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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 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) 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.

The Commission has launched a separate public consultation on the Evaluation of patient rights in cross-border healthcare. You can follow the relevant link if you wish to reply.

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

About you

* Language of my contribution

- ○ Bulgarian
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- ( ) Trade union
- ( ) Other

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* Organisation name

255 character(s) maximum

European Federation of Pharmaceutical Industries and Associations (EFPIA)

* Organisation size

- ( ) Micro (1 to 9 employees)
- ( ) Small (10 to 49 employees)
- (•) Medium (50 to 249 employees)
- ( ) Large (250 or more)

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

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- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
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- Sweden

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- Bosnia and Herzegovina
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- Chile
- China
- Christmas Island
- Clipperton
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
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- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
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- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States

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- Comoros
- Congo
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- Liberia
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
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- Uruguay
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○ **Anonymous**
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☑ I agree with the personal data protection provisions

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).

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?

	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:

EFPIA suggests adding: Promote the reuse of data for innovation and support and accelerate public and private research in health.

The current differences in data sources in EU Member States and the continued fragmentation of the European regulatory framework related to data, presents challenges to the full implementation of harmonized data collection.

EFPIA's vision supports European federated data networks that contribute to optimal decision-making for public health, research, development and healthcare delivery and allow to build up on existing databases. We encourage the continued pursuit of semantic interoperability (also by harmonizing the format of EHR) by the European Commission and ask for consideration to clearly articulate requirements at all levels of interoperability in the context of the implementation of the European Strategy for Data. Ideally this —in concert with consistent principles regarding how such data can be anonymized and pseudonymized depending on who is sharing the data, who sees it, and what they are doing with the data—to enable seamless connection of data sources in the context of the Health Data Space, enabling high quality insights to be derived by data partners and will work to build trust in the data ecosystem overall. The future system enabling data sharing within the EU must be interoperable and allow mechanisms to effectively and responsibly share data outside of the EU.

For European Health data to be trusted and relied upon, the data must be of high quality and usable for primary and secondary research. Access to high quality data and the ability to generate insights from that data is a critical step towards personalized healthcare and improving patients' treatment and outcomes. Better access to data will pave the way for more holistic treatment with higher efficacy leading to better care and reduced waste of resources.

The European citizen needs to be informed more about the benefits of better data management in the healthcare sector e.g. personalized healthcare, future of data driven healthcare, overall healthcare cost reduction, better management of pandemics as well as disease control in normal times, and how it impacts them. Also, that it would increase the capacity to conduct research based on existing health data. EFPIA agrees with the need to take additional steps to enable an individual's ability to exercise their data portability rights and to invest in building public understanding of, and trust in, how health data is used in research.

We are committed to working with the Commission to develop self-regulation for the sector and go beyond the Code of Conduct for scientific research and pharmacovigilance currently under review, to adopt the right framework and rules based on pragmatic and tailored solutions. As well as accepted principles for anonymization and pseudonymization that are appropriate for the different users and uses of the data, to facilitate primary and secondary research.

EFPIA has taken a proactive approach by developing its own Code of Conduct that is currently consulted and validated with Data Protection Authorities.

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 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	○	○	○	○	○	○

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:

From provided options, EFPIA supports an EU body tasked with supporting data exchange in healthcare, given its remit would allow to build on existing solutions and endorse standards developed by others. It is important to learn from good practices at the Member States level and involve all stakeholders in the consultation process. A European coordination acting as a catalyst for focused development and implementation of harmonized principles, quality and interoperability throughout Europe will be required to avoid fragmentation.

In order to ensure the validity of the proposed EU system and that the data to be collected can be used to achieve EHDS objectives, the establishment of (mandatory) common requirements covering certain key issues such as interconnectivity, comparability of the collected data, data quality and the promotion of data protection is a prerequisite.

