

Medidata and the EU Data Act



This Information Sheet is provided for informational purposes only and is not legal advice. Consult your own legal counsel if you have questions on how the EU Data Act applies to your organization.



Introduction

Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data, and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (together, the “EU Data Act”) sets out harmonised rules on fair access to and use of data. As part of the broader European Union data strategy, the EU Data Act aims to make it easier for individuals and businesses to access and share data generated through their use of products and services including SaaS applications.

The EU Data Act entered into force in January 2024 with key provisions coming into effect September 12, 2025. It grants European Union (EU) Customers additional rights with respect to the data inputted, outputted and generated using the Medidata Platform.

Frequently Asked Questions

How does this impact our services agreement with Medidata?

- The EU Data Act grants EU Customers additional rights with respect to switching to different data processing services. Medidata will comply with its obligations under the EU Data Act during the switching process initiated by an EU Customer.
- Medidata has adopted EU Data Act Terms, which EU Customers can access [here](#) in Medidata’s KnowledgeHub or by contacting their account representative. Our EU Data Act Terms apply to existing EU Customers as of September 12, 2025. New EU Customers can review these terms prior to executing a full service agreement with Medidata.

Where can I find information on the types of Exportable Data associated with Medidata products?

- EU Customers can find more information on how to export their data by visiting Medidata’s KnowledgeHub [here](#) and reviewing the documentation associated with their specific product portfolio. New EU Customers should consult with their account representative to gain access to the materials in Medidata’s KnowledgeHub as part of their review of Medidata offerings.
- Medidata already permits customers to download or export their data using commonly used formats such as CSV, XM, and JSON. Exportable Data is made available through GUIs in the Medidata platform or through our REST APIs.
- You can find more information on how to facilitate available data export using available tools for products within your portfolio by visiting Medidata’s KnowledgeHub [here](#).

What is the process for initiating the switching process to a different Data Processing Service?

- A summary of our switching process can be found [here](#) in Medidata’s KnowledgeHub.
- To initiate the process, an authorized legal representative from your organization must submit a formal written request in accordance with the switching process. The Initiation Period for switching will not begin until all necessary information has been provided to Medidata.

For more information on how the EU Data Act impacts your relationship with Medidata, please contact your account representative.