European Commission European Commission

COMBINED EVALUATION ROADMAP/INCEPTION IMPACT ASSESSMENT

This combined evaluation roadmap/Inception Impact Assessment aims to inform citizens and stakeholders about the Commission's work in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are, in particular, invited to provide views on the Commission's understanding of the current situation, problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	A European Health Data Space
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG SANTE, Digital Health, European Reference Networks, (Unit B.3)
LIKELY TYPE OF INITIATIVE	Legislative proposal
INDICATIVE PLANNING	Q4 2021
ADDITIONAL INFORMATION	https://ec.europa.eu/health/ehealth/home_en

A. Context, Evaluation, Problem definition and Subsidiarity Check

Context

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 and reduce inequalities.** It should **promote access to health data** for research and innovation on new preventive strategies, as well as on diagnosis and treatment of diseases to improve health outcomes, while ensuring that **citizens have control over their own personal data**. This initiative is part of the Commission Work Programme for 2021. The **COVID-19 pandemic** has highlighted the importance of having timely access to health data for research and policy-making purposes, and the European Council has recognised the urgency to make progress towards the EHDS.

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 unprecedented developments in digital technologies to introduce innovation in health and care, increasing **accessibility, availability and affordability of high-quality healthcare**. 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 citizens' interests and rights, in particular as regards the processing of sensitive personal data relating to individuals' health. The strategy announced the Commission's plans for European data spaces, including in the area of health data, and for European federated cloud-to-edge infrastructures for the hosting of such data spaces, as well as other measures for thriving data-sharing ecosystems. As a further follow up, and to support the sharing of protected data held by the public sector, the Commission adopted a proposal for a Data Governance Act in November 2020.

Based on the existing **cross–border healthcare Directive** Member States collaborate through a voluntary network connecting national authorities responsible for eHealth (the 'eHealth Network'). Existing arrangements and tools only partly deliver and respond to the persisting challenges. Digital technologies provide innovative solutions that contribute to the transformation of healthcare systems and improve citizens' health outcomes. The cross-border healthcare Directive includes elements related to the provision of digital health services. Further to the Communication on enabling digital transformation of health and care in the Digital Single Market (2018), the **European Parliament** called for action to enable the digital transformation of health and care. During the COVID-19 crisis, many Member States have adopted additional legislation concerning the provision of digital health services, especially tele-health.

The Commission has outlined its approach to artificial intelligence (AI) in the White Paper on AI (2020) and in the Report on the safety and liability aspects of AI (2020). Following up on the White Paper on AI, the Commission is working on horizontal safety requirements for AI, as well as the revision of certain sectorial safety legislations and of the liability framework. It is planning to adopt its proposal for a horizontal framework for an ethical use of AI at the beginning of 2021. The Commission will continue to monitor the discussions on the horizontal framework on AI and their impact on the health sector and may consider whether this calls for a specific sectoral policy

initiative.

Evaluation

In line with the 'evaluate first' principle, the European Health Data Space initiative and the accompanying impact assessment will be based on the results of an evaluation of the existing framework for cross-border exchanges of health data.

The evaluation will especially:

- assess the extent to which the eHealth Network supports and facilitates cooperation and the exchange of health data between Member States and its efficiency;
- assess how and to which extent the provisions of the cross–border healthcare Directive are sufficient for the cross-border free movement of digital health services and products and if they allow the re-use of health data for future developments in treatment, health research, innovation, policy-making and regulatory activities; examples of such complex developments include artificial intelligence-based data analysis and innovative digital health and care applications;
- look into the coherence and complementarity with other legislation such as on data protection and the proposal for the Data Governance Act;
- assess to which extent new EU legislation is necessary to ensure free movement of digital health services and products and to remove barriers for the deployment of AI systems in healthcare; potential administrative burden and complexity linked to the implementation of this legislation will be assessed.

The evaluation will focus on the period from 2013 to 2020 and will cover all EU Member States. The preliminary results of the evaluation will be used for the impact assessment, for the refinement of the problem definition and the policy options, and will feed into the analysis.

