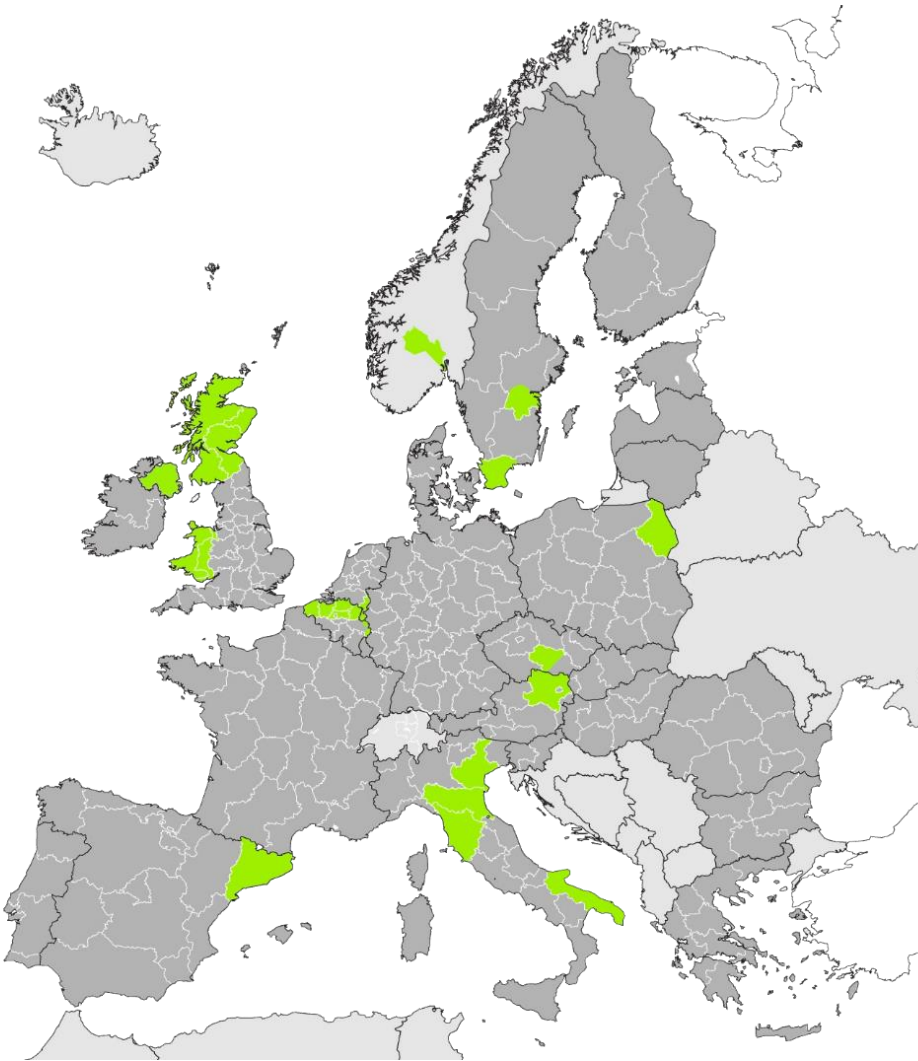
EUREGHA CONTRIBUTION IN SHAPING A **EUROPEAN HEALTH DATA SPACE**

July 2021



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European Regional and Local Health Authorities

EUREGHA position on a European Health Data Space

The reference network for the European Regional and Local Health Authorities (EUREGHA) supports the European Commission's project to harvest the short and long-term benefits of health data by creating a European Health Data Space. EUREGHA believes that building a Europe-wide infrastructure in this field would be extremely valuable for the efficient collection and use of data and the improvement of outcomes for patients and entire health systems throughout the continuum of health care. European cooperation on health and the importance of digital transformation of healthcare systems are key nodes in future health challenges, as the COVID-19 pandemic has shown in the last year.

