COCIR response to the European Health Data Space [1]
(combined roadmap/inception impact assessment)

COCIR welcomes the opportunity to provide feedback on the combined evaluation roadmap/inception impact assessment on the European Health Data Space.

COCIR is fully supportive of the European Data Strategy that aims to establish common European data spaces. There is the urgent need for a common European data space, which promotes timely access to health data for public and private research and better health outcomes, and offers measures for effective data sharing ecosystems. Already in November 2019, COCIR published its initial views[2] on a European Health Data Space.

COCIR therefore fully agrees the European Commission should make the European Health Data Space a key priority. The challenges in itself are not new, but the current COVID-19 pandemic crisis has clearly demonstrated the need and urgency of making concerted efforts and targeted investments, addressing existing barriers in accessing and sharing health data and providing all EU citizens equitable access to the best available care.

Now is a critical time to act and to ensure that Member States together with the European Commission take the lead in creating the European Health Data Space to make the most of the potential of digital health to provide high-quality healthcare for all in the EU.

For many years COCIR, as the leading industry voice on digital health, has been vocal on the identified challenges and has been coming up with constructive proposals and efforts to address these. COCIR therefore strongly supports the proposed objectives and the policy options under consideration.

Herewith COCIR would like to provide its detailed feedback to the various policy options that have been outlined.

Objective 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

a) <u>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</u>

- A clear and consistent legal and governance framework for the European Health Data Space, including governance mechanisms for primary and secondary use of health data, is needed. It should be coherent with other legislation, in particular on data protection and the future Data Governance Act and Data Act.

- Access to and exchange of health data remains very limited in the EU. This is due to the fragmented and diverging implementation of the General Data Protection Regulation, and

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space-
[2] https://www.cocir.org/fileadmin/Publications_2019/19106_COC_EU_Health_Data_SPACE_web.pdf

health data processing rules in Member States. This in turn reduces the EU competitiveness and innovation potential at a global level.

Health data processing rules and legislation differ from one country to another. For example, across the EU medical images without patient information should be considered as anonymised data for the purposes of scientific research and innovation. In some Member States medical images are not considered anonymised unless they are aggregated This interpretation is also maintained, even if no sensitive patient information remains linked to the image. This creates significant hurdles in Europe for the creation of machine learning capacity and medical software development, for which companies have to be able to process a large amount of high-quality health data.

- COCIR has contributed to the 2020 study organised on the assessment of Member States' rules on GDPR and the use of health data, and would welcome the publication of the outcome and/or recommendations to get a more comprehensive understanding of the legal implementations at the national level.

- In order to overcome the current fragmentation and create legal certainty and trust, the European Commission should, based on the assessment of Member State rules, carefully explore the interplay of the future EHDS proposal with the GDPR and the possibilities to address these issues, in particular with regard to health data for primary and secondary use. More harmonisation between Member States would enable to overcome the current fragmentation organisations face while at the same time rigorously protecting the rights of the citizens.

- In addition, data localisation and other data protection or healthcare-related rules defined at the local level that have similar crippling effects on the use and cross-border exchange of health data should be removed, where found to be unjustified. For example, if medical images without patient data were considered as anonymised, there would be no restriction in terms of data transfer and cross-border exchanges.

- There may also be an opportunity to streamline or remove local conditions on data processing for scientific research, which Member States may have implemented on the basis of GDPR Article 9(4) – as was also identified by the European Data Protection Supervisor[3].

- A better definition of 'secondary use' is critical today. The existing rules only allow a data processor or joint controller data access for the duration of a specific research project. This falls short of the ambition to turn research findings into new innovations that are made available to patients and doctors. For healthcare companies, engaging in research and innovation is for instance only meaningful when there is a possibility to access research data with the rights to post-process them for additional engineering purposes, which would eventually lead to the development of new health solutions.

- "Scientific research" should be better defined and extended in order to clarify that the term includes private companies doing research and product development. Global digital health research extends far beyond academic research conducted by public universities and academia. The lack of clarity of the term "scientific research" creates a lot of uncertainty for all market stakeholders.

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[3] https://edps.europa.eu/data-protection/our-work/publications/opinions/preliminary-opinion-82020-european-health-data-space_en

- Identified gaps should also be further addressed through a soft law approach, starting with guidance from the European Data Protection Board, including on the following non-exhaustive list of topics:

  o Guidelines on the concepts of personal data and non-personal data;
  o Guidelines on pseudonymisation and anonymisation techniques, specific to health data, including imaging;
  o Guidelines on processing of data concerning health for the purpose of scientific research and innovation
  o Guidelines on the use of genetic data
  o Guidelines on blockchain technology
  o Opinion on the roles and responsibilities of the parties involved within the context of the European Health Data Space, in particular as regards the identification of controllers and joint controllers (this has also been identified by the European Data Protection Supervisor in its preliminary opinion 8/2020 [4]).