Problems the initiative aims to tackle

The planned legislative framework will tackle the issues and barriers that are specific to the exchange of and access to health data and the use of digital services and products including artificial intelligence in health:

- **Insufficient health data exchange negatively impacts on the provision of healthcare services (primary use of health data).** The level of digitalisation at national level varies considerably and interoperability between healthcare providers remains limited. The eHealth Network – and its related IT infrastructure – has improved the cross-border exchange of health data for healthcare, such as patient summaries and e-prescriptions. However, among other challenges, its voluntary nature and the non-binding nature of its guidelines has affected the uptake and impact of its decisions.
- **Exercising access and control over their own health data** is often difficult for patients. Electronic health records (EHRs) are not yet a reality across the whole EU, and many patients cannot easily access and use the information they contain, or transfer them between healthcare providers, including when they move across borders. This leads to duplication of efforts, inefficiencies, delays of treatment and higher costs for healthcare systems and patients. The interoperability of EHR and of mobile health tools is limited, meaning that this information cannot be easily used in the treatment of patients.
- **There is fragmentation of digital standards and limited digital interoperability between healthcare systems.** Recommendations on a European Electronic Health Record Exchange Format exist. Nevertheless, in practice they are not sufficiently applied, which reduces interoperability between systems and creates barriers in the Single Market. Few Member States apply the voluntary eHealth Network guidelines. The resulting market fragmentation hampers the free movement of digital health products and services with duplications and increased costs for healthcare systems, patients, researchers and public institutions. This fragmentation poses a significant challenge for businesses and enterprises and national healthcare systems when integrating innovations in healthcare.
- **Access to, and exchange of, health data for scientific research and innovation, policy-making and regulatory activities remains very limited in Europe (secondary use of health data).**
    - The **collection, access, storage, use and re-use** of personal health data in healthcare poses specific challenges. The General Data Protection Regulation (GDPR) sets out the EU data protection rules. However, Member States may further specify some aspects in specific areas, such as health data, which they

have done to a large extent. As a result, the processing of personal health data in Member States is fragmented, leading to obstacles and to limited access of researchers and public institutions, that in turn reduces the EU competitiveness and innovation potential at a global level.
    - Member States have different approaches for access to and sharing of health data. Some Member States have set up national bodies facilitating access to health data; however, such bodies do not exist in all Member States. Limited cooperation, governance and IT infrastructure at EU level hinders health data access for researchers, public institutions and regulatory bodies. The horizontal proposal on the Data Governance Act which lays down a governance framework for the common European data spaces can address these limitations only partially due to the specificity of health data.
    - Evidence-based policy-making and regulatory action would benefit from additional access to timely, accurate, representative data of high quality held by public and private organisations (e.g. private healthcare providers). The re-use of health data held in cross-border databases is difficult due to the different applications of the GDPR in the areas of health and research in the Member States. This limits the sharing of privately and publicly held health data and genetic data (1+ Million Genomes initiative) with researchers, innovators, public bodies or regulators.
- **The use of digital health services and products for the provision of healthcare** has increased substantially during the last years and particularly during the COVID-19 pandemic. However, the **free movement and provision of these services and products** is limited, as heterogeneous legal bases, different methods of certification and authorisation, liability and reimbursement rules have been put in place at national level, resulting in limited mutual recognition. Moreover, the organisation and financing of the health sector requires a specific approach on digital health technology.
- An increasing number of digital health tools integrate artificial intelligence (AI). The Commission is already working on a horizontal framework for AI covering safety and fundamental right-related aspects, which is intended to apply across different sectors, including healthcare products. However, specific health-related aspects building upon the future AI framework, including **training, testing and validation** of AI systems in health, as well as aspects not covered by this horizontal framework may need further consideration. The **rights and obligations** of those digital health products and services are currently not always clear. The use of AI tools, and notably the opacity of certain applications, can make it difficult to allocate responsibility or to ensure compliance. **It is important to ensure appropriate assurances of fundamental rights and of compensation for damages.**

Basis for EU intervention (legal basis and subsidiarity check)

Articles 114 of the Treaty on the Functioning of the European Union, potentially combined with other Article 16 on data protection, could provide the legal basis for this action. The proposed initiative aims at fostering the internal market for healthcare services and products and supporting the free movement of people, while protecting the fundamental rights of individuals in the area of health.

Free movement of people, products and services is ensured when people can take their health data with them and when health data can move and be accessed cross-border while respecting data protection rules and a high level of security. In order to overcome the current fragmentation of access, sharing and use of health data at national level, an EU initiative is important in view of the effects and their scale at EU level.

The current situation of fragmentation, differences in and barriers to access health data in the cross-border context, including by patients, researchers and policy-makers, as well as limited interoperability, shows that action by Member States alone is not sufficient and that it requires a common framework at EU level.