The ultimate approach could be to build up on existing standards such as ISO/IEC Health informatics standards that will support EDHS, e.g., ISO 23903:2021: Interoperability and integration reference architecture – Model and framework or ISO 27789:2013: Audit trails for electronic health records and initiatives such as Gaia X which aim to bring technical and semantic interoperability that is essential to unlock the power of health data. It takes the burden away to build a trustworthy and compliant data service stack, to enable the scale that is essential for research and innovation to thrive within Europe.

Of relevance to the greater interoperability is industry experience with the development of federated data networks most notably the European Health Data and Evidence Network (EHDEN). EHDEN, whose five-year programme was formally launched in November 2018, is disease-agnostic. Its mission is to develop a federated network of Data Partners harmonized to a common data model (OMOP OHDSI) to enable execution of research across disparate database types and locations. The OMOP CDM and OHDSI framework do not support every conceivable use case, and likely a mixed ecology of applications, methods and tools will be required to do so, which is a reality of working in the real world setting, but further interoperability, e.g. between HL7 FHIR (for facilitating health data exchange) and OMOP CDM (designed for RWD analysis), in particular to support outcomes research are being addressed, and hopefully accelerated. Federation and the use of the OMOP CDM is also now supporting therapeutic area focused initiatives. Drawing on this experience, EFPIA advocates for the adoption and development of standardized outcome measures as well as expansion of use of common data models and quality standards.

Collaboration on data standards and methodology guidelines will be necessary for interoperability across data sets and enabling evidence generation across country boundaries, particularly for rare diseases and where there are rare outcomes, as well as for vaccine-preventable diseases where there is a value added and currently missing links at EU level regarding vaccination recommendations, schedules and coverage rates (VCR). Improved efforts on data quality, harmonization and interoperability should come hand in hand with the broad deployment of robust national immunization systems. As shown during the COVID19 pandemic management, the European Centre for Disease prevention and Control (ECDC) has a key role to play as an expert agency for coordination, guidance and support to EU Member States.

An important approach to standards setting is understanding what must be locked down and by when. If standards are set too soon and/or too widely, standards can limit beneficial exploration (such as when there is a need to further enrich the data model in specific disease areas); if set too late or not at all, uncertainty will limit progress. There is a substantial literature (e.g. article by James Surowiecki in WIRED: Turn of the Century|WIRED) on the role of open standards (e.g. OMOP) and their impact on innovation in other technology settings which should inform these guidelines and standards and the process for determining them. EFPIA recommends that there should be broad learning from other types of data platforms established by Pharma or academic institutions in addition to other regulators (e.g. FDA) and stakeholders in the research ecosystem (also including med tech).

All data related standards and rules need to keep the future in mind. It needs to change rapidly with the change in technology and advent of new evidence. This should be an evolving process. Hence, sector specific data rules relevant to every sector need to be issued by the specific sector and owned/controlled accordingly.

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	○	○	○	○

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:

One of the main benefits for all stakeholders involved in research of measures facilitating access to, control and transmission of health data for healthcare is the ability to conduct primary and secondary research that could lead to new innovative, transformative therapies for patients. Access to, and transmission of health data, could transform drug development through the ability to use real world data for comparison in a clinical trial, speeding development of a potentially transformative therapy. Similarly, access to and transmission of health data allows pharmaceutical companies to research the genetic basis for disease and develop targeted therapies to address areas of high unmet need. If the health data space and the rules surrounding access to the data are not carefully thought through, there could be unintended consequences that could limit the utility of the data for developing innovative medicines for patients.

Today, health outcomes vary dramatically both between and within countries in the EU, but this is often not visible due to differences in how these outcomes are defined and measured. This has been starkly exemplified by the COVID-19 crisis, where it has been difficult to compare even mortality rates between EU Member States due to different data collection standards and methodologies. Working towards a common approach in measuring outcomes is an essential tool in better understanding their variation in the EU. This allows for better assessment of real efficacy and healthcare value. Publishing these data in a transparent way, following the model of countries like Sweden, can inform service providers on the preferred service design. It can also empower patients by allowing comparisons to be made over time, and between providers and services, therefore contributing to more informed decisions.

