens across borders				■		
Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format					■	
Promote the use of digital health products and services by healthcare professionals and citizens			■			
Support decisions by policy-makers and regulators in health				■		
Support and accelerate research in health					■	
Promote private initiatives (e.g. for innovation and commercial use) in digital health			■			
Other					■	

Please specify (other plus additional comments) - included in questionnaire:

EPF - As further highlighted by the COVID-19 crisis, a correct use of health data is fundamental to accelerate research,support and monitor decisions by policy-makers, regulators and payers in health, to improve safety and efficacy of care. It can also have a direct positive impact on patients, for instance to improve self-care. In EPF's views, 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 and avoiding 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 access it freely, decide who to share it with, and on what conditions. This is currently far from the case as already identified in our response to the EHDS Inception Impact Assessment (IIA) and confirmed by the IIA itself.

Fundamentally, the EU framework should firstly support and enable the access for patients to their individual healthcare data and the EU should look into carefully driving minimum standards to ensure that such possibility is granted across Europe, while taking into consideration the existing difference between health systems.

Promoting the use of safe and trustworthy digital health products and services by healthcare professionals and Europeans is also essential. However, the right measures will have to be put in place to ensure that: healthcare professionals are fully skilled to both use digital tools and communicate about them in a simple and clear manner; the tools are safe, adequately assessed and labelled as safe and trustworthy, linked to clear liability frameworks, and, where applicable, easy to use by patients. Improving digital health literacy and health literacy of patients should also be seen as an essential tool to promote the use of digital health in Europe.
To improve and harmonise access to digital health products and services, the EHDS should also drive forward the introduction of more coherent reimbursement rules at the European level. In adopting a more harmonised framework, however, actively promoting or encouraging the use of digital health resources and services must be done with some care, especially given the vastly different health and social care systems operating in countries.

Concerning the promotion of private initiatives, following the EPF principles on the value of innovation in medicine, innovation should be encouraged provided that it demonstrably provides added value for patients, meaning that it is driven by public interest, it responds to true unmet needs and it is affordable, accessible and sustainable. To achieve this, more meaningful and stronger involvement of patients in digital health innovation processes is fundamental.

Finally, including access to clinical trials across borders should also be considered as a key element of facilitating delivering healthcare for citizens across borders. It is currently not included in the scope of the Cross-Border Healthcare Directive and it can be considered a clear gap. The framework should also aim at improving efficiency and better coordination among healthcare providers and professionals between countries.

To summarise our views on this element of the questionnaire, the scope of the aims of these initiatives is positive however, potentially, overly broad. In developing the EHDS framework, primary consideration should first of all be given to ensuring that the needs of patients and citizens are met, in particular regarding access and control of their data. Furthermore, the development of an EU framework should keep in consideration differences and peculiarities within and across the national European health systems with extreme care to avoid a one-size-fits-all approach that would potentially exacerbate existing inequalities.

1.1. Access to and exchange of health data for healthcare

Currently, several Member States exchange health data across borders within the framework of the cross border healthcare Directive to support patients in obtaining care when travelling abroad. Health data such as electronic prescriptions and patients' summaries are exchanged through an EU infrastructure called MyHealth@EU. Patient summaries provide information on important health related aspects such as allergies, current medication, previous illness, surgeries, etc. Work is being carried out to support the exchange of additional health data, such as medical images and image reports, laboratory results and hospital discharge letters and to provide citizens with access to their own health data.

Moreover, access and control of citizens' over their own health data should be improved. The COVID-19 crisis also showed the importance of citizens being able to access and share in electronic format some of their health data (e.g. test results, vaccination certificates) with healthcare professionals or other entities of their choice. Facilitating such access and sharing by individuals of their health data in electronic format may require extending the rights of individuals with respect to their health data beyond those guaranteed in the GDPR.

Furthermore, some conditions need to be in place to ensure easy, lawful and trusted exchange of health data across borders.

- Healthcare providers need to have digital systems in place to exchange data securely with other health professionals and digital health devices.
- Healthcare providers need to comply with the applicable provisions of the GDPR, in particular the requirement to rely on a legal basis in order to be able to lawfully exchange health data cross borders.
- Data need to be in the same format and correspond to a common data quality, cybersecurity and other interoperability standards on which healthcare professionals can rely.
- Relevant mechanisms may also be implemented to support the uptake of these standards (such as labelling, certification, authorisation schemes and codes of conduct).
- Cooperation of national digital health bodies in the development of interoperable standards and specifications.