In most Member States, regional and local authorities share competencies in the health sector and play a crucial role in the organisation of healthcare systems, the provision of health care services, and investing in health and care innovation. Moreover, they represent the natural interface between citizens, national and European institutions and are pivotal in strengthening the collaboration between the public and private sectors. For these reasons, regional and local health authorities should be fully engaged in the design and the implementation of a European Health Data Space.

EUREGHA's vision supports the exploitation of advantages and opportunities provided by the digital revolution and technological innovations by adopting a patient-centric, value-based, and risk-evaluation approach and promoting cross-border cooperation between States and border regions.

Among the core principles, it is essential to put the willingness and needs of the patient at the centre of this ambitious initiative. A patient-centric approach entails a massive and proactive engagement of citizens with the general public that could trigger a profound debate on the opportunities and advantages of data sharing, raise awareness about its implications, and foster participatory policy and decision-making processes. In defining the rules for data exchange and access, the patient's right to privacy and choices about the use of their data must be safeguarded. In addition, a system of collection and exchange of data based on the needs of patients will make it possible to make progress in the development of personalised medicine and, consequently, in the improvement of treatment and its results.

Specifically, EUREGHA advocates for the following point to be widely considered in the European Health Data Space's pillars:

Data governance and rules for data exchange

The organisation and functioning of health systems vary from country to country and often from region to region, reflecting deep differences in the regulatory frameworks and methodologies for collecting and using health data. It is thus crucial for the European Commission to consider the technical and legal issues that might arise in creating such an infrastructure to avoid conflicting legislation. Practical planning cooperation in delivering coordinated data services are needed, particularly in view of innovative approaches, between the public health sector, private entities, and stakeholders at regional, national, and European levels. The European Union can play a leading role in this process. Still, it must consider the legislative fragmentation and the structural and infrastructural capabilities and obstacles of local administrations to implement potential solutions in the EHDS framework.

Moreover, to encourage regional authorities to respond and contribute effectively to the set-up of a European framework, it is necessary to emphasise the potential benefits of this project in terms of local economic development and growth. The active involvement of regional authorities in the mission proposed by the European Commission must take place not only on the level of European political planning but also on the operational level using the European Structural and Investment funds to support the implementation the EHDS. Investing in the structure and creating multi-level synergies will allow the construction of a solid and integrated European Health Data Space.

Finally, citizens' engagement in the data governance model functioning is fundamental. Regional and local authorities, being the government level closer to citizens, should have an instrumental role in the citizen engagement in this domain.

Data quality and interoperability

The European Union can play a crucial role in improving data quality and interoperability.

Setting standards for high-quality data represents a vital step. There is a need to have a straightforward and common direction in the definition of high standards and pool standards and technical requirements together. EUREGHA strongly believes that the efforts of international standard bodies should be coordinated with digital health bodies that work at the national and regional levels. The identification and use of countries' and regional existing legislative frameworks may be beneficial to certify, apply and enforce those standards, fostering a wide adoption as well as facilitating health interoperability within and between countries.

Ensuring interoperability is instrumental not only to foster a European framework for re-use of health data but also to improve its primary use in the cross-border healthcare provision cooperation, where regional authorities have an important role.

According to the vision of EUREGHA, introducing the concept of value in the identification and elaboration of standards would be fundamental to move towards a solid standardisation and deliver the best possible outcomes most efficiently.

Concerning interoperability, the thrust of the European Union in this regard must take into account the differences of regional health systems, intercepting their weaknesses and supporting local authorities in bridging existing gaps, for example, in data collection and sharing techniques.

Infrastructure and technology

EUREGHA recognises the potential leading role of the European Union on data-driven technologies and on eliminating barriers to digital health services in accordance with the GDPR and standards and protocols established within the EHDS framework.

EU regulations consider AI as a medical device and, as such, similar existing approaches apply. In this framework, AI systems should always represent a tool to support healthcare professionals in making their decisions. Still, they should not be the only point of reference to guide the decision-making process and not change the relationship between patients and healthcare professionals. For this reason, guidelines are needed that can address the ethical issues that may arise from the use of Artificial Intelligence and its potential future implications. In this respect, the principle of transparency must be always followed in the development and use of AI and decisions affecting the patient. The patient's perspective and emotional condition should be included at any stage or circumstance

To ensure greater transparency and awareness, education and transferring skills tools will be required not only among cross-border national healthcare systems but also among regions. Regional authorities can significantly contribute to spreading digital literacy, building public understanding of and trust in how health data is used in research for the benefit of the overall European community.