According to the OECD, 20% of healthcare expenditure is spent inefficiently, making no meaningful contribution to patients' outcomes. Smart healthcare spending will allow us to improve health outcomes while not increasing overall costs, or even create savings in the long-term that can be reinvested for better health.

Today, through collected high-quality data and artificial intelligence, it is possible to assess the real added value of healthcare interventions that will concern patients belonging to a certain cohort (e.g. chronic diseases). Using real world data and interconnecting information flows AI allows identifying unmet medical need, assessing the benefit-risk, and examining all direct healthcare costs along the patient journey (drugs, hospitals, and so on). This level of insight into the healthcare sector enables data-driven decision-making for public and private partners. A trustworthy AI regulation is supportive and needed to maximize the efficiency of the EHDS. An ideal scenario would foresee the AI Act and EHDS are interlinked, and potential AI tools could be used in the EHDS approach to a beneficial healthcare system.

Wider application for digital health services will allow for the shift from a health system that is centered on providers to one that is centered on people's individual needs and preferences has important implications for how we measure health system performance.

Addressing roadblocks in the patient journey and removing duplicative interventions can reduce unwarranted costs and potentially improve health outcomes. Integrated care has the potential to increase the continuity of care and reduce unnecessary waiting times, support patients' empowerment and foster health systems sustainability and resilience. For some diseases and conditions, especially the most complex ones, the implementation of standardised patient pathways can help improve this care coordination. Digital health services and EHRs are also crucial tools to strengthen care coordination and service integration, as well as to improve empowerment and self-management through patient access to their own health data.

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 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. 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:

The above questions are difficult to address without further context of what the intent would be of the rules that are placing conditions on access to data. Moreover, we do not consider the distinction between the different purposes in this form to be purposeful. According to recital 159 of the GDPR, scientific research includes "basic research, applied research and privately funded research". A distinction between "research purposes" on the one hand and "innovation purposes" on the other hand is therefore neither in line with the GDPR nor meaningful.In terms of main barriers to access to health data for research, innovation, policy-making and regulatory decision, the following should be addressed:
·National laws/rules on health and research data in addition to GDPR + different preferences on choice of legal basis: Disparity between Member States legislation, guidance, and between national data protection regulators on appropriate legal basis for primary processing, and – especially – secondary use of data for scientific research purposes: this lack of clarity can be perceived as an obstacle for scientific research, because entities involved often prefer to err on the side of caution, that side often being reliance on consent including when the GDPR does not require it. If consent was not (or simply cannot) be obtained, research efforts are sometimes paused or cancelled. Moreover, it could lead to the inability to study medications for later uses that could not be envisioned at the time of the original study. A perfect example of where this idea that consent is the only legal basis for secondary research would be problematic is in the trials of therapeutics for COVID-19. In an effort to combat COVID-19, many pharmaceutical companies looked at existing therapies that may produce an anti-inflammatory effect, to see if these therapies had a mode of action that could possibly render them effective against COVID-19. If this is interpreted as secondary use of the data, it is unlikely such data could be used for these purposes without anonymization or reconsenting, because the informed consent forms used in the original studies could never have contemplated investigating the product for a pandemic infection that was not in existence. Conversely, in those countries with strong and clear legislation covering privacy aspects of research data (e.g., Finland), we see that such legislation acts as an enabler for very meaningful research, including research that speeds up access to innovative treatments. These are examples of national legislation that complements the GDPR in a sound and workable way, enabling scientific research. While we believe that the EU needs to adopt principles regarding anonymization that reflect the user, the use, and the data environment (several of which exist), we do not support a one-size-fits all approach to anonymization. We are concerned that efforts to define a one-size-fits-all approach to anonymization can actually lead not to a lack of sufficient anonymization, but to over anonymization that renders the data not useful and, at worst, potentially inaccurate. The emphasis should be on providing a framework for defining the appropriate safeguards enabling the use of data that is sufficiently rich for the intended purpose. For example, what if the rules suggest removing all free-text fields from a clinical trial dataset, as these could be used to identify a particular subject (patient). The vast majority of adverse event data is captured via free text fields. As a result, if these fields are stripped of the information during the anonymization process, the richness of the data is lost, and a researcher cannot come to conclusions as to the safety of the product or the risk of certain adverse events occurring. It is also impossible to discern patterns in adverse events and when or how they might occur. Therefore, it is difficult to answer whether additional rules are needed at the EU level regarding anonymization, unless these can contribute to a risk and context-based approach. Similarly, we believe that the lack of consistent principles and confusion over the terminology of anonymization and pseudonymization requires addressing at the EU level.