The questions below seek to gather stakeholders' views on the rights and tools that would support access by citizens to their own health data (beyond the rights guaranteed in the GDPR).

Q3. How important is it for you to be granted the following rights?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
The right to access my health data in electronic format, including those stored by healthcare providers (public or private)						
The right to transmit my health data in electronic format to another professional/entity of my choice						
The right to request public healthcare providers to share electronically my health data with other healthcare providers/entities of my choice						
The right to request healthcare providers to transmit my health data in my electronic health record						
The right to request app providers to ensure the transmission of my health data in my electronic health record						
Healthcare providers that fail to provide me access to my health data in an electronic format and to transmit it to a healthcare provider/entity of my choice are sanctioned or receive a specific fine						

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

EPF - 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 and 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 access and control should therefore be considered as the key priority of the EHDS, and subject to prioritisation when developing such European framework.**

These challenges lead to a fragmented approach on health data while exacerbating differences across and within countries and limiting patients' trust. The EHDS should therefore be built with patients and their data at the centre, ensuring adequate data protection, clear rights, and instruments to grant access and control over their personal health data, how it is used, and ensure data portability. This objective could be reached through the development of user-friendly and co-designed tools and platforms, clear guidelines and information tailored to patients, carers, and the public.

Furthermore, access should indeed be linked to measures ensuring that failures in providing access and control to patients' health data, or 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 the handling and processing of data will be organised and through which platforms/providers (e.g., if not located in Europe).

In addition to the options provided by the questionnaire, EPF would like to highlight the need to provide clear opportunities to patients to feed information and corrections to their Electronic Health Records. Information which is out of date, incomplete or incorrect has the potential to lead to mistakes and errors, both in care, but also for planning, policy and research. This was identified as a key ask in our recent EPF survey on EHRs.

Furthermore, 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.

Finally, granting the following rights is linked to a series of already mentioned underlying issues such as infrastructures, interoperability, access to digital means and health literacy. It is essential that these issues will 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.

Q4. Which of the following elements do you consider the most appropriate for controlling access and sharing your health data with healthcare professionals?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access my health data through a personal digital storage and share it with health professionals of my choice						
Access my health data that is exchanged between health professionals or with other entities via a digital infrastructure						
Access my health data that is exchanged between health professionals across borders via an EU electronic infrastructure						
Access my health data on a mobile application and share it with healthcare professionals or other entities of my choice						
The infrastructure or personal digital storage for accessing the data should be secure and prevent cyberattacks						
Other						

Please specify:

EPF - In EPF's view, all of the options listed in the questionnaire above should be part of a comprehensive framework that should first of all allow patients to fully and barrier-free access and control their health data and be able to decide how to access it, how to share it and for which purposes. This is an essential precondition that should be met even before diving into questions regarding tools, platforms and different means.

Providing different options to patients to better control, access and share their data would ultimately offer more chances to better engage with it, also taking into consideration accessibility questions linked to **visual/cognitive impairment or disabilities,** different levels of health systems digitalisation, health and data literacy, digital literacy and the availability of digital health platforms and tools.

While a harmonised EU unique electronic infrastructure should be a key goal of the European Health Data Space, it will be necessary to take into consideration the current different levels of health systems digitalisation to ensure that nobody is left behind while we try to achieve a stronger European coordination.

Furthermore, in EPF view, protecting data from potential cyber attacks should be considered as the utmost priority underlying all kinds of data infrastructure or data sharing methods. 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.

The questions below seek to gather stakeholders' views on the measures needed to enhance the sharing of health data between healthcare professionals including across borders. Some common standards and technical requirements agreed at EU level could be applicable to healthcare providers in this view.

Q5. In your view, who is best suited to develop these standards and technical requirements at EU level to support exchange of data in healthcare?

(single choice)

- National digital health bodies cooperating at EU level
- An EU body
- Other

Please specify:

EPF - In EPF's view, all 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 ensuring patients' involvement in the governance. Collaboration at all levels is crucial. Furthermore, the EHDS approach should build on common principles such as the **FAIR** pillars:[1] data should be findable, accessible, interoperable, and reusable.