Member States adopt rules that can often be divergent and even conflicting with each other, which may affect negatively the rapid development and deployment of artificial intelligence (AI), and digital health in general, and result in limited provision of digital health services and limited flow of health data across borders. Therefore, the cross-border movement of digital services and products as well as the cross border access to health data are limited in the EU. This also impacts on free movement of people which cannot ensure the portability of their health data when moving abroad.

Legislative action is needed at EU level in order to reduce these divergences and ensure a

smooth functioning of the digital single market, in full compliance with the protection of personal data in health under GDPR. Considering the scale and effects of the proposed actions, these actions can be better achieved at Union level.

B. Objectives and Policy options

Objectives:

The sectoral legislative proposal establishing a regulatory framework for a European Health Data Space (EHDS) will aim at:

1) Ensuring access, sharing and optimal use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, timely, transparent and trustworthy way, and with an appropriate institutional governance;
2) Fostering a genuine single market in digital health, covering health services and products, including tele-health, tele-monitoring and mobile health;
3) Enhancing the development, deployment and application of trustworthy digital health products and services, including those incorporating artificial intelligence in the area of health.

The policy options will be further developed based on the evaluation findings and analysis in the impact assessment and will also take into account other relevant initiatives e.g. in the area of artificial intelligence.

Baseline scenario:

The baseline covers the development of the situation based on the existing legislation and the creation of the common European data spaces without specific health provisions. Member States would continue implementing the cross-border healthcare Directive, supported by the eHealth Network.

The exchange of patient data for healthcare (primary use) would continue between healthcare professionals, for specific use cases and on a voluntary basis, thus not fully satisfying the needs of patients.

For the access to health data for research, policy and regulatory activities (secondary use), Member States would continue to develop their own national policies and legislation, framed to a certain extent by the draft proposal for a horizontal framework for common European data spaces and the GDPR. Sectoral aspects, such as the types of data and modalities for access would not be addressed, leaving the access to and re-use of health data to a large part still fragmented, limiting the effectiveness of public health action such as in the case of infectious diseases (e.g. COVID-19) or rare diseases.

The cross-border provision of digital health services and products, such as tele-health, as well as AI applications in health and personalised medicine would remain limited and fragmented due to divergent national laws. Patients may have access to their data, but not necessarily in electronic format and their ability to transmit their data would remain limited.

For digital health services and products, particularly for those based on AI, questions on liability would remain. Different national rules would be applicable, hampering the development and deployment across Europe of digital health applications, including AI systems, in healthcare.

Policy options:

The Commission will assess different sets of measures in order to address the policy problems identified. Such sets of measures are gradual in their level of intervention, ranging from voluntary guidance to mandatory provisions, from implementation at national level to EU level or a combination thereof, and from funding at EU, national and/or private level.

Objective 1: Ensuring access, sharing and use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, transparent and trustworthy way:

a) Establishing an appropriate legal and governance framework to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities.

Options will cover governance mechanisms for primary and secondary use of health data. The scope and mandate of the voluntary eHealth Network could be revised. Complementing the Data

Governance Act, the designation of national digital health bodies, which would be the sectoral counterparts of authorities supervising data intermediary services and working on interoperability, will be analysed. Moreover, in the same framework, sectoral bodies dealing with secondary use of health data, including data altruism, could be set up at national level and could be brought together at EU level. Coordination mechanisms could be created between the two. Options will also explore: support for public authorities (e.g. medicine agencies, epidemiological institutions, national health institutes, HTA bodies, EMA, ECDC) for accessing health data and supporting evidence-based decision-making, in full compliance with data protection rules; access to genetic data and the link with health data; options concerning re-use of data held by private data holders; and options concerning the support for training and testing of AI health applications. The interplay with the GDPR, in particular articles 9 and 89, with regard to regulation of health data will be carefully explored.

b) Lowering technical barriers hindering data use and re-use, in particular those related to infrastructure, interoperability, data quality and standards in the health field.

Options on infrastructure for use of data for healthcare will be explored building on the eHealth Digital Service Infrastructure (MyHealth@EU) for the cross-border exchange of patients' data when traveling abroad. Options will be examined regarding strengthening the interoperability of electronic health records, in line with the European Electronic Health Record Exchange Format, as well as semantic and technical interoperability of different types of data. Concerning access to data for research, policy-making and regulatory purposes, options will cover different models for interoperable data access infrastructures, including European federated cloud, and related services to facilitate secure, cross-border storage, processing and analysis of health data. The link with other infrastructures, such as those developed under the 1+ Million Genomes initiative, will also be explored.

c) Ensuring access and control of patients and citizens over their own health data.