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:

EC and Members States should consider providing a mix of financial and non-financial incentives for data holders to share their data, both with public and private market participants. Such incentives could potentially include traceability of the data, financial rewards/tokenization, reciprocity in access to data, giving credit to data providers and curators in publications that are based on the data, as well as IP-based incentives. An ethics framework would be important to detail the conditions for data agreement and data tracking. Transparency for data sharing shall be key and patients shall be notified when their data are being anonymized. Data from public sources should be made readily and publicly available under the monitoring of a national body, in accordance with national law. Private databases are usually protected by IP rights and neighboring rights which are rewarding creativity and investment; accordingly, only limited exception should allow access to private databases without data holder's authorization.

Transparency and access to results of clinical studies are an ethical obligation that we as an industry take very seriously. On 1st January 2014, EFPIA/PhRMA published their Principles for Responsible Clinical Trial Data Sharing which demonstrates the innovative industry's commitment to go even beyond the legal requirements of the clinical trial data sharing in both the European and US based member companies. Any future rules on facilitating access to health data held by private stakeholders should take into account the legal requirements of EU Clinical Trials registries and align with clinical trials transparency rules.

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:

Sharing of health data held by private stakeholders must remain voluntary.

The extent to which private stakeholders will be willing to share the data depends upon a number of factors, including:
1. The type and nature of the health data (including whether it had to be generated, the value added by the owner, and effort and investment needed)
2. The level of governance and protection provided for the data, in the event that it is shared, (e.g., some data may only be shared under circumstances similarly regulated like the data access under CSDR (https://www.clinicalstudydatarequest.com/))
3. The extent to which the data provides a competitive edge that is relevant to successfully compete on the market, or in R&D, or is expected to be relevant to enable and sustain future R&D and competitiveness.

Given the above, a "one size fits all" approach to incentivizing data sharing is unlikely to work. Incentives to share should instead take various forms of protection, including:
1. Maintaining a strong regulatory data protection and trade secrets regime in Europe, which continues to recognize the importance of incentivizing the generation of valuable data of the type in scope.
2. A technical solution, legal-contractual solution, and/or governance process in EHDS which would allow companies who voluntarily choose to share certain commercially relevant confidential data (CCV data) in certain circumstances to do so safely.
3. A fee or other return in kind (such as access to data of others or access to results), which may work for some types of data.

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	○	○	○	○

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.

It is critical to address the confusion over what constitutes anonymization and what constitutes pseudonymization with rules that do not render the data useless. Additionally, the European Strategy for Data provided an analysis of what needed to change in order for Europe to realise its digital potential. It highlighted the barriers in accessing data and also legal and regulatory fragmentation. The Data Governance act is intended to be part of the means of addressing these problems. It will also support the evolution of a "European" approach to data governance. The DGA may create the impression that consent is the only legal basis on which data can be processed for scientific research purposes, whereas the guidance from the EDPB and Commission makes clear that other legal bases may be more appropriate. EFPIA considers it important that the DGA should be entirely consistent with GDPR and acknowledge explicitly all the legal bases provided for processing personal data. Additional rules should build on the existing frameworks, especially GDPR. In particular, these rules should operationalize the mechanism of "deemed compatibility"

under GDPR Art 5.1.b when the secondary use is directed towards scientific research.One of the goals of the Data Governance Act is to strengthen the EU's digital economy. Enabling data-driven scientific research is critical to this objective. Specific ways of managing data will need to be developed in the context of the sectoral data spaces to reflect the needs and responsibilities of each sector. Nevertheless, it is important that the Data Governance provides a consistent and broad interpretation of scientific research.