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

Q6. In your views, how should these standards and technical requirements be made applicable at national level and across the EU?
(single choice)

- Through a labelling scheme (a voluntary label indicating the interoperability level)
- By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
- By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)
- Other

Please specify:

EPF - Authorisation Scheme managed by national bodies. 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 a crucial goal of the European Health Data Space Building on this approach, In EPF's view, a strong 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 operability as part of the mandatory prior approval, which may be useful for identifying good practices, increasing trust, transparency and understandability of the process.

In addition to the requirements laid down in the proposed Data Governance Act, providers of personal data spaces/data sharing services could be subject to sectoral requirements to ensure interoperability of health data exchanges. The question below seeks to gather stakeholders' views on any additional measures needed.

Q7. Which of the following measures would be the most appropriate: (single choice)

- By a labelling scheme (a voluntary label indicating the interoperability level)
- By a certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)
- By an authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)
- Other

Please specify:

EPF - Authorisation Scheme managed by national bodies. 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 Building on this approach, In EPF's view, a strong 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 operability as part of the mandatory prior approval, which may be useful for identifying good practices, increasing trust, transparency and understandability of the process.

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As per Question 6

The question below seeks to identify and assess the impacts (benefits and costs) that would arise from measures facilitating the access to, control and transmission of health data for healthcare including across borders.

Q9. In your views, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare?

Access to efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Facilitated access to healthcare across borders in the EU				

Benefits for patients

	No impact	Moderate impact	High impact	I don't know / No opinion
Transparency on the processing of their health data				
Reduced costs stemming from not duplicating efforts and tests				
Reduced administrative burden				

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better healthcare provision (including risks and errors)				
Reduced costs and reduced duplication of efforts				
Reduced administrative burden				
Technological progress				

Other

Please specify:

EPF - 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. This is particularly important if we consider the ageing population and increasing prevalence of multimorbidity. With many patients often dealing with different hospitals, departments and healthcare professionals at the same time, easily accessing patient information can strongly reduce complications and improve care quality and efficiency (e.g., checking drug prescriptions between professionals)

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.

In EPF's view, all benefits listed in Q9 are important for patients. Improving access to better, more affordable and efficient care, within and across border, with fewer risks for patient and reduced administrative burdens, provided that there is active collaboration with Healthcare Professionals, (e.g., HCPs to actively and properly consult electronic health records before consultation) should be taken into consideration as the overarching goal of the European Health Data Space.

An additional benefit linked to increased accessibility to health data could be linked to receiving clear feedback on the type of research your data is used in, in order to increase transparency.

1.2. Access and use of personal health data for research and innovation, policy-making and regulatory decision

Access to health data for research, innovation, policy-making and regulatory decisions within the EU is

currently quite complex and subject to national laws. In the proposed Data Governance Act the EU Commission proposed rules:

- on access and sharing of data across sectors
- on access to data held by public bodies
- on data intermediary services (sharing of data between businesses and sharing of data between citizens and businesses)
- on sharing of data by individuals and companies through a trusted third party for wider good purposes (e.g. research) and based on their consent (so called "data altruism").

Health data are considered to be particularly sensitive and their processing is subject to stricter requirements under the General Data Protection Regulation. The proposed Data Governance Act allows for the possibility for additional sectoral legislation to set up and further specify the role of national bodies taking decisions on access to data by third parties; also in the area of health, such sectoral legislation must ensure full compliance with EU data protection rules. The Data Act currently in preparation will also assess how non-personal data held by businesses could be shared with the public sector for better policy making.

The questions below seek to gather stakeholders' views on the measures needed to facilitate the access to health data by researchers, innovators, policy-makers and regulators, in a trustworthy manner and in line with EU data protection rules.

Q10. What mechanism do you consider more appropriate to facilitate the access to health data for research, innovation, policy-making and regulatory decision?

Please rank from the most (1) to the least (4) preferred option

	1	2	3	4	I don't know / No opinion
Voluntary appointment of a national body that authorises access to health data by third parties					
Mandatory appointment of a national body that authorises access to health data by third parties					
A public body collects the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data					

A private not-for-profit entity collects the consent of individuals to share their health data for specified societal uses ("data altruism") and manages their health data – as designed in the proposed Data Governance Act					

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

EPF - First of all, 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 inclusion of patients' representatives in its governance/decision-making structures.