EUREGHA responses to the public consultation

EUREGHA has officially contributed to the public consultation on **a European Health Data Space,** launched by the European Commission in early May. By sending its position on the European Health Data Space, EUREGHA makes sure that the European Commission considers the crucial role of regional and local authorities, as well as regional systems, as reference unit in the collection, exchange and management of health data in the European Union.

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

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 5 years are you aware of any changes in the following aspects of health data sharing across border? (Options: 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 (**No changes**)
- Continuity and access to safe and high quality healthcare (**No changes**)
- Development of methods for enabling the use of medical information for public health and research (**No changes**)
- Development of common identification and authentication measures to facilitate transferability of data (**No changes**)
- Access of patients to an electronic copy of the electronic health record (**No changes**)
- Cross-border provision of telemedicine (**No changes**)

Q2. *Should a European framework on the access and exchange of personal health data aim at achieving the following objectives? (Options: 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 (**To a great extent**)
- Facilitate delivering healthcare for citizens across borders (**To a great extent**)
- Promote citizens' control over their own health data, including access to health data and transmission of their health data in electronic format (**To a great extent**)

- Promote the use of digital health products and services by healthcare professionals and citizens (**To a great extent**)
- Support decisions by policy-makers and regulators in health (**To a great extent**)
- Support and accelerate research in health (**To a great extent**)
- Promote private initiatives (e.g. for innovation and commercial use) in digital health (**To a great extent**)
- Other (**To a great extent**)

Please specify: Among the major expected outcomes, the economic growth of local areas involved in the framework should be considered. As regions are responsible for the direct management of European funds in support of this initiative, particularly the Structural Funds, this emphasis would encourage regional authorities to respond and contribute constructively and effectively to the set-up of a European framework.

1.1. Access to and exchange of health data for healthcare

Q3. *How important is it for you to be granted the following rights? (Options: 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) (**To some extent**)
- The right to transmit my heath data in electronic format to another professional/entity of my choice (**To some extent**)
- The right to request public healthcare providers to share electronically my health data with other healthcare providers/entities of my choice (**To some extent**)
- The right to request healthcare providers to transmit my health data in my electronic health record (**To some extent**)
- The right to request app providers to ensure the transmission of my health data in my electronic health record (**To some extent**)
- 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 (**To some extent**)

Q4. Which of the following elements do you consider the most appropriate for controlling access and sharing your health data with healthcare professionals? *(Options: 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 (**To a great extent**)

- Access my health data that is exchanged between health professionals or with other entities via a digital infrastructure (**To a great extent**)
- Access my health data that is exchanged between health professionals across borders via an EU electronic infrastructure (**To a great extent**)
- Access my health data on a mobile application and share it with healthcare professionals or other entities of my choice (**To a great extent**)
- The infrastructure or personal digital storage for accessing the data should be secure and prevent cyberattacks (**To a great extent**)
- Other (**To a great extent**)

Please specify: Despite the support for the points proposed above, it is crucial to consider the technical and legal issues that might arise in creating such an infrastructure. There may be a problem of conflicting legislations.

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: There is a need to have a strong and common direction that can develop a common definition of high standards and pool all standards and technical requirements together. We believe that international standard bodies with the cooperation of national digital health bodies may be the best solution. In this perspective, WHO rules and principles and EU-driven initiatives (such as the EHDEN project) may be a point of reference for the development of international standards and global data sharing.

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**

Please specify: The right approach may be to identify and use existing schemes already in place to certify, apply and enforce those standards. It is essential to adopt a risk-evaluation approach, stressing the pros and cons of the solutions proposed in the question. Moreover, to provide a comprehensive answer to the question, we should specify the definition of standards and what standards we refer to.