- In addition, the European Commission may help identifying and bringing together stakeholders that would have an interest in exploring a Code of Conduct in accordance with GDPR Article 40 on health-specific topics (e.g. health research, anonymisation, mHealth, genetics,…)

- The data governance framework should define various scenarios for the use and exchange of health data. When defining the conditions for use, such framework should take into consideration the level of access to the data (identifiable, pseudonymised, anonymised) as well as other safeguards and privacy-enhancing technologies (synthetic data, federated learning models, secure multi-party computation). At all times, access to the data and accompanying restrictions should be non-discriminatory, proportionate and duly justified.

- The European Health Data Space and its data governance framework should be open to health data in the wider sense. For instance, data generated by or collected from wearable deivces, including consumer devices, have also potential clinical value and are important for research and innovation for digital health solutions.

- There should be a clarification for organisations regarding the rights and incentives to create or enrich specific databases (e.g. by annotating data). These may also include non-financial incentives, which for instance could take the form of rights to use and process the specific database.

- The data governance framework should further define rules for data sharing services and data altruism organisations specific to health.

- In particular, there would also be an opportunity to specify digital tools and consent mechanisms that would provide flexibility and granularity to the citizen in the most transparent and user-friendly way. Conditions could be defined to allow consent, where appropriate, for specific purposes or a range of trusted actors. A kind of broad consent could be introduced to facilitate the accessibility of data for processing activities that were not identified at the time of data collection, without increasing *consent fatigue*.

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[4] *ibidem*

- For the purpose of scientific research and innovation there is also a need for access to retrospective data. There should be clarity on the necessity and proportionality of obtaining consent, in particular where data has been pseudonymised.

- The data governance framework should consider the use and exchange of health data for various purposes, including the primary and secondary use of data, public health activities, validation and testing of data and models, uses for real world evidence, etcetera.

- Governance rules should entail both input and output processes, taking into account the interlinking of systems and the use of APIs. Appropriate consideration should be given to a clear and harmonised approach on data protection, cybersecurity, interoperability and data quality.

- The data governance framework should specify rules and procedures to ensure the accuracy and validity of data sets.

- Considering the involvement of various competent authorities, both at the EU and at the national level, it is paramount that strong coordination and consistency mechanisms are put into place. There may be an enhanced role for the eHealth network in coordinating the activities and oversight of the European Health Data Space.

- To maximise the potential of the European Health Data Space there should be opportunity to access and use data within the context of regulatory sandboxes, testing and experimentation facilities or digital innovation hubs.

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

Infrastructure
- A well-defined, common distributed data infrastructure is fundamental to facilitate a consistent and secure use and re-use of health data. Although multiple initiatives exist across Europe, there is a lack of standardisation and scale.

- To achieve the ambitions set out in the EU Data Strategy, the existing initiatives require pan-European participation and capacity to scale. For instance, the Gaia-X initiative is one of the leading examples that creates the foundation for a federated, open data infrastructure based on European values and a credible, trustworthy and trusted infrastructure for the hosting of the European Health Data Space. This is an example of an initiative that holds the potential of achieving the scale required to access and share health data securely and confidently, governed and controlled by each Member State in a consistent manner and should be embraced at EU level.

- In any case, in order to be successful any future federated infrastructure shall need to consider interconnectivity that takes into account legacy systems and other existing initiatives and data models, both from the public and private sector.

Interoperability, data quality and standards
- Achieving interoperability and seamless exchange of data and information is critical to the success of the European Health Data Space and improvements in clinical operations, patient outcomes and cost of healthcare.

- The interoperability of electronic health records, in line with the European Electronic Health Record Exchange Format, as well as semantic and technical interoperability should be

strengthened. The governance framework should prioritize standardization needs and improve data interoperability.

- There should be continuing efforts by the European Commission and the Member States to improve the uptake of interoperability, not only in terms of cross-border exchange, but equally important by increasing the intra-border capacity.

- These efforts should also extend to the swift introduction of new domains laid down in the Commission's recommendation on the European EHR exchange format and as currently being prepared within the X-eHealth project, as well as other relevant health data sets, such as genomic data.

- Standardisation should be a natural extension of existing structures, such as the eHealth Network and the Multi-Stakeholder Platform (MSP) for ICT standardisation, taking into account the reality of the existing global standardisation arena. This must be organised with due stakeholder engagement, in particular with industry and lead to articulation of harmonised demand-side priorities without interfering with standardisation program setting by SDOs, which are mostly private endeavors.

- Interoperability should be further incentivised through procurement processes and reimbursement procedures for digital health solutions. Establishing a European conformity assessment scheme for interoperability could help reduce the fragmentation and administrative burden of interoperability requirements when selling into multiple EU Member States. Such conformity assessment scheme could include learnings from programmes like EURO-CAS and should co-opt vendor-owned test labs by accepting their results under certain conditions, e.g. audit of test tools, witnessing testing from time to time, or random re-verification of a small share of the test cases.

