

## Exhibit: Medidata EU Data Act Terms

If Customer is eligible to exercise Switching rights under the EU Data Act as set forth in Section 2 (Application) below, these Medidata EU Data Act Terms shall be incorporated by reference into the Agreement.

### 1) Definitions.

- a) *“Agreement”* means the Medidata Services Agreement, Medidata Partner Agreement or other master agreement between Customer and Medidata.
- b) *“Applicable Sales Order”* means the applicable Sales Order for the related Medidata Data Processing Services under an Agreement.
- c) *“Customer”* means the legal entity, whether sponsor or CRO, that has executed the Applicable Sales Order governing the Medidata Data Processing Services subject to Customer’s Switching request.
- d) *“Customer Metadata”* means Medidata-generated metadata that is (a) directly related to Customer’s use of the Medidata Data Processing Service(s); (b) required by Medidata to operate and maintain the Medidata Data Processing Service(s); and (c) necessary for Customer to restore service functionalities in a destination provider of Data Processing Services or an On-Premises ICT Infrastructure.
- e) *“Data”* has the meaning given by the EU Data Act.
- f) *“Data Processing Service”* has the meaning given by the EU Data Act.
- g) *“Data Recovery Period”* means the period of at least thirty (30) calendar days from the end of the Migration Period until termination of the Agreement or withdrawal of Customer’s Switching Notice under Section 7(b).
- h) *“Digital Assets”* has the meaning given by the EU Data Act.
- i) *“EU Data Act”* means 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, available [here](#).
- j) *“Exportable Data”* has the meaning given by the EU Data Act (notwithstanding references to specific articles of the EU Data Act in the EU Data Act definition), which includes Customer Data as defined in the Agreement and Customer Metadata. Exportable Data excludes the following by definition: (1) Data not directly or indirectly generated or cogenerated by Customer’s use of the Medidata Data Processing Service(s); and (2) assets or Data protected by intellectual property rights, or constituting a Trade Secret, of Medidata or third parties;
- k) *“ICT”* means information and communication technology.
- l) *“Initiation Period”* means the period of thirty (30) calendar days from the end of the Intake Period.
- m) *“Intake Period”* means the period of fourteen (14) calendar days from the date of Customer’s submission of a Switching Notice.
- n) *“Medidata Data Processing Service”* means a Data Processing Service provided by Medidata, as referenced in Customer’s Applicable Sales Order (as may be updated from time to time), subject to certain provisions of the EU Data Act.
- o) *“Medidata’s KnowledgeHub”* means the documentation provided by Medidata, accessible [here](#).

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- p) “*Medidata Operational Data*” means Medidata-generated data (including metadata) that is (a) not directly related to Customer’s use of the Medidata Data Processing Service(s) and (b) derived from Medidata’s systems and operation of the Medidata Data Processing Service(s).
  - q) “Medidata’s Trust and Transparency Center” means the documentation provided by Medidata, accessible [here](#).
  - r) “*Migration Period*” means the period of thirty (30) calendar days from the end of the Initiation Period, as applicable in accordance with Section 7 (Switching Initiation and Process) and as may be extended in accordance with Section 8 (Extended Migration Period).
  - s) “*Month End*” means the last day of a calendar month.
  - t) “*Non-Personal Data*” has the meaning given by the EU Data Act.
  - u) “*On-Premises ICT Infrastructure*” has the meaning given by the EU Data Act.
  - v) “*Parallel Data Processing Service*” means a Data Processing Service offered by a different provider and procured by Customer for its own use in parallel with a Medidata Data Processing Service.
  - w) “*Personal data*” has the meaning given by the EU General Data Protection Regulation (Regulation (EU) 2016/679).
  - x) “*Processing*” has the meaning given by the EU Data Act.
  - y) “*Switching*” (or “*Switch*”) has the meaning given by the EU Data Act.
  - z) “*Switching Charges*” has the meaning given by the EU Data Act.
  - aa) “*Switching Completion Notice*” has the meaning given in Section 7 (Switching Initiation and Process) and takes effect as described in that Section.
  - bb) “*Switching Notice*” has the meaning given in Section 5 (Customer’s Decision to Switch).
  - cc) “*Trade Secret*” has the meaning given by the EU Data Act.
- 2) *Application*. These EU Data Act terms only apply (i) if the Customer address listed in the Applicable Sales Order is in the European Union and (ii) only with respect to Medidata Data Processing Service(s) subject to certain provisions of the EU Data Act. Pursuant to Chapter VI, Article 31 of the EU Data Act, Chapter VI Articles 23(d), 29, 30(1) and 30(3) do not apply to the custom-built portions of Medidata Data Processing Services.
- 3) *Compliance with EU Data Act*. Both parties will comply with their obligations under the EU Data Act related to Switching from the Medidata Data Processing Service(s), including cooperating in good faith as required by the EU Data Act.
- 4) *Customer’s Right to Switch*. Customer may, upon request, Switch from a Medidata Data Processing Service to a Data Processing Service offered by a different provider and/or port all Exportable Data and Digital Assets to an On-Premises ICT Infrastructure without undue delay during the Initiation Period and Migration Period. For clarity, this right to Switch will not prevent Customer from continuing to access the Medidata Data Processing Service(s) during the Data Recovery Period as described in Section 7 (Switching Initiation and Process).
- 5) *Customer’s Decision to Switch*. If Customer decides to Switch from a Medidata Data Processing Service as permitted in Section 4 (Customer’s Right to Switch), Customer must first notify Medidata of Customer’s decision by having a duly authorized representative submit the request, substantially in the form of Appendix A attached