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**

Please specify: As for the Q6 answer, the right approach may be to identify and use existing schemes already in place to certify, apply and enforce those standards. It is essential to adopt a risks evaluation approach, stressing the pros and cons of the solutions proposed in the question. Moreover, to provide a comprehensive answer to the question, we should specify the definition of standards and what standards we refer to.

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 answers provided**)

Q9. *In your views, what would be the benefits for stakeholders of measures facilitating access to, control and transmission of health data for healthcare? (Options: No impact, moderate impact, high impact, I don't know/No opinion)*

Access to efficient and safe care

- Facilitated access to healthcare across borders in the EU (**Moderate impact**)

Benefits for patients

- Transparency on the processing of their health data (**Moderate impact**)
- Reduced costs stemming from not duplicating efforts and tests (**Moderate impact**)
- Reduced administrative burden (**Moderate impact**)

Benefits on healthcare systems efficiencies

- Better healthcare provision (including risks and errors) (**Moderate impact**)
- Reduced costs and reduced duplication of efforts (**Moderate impact**)

- Reduced administrative burden(**Moderate impact**)
- Technological progress (**Moderate impact**)

Other (please specify): The answer to the points addressed can change depending on the subject of reference. From the individual perspective and in terms of cross-border facilities, we would have a high impact. However, benefits depend on the capacity of introducing the electronic system locally in the first place. This might lead to a marginal benefit for a small number of people compared to the population as a whole. If authorities are not able to introduce electronic systems at the local level, costs would be higher with very marginal benefits returns for the individuals. Although reducing the administrative burden is more beneficial for the organisers, if authorities make small changes or additions in their data sharing system to transmit data to another EU country, the reduction in the administrative burden across the local system would be minimal and, consequently, we may obtain only a few benefits.

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

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, or flag I don't know/No Opinion*

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

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? Options: 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; No in al cases; I don't know/No opinion)*

Health data categories

- Health data from medical records (**I don't know/No opinion**)

- Administrative data in relation to reimbursement of healthcare (**I don't know/No opinion**)
- Social care data (**I don't know/No opinion**)
- Genetic and genomic data (**I don't know/No opinion**)

Format (for any of the above data categories)

- Anonymised aggregated format (e.g. statistics) (**I don't know/No opinion**)
- Pseudonymised format (without identifiers of individuals) (**I don't know/No opinion**)
- Fully identifiable format (**I don't know/No opinion**)

Eligibility

- Criteria and conditions for providing / accessing data in the EHDS are defined (**I don't know/No opinion**)
- Safeguards for the access to health data for the purpose of re-use, in line with ethical and data protection requirements, are defined (**I don't know/No opinion**)
- Limit the transfer of non-personal health data outside the EU/EEA (**I don't know/No opinion**)

Security

- Conditions for the secure access to health data are defined (**I don't know/No opinion**)

Other (Please specify): It is tricky to answer this question as it depends on the problem we try to address, and there are many different scenarios to consider. As a network of regional and local health authorities, we gather the experiences of health departments located in different countries, and one of the challenging aspects concerns the implementation of data collection and sharing at the local level. Sometimes, data are not incorporated in electronic health records, and there are still problems in the legal implementation of GDPR at the local level. It is necessary to improve local systems to ensure high-quality data collection and sharing at the European level, as well as interoperability.

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: (Options: 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) (**I don't know/No opinion**)
- Access to health data is granted by a national body, in accordance with national law (**I don't know/No opinion**)

- Access to health data is granted by a national body, subject to agreement of data subjects (**I don't know/No opinion**)
- Other (**I don't know/No opinion**)

Please specify: The answer to this question may vary according to the composition of the regional healthcare systems. For example, the healthcare provider's role can be different from one region to another.

Q13. *Which incentives would facilitate sharing of health data held by private stakeholders? (Options: not at all, to a limited extent, to some extent, to a great extent, completely, I don't know/No opinion)*

- A fee (**To a limited extent**)
- Other (**I don't know/No opinion**)

Please specify: It may be appropriate to introduce fees, but they never work as an incentive. Creating incentives is a very sensitive issue to push private stakeholders to share their data. Incentives may vary depending on the stakeholders and the type of national/local healthcare system.