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

- Citizens should be empowered to access and manage their own health data. The interoperability of electronic health records and digital health tools should be improved to fully deliver on the right to portability of health data for citizens and to provide the essential clinical information in a patient-friendly language. This is also needed to enable data altruism, where citizens can donate their health data to advance science and care – at scale across EU population.

- The European Commission should further explore tools (e.g. personal information management systems) and technologies (e.g. blockchain) that enable citizen-controlled management of their health data, while ensuring interoperability and connectivity with the wider healthcare environment, including for instance EHR systems or the European Health Data Space.

- The European Commission and the EU Member States should make efforts to ensure a more harmonised approach on identity within healthcare. Such initiative should leverage the eIDAS framework, the possibility of a digital EU electronic identity and ongoing developments in the area of self-sovereign identity management.

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

- The European Health Data Space should enable an equal playing field for application and service developers. European players, particularly SMEs, can take the lead in developing a frontier

market that has the potential to transform healthcare in Europe, and to set an example globally. This opens up a market for virtual healthcare services (e.g. e-consultations, e-interventions, telehealth, tele-radiology, remote care management), as well as for digital health science (e.g. clinical data trials, trustworthy and ethical artificial intelligence). The value created from access to European data pools is significant and ranges from developing new applications, to training AI algorithms, to providing better patient experience, to realizing operational efficiency gains. It will enable European players to scale and compete globally while contributing to the EU agenda of growth and jobs and to Europe's leadership in healthcare innovation in the global context.

- Companies lack expertise and resources to handle the multitude and complexity of national reimbursement processes, limiting the potential to scale up. The European Commission should perform a baseline measurement on market access conditions for digital health solutions as a first step for a coordinated action plan.

- The European Commission should facilitate information exchange and discussions between Member States on the use of clinical evidence for digital health solutions within reimbursement processes.

- The European Commission and Member States should, where possible, work on a uniform process to move from CE marking to reimbursement for digital health solutions. This could include also uniform approaches in terms of classification, procedures, documentation and evidence generation.

- The European Commission should explore with Member States the conditions for mutual recognition of digital health solutions, including mobile health applications.

- The European Commission and Member States should cooperate in establishing harmonised rules for public procurement building upon European or international frameworks and standards.

- As part of the revision of the Patient Rights Directive the European Commission should consider the possibilities and scenarios for reimbursement towards patients in case of cross-border digital health services.

- The European Commission should consider how to improve trust in digital health solutions, including increased knowledge and uptake by healthcare providers and healthcare professionals.

- The European Commission should make effective use of the instruments available under the Multi-Annual Financial Framework, including the EU4Health Programme, Digital Europe Programme, CEF Digital and others, to structurally improve the digital capacities and capabilities at national level to ensure equitable access to high-quality healthcare for all EU citizens.

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

- The existing EU legislation on the protection of fundamental rights, consumer protection as well as on product safety and liability remains relevant and applicable to a large number of existing and emerging AI applications. For instance, the EU Medical Devices Regulation (EU MDR) in combination with the General Data Protection Regulation (GDPR) already contain requirements

for AI in healthcare to be safe and performant. These requirements, both ex-ante and ex-post, ensure that medical devices based on AI are safe and performant throughout their entire lifecycle, including the management of changes in software.

- In order to facilitate the practical implementation of the existing legal requirements, COCIR supports the adoption of practical guidance, preferably accompanied by the development of international standards. For a detailed analysis of AI in the EU Medical Device legislation, we refer to the comprehensive analysis we have developed.

- COCIR shares the view that the existing regulations generally cover AI in healthcare in an appropriate manner. In any event, in case of still introducing AI specific provisions, it should be done very carefully not to create conflicts or duplications between the various regulations and new barriers for the development of AI-supported medical devices. Therefore, any potential gaps should be clearly identified, assessed and, if needed, addressed, always taking into account the existing regulations to ensure legal consistency and certainty.

COCIR remains fully committed to work with the European Institutions, the Member States and other involved stakeholders in setting up a European Health Data Space to the benefit of European citizens, industry and society.

COCIR publications
COCIR AI Use Cases (last updated December 2020)
COCIR Market Access Pathways for Digital Health Solutions (November 2020)
COCIR Analysis on AI in Medical Device Legislation (September 2020)
mHealth: COCIR recommendations for an effective deployment (June 2020)
The vital role of Artificial Intelligence in a time of COVID-19 (June 2020)
European Health Data Space: Towards a better patient outcome (November 2019)
Artificial Intelligence in Healthcare (April 2019)

COCIR responses to consultations
COCIR response on an EU digital ID scheme (October 2020)
COCIR response on Artificial Intelligence – ethical and legal requirements (September 2020)
COCIR response on Open Data – Availability of Public Datasets (August 2020)
COCIR response on the data governance framework of common European data spaces (July 2020)
COCIR response to the White Paper on Artificial Intelligence (June 2020)
COCIR input on the European Strategy for Data (May 2020)
COCIR response on the application of the General Data Protection Regulation (April 2020)

About COCIR
COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries. www.cocir.org