Public body and mandatory should be the preferred options to ensure clearer framework and reduce fragmentation. Private not-for-profit entities selected as the least preferred option as it would open additional questions concerning the nature of such entities, their affiliation and governance.

Concerning the data altruism term, as identified in our Data Governance Act 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 basis, those who are not able to do this or who do not want to share their data should have of course equally be granted full access to high-quality care.

Q11. In your opinion, would additional rules on conditions for access to health data for research, innovation, policy-making and regulatory decision be needed at EU level?

(multiple choices possible)

Health data categories

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Health data from medical records								
Administrative data in relation to reimbursement of healthcare								
Social care data								
Genetic and genomic data								

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

See below

Format (for any of the above data categories)

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Anonymised aggregated format (e.g. statistics)								
Pseudonymised format (without identifiers of individuals)								
Fully identifiable format								

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

See below

Eligibility

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Criteria and conditions for providing /								

accessing data in the EHDS are defined								
Safeguards for the access to health data for the purpose of re use, in line with ethical and data protection requirements, are defined								
Limit the transfer of non-personal health data outside the EU/EEA								

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

See below .

Security

	Yes, for policy and regulatory purposes	Yes, for research purposes	Yes, for innovation purposes and commercial use	Yes, for treating other patients	Yes, for education purposes	Yes in all cases	Not in all cases	I don't know / No opinion
Conditions for the secure access to health data are defined								

Other

Please specify:

EPF - The questions above (Q11) refer to whether additional rules are needed to frame conditions for access to health data for research, innovation, policy-making and regulatory decisions be needed at EU level, in compliance with general data protection rules at EU level. **Given the very broad spectrum of issues touched by the question (and sub-questions), and the question in itself, it is important to clarify EPF's choices.**

While we flagged the option that would suggest to 'have additional rules in all cases', 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 EDPS, EDPB and national data protection authorities, EU projects). Our intention is to suggest that 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 EDHS 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 concerning data sharing outside of the EU, it is also important to clarify that the rules should be shaped to avoid jeopardising research happening beyond our borders, provided that 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.

Independent of the rules/guidelines adopted in shaping the European Health Data Space, we would like once again to stress that the primary focus should always be on ensuring safe, clear, protected and transparent patients' access and control to their health data.

Q12. How appropriate do you consider the below elements in facilitating access to health data held by private stakeholders (hospitals, businesses) for research, innovation, policy-making and regulatory decision:

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Access to health data is granted by the data holder, on its own decision (current situation)						
Access to health data is granted by a national body, in accordance with national law						
Access to health data is granted by a national body, subject to agreement of data subjects						
Other						

Please specify:

EPF - As previously highlighted in other instances within the consultation, we find this question rather overly broad and complex to frame and respond with precision to several of its aspects (e.g., not all hospitals are technically 'private').

As EPF's response, we would like to stress again that, first and foremost, 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 and if they are able to control and monitor access to their data. They are in general less inclined to share for the purposes of (vaguely defined) innovation, particularly where third parties and private companies are involved.

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

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 initial consent by data subjects. The consent by data subjects should be shaped keeping into consideration potential unwanted impact on data use for research, innovation, policy-making and regulatory decision, for instance taking into consideration broad or dynamic consent.

With this in mind, the third option is perhaps to be considered the most suitable. However, it requires clear, transparent and easily accessible information being available about the use of patient data (outside of a clinical sense) and grant patients easy mechanisms to monitor and control access and, if desired, opt out and ask for the erasure of their data (right to be forgotten).

Q13. Which incentives would facilitate sharing of health data held by private stakeholders?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A fee						x
Other						x

Please specify:

EPF - Similar to our response to Q12, private stakeholder is again a very broad concept. Once the re-use of data or secondary purposes is regulated, private entities should be able to provide these data for those purposes (these situations are related to the public interest, regulatory purposes, actions for the security and safety of citizens, research). Facilitating trustworthy and harmonised procedures and tools related to data processing and transfer, would facilitate data sharing, while reinforcing security standards.

Furthermore, to facilitate sharing of health data collected during routine clinical care in the private sector, lessons could be learned from the research setting. A number of initiatives have recently been developed to encourage sharing of data from clinical trials run by private sponsors (e.g. Datacelerate) and organisations like UK Biobank have created frameworks whereby data generated from their samples by private stakeholders must be returned for re-use and sharing. These types of initiatives seem to be successful and they are based on an ethical and societal imperative to share health data, providing practical pathways for data sharing that respect patient privacy and minimise administrative burden – and, most importantly, are beneficial for all involved parties.

