COCIR INPUT ON THE EUROPEAN STRATEGY FOR DATA

COCIR welcomes the opportunity to provide feedback to the European Strategy for Data as presented by the European Commission on 19 February 2020 [1].

COCIR appreciates that the European Commission is following through on its earlier commitments set out in its 2018 Communication "Towards a common European data space" [2].

Already in November 2019 COCIR published its White Paper "European Health Data Space: towards a better patient outcome" [3], laying out its preliminary views on how the creation of a European Health Data Space could be organised and how it could contribute to better patient outcomes.

COCIR fully shares the view that a European Health Data Space would greatly contribute to the development of preventive and personalised health care, driving research and innovation, leading to better outcomes for patients and the society as a whole.

Complementing its response to the survey questions, COCIR would like to emphasise the following points

- **Data governance**

Coordinated actions are needed to build a fitting data governance model. Legislation in certain areas can aid governance, providing legal certainty and clarity, promoting common data formats, and safeguarding the digital single market by preventing market fragmentation and data localisation measures.

Regulatory sandboxes should allow for an agile approach in testing and bringing to the market new innovative technologies.

Access to data - Access to data should be fair, transparent and non-discriminatory. Providers of data should ensure that data sets adhere to FAIR principles (findable, accessible, interoperable and re-usable).

Data sharing - The European Commission should make full use of the possibilities provided by the Open Data and Public Sector Information Directive, based on the principle of "as open as possible, as closed as necessary".

A comprehensive impact assessment should however be done before introducing mandatory data access rights, taking into consideration the sector-specific context, including competition issues and market failures.

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[1] https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age/european-data-strategy
[2] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=COM:2018:0232:FIN
[3] https://www.cocir.org/media-centre/publications/article/european-health-data-space-towards-a-better-patient-outcome.html

Data sharing should be further facilitated through data sharing template agreements and licenses.

Standardisation and interoperability - Common data standards will drive more interoperability and portability. The entire data value chain could benefit from a more harmonised approach. To fully realise the value of data it is also essential that data quality and data provenance are fully taken into account.

The European Commission and the Member States should encourage and incentivise this through tendering and procurement processes and by establishing technical roadmaps that support long-term planning and durability.

- **Enablers**

Investment in technical infrastructure – A pan-European technical infrastructure is necessary to provide equitable access to data. The European Commission and the Member States should leverage existing structures for national and cross-border exchange of data where possible.

The overarching platform should be technology-agnostic and modular, providing a general framework to which new collections of data can be connected via APIs.

Public-private partnership - The European Commission should support the proposed public-private partnership on health innovation under Horizon Europe that will offer a platform to advance health research, development and innovation through integration and exchange of data between public and private stakeholders.

The partnership can play an important role in promoting the pooling, integration and sharing of high-quality, harmonised, interoperable data with documented provenance.

- **Competences**

Investment in education and digital skills - The European Commission should mobilise funds, using the programmes available under the Multiannual Financial Framework effectively, to allow increasing and structural investment in education and digital skills.

COCIR is looking forward to the Commission taking an ambitious approach in the expected Digital Education Action Plan and the Skills Agenda for Europe.

- **Common European Data Space in strategic sectors**

Common European Data Spaces - The scope of data spaces should be well-defined to ensure new measures, ideally sector-specific, are assessed against the relevant applicable regulatory frameworks.

European Health Data Space - The potential of existing measures should be further explored. Structural weaknesses and inconsistencies should be addressed, for instance under the General Data Protection Regulation, in order to support innovative and cooperative ways of sharing data to advance scientific research and insights.

The establishment of a code of conduct for the processing of health data can enable a sector-driven approach that will help building a common understanding and trust among the healthcare industry, healthcare providers, healthcare professionals, patients and other stakeholders.

Importantly the European Commission and the Member States should also focus on the swift and accelerated implementation of actions on the European EHR exchange format.

- **Conclusion**

The ambition of the European Commission in its European Strategy for Data to establish a European Health Data Space will depend on the ability to overcome the current fragmented approach and to provide legal certainty in order to enable a trusted framework where all stakeholders feel confident in using and sharing health data, leading to better insights and health outcomes benefiting all.

The European Health Data Space needs to be an EU priority. The European Commission must strongly and structurally invest in infrastructure and people to expedite the digital transformation of health and care. It should encourage the development and uptake of common data formats and standards, and incentivise deployment of interoperable solutions and best data sharing practices.

Legal clarity and consistency are necessary to create a trusted framework with clear governance. Practical rules on data sharing and free flow of data between trusted parties (also non-EU) will be key in driving innovative health research that will ultimately benefit all EU citizens.

COCIR remains fully committed to working with the European Commission, the Member States and other involved stakeholders in taking the next steps, to bring forward the European Strategy for Data and the European Health Data Space.

Brussels, 31 May 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