

## Consultation response

# Digital health data and services: the European health data space

AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €3 trillion in 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

The American Chamber of Commerce to the European Union (AmCham EU) shares the European Commission's view that EU-level action is required to address the fragmented environment of European health data, the lack of data available for (re-)use in scientific research and the need for increased uniformity in Member States' applications of data regulations.

AmCham EU notes the particular importance of data sharing to the life sciences and healthcare sectors. In order to remain globally competitive, European approaches to data must foster a life sciences ecosystem that can capitalise on innovative health technologies. This demands that large, representative and interoperable datasets are available to companies active in health and the life sciences to develop treatments, therapies, medical devices and technologies that are better suited to both individual and societal needs. The European Health Data Space (EHDS) initiative provides a platform for the development and use of such datasets through secure access to health data. It endeavours to bring together the many different elements in the ever-evolving area of digital health. AmCham EU submits the following recommendations for the initiative:

- Across all of the policy options presented in this Inception Impact Assessment, AmCham EU recommends that any proposed legislation balances the need for legal certainty with the flexibility the rapidly changing domain of data science demands, so that all market participants have maximum capacity to engage in and benefit from the EHDS. This will be best achieved through open, transparent and structured stakeholder involvement. The importance of international data flows for Europe's competitiveness, economic growth and innovation potential cannot be overstated.
- A great deal of work has already been undertaken by international and European standardisation bodies, fora and consortia to overcome the technical barriers hindering data use and re-use related to infrastructure, interoperability, data quality and standards in health. Therefore, AmCham EU urges the Commission to take full account of this work and stands ready to contribute to any discussions on initiatives to build on the existing body of work.
- Alongside legislative tools a marked effort is needed to foster a better culture of data sharing in Europe. To achieve this, open and inclusive data governance mechanisms and structures are imperative in addition to initiatives which increase digital literacy and public perceptions of data use. AmCham EU supports the Commission's ambition to improve citizens' access and control of their own data and urges the Commission to support initiatives to drive citizen education on their data rights in order to foster greater comfort with data altruism and the EHDS more widely.
- AmCham EU calls for more discussion at EU level on developing the role of data intermediaries with regard to common understanding about their nature, role and objectives.
- AmCham EU urges the creation of EU-coordinated 'national digital health bodies' alongside a wider consultation on the role and governance of such bodies.

AmCham EU is committed to continuing the dialogue with policymakers and stakeholders on the essential role of data to enact the digital transformation and achieve better health for all citizens.