



Brussels, **XXX**
[...](2026) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

laying down the minimum metadata elements and their characteristics to be provided by health data holders for dataset descriptions for the secondary use of electronic health data under Article 77(1) of Regulation (EU) 2025/327 establishing the European Health Data Space

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847¹, and in particular Article 77(4), first sentence, thereof,

Whereas:

- (1) Article 77(1) of Regulation (EU) 2025/327 requires health data access bodies to make publicly available dataset catalogues with description, in the form of metadata, of the datasets available for the secondary use of electronic health data, including information on the source, scope, main characteristics and nature of the electronic health data in the datasets and the conditions for making those data available.
- (2) For that purpose and in accordance with Article 60(3) of Regulation (EU) 2025/327, health data holders are to communicate to the health data access bodies such a description of the dataset they hold, irrespective of whether the datasets contain personal and/or non-personal electronic health data.
- (3) In accordance with Article 60(3) of Regulation (EU) 2025/327, health data holders are required to verify, at least annually, that dataset descriptions are accurate and up to date. This is essential to ensure the reliability and usability of dataset catalogues for the secondary use of electronic health data.
- (4) As provided for in Article 77(1) of Regulation (EU) 2025/327, dataset catalogues are to be standardised and machine-readable, in order to ensure semantic and technical interoperability across Member States. This is necessary to enable the interconnection of national dataset catalogues and dataset catalogues of authorised participants into the EU dataset catalogue established under Article 79 of that Regulation. Health data holders should therefore use a common approach to metadata for dataset descriptions when providing the minimum metadata elements and the characteristics of those elements.

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¹ OJ L, 2025/327, 5.3.2025, ELI: <http://data.europa.eu/eli/reg/2025/327/oj>.

- (5) It is appropriate that the HealthDCAT-Application Profile (HealthDCAT-AP) is used as that metadata framework. HealthDCAT-AP builds on the general DCAT-Application Profile and is a technical specification developed and maintained by the Commission, specifically designed to support the description of health datasets made available for the secondary use of electronic health data. Those specifications are provided in accordance with the operational decisions of the relevant bodies established pursuant to Articles 92 and 95, within the governance framework of the European Health Data Space.
- (6) This Regulation contributes to the interoperability of digital infrastructures supporting the European Health Data Space, including those related to cross-border data access. An interoperability assessment has been carried out and the resulting report will be published on the Interoperable Europe Portal upon adoption of this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 98(1) of Regulation (EU) 2025/327,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down the minimum metadata elements for dataset descriptions, and the characteristics of those elements, that health data holders are required to provide to health data access bodies pursuant to Article 60(3) of Regulation (EU) 2025/327 for the secondary use of electronic health data, as well as the metadata framework to be used for that purpose.
2. This Regulation also applies, where relevant, to authorised participants in HealthData@EU when providing dataset descriptions in accordance with Regulation (EU) 2025/327.
3. This Regulation shall not prevent health data holders from providing additional metadata elements and their characteristics on a voluntary basis, using for that purpose the metadata framework referred to in the first paragraph.

Article 2

Definitions

For the purposes of this Regulation, the definitions in the HealthDCAT-AP referred to in Part A of the Annex shall apply.

Article 3

Requirements for minimum metadata elements

The list of the minimum metadata elements that health data holders shall provide for dataset descriptions, and the characteristics of those elements, is set out in Part B of the Annex.

Health data holders shall express the minimum metadata elements listed in Part B of the Annex by using the definitions, structure, cardinalities and controlled vocabularies set out in the HealthDCAT-AP referred to in Part A and C of the Annex.

Article 4

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 26 March 2029.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN



Brussels, XXX
[...] (2026) XXX draft

ANNEX

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to the

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ANNEX

Part A - Technical reference

The metadata framework referred to in Article 1 is based on the HealthDCAT-AP, which is maintained and made publicly available by the Commission¹.

Part B - Metadata elements

The elements listed hereafter shall be expressed using the technical specifications of the HealthDCAT-AP as referenced in Part A of this Annex. Where applicable, controlled vocabularies defined in HealthDCAT-AP must be used.

Property	Description
Access rights	Describes the level of access applicable to the dataset (e.g. public, restricted or non-public).
Applicable legislation	Identifies Union legal acts or national legislation that specifically govern the establishment, maintenance or availability of the dataset, where such legal acts or legislation exists.
Code values	Identifies classification systems or controlled vocabularies reflected in the content of the dataset (e.g. disease classifications, procedure classifications), where applicable.
Coding system	Identifies standardised coding schemes used to encode data elements within the dataset (e.g. ICD-10-CM, SNOMED-CT, DRGs), where applicable.
Contact point	Provides contact details for enquiries related to the dataset.
Conforms to	Identifies a standard or technical specification that defines the structural or syntactic organisation of the dataset as a whole.
Custodian	Identifies the organisation responsible for holding, managing and maintaining the dataset over time (health data holder).
Description	Provides a free-text summary describing the content and purpose of the dataset.
Distribution	Provides a technical representation or format in which the dataset is made available for secondary use.
Geographical coverage	Indicates the geographic area to which the dataset relates (e.g. Member State, region or EU-wide), where applicable.
Has personal data	Indicates whether the dataset contains personal data within the meaning of Article 4, point (1), of Regulation (EU) 2016/679 of the European Parliament

¹ <https://healthdataeu.pages.code.europa.eu/healthdcat-ap/releases/latest/>

	and of the Council ² .
Health data access body	The competent health data access body responsible for facilitating access to the dataset under the European Health Data Space, where the dataset is subject to restricted or non-public access.
Health data category	Identifies the categories of electronic health data contained in the dataset and listed in Article 51(1) of Regulation (EU) 2025/327.
Health theme	Indicates a high-level health topic or theme associated with the dataset (e.g. cardiovascular disease, cancer).
Identifier	Provides a unique and persistent identifier for the dataset (e.g. uniform resource identifier (URI), digital object identifier (DOI) or catalogue identifier).
Is structured	Indicates whether the dataset is structured, meaning that it is organised according to a predefined schema or model that defines its variables, attributes or fields.
Keyword	Provides keywords or tags describing the dataset and supporting search and discovery.
Language	Indicates the language or languages in which the dataset content is expressed.
Number of records	Indicates the total number of records contained in the dataset, where applicable.
Number of unique individuals	Provides an estimated number of unique natural persons represented in the dataset, where the dataset contains personal data and where applicable.
Provenance	Describes the origin, source or creation process of the dataset.
Publisher	Indicates the entity making the dataset available, which may differ from the creator or custodian.
Temporal coverage	Indicates the time period covered by the dataset (e.g. years of data collection), where temporal information exists.
Title	Provides the official name or title of the dataset.
Type	Indicates the general category or nature of the dataset (e.g. registry, administrative dataset, research dataset, synthetic dataset).
Variables	A structured description of the variables contained in the dataset, including, where applicable, the variable name, definition, data type, coding system or value domain.

² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <http://data.europa.eu/eli/reg/2016/679/oj>).

Was generated by	Identifies the activity or process through which the dataset was generated (e.g. registry, clinical study, administrative process).
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Part C - Controlled vocabularies

When providing dataset descriptions, health data holders shall use the controlled vocabularies listed below:

Metadata property	Controlled vocabulary	Source
Health data category	The categories listed in Article 51(1), points (a) to (q) of Regulation (EU) 2025/327	Article 51(1) of Regulation (EU) 2025/327

Where controlled vocabularies are required for the minimum metadata elements laid down in this Regulation, those defined in the HealthDCAT-AP, as referenced in Part A of this Annex, shall be used.