＊Contribution ID: 5aca6ed9-d7a1-4740-a8c2-58d7f04e3a2d
Date: 03/05/2021 17:39:25

Digital health data and services – the European health data space

Fields marked with * are mandatory.

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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1593073685620&uri=CELEX%3A52020DC0066) 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 as regards the processing of sensitive personal data relating to their health. As a follow up, the Commission adopted its Data Governance Act proposal (2020) (https://ec.europa.eu /commission/presscorner/detail/en/ip_20_2102) 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 (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space-). 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.

The Commission has launched a separate public consultation on the Evaluation of patient rights in cross-border healthcare. You can follow the relevant link (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Evaluation-of-patient-rights-in-cross-border-healthcare) if you wish to reply.

Depending on your answers, the questionnaire may take approximately 40 minutes.

About you

Language of my contribution

> English

I am giving my contribution as

> Non-governmental organisation (NGO)

First name

> Paul

Surname

> DE RAEVE

Email (this won't be published)

> efn@efn.be

Organisation name

255 character(s) maximum

> European Federation of Nurses Associations (EFN)

Organisation size

> Micro (1 to 9 employees)

Transparency register number

255 character(s) maximum

Check if your organisation is on the transparency register (http://ec.europa.eu/transparencyregister/public
/homePage.do?redir=false&locale=en). It's a voluntary database for organisations seeking to influence EU
decision-making.

> 87872442953-08

Country of origin

Please add your country of origin, or that of your organisation.

> Belgium

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

○ **Anonymous**

Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

◉ **Public**

Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions (https://ec.europa.eu/info/law/better-regulation /specific-privacy-statement)

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 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 individuals' interests and rights on their health data in compliance with the General Data Protection Regulation (GDPR) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R0679&qid=1616767366058).

Q1.   The   cross-border   healthcare   (https://eur-lex.europa.eu/legal-content/EN/LSU /?uri=CELEX:32011L0024) 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 5 years are you aware of any changes in the following aspects of health data sharing across border?

	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	○	○	○	○	●	○

Q2. Should a European framework on the access and exchange of personal health data aim at achieving the following objectives?

	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:

> The use of nursing data for continuity of care (SNOMED and ICNP)

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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024& qid=1614771825105) 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 (https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en). 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 cross 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 heath 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	○	○	○	○	◉	○

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:

```
The use of nursing data for continuity of care (SNOMED and ICNP)
```

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?

○ National digital health bodies cooperating at EU level
◉ An EU body
○ Other

Please specify:

[   ]

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

○ 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

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:
○ 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

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.

Q8. (For healthcare professionals only) **In your views, what would be the costs on healthcare professionals/providers of measures facilitating access to, control and transmission of health data for healthcare?**

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs for national healthcare providers (setting up infrastructure, complying with defined standards, etc.).	○	◉	○	○
Costs for healthcare professionals and providers (human resources, finances, etc.)	○	○	◉	○
Information and monitoring	○	○	◉	○
Other	○	○	◉	○

Please specify:

```
Increase of the workload of the healthcare professionals - especially nurses.
```

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:

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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767) the EU Commission proposes 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 (https://eur-lex.europa.eu/eli/reg/2016/679/oj). 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	◉	○	○	○	○

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?

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	☐	☐	☐	☐	☐	☑	☐	☐

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	☐	☐	☐	☐	☐	☑	☐	☐

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	☐	☐	☐	☐	☐	☑	☐	☐

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:

_____

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:

> The use of nursing data for continuity of care (SNOMED and ICNP)

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	○	◉	○	○	○	○
Other	○	○	○	○	◉	○

Please specify:

> The use of nursing data for continuity of care (SNOMED and ICNP)

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	○	○	○	○	◉	○
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)	○	○	○	○	◉	○

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	○	○	◉	○	○	○

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.

Q16. (For healthcare professionals only) **In your views, what would be the costs on healthcare professionals/providers of measures facilitating such access?**

	No impact	Moderate impact	High impact	I don't know / No opinion
Implementation costs (setting up infrastructure, complying with defined standards, etc.).	○	○	◉	○
Operational costs such as human resources, finances, etc.	○	○	◉	○
Information and monitoring	○	○	◉	○
Other	○	○	◉	○

Please specify:

```
Cost related to the use of nursing data for continuity of care (SNOMED and ICNP)
```

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	○	○	◉	○
Increased safety of health care and of medicinal products or medical devices	○	○	◉	○
Faster innovation in health	○	○	◉	○

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)	○	○	◉	○
Reduced administrative burden in accessing health data	○	○	◉	○
Technological progress	○	○	◉	○

Other

Please specify:

[   ]