Options will be explored from establishing a right to portability of health data for citizens to mandating the development of specific tools to facilitate citizens' access to and portability of their own health data, including citizen-generated data.

Objective 2: Fostering a genuine single market in digital health covering digital health services and products, including tele-health, tele-monitoring and mobile health:

Options will investigate ways to remove barriers to the cross-border movement of digital health services and products, including data-intensive ones, as well as the rights of patients to benefit from those services and products, and their interoperability with electronic health records and healthcare systems.

Objective 3: Enhancing the development, deployment and application of trustworthy digital health products and services, including those incorporating artificial intelligence in the area of health:

Options will be analysed on liability rules related to the use of data-intensive digital health services, including those incorporating artificial intelligence, also complementing the horizontal initiatives on artificial intelligence.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

A common legal, governance, data quality and interoperability framework, while requiring some economic investments from Member States and relevant stakeholders, will benefit patients, healthcare professionals, policy makers, regulators, researchers and innovators in the area of health at large.

The initiative is expected to facilitate the deployment of innovations that can increase the cost-effectiveness for patients and healthcare systems by shortening the time of diagnosis, optimising treatment options, avoiding duplication of tests and efforts, reducing medical errors, reducing inefficiencies in healthcare, facilitating personalised medicine, improving the effectiveness of prevention programmes, improving the monitoring of medicinal products and medical devices effectiveness and safety and facilitating epidemiological surveillance.

This initiative aims at increasing significantly the capability of researchers, policy-makers and regulators to access health data, both at national and trans-national level.

The initiative is expected to boost innovation by reducing barriers and facilitating easier access to health data for re-use. It will create opportunities for innovation that could better support the

achievement of public health priorities, as well as a stronger market for EU health technology companies and digital products and services in the EU. Such innovation opportunities are also expected to increase competitiveness in the health sector. The benefits of increasing coordinated access to health data range from lower technical costs to lower time to develop new health innovations.

The initiative will improve the achievement of the Single Market by removing barriers to cross-border provision of digital products and services in the area of health, including to the benefit of SMEs. The initiative will support the uptake of new AI-based services and products to facilitate amongst others treatment and preventive strategies, which in turn will contribute to growth and investment by relevant stakeholders, resulting in a positive macroeconomic effect.

The promotion of digital transformation in healthcare is also expected to reinforce the sustainability and cost-effectiveness of healthcare systems. The initiative will likely improve the availability and quality of data in the healthcare sector, leading to fewer errors, less duplication of efforts and better medical outcomes.

The implementation of the European Health Data Space initiative and the digital transformation of health and care will be supported with EU funding under the next Multiannual Financial Framework (Recovery and Resilience Facility, European Regional Development Fund, European Social Fund+, Invest EU, EU4Health, Digital Europe Programme and Horizon Europe) and should also benefit from national investments.

Likely social impacts

The initiative will improve access to healthcare and reduce inequalities, notably by removing obstacles to the free movement of digital health and data-intensive services and products, more specifically:

- it will support research on new preventive strategies and on effective treatments and medical devices, thus contributing to improving citizens' health and their quality of life (for example by supporting the implementation of the Europe's Beating Cancer Plan and the pharmaceutical strategy);
- it will improve the access to innovative healthcare services throughout Europe, enhance the provision of high-quality cross-border healthcare and the protection of patients while travelling abroad;
- it will facilitate the adoption of digital technologies in health, in particular AI, which can play a role in helping clinicians and other healthcare personnel work more efficiently and overcome staff shortages (for example, in medical deserts), as well as provide remote care where needed;
- it will also reduce unnecessary tests by supporting patients to share their health data with their healthcare providers; the initiative is likely to support the free movement of people and support patients travelling or living abroad, or seeking medical advice abroad; and
- by implementing measures to enhance the control of citizens over their health data, this initiative will contribute to increasing the trust of citizens over digital health services and products.

The further digitalisation of the healthcare sector will require the development of new skills for workers in this area which they can acquire through relevant training, lifelong learning and educational curricula. Therefore, the initiative should be complemented by EU and national funding to support such training needs.

Likely environmental impacts

By enhancing interoperability, re-use of health data and the portability of patients' data, the initiative will improve the efficient use of resources and data (e.g. by reducing unnecessary tests and visits of patients to hospitals). Digitalisation in healthcare increases the sector's environmental footprint. Yet, by enhancing interoperability, re-use of health data and the portability of patients' data, this initiative will improve the efficient use of resources and data (e.g. by reducing unnecessary tests and visits of patients to hospitals), which will have a positive effect on the environment.

