



**U.S. CHAMBER OF COMMERCE**

## **U.S. Chamber of Commerce Comments concerning the European Commission Consultation on European Health Data Space**

The U.S. Chamber of Commerce (Chamber) welcomes the opportunity to provide the European Commission with comments on its Digital health data and services – the European health data space survey.

The Chamber is the largest business advocacy organization in the world, operating in all 50 states and in over 50 countries to promote free enterprise and advance American trade and investment globally, representing companies of every size and from every sector, working with state and local Chambers and over 100 AmChams around the world. The Chamber is a longtime advocate for strong commercial ties between the United States and the European Union. According to a Chamber study jointly commissioned with AmCham EU, the U.S. and EU are jointly responsible for more than one-third of global GDP, and transatlantic trade and investment supports 16 million jobs on both sides of the Atlantic. The Chamber is also a leading business voice on digital economy policy, including on issues of data privacy, cross-border data flows, cybersecurity, digital trade, artificial intelligence, and e-commerce. In the U.S. and globally, we support sound policy frameworks that promote data protection, support economic growth, and foster innovation.

Technology holds enormous benefits to enhance our ability to innovate and deliver health care. Whether applied to the research ecosystem for new medicines, the infrastructure of clinics, hospitals, and health care centers, or to the models for delivering health care information and services to rural populations, digital health technology utilization is central. As the European Commission develops its strategy for the health data space, policymakers have a critical opportunity to craft an approach that: boosts Europe’s digital and data-driven competitiveness, improves its attractiveness to foreign investors, catalyzes R&D in support of public health, facilitates strong economic growth, and, most importantly, improves the lives and health of European citizens. The COVID-19 pandemic and economic crisis amplify the importance of the choices that the EU faces. Our high-level recommendations for your consideration are below.

### **General Recommendations**

A health data space built on the principles of contractual freedom, appropriate patient privacy and IP protections, voluntary data sharing, and an open international data transfer regime would advance Europe’s digital transformation, drive public health outcomes, and support economic growth. Such a framework would embrace a multi-stakeholder approach to data governance, support and leverage global, consensus-based standards to incentivize data sharing of all kinds.

The digital health data space should maintain an open architecture, enabling the international exchange of health data—and be open to market competition for the cloud services needed to operate them. Importantly, the protection of trade secrets and intellectual property rights, especially for data shared in these new data spaces, will be essential to maintain a competitive environment.

Overly complicated and prescriptive regulations should also be avoided so that data-driven start-ups will be able to comply and benefit from these ambitious projects. Further, a one-size-fits-all regulatory approach for industries will undermine European competitiveness and depress economic

growth and job creation across the Single Market. Instead, sectoral regulators must be empowered to clarify and ease requirements wherever possible to encourage and enable data sharing.

The 2020 European Commission [Data Strategy paper](#) referred to private sector data in ways that suggest that the EU might decide to designate data for public use at some point in the future. There are real potential downsides here. For example, compulsory disclosure of data collected during clinical trials and long-term research projects would jeopardize significant data generation investment from life sciences companies, thereby disincentivizing future R&D in Europe and preventing the development of innovations to help patients. Data sharing in the health sector—as in other sectors—should be strictly limited to a voluntary basis and should be done through privately negotiated contracts. Obligations to share data on a mandatory basis must be avoided, and we call on policymakers to shape future criteria for data sharing in a proportionate manner and to allow for an ongoing dialogue with all relevant stakeholders.

### **Standards Policy in Support of Open and Competitive Markets**

The Chamber works to advance important standards policy in support of open and competitive markets. The development of global standards in collaboration with the private sector is the best way to promote common approaches that are technically sound to deliver on technology solutions and policy objectives.