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	○	○	○	◉	○	○

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:

The Covid pandemic proved the essentiality of cross-border exchange of healthcare data of patients. Such sharing especially in exceptional circumstances could save lives and also facilitate safer cross-border travel (Covid passport or through QR Code through mobile phone certifying health status). The Digital Green Certificate sets a precedent, on which other initiatives could be built such as the implementation across the EU of an e-vaccination card covering all available vaccines and an interoperable, Pan-European system of existing or newly created national Immunization Information Systems (IIS). This would support control of infectious diseases and could help improve the implementation of national vaccination programmes by identifying gaps in vaccine uptake in the population, facilitating communication to at-risk groups, and ultimately empowering citizens and improving public health. Additionally, such systems could also support national and EU preparedness towards future pandemics.

One of the key issues that arose during the pandemic has been one of healthcare systems, public health and governments having insufficient or no relevant data on which to base critical decisions. The right data are not in the right place to answer the right questions at the right time. A very significant learning has been the need for real world, observational data, in the right hands, to research applicable insights from the past, contemporary insights from today, and implications for the future management of pandemics. We learned an important lesson globally that firstly collaboration is a prerequisite for-the breakthrough research; the technologies allow us to adapt quickly to a new situation, ensuring continuity of care, and research and clinical trials. More effective transfer of high-quality data would enhance the ability to deliver care and boost preparedness for potential future crises.

In the concept of federated data networks, which is a managed architecture that allows for the sharing of

mutual resources for Real World Data (RWD) use, for primary, clinical, or secondary, research use, whilst preserving the primacy of the RWD at a local level, we can ensure access to RWD in a timely manner. Standardization of data to a common data model addresses a central need to be able to curate data for analysis on a contemporaneous and continuous basis, not on a per study basis.

Important aspect in generating greater trust in data sharing is investment in digital literacy for citizens and healthcare professionals to truly exploit the potential of data ecosystem. Education about the existing safeguarding mechanism will enhance trust and encourage sharing of health data for a positive benefit to health. Resources such as the Data Spectrum developed by the Open Science Institute (OPI) could be used to help to understand the language of data. OSI works towards unpacking data's challenges and its benefits and they recognise that for that there needs to be precision about what these things mean. They should be clear and familiar to everyone, so we can all have informed conversations about how we use them, how they affect us and how we plan for the future.

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.

For the pharmaceutical sector, the deployment and use of digital health products and services could mean healthcare where we predict and prevent disease based on your personal genetic makeup. By combining genotypic and phenotypic data sets, and applying data techniques like AI, machine learning, etc., we think we have the potential for outcomes that will help identify and stratify patients in transformational ways.

Additionally, the pharmaceutical industry is committed to modernizing clinical trials in order to speed the delivery of safe and effective medicines to patients, to reduce the burden of participating in clinical trials, and to increase representation of diverse patient populations in clinical trials. The use of digital products and services in clinical trials could potentially reduce patient burden by enabling trials that use decentralized techniques. Moreover, the ability to gather continuous data from digital tools in clinical trials could potentially speed drug development and availability of new, transformative therapies.

Wider deployment and use of digital health products and services has also a potential to improve patient and healthcare professionals experience by reducing the frequency of commuting for the face-to-face consultations (which impacts also the greenhouse gas emissions by reducing carbon footprint). Also, the new technologies i.e., drones enable delivery of medicines to remote areas. It allows to reduce the delivery time and to accelerate the provision of vital medical supplies during the crisis situation.

