

COCIR response to the consultation on the legislative framework for the governance of common European data spaces ¹

COCIR welcomes the opportunity to provide feedback to the European Commission's inception impact assessment on a legislative framework for the governance of common European data spaces.

COCIR has presented its views on the European Strategy for Data² and is fully supportive of the creation of common European data spaces, and in particular a European Health Data Space, which would greatly contribute to the development of preventive and personalised healthcare, driving research and innovation, leading to better outcomes for patients and the society as a whole.

COCIR fully endorses the Commission's view that

- the use and sharing of data has a crucial role in addressing the ongoing COVID-19 pandemic crisis
- the availability and access to data holds immense potential for innovation and value creation
- horizontal measures should be further supported by EU funding programmes and sector-specific measures

The development of many products and services is based on data availability. An EU level action is required to maximise the potential and to adequately address cross-border challenges that exist in healthcare and health research, as also experienced during the current pandemic crisis. The creation of common European data spaces should therefore be a priority.

COCIR would like to stress that the successful creation of the common European data spaces, and a European Health Data Space, relies on the adequate level of investment. In light of the ongoing negotiations on the Multiannual Financial Framework and the Next Generation EU, and more specifically the agreement reached during the most recent EUCO Summit, it is of utmost importance to ringfence significant funds to realise the European Strategy for Data through the various instruments.

When designing the future governance framework for the common European data spaces, COCIR encourages the Commission to consider the following elements in each of the actions identified:

- To unlock value from data held by public sector bodies
 - **Reassess** and update the thematic areas specified in the Open Data and Public Sector Information Directive in order to include healthcare-specific public data, based on the principle of "as open as possible, as closed as necessary" and in adherence to FAIR principles, making data findable, accessible, interoperable and re-useable.
 - **Ensure** access to data and free movement of data across the EU and beyond in a fair, transparent and non-discriminatory way, in full compliance with privacy rules.
 - **Remove** data localisation restrictions at Member State level which are not in line with the standards established by EU data protection laws.

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12491-Legislative-framework-for-the-governance-ofcommon-European-data-spaces

² https://www.cocir.org/fileadmin/Position_Papers_2020/COCIR_input_European_Strategy_for_Data.pdf



- To support the voluntary data sharing for the common good
 - **Facilitate** a more user-centric approach, highlighting available and trustworthy initiatives, that will make it easier for individuals to share data, if they wish to do so, in full compliance with the GDPR.
 - **Establish** common European structural and technical means that accommodate more cooperative ways of sharing data, for instance through broad consent mechanisms and personal information management systems.
 - **Step up** efforts to earn citizens' trust, educate and make them aware of the benefits that data sharing can bring to their lives and health and wellbeing.
- To tackle interoperability and standardisation issues
 - **Prioritise** standardisation needs and improve data interoperability through a natural extension of existing structures, such as the MSP on ICT standardisation, taking into account the reality of the existing global standardisation arena which involves European and international standards development organisations as well as relevant industry consortia.
 - Organise due stakeholder engagement, in particular with industry, that should lead to
 articulation of priorities without interfering with standardisation program setting by SDOs,
 which are essentially private endeavours that enable broad consensus and acceptance of
 best practices and state-of-the-art.
 - Incentivise deployment of interoperable solutions and best data sharing practices
- To set up structures for data sharing
 - **Foster** novel intermediaries that can support business-to-business data sharing with a range of services such as match-making, offering dedicated sharing platforms, including technology on controlled access and use, as well as legal support. Such data trusts can take the form of EU consortia which make data accessible, develop AI and virtual services, and create insights for the public good.

Whereas all of the above constitute recommendations that will help drive the ambitions of the European Data Strategy and the success of the common European data spaces, COCIR strongly believes that it is essential to

- 1. **Create** a trusted framework that overcomes the current fragmented approach and provide legal certainty on the use and sharing of data (including secondary use of data, public interest, and research and other purposes)
- 2. **Promote** a strong interoperability culture, based upon FAIR principles, incentivising the deployment of interoperable solutions and best data sharing practices, supported by industry-accepted standards
- 3. **Invest** significantly in infrastructure and people to expedite the digital transformation needed to fuel the potential of common European data spaces.

COCIR remains fully committed to work with the European Institutions, the Member States and other involved stakeholders on the realisation of common European data spaces.

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COCIR References

COCIR input on the European Strategy for Data European Health Data Space – Towards a better patient outcome

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

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