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hereto, to [mdsol.NAM.dataprivacy@3ds.com](mailto:mdsol.NAM.dataprivacy@3ds.com) (the “Switching Notice”) and, if applicable, include the necessary details of any destination provider of Data Processing Services. Medidata may request more information from the Customer upon receipt of the Switching Notice.

- 6) **Medidata’s Switching Obligations.** If Customer submits a Switching Notice as described in Section 5 (Customer’s Decision to Switch), then Medidata will do the following during the Initiation Period, Migration Period, and Data Recovery Period, as applicable:
  - a) provide reasonable assistance to Customer and third parties authorized by Customer in the Switching process;
  - b) act with due care to maintain business continuity and continue the provision of the Medidata Data Processing Service(s) under the Agreement and Applicable Sales Order;
  - c) provide clear information concerning known risks to continuity in the provision of the ongoing Medidata Data Processing Service(s) under the Agreement and Applicable Sales Order;
  - d) maintain a continued high level of security throughout the Switching process, in particular for Exportable Data and Digital Assets during their export and during the Data Recovery Period, in accordance with applicable laws;
  - e) enable Customer, in a manner consistent with the functionality of the Medidata Data Processing Service(s), to export the categories of Data and Digital Assets described in Section 7 (Switching Initiation and Process); and
  - f) otherwise support Customer’s exit strategy for the relevant Medidata Data Processing Service(s) in accordance with our internal switching policies and procedures as summarized in Medidata’s KnowledgeHub, including by assigning a Medidata support agent during the Intake Period to coordinate Medidata’s assistance with the Switching process and by providing all relevant information.
  
- 7) **Switching Initiation and Process.** If Customer submits a Switching Notice as described in Section 5 (Customer’s Decision to Switch), then Customer will be responsible for initiating the Switching process (if applicable) during the Initiation Period with at least two (2) working days’ prior notice to its assigned Medidata switching agent, subject to the following:
  - a) if Customer has opted for Switching as described in Section 5 (Customer’s Decision to Switch) but does not initiate the Switching process in compliance with this Section by the end of the Initiation Period, then in relation to any Medidata Data Processing Service(s) covered by Customer’s decision:
    - i) neither a Migration Period nor Data Recovery Period will apply;
    - ii) Customer will be deemed to have withdrawn its Switching Notice (without limiting Customer’s ability to submit another one which will trigger a new Intake Period); and
    - iii) the Agreement and Applicable Sales Order will remain in force.
  
  - b) If Customer has opted for Switching as described in Section 5 (Customer’s Decision to Switch) and initiates the Switching process in compliance with this Section by the end of the Initiation Period, then in relation to any Medidata Data Processing Service(s) covered by Customer’s decision:
    - i) a Migration Period and Data Recovery Period will apply;
    - ii) the categories of Data and Digital Assets that can be exported during the Switching process are the Exportable Data as listed for each Medidata Data Processing Service outlined in Medidata’s KnowledgeHub, which may be updated based on Medidata’s evaluation of the Switching Notice;

