

European Health Data Space

What You Need to Know

- The European Commission launched the European Health Data Space (EHDS), which forms part of the Commission's proposed wider "Data Strategy" to leverage quality data for use by public authorities and businesses across certain sectors and areas of public interest.
- The EHDS will provide a common framework across EU Member States for the sharing and exchange of quality health data (such as electronic health records, patient registries and genomic data) throughout the EU. According to the Inception Impact Assessment, the EHDS has the following three objectives:
 - **ensuring access, sharing and optimal use of health data** for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, timely, transparent and trustworthy way, and with appropriate institutional governance;
 - **fostering a genuine single market in digital health**, covering health services and products, including tele-health, tele-monitoring and mobile health; and
 - **enhancing the development, deployment and application of trustworthy digital health products and services**, including those incorporating artificial intelligence in the area of health.

Covington's experience in the life science sector enables us to understand not only the opportunities for the sector, but also the challenges and risks.

Why Does It Matter?

- In particular, the EHDS wants to ensure that electronic health records are secure and interoperable in order to allow for EU-wide healthcare services.
- The EHDS contains an important framework for the re-use of health data for a wide variety of purposes, including scientific research, product innovation and the development of algorithms. The health data made available include electronic health records, clinical trial data, medical device data, registries, etc. While the framework promises increased access to a tremendous amount of very valuable data, it also presents a challenge for all those that hold the data and would will be compelled to produce it.

Why Covington?

Covington's experience in the life science sector enables us to understand not only the opportunities for the sector, but also the challenges and risks. Our extensive experience in the field of protected confidential information and data privacy can help clients better assess the risks of having to open up data sets, but also the limitations on the allowed use of other data sets. Our public policy team is also well-positioned to help clients influence the legislative process.

For more information, please reach out to Kristof Van Quathem, Anna Sophia Oberschelp de Meneses, or another member of our team.



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