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.

```
Europe needs a lighthouse centre of research, innovation and expertise that
would coordinate efforts and be a world reference of excellence with the end-
user central in the design and implementation of digital solutions. The
involvement of social and civil society dialogue partners is a crucial factor in
ensuring that human-centred approach leads to change and social impact. It is
therefore key that coordinated action and end-user co-creation will need to
guide EU digitalisation developments to make policies and IT solutions "fit-for-
practice" in all EU Member States. The full potential of the EU EHR and AI will
be exploited when different national systems of EHR become interoperable with
each other, or when a cross-national EHR system gets implemented in the EU.

We also need to ensure that the IT tools, and the data revolution support and
facilitate the shift towards a resilient health and social care ecosystem, and
support nurses to deliver frontline high quality and safe care. Therefore, it is
key to build trust: citizen and patient' trust is a central concept in
developing digital tools. Due to the close relation nurses have with citizens
(prevention), the patients (care and cure), families and informal carers
(informal care), nurses are ideally placed to make digitalisation trustfulness.
```

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 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024& qid=1614771825105). 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	○	○	○	○	◉	○
Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure	○	○	○	○	◉	○

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:

[   ]

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.

```
To develop sustainable healthcare ecosystems, co-creation and co-design with the
end-user becomes essential. But, due to the current lack of end-user co-
creation, there is a lot of patchwork, too many digital health apps and tools,
leading to a kind of 'blockage' for the end-user. The need of patients and
citizens to be able to access their own health data is becoming an important
priority at EU level, however, it is central that such tools respond to real
frontline needs and facilitate their daily work, allowing healthcare professions
to spend more time frontline with the citizens/patients. As such, frontline
nurses' input is crucial to develop EHR features able to smooth and boost
continuity of care. Therefore, nurses need to be engaged in the co-development
of EHR to ensure it responds to frontline and patients' needs. Within the health
and social care ecosystems, digitalisation needs to be viewed as a supporting
tool and not the solution itself. Therefore, its integration needs to go hand in
hand with changes in workflow and working methods, but also with the development
of the e-capacity of health care professionals, informal carers and patients.
```

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:

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 tele-health established at EU level	◯	◯	◯	◯	⦿	◯
Through minimum standards for tele-health equipments established at EU level	◯	◯	◯	◯	⦿	◯
Through liability rules established at national level	◯	◯	◯	◯	⦿	◯
Through liability rules established at EU level	◯	◯	◯	◯	⦿	◯

Other

Please specify:

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)	○	○	◉	○	○	○
A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level)	○	○	○	○	◉	○
An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority)	○	○	○	◉	○	○
Other	○	○	○	○	◉	○

Please specify:

> The use of nursing data for continuity of care (SNOMED and ICNP)

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	○	○	○	◉	○	○
European guidelines on assessments for digital health products	○	○	○	◉	○	○
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	○	○	○	○	◉	○
Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services)	○	○	○	○	◉	○

Facilitate reimbursement of all tele-health services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition)	○	○	○	○	◉	○
National authorities make available lists of reimbursable digital health products and services	○	○	○	○	◉	○
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	○	○	○	○	◉	○

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

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

	Strongly agree	Somewhat agree	Neutral	Somewhat disagree	Strongly disagree	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	○	○	○	●	○	○
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.	○	○	○	○	●	○
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	○	○	○	○	●	○
Other	○	○	○	○	●	○

Please specify:

```
The use of nursing data for continuity of care (SNOMED and ICNP)
See EFN Article - "Leveraging the trust of nurses to advance a digital agenda in
Europe: a critical review of health policy literature" https://open-research-
europe.ec.europa.eu/articles/1-26/v1
```

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:

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).	◉	○	○	○	○	○
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?)	◉	○	○	○	○	○

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:

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?

```
The nursing workforce, which is the largest healthcare professional of all, will
be key in the deployment of AI technologies in healthcare settings. The success
(or not) of AI in Europe will largely depend on end-users using them - and they
will only do so if they have been rightly involved as co-designers of these
technologies, trust them and see the added-value they bring in. Therefore, it is
key to have nurses involved as end-users in the co-creation and co-design of AI.
They are the ones who will use it tomorrow. Therefore, they need to be involved
in it since the very beginning of the developments.
See EFN Article - "Leveraging the trust of nurses to advance a digital agenda in
Europe: a critical review of health policy literature" https://open-research-
europe.ec.europa.eu/articles/1-26/v1
```

Thank you for your contribution to this questionnaire. In case you want to share further ideas on these topics, you can upload a document below.

Please upload your file:

Final comments:

Contact

Sante-consult-b3@ec.europa.eu