Data standards are the principal component of health informatics that allow the flow of information through the healthcare infrastructure and are critical to the process of data sharing as technical standards support syntactic and semantic interoperability. We note the recent [E.U.-U.S. Summit Statement](#) which calls for the promotion of “collaborative research and innovation exchanges” between research funding agencies and “intent to explore the possibility of developing a new research initiative on biotechnology and genomics, with a view to setting common standards” through a new collaboration between the EU Joint Research Centre and the U.S. National Institutes of Standards and Technologies.

The proactive sharing of implementation concepts and practices that correspond to common data quality, cybersecurity and other interoperability standards on which healthcare professional can rely is important. Harmonized data standards will improve patient safety, efficiencies and security, as well as facilitate clear communication enabling data exchange across organizations and borders. The Chamber encourages the Commission to leverage public-private partnerships in developing policy by incorporating consensus-based standards, available accreditation schemes, and globally recognized practices to meet EU compliance interests.

### **An Open, Balanced, and Predictable Data Protection and Data Transfer Regime**

The *General Data Protection Regulation* serves as the foundation for data governance in the European Union. As written, GDPR serves as a unified data protection framework equally applicable across the Single Market. In practice, however, derogations by member states and divergent interpretation and enforcement by national supervisory authorities have fragmented the EU’s data protection landscape. An EU health data space should balance the need to provide high-standard data protection outcomes for European citizens, while also enabling data sharing to promote innovation in the health care sector. Predictable, risk-based interpretations of GDPR are necessary to strike this balance, including processing personal information under the legitimate interest and public interest bases.

Cross-border data transfers are essential to advancing digital healthcare, public health, and data governance more broadly. Health and life sciences manufacturers rely on cross-border data flows and would benefit significantly from a well-designed European health data space. These companies rely heavily on sharing clinical trial data and multijurisdictional research for drug discovery and health-related innovation. Cross-border data flows facilitate much of the basic and applied research that is critical to the successful development of novel therapies, medicines, and vaccines. This work has taken on even greater importance in light of the COVID-19 pandemic, and governments should maintain and enhance incentives to facilitate the development of technological solutions.

For the Health Data Space to fully achieve its goals –delivering the highest quality care to patients within the EU and driving global, cutting edge biomedical R&D initiatives – it is imperative that the Health Data Space be constructed to enable the international exchange of health data. An EU Health Data Space that does not clearly prioritize or address the need to ensure the global exchange of data may lead to suboptimal public health outcomes and may discourage, rather than encourage, greater global scientific R&D endeavors– an outcome clearly incongruent with the vision of the Commission’s Strategy for Data. Recognizing the breadth of the Health Data Space proposal and the immediate need to resolve intra-European data flows to support the healthcare within the EU, we encourage the European Commission Failure to address this specific concern may undermine the Commission’s ambitions with its Strategy for Data and the EU Health Data Space, compromising public health outcomes and R&D initiatives both within and beyond the borders of the EU.

### **Trade Secrets Protections and Intellectual Property Rights**

Effective IP protection has been the driving force behind substantial R&D investments that have enabled major technological advancements, and the creation of new therapies and vaccines. Without adequate incentives and effective enforcement of intellectual property rights, manufacturers and content producers likely would focus less of their R&D investment in Europe. The Chamber seeks to understand the health data strategy’s impact on companies’ ability to protect proprietary data, and we urge close consultation with the private sector before any revisions to the IP system are contemplated.

### **Conclusion**

Given the COVID-19 pandemic and the urgent need to revitalize our economies, the European health data space should advance digital transformation of healthcare in a manner that is open, facilitates voluntary data sharing to drive health-related R&D, and trade-enhancing. The U.S. business community is proud of its longstanding and substantial contributions to the transatlantic commercial relationship. American companies are eager to be part of the solution as Europe strives to build a robust digital economy, and we look forward to continuing out engagement with the Commission on this and other matters. Thank you for your consideration of our views.

### **Contact**

Marjorie Chorlins  
Senior Vice President for European Affairs  
mchorlins@uschamber.com / +1 202-463-5305  
EU Transparency Register: 483024821178-51