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

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	○	○	○	○	○	○

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
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:

In order to assure high quality AI solutions and to safeguard the EU's competitiveness in the international AI marketplace, easy yet compliant access to a significant amount of high quality, representative data will be indispensable. The creation of a secure data ecosystem to achieve a basic level of quality, relevance and interoperability allowing to link different sources of health data across Europe is a prerequisite to reducing bias, discrimination and ensuring highest levels of safety and robustness of AI solutions in healthcare. Collected data needs to be considered within the context and therefore its limitations to be specified. One critical issue involved in the use of Artificial Intelligence in healthcare is the risk of bias when datasets used to train the AI model do not reflect the diversity of real-world situations. The risk is higher when the availability of data depends on data subject consent - sometimes preferred for processing sensitive health data - as this is filtering out based on individual choices and not based on scientific criteria like data quality. When bias has been introduced at the outset, using the AI solution may then provide sub-optimal or misleading output and ignore outliers.

We support the mapping and "FAIR-ification" of existing health data registries and other databases to build up on existing sources and to make the machine-readable metadata findable for automatic discovery. The Commission's plans to create a single market for data, notably a EHDS promises to unlock the power of data for AI-enabled healthcare and a well-functioning EHDS should incentivise data sharing and harmonise applicable rules to remove barriers to the collective benefits across Europe. In order for all stakeholders, including providers and operators, to train, test, develop and apply a trustworthy, reliable AI system, clear rules favouring industry on data access and processing within EHDS should be laid out.

The critical challenges that cut across the pharmaceutical value chain and are influencing the pace and scale of AI development and implementation include maximising the utility of data (including identifying, accessing and integrating high quality interoperable data in a way that is equal, non-discriminatory, transparent and protected to ensure that advances resulting from AI are equally accessible to citizens), modernising the IT infrastructure, navigating the evolving regulatory landscape, adopting a rules-based approach to data ethics and responding to the impact of AI in the future of work.

GDPR is aimed at standardising and strengthening the protection of personal data, including strengthening the rights of individuals to be better informed about how their data are to be used. It also sets out clear responsibilities and obligations on health care professionals and companies using such data, with stringent penalties for infringements, which in some cases may be in conflict with driving innovation in AI, in the absence of further guidance. Patient's data protection also builds on voluntary ethical guidelines for AI in healthcare. Setting EU and global standards would be helpful for AI and would work to build trust in these technologies and industry. Aligning data protection with the emerging needs of innovation will enable more sharing of data in a secure and responsible way, moving the EU from the prohibitive environment and attitude towards data sharing as we currently are experiencing, shifting focus back to the original intent of the GDPR to use data for the benefit of society.

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?

	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:

EFPIA recognises the work of the EC's High-Level Expert Group on the Ethics Guidelines for Trustworthy AI and is supportive of all the 7 key requirements, nevertheless, considers the following four principles critical to the use of AI in healthcare in Europe:

1. Benefit to society: AI systems are developed and implemented, according to EU core values and benefit people

2. Fair and Inclusive: AI systems should treat all people fairly and take deliberate steps to promote inclusivity and minimize any bias, including increasing access and protections to vulnerable populations

3. Transparency and accountability: the AI systems should be interpretable or explainable, and have mechanisms to ensure accountability for the impacts,

4. Privacy and security: AI systems should respect individuals' privacy and should be secure, resistant to being compromised by unauthorized parties or users.

The AI system needs to be designed as a system with clear decision-making rationale and use of AI in each specific case using appropriate methods, since this is an approach that combines the best of two worlds - the high sensitivity and specificity of AI systems, the speed and reproducibility and the flexible problem-solving capability of humans. Importantly, patients and citizens should be central to the feedback loop in the context of AI and digital technologies to build trust with patients and citizens and adjust to the needs of the users. EFPIA emphasizes the importance of designing systems to combine the need for high accuracy of AI solutions and the flexible-problem solving capability of humans. As AI systems become more sophisticated, there will be a continuing need to ensure effective human oversight in line with the recommendations of the HLEG. AI systems should promote fairness and inclusion and avoid bias as well as provide transparency and enable accountability.