Q14. Do you agree that an EU body could facilitate access to health data for research, innovation, policy making and regulatory decision with the following functions?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Bring together the national bodies dealing with secondary use of health data, for decisions in this area						
Setting standards on interoperability together with national bodies dealing with secondary use of health data						
Facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data					Final response X	
Acting as technical intermediary for cross-border data sharing						
Authorising access to cross-border health data (data processed in a cross border or EU wide manner, such as European Reference Networks)					Final response X	

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

EPF - The establishment of an EU body governing access to health data for research, innovation, policy making and regulatory decision can help harmonising the currently fragmented health data panorama in the European Union. All functions listed in the table above are important and necessary, and would be therefore complementary to ensure that such a body would be impactful and work in synergy with other existing initiatives in this field.

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, if we adopt an EU pathway, it will be necessary to shape it in a considerate way in order to avoid more regulatory obstacles and increase the burden of administration, potentially impeding rather than facilitating progress.

Q15. How useful would EU level action in the following areas be to address interoperability and data quality issues for facilitating cross-border access to health data for research, innovation, policy-making and regulatory decision?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Stakeholders participating in the EHDS cross-border infrastructure are subject to a voluntary labelling scheme on the use of data quality and interoperability technical requirements and standards		■				
Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards					■	
Stakeholders need an audit, certification or authorisation before participating in EHDS cross-border infrastructure					■	

Additional Comments (not in Questionnaire, but useful for accompanying paper response)

EPF - To ensure the most harmonised approach possible, we believe that a clearer framework based on mandatory application of technical requirements and standards, certified and audited, is needed. The adoption of a verified common technical language as a requirement for participating in the EHDS cross-border infrastructure, has the potential to further limit differences and facilitate cross-border access to health-data. Without operating with the same **technical requirements and standards, cooperation can not happen.**

At the same time, there is a balance to be struck to ensure that the measures put in place are not so burdensome or costly that organisations and bodies do not wish to (or cannot) take part. Technical requirements, standards, certification and authorisation procedures should be developed in consultation with a broad range of stakeholders. In addition the EU authority responsible for verification and auditing should be adequately resourced to ensure timely and accessible support, certification and authorisation for stakeholders.

Finally, careful consideration will have to be given to health systems diversity to avoid that countries less advanced in the field of digital health will not be left behind.

The question below seeks to identify and assess the impacts (benefits and costs) that would arise from measures facilitating cross-border access to health data for research, innovation, policy-making and regulatory decision.

Q17. In your views, what would be the benefits for stakeholders of measures facilitating such access?

Access to cutting-edge, efficient and safe care

	No impact	Moderate impact	High impact	I don't know / No opinion
Availability of new treatments and medicines		X		
Increased safety of health care and of medicinal products or medical devices			X	
Faster innovation in health			X	

Benefits on healthcare systems efficiencies

	No impact	Moderate impact	High impact	I don't know / No opinion
Better informed decision-making (including risks and errors)			X	
Reduced administrative burden in accessing health data		X		
Technological progress			X	

Other

Please specify:

EPF - As mentioned above in this consultation, 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. As concerns 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.

While all these benefits can have a considerable potential 'high impact', EPF's decision to respond, in some cases, 'moderate'is linked to a more realistic forecast of the impact, at least within the short to medium term, of the EHDS. Concerning the administrative burden, it is noteworthy to mention that additional rules, complexities and processes introduced by the EHDS could potentially have a negative/limited impact on administrative burden, if not carefully deployed and implemented at 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 are 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, it is clear that simply increasing access to (and sharing of) data is only a first step towards this goal.

Q18. Please indicate any other impacts on relevant economic, environmental, social or fundamental rights of a future European Health Data Space allowing for the access and use of personal health data for research, innovation, policy making and regulatory decision-making.

EPF - The creation of a European Health Data Space facilitating access and use of personal health data for research, innovation, policy making and regulatory decision-making has a potential positive impact for all levels in our health systems. 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.

Facilitate access and use of data, however, it must go hand in hand with providing patients with 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 possible consequences of the intended further processing for data subjects and adequate safeguards must be ensured (such as encryption and pseudonymisation).