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- iii) the categories of Data that are exempted from Exportable Data, without the exemption impeding or delaying the Switching process, are as follows:
  - (1) Data specific to the internal functioning of the Medidata Data Processing Service(s) that would, if exported, risk a breach of Medidata's Trade Secrets or a third party's Trade Secrets, namely Medidata Operational Data; and
  - (2) Data related to the integrity and/or security of the Medidata Data Processing Service(s) that would, if exported, expose Medidata to cybersecurity vulnerabilities;
- iv) as between the parties and without limiting any of Medidata's obligations under this Section, Customer will be responsible for:
  - (1) its storage of any copies of Data and Digital Assets (including Exportable Data) related to the Medidata Data Processing Service(s) outside Medidata's or Medidata's Subprocessors' systems;
  - (2) the security of any Data and Digital Assets (including Exportable Data) outside Medidata's and Medidata's Subprocessors' systems (including the security of Data and Digital Assets on systems managed or controlled by the destination provider of Data Processing Services or on Customer's own infrastructure);
  - (3) driving and managing the Switching process during the Initiation Period and Migration Period;
  - (4) all acts and omissions of third parties engaged by Customer in relation to the Switching process; and
  - (5) Undertaking to respect the intellectual property rights of any materials provided in the Switching process by Medidata as well as any of Medidata's trade secrets, and to provide access and to enable use of these materials to third parties mandated by Customer only insofar as necessary to complete the Switching process and only upon Medidata's explicit authorization;
- v) after the Migration Period:
  - (1) Customer may no longer migrate workloads or production data (or otherwise consume networking resources) for Switching purposes, but may complete other aspects of the Switching process such as data retrieval;
  - (2) Customer will:
    - (a) be responsible for notifying Medidata of Customer's successful completion of the Switching process by having a duly authorized representative submit notification [mdsol.NAM.dataprivacy@3ds.com](mailto:mdsol.NAM.dataprivacy@3ds.com) (a "Completion Notice") no earlier than the first day after the Migration Period and within one hundred and eighty (180) calendar days of the end of the Migration Period;
    - (b) be deemed to have terminated the Applicable Sales Order, with a minimum of thirty (30) calendar days after the date of Customer's submission of the Completion Notice, at the Month End following such minimum period;
    - (c) Customer shall be responsible for any remaining fees in the Applicable Sales Order, including without limitation any early termination fees as set forth in the Agreement; and,
    - (d) if Customer fails to submit a Completion Notice within one hundred and eighty (180) calendar days of the end of the Migration Period, Customer will be deemed to have withdrawn its Switching Notice at the end of such 180-day period (without limiting Customer's ability to submit another one);

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- (3) Medidata will notify Customer of any such termination and, subject to Section 9 (Customer's Partial Exit), fully erase all Exportable Data and Digital Assets generated directly by Customer or relating to Customer directly in accordance with the Agreement and Medidata's Data Processing Exhibit;
    - vi) Except for custom-built Medidata Data Processing Services as contemplated under Chapter IV, Article 31 of the EU Data Act, Medidata may impose Switching Charges on Customer reflecting the costs for Switching until January 12, 2027 which shall be calculated based on Medidata's costs incurred during the Switching process;
  - c) If Customer has opted for erasure as described in Section 5 (Customer's Decision to Switch), then in relation to the Medidata Data Processing Service(s) covered by Customer's decision:
    - i) if Section 7(b) also applies, then:
      - (1) a Migration Period and Data Recovery Period will apply as described in Section 7(b); and
      - (2) erasure of Exportable Data and Digital Assets will be governed by Section 7(b); and
    - ii) if Section 7(b) does not also apply, then:
      - (1) neither a Migration Period nor Data Recovery Period will apply;
      - (2) Customer will be deemed to have terminated the Applicable Sales Order at the end of the Initiation Period; and
      - (3) Medidata will notify Customer of such termination and, subject to Section 9 (Customer's Partial Exit), fully erase all Exportable Data and Digital Assets generated directly by Customer or relating to Customer directly in accordance with the Agreement, Applicable Sales Order and Medidata's Data Processing Exhibit.
- 8) *Extended Migration Period.* The Migration Period may be extended:
- a) by Medidata, if Medidata believes a Migration Period of thirty (30) calendar days is not technically feasible; notifies Customer during the Intake Period; and, in Medidata's notice, duly justifies the technical unfeasibility and defines an alternative Migration Period of no greater than seven (7) months; and
  - b) by Customer, if Customer wishes to have a longer Migration Period for any reason; notifies its assigned Medidata support agent during the then-current Migration Period; and, in Customer's notice, defines an alternative Migration Period.
- 9) *Customer's Partial Exit.* If, on the date of deemed termination of the Applicable Sales Order in relation to the Medidata Data Processing Service(s) under Section 7 (Switching Initiation and Process), Customer continues to use or order any other Services under the Agreement, Customer acknowledges that the Agreement will continue to apply to such other Services and agrees to defer full erasure under Section 7 (Switching Initiation and Process) of Data and Digital Assets necessary for provision of the separate Services.
- 10) *Unsuccessful Switching.* If the Switching process is not successfully completed, the parties will cooperate in good faith to identify the cause and achieve successful completion, enable a timely transfer of Data and maintain continuity of the Services. In particular, upon Customer's request, Medidata will support Customer in identifying the reasons for unsuccessful switching and, to the extent the reasons identified relate to Medidata's environment or Switching processes, advises how the technical problems identified can be solved. The rules applicable to Switching Charges apply to support provided by Medidata and other Medidata services referred to in this section. Customer may authorize a destination provider to act on its behalf.
- 11) *Unsuccessful Switching.* If the Switching process is not successfully completed, the parties will cooperate in good faith to identify the cause and achieve successful completion, enable a timely transfer of Data and maintain