Likely impacts on fundamental rights

The re-use of health data held by the healthcare sector bears inherent risks that require appropriate safeguards, in particular as regards individuals' rights to privacy and data protection and the security of such data.

Since several elements of this initiative relate to the processing of personal data, and in particular special categories of personal data, the measures will need to pay particular attention to ensuring

full compliance with the data protection legislation.

By promoting the application of patients' rights and easier access and portability of their health data, the initiative will also reinforce individuals' rights.

Further, the initiative is expected to contribute to strengthening the free movement of patients' within the EU.

Likely impacts on simplification and/or administrative burden

The proposed measures are necessary to reduce administrative burden for researchers, healthcare providers and national authorities, who are currently faced with very diverse, fragmented and decentralised systems for accessing health data, which renders difficult cross-border scientific research in the health area. At the same time, the possibility of patients to have their data transmitted between healthcare providers is likely to reduce unnecessary tests, with important impacts on the healthcare sustainability.

It will reduce inconvenience for patients by supporting the data transmission and portability and it can facilitate cross-border healthcare and competition between healthcare services.

Administrative burden will be assessed with other costs of the policy options considered for different stakeholders, including public bodies, policy makers, healthcare organisations, regulatory bodies and organisations carrying out research (whatever their legal status as public or private organisations). The proposed measures to facilitate access to health data will require additional expertise and resources in the public sector.

It is also expected that trade-offs between administrative burden for operators and positive health and research benefits exist and will be taken into account in the analysis. The more intensive use of health data and digital workflows, through digital health services and products is expected to reduce errors, duplication of clinical procedures and shorter procedures for approval of innovative digital health solutions, leading to a reduction of the administrative burden in healthcare systems.

D. Evidence base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will help to prepare the policy initiative, supported by an evidence collection exercise and a stakeholder consultation process. The impact assessment will be supported by several ongoing and planned studies to be finalised by mid-2021. The impact assessment will also benefit from substantial consultation actions some of which have already started in 2020.

Evidence base and data collection

The evaluation and impact assessment will be supported by:

- A study supporting the Impact Assessment.
- A study on the "Assessment of the EU Member States' rules on health data in the light of the General Data Protection Regulation", which will provide an overview of the legal and technical modalities applicable to health data sharing in the Member States and the governance mechanisms established to facilitate third parties' data access for re-use.
- A study on the regulatory gaps to cross-border provision of digital health services and products, including artificial intelligence and the evaluation of the existing framework for cross-border exchange of health data.
- A study on the use of Real World Data
- An analysis of different IT infrastructure and data governance options.
- The EDPS opinion on the European Health Data Space, the forthcoming EDPB guidelines on research in the field of health (if available) and other relevant EDPB guidelines.

Costs and benefits of the existing system, the baseline and the policy options will be mapped. The identified costs and benefits, as well as the impact on administrative burden, will be quantified to the extent possible, based on data and information collected through desk research and consultation activities with the interested stakeholders. The most significant environmental, social, and economic impacts of the considered options as well as implications for fundamental rights will be assessed and compared.

Consultation strategy

The Commission will consult all relevant stakeholders through public and targeted consultations to gather data and opinions. Stakeholders that will be consulted include, but are not restricted to,

national public health, digital health and data protection authorities, public and not-for-profit organisations as well as private for profit organisations active in the area of health, patients/citizens, economic actors and their professional associations (e.g. healthcare professionals, health tech sector, digital sector, scientific research), and scientific experts. The objective is to gather stakeholders' views on the achievements of the cross-border healthcare Directive, implementation and application problems and their underlying causes and on possible ways forward and their impacts.

Several consultations in particular on data protection in the health sector have taken place in 2020.

An extensive consultation process will be undertaken including the following actions:

- A 12-week questionnaire-based, online consultation will be published on the Commission's 'Have your say' page, expected to start in quarter one 2021. It will be available in all official EU languages and give any interested party the possibility to contribute.
- A set of targeted consultation activities, including surveys, interviews and case studies, will be conducted with stakeholders in the context of the studies.
- Events with stakeholders (e.g. conferences, workshops, seminars) may also be organised during the evaluation and impact assessment phase to complement the consultation process.
- The Commission will also consult with the competent national authorities where relevant.

A synopsis report, summarising the results of all consultation activities will be published on the consultation page of the European Commission once all consultation activities are closed.

Will an Implementation plan be established?

Pending further analysis of the policy options, an implementation plan could be developed.