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.

Section 2: Digital health services and products

New technologies offer digital health solutions to the current main challenges of the national healthcare systems. With the increase of digital literacy and adoption of digital health solutions, more and more patients now have the ability to access digital services and manage their data digitally.

Digital health services and products include remote care delivery, monitoring, diagnosis and therapeutic services but also the management of patient health data. Telemedicine can for example facilitate remote diagnosis or monitoring when patients and doctors/hospital are in different EU countries. Digital health services can be delivered via medical devices, such as remote monitoring of blood pressure, or specific software and algorithms are applied in analysing medical images or processing health data collected from wearable devices to process personalised medical suggestions.

National health authorities could pro-actively analyse the data from multiple sources to improve their healthcare system. Citizens could benefit from these services and products if they can be offered without barriers across the EU while ensuring data privacy and liability. To ensure this, solutions need to be found for adhering to minimum quality standards for example through certification and labelling, for interoperability and for reimbursement.

General principles for providing cross-border telemedicine services are set out in the cross-border healthcare Directive. According to this legislation the rules of the country where the patient is treated apply. The place of treatment is the country where the health care provider is established. EU countries need to ensure the following:

> Patients should receive a written or electronic record of the treatment
> Patients have the right to receive, upon request, the relevant information on the applicable standards and guidelines on quality and safety
> Transparent complaints procedures have to be in place.

Q19. How useful do you consider action in the following areas to ensure access and sharing of health data nationally and across borders through digital health services and devices?

Citizens

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Citizens have the possibility to transmit the data from m-health and tele-health into their electronic health records					X	
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure					X	

Healthcare professionals

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Healthcare professionals have the right to access to patients' digital health records and to data pertaining to the patient's use of digital health products or services.						
Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients						

Other

Please specify:

EPF - In responding to Q19, EPF would like to stress once again that the essential precondition for accessing patients' data is to ensure and safeguard 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 dynamic consent is granted and that they have control, including withdrawal options,on how and what kind of the data is accessed and for what purpose. Therefore in EPF view, actions to improve patients control over 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, it is clear that 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.

Q20. Please indicate the most important impacts of the deployment and use of digital health products and services. Please consider relevant economic, environmental, social or fundamental rights impacts.

EPF - 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 consideration a series of current challenges, including cultural and linked to 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.

Once again, we need to keep in primary consideration patient choice and control, often overlooked in the area of digital health. Since 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.

Q21. Do you think that tele-health could entail additional risks for the patients and for the doctors?

Yes

No

I don't know / No opinion

Please explain:

EPF - 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 depersonalisation of care, and adopting additional tools in already overcrowded schedules;
- Potential risks of mis-diagnosis, 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.

Q22. If you see such risks, how should they be addressed?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
Through protocols/rules for telehealth established at EU level	AE			X	X x/ POP	
Through minimum standards for telehealth equipments established at EU level			AE		x	
Through liability rules established at national level			X		AE	
Through liability rules established at EU level	AE				x	

Other

Please specify:

EPF - Given the broad scope of the European Health Data Space, there is a chance to promote better harmonisation at EU level to drive a higher level of coordinated protection and clarity for both patients and healthcare professionals, therefore reducing as much as possible unnecessary fragmentation

A more coordinated approach could also facilitate patients to travel across the EU without facing too diverse frameworks which 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, it is essential that such stronger harmonisation will take into consideration how 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. TOo 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.

Q23. How appropriate do you consider the following actions to foster the uptake of digital health products and services at national and EU level?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
A labelling scheme (a voluntary label indicating the interoperability level)		**AE**	**X x/POP**			
A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)			**AE**	**x**		
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)					**X AE**	
Other					**X AE**	

Please specify:

EPF - In EPF's view, ensuring clear authorisation schemes and certified interoperability of digital health products and services is essential to foster 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.

As concerns labeling, 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 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.

