The preparatory work for the Proposal for Regulation on the European Health Data Space (EHDS) took fully into consideration the state of play across Member States, including existing governance and level of digitisation. The proposal builds on the evidence gathered as part of the impact assessment and supporting studies, in particular on Member States’ rules on health data, existing regulatory gaps in the area of health data and digital health and interoperability of electronic health records.

The EHDS will rely on competent authorities designated by Member States. While addressing fragmentation and ensuring EU-level coherence, the EHDS will provide Member States with flexibility in terms of the degree of decentralisation they use for implementation and deployment of the EHDS. For example, Member States may decide whether to designate one or more health data access bodies and how to arrange their coordination.

The EHDS aims to build on rules that strengthen the control of citizens over their health data and incentivises their secure exchange across healthcare systems. It aims to use the common infrastructure building blocks developed in the context of common data spaces. The development of common cross-border data infrastructures and services will be supported by the EU4Health and Digital Europe programmes. Funding for development and deployment of cross-border and national cloud infrastructure interconnections is provided under Connecting Europe Facility (CEF) Digital programme.

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5 https://ec.europa.eu/health/funding/eu4health-programme-2021-2027-vision-healthier-european-union_en