Especially, EFPIA views the skills agenda as being critical when it comes to AI in healthcare. EFPIA supports partnerships between the public and private sectors, bringing together leadership and commitment from organisations to ensure coordination of research and innovation in AI. EFPIA sees the skills agenda as being critical when it comes to AI in healthcare. Healthcare professionals should have the right skills to allowing them to understand and utilise AI solutions and that there is an educational focus for example in HCP's curricula on use of AI-based solutions. Similarly, a focus on AI skills by patient communities would also be warranted.

There needs to be a balance between innovation and regulation to be sure the innovation does not go unregulated and ultimately violate someone's privacy or rights, and that regulations do not impede the pace of innovation. To realize this balance, building an ecosystem of trust is critical amongst all stakeholders that develop, use and benefit from AI systems.

The aspiration to leverage AI technology for the benefit of patients cannot be considered without all the value-adding steps executed by different healthcare partners throughout the value chain. In particular, the

innovative pharma industry uses AI for discovering and developing novel therapies, personalised medicine (including biomarker development), improving diagnostics (through advanced machine learning for imaging), business optimisation, and engaging with and empowering patients and healthcare professionals.

Other players in the healthcare ecosystem such as regulators and payers can also benefit from AI. For example, regulators are seeking to increase efficiencies in regulatory reviews and to inform decision-making through the use of AI. The EMA has outlined a number of principles for the acceptability of using AI that should be applied by regulators, payers and industry alike in their respective uses of AI in order to build trust. These principles include privacy, ethics, transparency, explainability, trustworthiness and auditing.

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?

EFPIA supports the Commission's approach to regulate AI based on risk, overall acknowledging CE marking system for high-risk applications in healthcare which is already addressed by MDR/IVDR. We would welcome an alignment of the risk levels described in the proposal with MDR for consistency. Under a risk-based regulatory system and in consideration of the scope of use, some AI-driven software may be categorized as low or intermediate risk under the MDR, whereas the draft proposal appears to classify all such devices as high risk. It could decrease the competitiveness on the market due to providers having difficulty in fulfilling market access regulations and therefore jeopardizing the uptake of AI-driven solutions by operators.

AI has a broad application in the pharma supply chain starting from the development and launch of novel therapies to process of business optimisation and engagement with patients and healthcare professionals. It has the potential to increase the success rates of new drugs being delivered to patients at a lower cost, with savings for the entire healthcare systems. To incentivise the investments in AI solutions in Europe, we recommend thorough assessment of the proposed requirements versus the support offered to smaller providers to navigate through the new rules.

The pharmaceutical industry has already embedded transparency in various aspects of its business. AI diagnostic tools and other patient-facing tools should be transparent around their function/training to some degree (or otherwise be independently tested for robustness), different approach should be applied in case of proprietary internal R&D tools, since the insights from those will be validated in conventional ways, e.g. animal studies and/or clinical trials.

EFPIA recommends defining levels of transparency that allow sufficient interpretability of the AI and underlying data sets, including auditing mechanisms which are key to establish an environment of trust. Control and retention of both the data sets used to train the model, and the code used to create the model would aid in transparency. It is also important that transparency requirements are carefully balanced to still allow sufficient incentivisation of the investments needed to stimulate the generation of the necessary data sets and AI solutions.

Europe needs to maintain pragmatic equilibrium between innovation, data user's rights and regulatory approaches in order to be the most preferred data venue for healthcare purposes. Europe's Technology aspirations and the Citizen's privacy rights and welfare are not mutually exclusive topics. An ecosystem approach with correct interoperability mechanism and a minimum regulatory set of rules will benefit society.

The difficulties imposed on the person in the street in understanding complex privacy statutes may not be repeated while creating the digital health data and services infrastructure.

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.

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Final comments:

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