Q24. How appropriate do you consider the following measures in supporting reimbursement decisions by national bodies?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know / No opinion
European guidelines on reimbursement for digital health products		**AE**		**Provided that differences between health systems are taken into consideration**	**X x/POP**	
European guidelines on assessments for digital health products			**AE**		**x**	
An EU repository of digital health products and services assessed according to EU guidelines to aid national bodies (e.g. insurers, payers) make reimbursement decisions		**AE**			**x**	
Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services)				**AE**	**x**	

Facilitate reimbursement of all tele health services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition)				**AE Change to →**	**X**	
National authorities make available lists of reimbursable digital health products and services				**AE Change to →**	**xX**	
EU funds should support/top up cross border digital health services that comply with interoperability standards and ensure the access and control of patients over their health data					**X AE**	

Q25. In your view, should access to EU funds for digitalisation in healthcare by Member States be conditional to interoperability with electronic health records and national healthcare systems?

Yes

No

I don't know / No opinion

→ Additional Comments (not included in questionnaire)

EPF - Creating an 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 taking 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 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 an 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 sure to make available lists of reimbursable digital health products and services as an additional transparency measure.

Finally, 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.

Section 3: Artificial Intelligence (AI) in healthcare

The objective of this section is to identify appropriate rules (e.g. on the deployment of Artificial Intelligence systems in daily clinical practice) that would allow EU citizens to reap the benefits of Artificial Intelligence in healthcare (e.g. improved diagnosis, prognosis, treatments and management of patients). Artificial Intelligence systems in healthcare are primarily used in providing medical information to healthcare professionals and/or directly to patients and this raises new challenges. The Commission will propose a horizontal Artificial Intelligence regulatory framework in 2021. This proposal will aim to safeguard fundamental EU values and rights and user safety by obliging high-risk Artificial Intelligence systems to meet mandatory requirements related to their trustworthiness. For example, ensuring that there is human oversight, and clear information on the capabilities and limitations of Artificial Intelligence.

Q26. How useful do you consider the following measures to facilitate sharing and use of data sets for the development and testing of Artificial Intelligence in healthcare?

	Not at all	To a limited extent	To some extent	To a great extent	Completely	I don't know /No opinion
Access to health data by Artificial Intelligence manufacturers for the development and testing of Artificial Intelligence systems could be securely, including compliance with GDPR rules, facilitated by bodies established within the EHDS		AE	No Change to →	X	X x/POP	
Bodies established within the EHDS provide technical support (e.g. on control datasets, synthetic data, annotation/labelling) to data holders to promote suitability of their health data for Artificial Intelligence development.			AE		x	
Bodies established within the EHDS, alone or with other bodies established under the Testing and Experimenting Facilities, provide technical support to medicine agencies, notified bodies for medical devices, and other competent bodies in their supervision of Artificial Intelligence products and services				AE	x	
Other					x	

Please specify:

EPF - Firstly, as discussed throughout this consultation, patients' access and control to health data access should be an essential condition of every aspect of the EHDS, including in relation to AI.

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. 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.

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 options listed in Question 26 are good examples on how the EHDS could play a facilitation and technical support role. The EHDS framework can facilitate AI manufacturers' access to data in a secure and compliant framework in line with GDPR rules and to minimise potential risks in terms of data protection. The second option refers to an equally important element of building AI on good quality and unbiased data: through technical support, the EHDS can ensure that data will be 'by default' suitable for AI purposes. Finally, the EHDS should indeed also serve as a supporting framework to promote an harmonised approach to assess AI products and services for medicine agencies, notified bodies or other competent bodies.

Finally, the EHDS should carefully consider the type of use of data 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).

Q27. In your view, is the introduction of Artificial Intelligence in healthcare creating a new relationship between the Artificial Intelligence system, the healthcare professional and the patient?

Yes

No

I don't know/No opinion

Please specify:

EPF - In EPF's view, as confirmed by our 2020 membership survey on Artificial Intelligence, AI has indeed the potential to create 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 even potentially issues in terms of increased social isolation and loss of the essential human component in healthcare. In our 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 adequate 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.

Furthermore, explainable and ethical AI solutions should be preferred over “black box” methodologies, with rules for transparency and data governance. EPF would also like to reiterate the importance of quality of data, already included in our response to Q26, as an element to ensure that this new relation will lead to benefits and minimise risks. For instance, if decisions are increasingly made using analyses of data/metrics, to identify patterns and areas for improvement within healthcare, change in practice etc, we should always make sure that the data correctly captures as much as possible experiences and needs of patients and citizens, therefore

Finally, it is important to stress that what mentioned above applies not only to clinical practice but also to the broader delivery of services, public health interventions, and policy making in the field of healthcare.