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? (Options: 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 (**To a great extent**)
- Setting standards on interoperability together with national bodies dealing with secondary use of health data (**To a great extent**)
- Facilitating cross-border queries to locate relevant datasets in collaboration with national bodies dealing with secondary use of health data (**To a great extent**)
- Acting as technical intermediary for cross-border data sharing (**To some extent**)
- Authorising access to cross-border health data (data processed in a crossborder or EU wide manner, such as European Reference Networks) (**To a great extent**)

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? (Options: 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 (**To a limited extent**)
- Stakeholders participating in the EHDS cross-border infrastructure are subject to the mandatory use of specific technical requirements and standards (**To a limited extent**)
- Stakeholders need an audit, certification or authorisation before participating in EHDS cross-border infrastructure (**To a great extent**)

Q16. (*For healthcare professionals only) In your views, what would be the costs on healthcare professionals/providers of measures facilitating such access?* (**No answers provided**)

Q17*. In your views, what would be the benefits for stakeholders of measures facilitating such access? (Options: No impact, moderate impact, high impact, I don't know/No opinion)*

Access to cutting-edge, efficient and safe care

- Availability of new treatments and medicines (**Moderate impact**)
- Increased safety of health care and of medicinal products or medical devices (**High impact**)
- Faster innovation in health (**High impact**)

Benefits on healthcare systems efficiencies

- Better informed decision-making (including risks and errors) (**Moderate impact**)
- Reduced administrative burden in accessing health data (**Moderate impact**)
- Technological progress (**Moderate impact**)

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.*

First of all, it should be made clear what is meant by health data. A large amount of health data is probably generated by other sources than the healthcare provider but rather by the patient itself by wearing smart watches, logging information in different kinds of apps etc., and stored by the service provider (e.g., Google, Apple, Amazon, Microsoft etc.). It can be challenging to know who the data owner really is and what is needed legally speaking to share this data. The re-use of data should be subject to an ethical review which potentially could be done jointly at a EU level. Innovation and product development based on EHDS will probably, to a large extent, have a medical purpose which is why it will be important to understand and make clear how the infrastructure and services of EHDS relate to and are affected by the EU

regulations for medical devices (MDR/IVDR). For a citizen, it might be challenging to feel like you are in charge of your health data (where is it being used, to what aim and by whom?). If a person wants to end their participation in EHDS, is it possible to erase all health data (and possibly personal data) within the system? Might it require some form of blockchain technology?

Section 2: Digital health services and products

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? (Options: not at all, to a limited extent, to some extent, to a great extent, completely, I don't know/No opinion)*

Citizens

- Citizens have the possibility to transmit the data from m-health and tele-health into their electronic health records (**To a great extent**)
- Citizens have the possibility to transmit the data from m-health and tele-health into the EU health data exchange infrastructure (**To a limited extent**)

Healthcare professionals

- 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. (**I don't know/No opinion**)
- Healthcare professionals can request transmission of the data from prescribed apps and other digital health services into the electronic health records of the patients (**I don't know/No opinion**)

Other (Please Specify): Concerning citizens, embedding the possibility to allow citizens to transmit data directly into the data exchange might have a great impact. It would be preferable to explore earlier if you could put it into existing operational solutions rather than in a new solution. The link to a EU health data exchange infrastructure might be helpful to use anything outside of regional or national systems to fix challenges in exchanging records at the local level. Still, there may be more effective solutions already in place. Concerning healthcare professionals, authorisation by patients remains an essential factor, without which professionals cannot access their data. In this perspective, the use of the word 'right' takes on too strong a value.

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.*

Innovation and product development based on EHDS will probably, to a large extent, have a medical purpose. For this reason, it will be important to understand and make clear how the infrastructure and services of EHDS relate to/are affected by the EU regulations for medical devices (MDR/IVDR).