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- 12) *Required Information.* Medidata will provide Customer with the following information and keep it up to date:
  - a) information about available procedures for Switching and porting to and from the Medidata Data Processing Service(s), including information about available Switching and porting methods and formats as well as restrictions and technical limitations known to Medidata, through Medidata's KnowledgeHub or equivalent successor tool;
  - b) details of all data structures, data formats, relevant standards and open interoperability specifications available or applicable for the Exportable Data referred to in Section 7(b)(ii) through Medidata's KnowledgeHub;
  - c) information about the jurisdictions to which the ICT infrastructure deployed for Data Processing of the Medidata Data Processing Service(s) is or may be subject is available at Medidata's Trust and Transparency Center; and
  - d) a general description of the technical, organizational, and contractual measures adopted by Medidata as provider of the Medidata Data Processing Service(s) to prevent international governmental access to or the transfer of Non-Personal Data held in the European Union, where such access or transfer would conflict with EU or EU Member State law, on Medidata's Trust and Transparency Center or through the Medidata Data Processing Exhibit referenced in the Agreement.
- 13) *Separate Rights.* Nothing in these EU Data Act terms will limit Customer's separate right to delete or export Customer Data in accordance with the Agreement or Medidata Data Processing Exhibit, or to terminate the Agreement in accordance with the termination provisions of the Agreement,
- 14) *Notices.* All notices given under this Section must be in writing in accordance with the above provisions by authorized legal representatives of Customer.
- 15) *No Additional Obligations.* Medidata has no obligations under Chapter VI of the EU Data Act or through these terms for offerings not in scope of the EU Data Act including non-production services or those not generally available. For avoidance of doubt, with respect to non-production, non-generally available or any custom-built services or highly configured services, Medidata shall not be obligated to:
  - a) Facilitate functional equivalence for third party Data Processing Services for Medidata Data Processing Services;
  - b) Develop new technologies or services to guarantee functional equivalence in, or interoperability with, an environment other than Medidata Data Processing Services; and,
  - c) Rebuild any Medidata service within the infrastructure of a destination provider.
- 16) *Interoperability.* Unless Customer has submitted a Switching Notice as described in Section 5 (Customer's Decision to Switch) for the relevant Medidata Data Processing Service, Customer may export Data from a Medidata Data Processing Service to a Parallel Data Processing Service as described in Medidata's KnowledgeHub (as may be updated from time to time), subject to the following:
  - a) subsections (b) and (d) of Section 6 (Medidata's Switching Obligations) and subsections (b) (i), (iii) and (iv) of Section 7 (Switching Initiation and Process) will apply mutatis mutandis to facilitate interoperability for the purpose of such parallel use of Data Processing Services; and

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- b) if Medidata imposes any data egress charges for such Data exports, Medidata may do so only in accordance with the provisions relating to such charges under the EU Data Act.
- 17) *Compliance Review.* Medidata may monitor or review the movement of Data or Digital Assets away from a Medidata Data Processing Service to verify that Customer's Switching process or Data export complies with this Section.
- 18) *Availability and Changes to EU Data Act Terms.* Medidata may update these terms to adopt any model clauses endorsed by the European Commission, or to make additional clarifications based on regulatory or legal guidance issued after September 12, 2025. Customer may store and reproduce this Section at any time by printing (and/or saving) these Medidata EU Data Act terms as a PDF or requesting a copy from their account representative.

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Appendix A  
Sample Switching Notice

Name of Customer:	
Agreement:	<i>(ex, Medidata Services Agreement, dated [__])</i>
Switched Services:	<i>(ex, all Services covered by the Agreement) or (list explicit Services subject to Switching if only part of the Services are to be covered by Switching)</i>

[OPTION 1]

On behalf of the Customer, I/we inform you that the Customer initiates switching of the switched Services as of *(specify starting date)*. The notice period is *(specified by the Customer: maximum two months, may be shorter at the Customer's discretion)*.

[OPTION 2]

On behalf of the Customer, I/we inform you that the Customer initiates switching of the following services: ...

[OPTION 3]

The Customer informs you that it intends to switch to *(details of new provider/on premise infrastructure of Customer)*.

Contact details of person responsible for switching: *(details of Customer's representative responsible for switching process)*.

\_\_\_\_\_

*[signature of Customer's authorized representative]*

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