Q28. How useful do you consider the following measures to ensure collaboration and education between Artificial Intelligence developers and healthcare professionals?

	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree	I don't know / No opinion
Artificial Intelligence developers are obliged to train healthcare professionals on the use of Artificial Intelligence systems provided (e.g. how Artificial Intelligence predictions should be best understood, applied in daily clinical practice and used for the best interests of the patients).	X x/POP **Change to →**	AE X				

Health care professionals and/or providers should demonstrate understanding of the potentials and limitations in using Artificial Intelligence systems (e.g. adopt protocols indicating in which cases a third opinion should be obtained when the Artificial Intelligence system reached a different opinion from the physician?)	X x/POP AE					

Additional comments (not included in questionnaire)

EPF - As already mentioned in EPF's response to Q27, training of healthcare professionals is essential for a safe and proper deployment of Artificial Intelligence in healthcare. EPF welcomes the proposal by the European Commission to have AI developers deliver mandatory training on the use of AI products. At the same time, however, this should be taken into consideration in the context of a broader improved education and training framework for healthcare professionals to ensure that they are fully equipped with all the necessary skills to engage with AI. Training on the use of AI products for healthcare professionals should include information on ways to explain to patients, using plain language, how AI is being used to support their clinical decision-making.

Such a framework should take into consideration the known difficulties in additional education for healthcare professionals (e.g., digital divide, staff shortages and busy schedules). Furthermore, as suggested by the European Commission, it would be important to certify that healthcare professionals and providers have indeed the competences needed to operate AI systems and related protocols to ensure the utmost safety for patients.

Q29. In your view, are there specific ethical issues involved in the use of the Artificial Intelligence in healthcare?

Yes

No

I don't know / No opinion

Please explain what these issues are and how do you believe they could be addressed:

EPF - The application of AI in healthcare raises a series of concerns, in terms of ethics, safety and fundamental rights for citizens and patients.

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 (for example) treatment, 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 actually 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 have an effect on 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 andethical 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.

As a final comment, as we rapidly move towards more digitalisation in the field of healthcare, EPF would like to reiterate the importance of actions to raise awareness and increase patients' literacy to support better engagement with such innovation, including AI.

Q30. Are there general comments you would like to make about measures needed to support the appropriate and trustable development, deployment and use of Artificial Intelligence in healthcare that would be aiding the best interest of the patients?

EPF - The EU now has the chance to develop a strong AI framework that benefits people, businesses and governments, matching innovation with safety and trust. The EU can achieve this goal by involving patient organisations as key stakeholders in shaping policy to ensure trustworthy, ethical, safe, and inclusive artificial intelligence in healthcare.

The EU framework for AI in healthcare within the EHDS, as already identified in our 2020 response to the EC White Paper on AI, should take into consideration the following elements:

- Address the key challenges of AI in health, from ethical issues such as limiting human autonomy, human oversight, risks of social isolation, transparency and potential misuse of AI leading to issues such as overdiagnosis or unwanted exposure of patients' personal profiles.
- Focus on the dependency of AI on large amounts of good quality, unbiased, standardised, and interoperable data. Such data should also be treated keeping in mind the highest possible levels of data protection for patients.
- Ensure involvement of citizens, patients and other relevant stakeholders – healthcare professionals, in particular – as a key action to achieve a European ecosystem of excellence for AI in healthcare.
- Transparent, effective, and sustainable AI research and innovation. This should be built on principles such as accessibility and affordability of AI research and innovation results and products and on innovation priority-setting based on the patients' unmet health needs.
- Boost healthcare professionals' skills and digital health literacy as a precondition to exploit AI at European level.

From the patients' point of view, this last point is linked to the crucial role of **information for patients:** Patients and consumers 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 a matter of prudence, responsible parties (e.g. health professionals, authorities, industry) should follow the existing principles for informed consent and decision making.

As with medical/health services, products and processes, informed consent and decision making is intended to support patients in the correct use of services and to reduce the risks and improve favourable outcomes according to the needs of people. However, these 'Instructions for Use' must be understandable and useful for them to achieve this goal. As with medications, the 'Guideline on Readability' of the European Commission states that all new applications, innovations or important changes should be tested for readability and understanding.

Final comments:

** Include Reference to accompanying paper and link to additional reference documents.