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: In terms of diagnostics, sometimes not having face-to-face contact with patients results in a lack in the diagnosis capacity of doctors and nurses. According to local studies in the north of the Netherlands, another potential risk could be the increase in negative moods (concern, anxiety, uncertainty) in patients with regard to telehealth. Then, if you have telemedicine and synchronise your data to your healthcare provider, you need to make sure that someone is checking the data, and you need to make an explicit agreement if data is not checked.

Q22. *If you see such risks, how should they be addressed? (Options: 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 (**I don't know/No opinion**)
- Through minimum standards for telehealth equipments established at EU level (**I don't know/No opinion**)
- Through liability rules established at national level (**I don't know/No opinion**)
- Through liability rules established at EU level (**I don't know/No opinion**)

Other (Please Specify): The question seems to lack the patient perspective. A bottom-up approach must be adopted, taking into account the needs and engagement of the patient. A patient-centric approach entails a massive and proactive engagement of citizens, raise awareness of the opportunities and risks of these tools, and foster participatory policy and decision-making processes.

Q23. *How appropriate do you consider the following actions to foster the uptake of digital health products and services at national and EU level? (Options: 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) (**To a limited extent**)

- A certification scheme granted by third parties (a mandatory independent assessment of the interoperability level) (**To some extent**)
- An authorisation scheme managed by national bodies (a mandatory prior approval by a national authority) (**To a great extent**)
- Other (**I don't know/No opinion**)

Please specify: An authorisation scheme managed by national bodies would be a very beneficial action, especially for medical devices. Labelling could be seen more in a complementary perspective, especially concerning quality.

Q24. *How appropriate do you consider the following measures in supporting reimbursement decisions by national bodies? (Options: 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 (**Not at all**)
- European guidelines on assessments for digital health products (**To a great extent**)
- 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 (**To a great extent**)
- Extend the possibilities at national level for reimbursing all tele-health services (including telemedicine, telemonitoring, remote care services) (**To a great extent**)
- Facilitate reimbursement of all telehealth services (including telemedicine, telemonitoring, remote care services) across the EU (i.e. mutual recognition) (**To some extent**)
- National authorities make available lists of reimbursable digital health products and services (**To a great extent**)
- EU funds should support/top up crossborder digital health services that comply with interoperability standards and ensure the access and control of patients over their health data (**To a great extent**)

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

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? (Options: 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 (**To a great extent**)
- 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. (**To a great extent**)
- 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 (**To a great extent**)
- Other (**I don't know/No opinion**)

Please specify: Access to health data for the development of AI systems is an obvious need. It must be supported as long as the GDPR and standards and protocols established within the EHDS are respected. Technical support from the bodies created within the framework of the EHDS is crucial to provide a certain uniformity of criteria throughout Europe and provide tools to help Agencies and regulators (such as EMA, for example). However, there are ethical issues to consider and to avoid that projects with data protection deficiencies are validated. For example, granting access for the development and training of algorithms is a business for the data holder, and there are many discussions on the legitimacy of doing these practices regarding manufacturing. If AI manufacturers are allowed to access the EU data, it has to be done in a secured control way. Only in this case, it might be useful.

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

Q28. *How useful do you consider the following measures to ensure collaboration and education between Artificial Intelligence developers and healthcare professionals? (Options: Strongly agree, somewhat agree, neutral, somewhat 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). (**Strongly agree**)

- 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?) (**Strongly agree**)

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:

It is paramount for healthcare providers to ensure transparency of AI systems and make decisions with a patient-centric and case-by-case approach. A lack of these factors could lead to building bias in AI. An ethical aspect that must be taken very seriously concerns health inequalities and discrimination when using Medical Devices. For example, in the case of a Medical Device that makes it easier for patients to monitor their disease, it would be necessary to consider the level of use of technological elements and the economic capacity to have more or less up-to-date mobile phones.

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?*

Transparency must always be at the centre of clinical and decision-making processes.

EUREGHA is the reference network for European Regional and Local Health Authorities. We bring together a critical mass of knowledge and expertise and encourage diversity with the purpose of helping our members to improve the efficiency and quality of health systems and services in Europe.

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