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COMMISSION STAFF WORKING DOCUMENT

Accompanying the Commission Implementing Regulation laying down the minimum metadata elements and their characteristics for dataset descriptions under Article 77(4) of Regulation (EU) 2025/327 on the European Health Data Space

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GLOSSARY

The explanations below are provided for ease of reading of this Staff Working Document. They do not replace or alter the definitions and legal provisions set out in Regulation (EU) 2025/327 or other applicable Union law.

Term or acronym	Meaning or definition
EHDS	European Health Data Space, established by Regulation (EU) 2025/327.
SWD	Staff Working Document accompanying the implementing act under Article 77(4) of Regulation (EU) 2025/327.
HDAB	Health data access body. A body designated under Article 55 of the EHDS Regulation to perform tasks related to access to electronic health data for secondary use, including the publication of dataset catalogues.
UHDAS	The service referred to in Article 75(2) of the Regulation, Union health data access service, which acts as the contact point for Union institutions, bodies, offices and agencies and is responsible for making electronic health data available for secondary use.
HealthData@EU	The cross-border infrastructure for the secondary use of electronic health data referred to in Article 75 of the EHDS Regulation.
DCAT-AP	Data Catalogue Application Profile. A common European metadata profile used to describe datasets, data services and catalogues in a consistent and machine-readable manner. It provides the broader metadata framework on which HealthDCAT-AP builds.
HealthDCAT-AP	The health-specific metadata profile building on DCAT-AP and used as the technical reference framework for dataset descriptions under the implementing act.
Dataset catalogue	A publicly available, standardised and machine-readable catalogue containing descriptions, in the form of metadata, of datasets available for secondary use.
Dataset description	Catalogue-level metadata describing a dataset, including information on its source, scope, main characteristics, nature and access-related conditions.
Metadata	Catalogue-level descriptive information about a dataset used to identify, understand, compare and search datasets.
Metadata element	A specific item of metadata required or supported in a dataset description, such as a title, description, contact point, health category, time span or information on variables.
Health data holder	An entity falling within the scope of the EHDS Regulation that holds electronic health data and is required, where applicable, to provide dataset descriptions to the relevant HDAB.
Health data user	A person or entity seeking access to electronic health data for secondary use in accordance with the EHDS Regulation.
Authorised participant	An entity referred to in Article 75(4) or (5) of the EHDS Regulation that is authorised to join and remain connected to HealthData@EU.

Secondary use	The use of electronic health data for purposes other than the initial purpose for which the data were collected, in accordance with Chapter IV of the EHDS Regulation.
Catalogue federation	The connection of national dataset catalogues and catalogues of authorised participants into the EU dataset catalogue referred to in Article 79 of the EHDS Regulation, enabling consistent and machine-readable search and comparison.
Controlled vocabulary	A predefined list of values used to ensure that metadata is expressed consistently across catalogues.
Interoperability	The ability of systems, catalogues or metadata descriptions to work together.
Variables	The main fields or variables represented in a dataset, where relevant.
Structured dataset	A dataset organised according to a predefined table, schema, model or similar structure.
Coding system	A classification, terminology or coding scheme used in a dataset, for example to describe diagnoses, procedures, medicines or other health-related concepts.
Provenance	Information on the origin of a dataset or the process through which it was generated.
One-off onboarding effort	The initial effort required to prepare and check an initial dataset description for inclusion in a catalogue.
Analytical metadata profile	A cumulative metadata profile developed for analytical and cost-modelling purposes in this SWD.
Cost proxy	An estimate used as the closest available approximation of the likely effort associated with the metadata requirements established by the implementing act.
Have Your Say feedback mechanism	The Commission feedback mechanism through which stakeholders could submit comments on the draft implementing act and its Annex.
ISC	Interservice consultation within the European Commission.
Administrative costs	Costs resulting from administrative activities needed to comply with the metadata requirements, in particular providing, entering, submitting or checking dataset descriptions.
Compliance costs	Costs directly linked to complying with the metadata requirements of the implementing act. In this SWD, compliance costs comprise one-off adjustment costs and administrative costs.

1. INTRODUCTION

1.1. Purpose of the Staff Working Document

This Staff Working Document accompanies the implementing act pursuant to Article 77(4) of the Regulation on the European Health Data Space (EHDS)[1]. The implementing act lays down a harmonised minimum set of metadata elements and their characteristics that health data holders are to provide for dataset descriptions and identifies HealthDCAT-AP as the metadata framework to be used for that purpose.

This SWD is not an impact assessment and does not reassess the policy need for the dataset catalogue obligation or the content of the implementing act. Its purpose is to provide a proportionate assessment of the incremental costs attributable to the metadata requirements established by the implementing act and to set out the evidence, assumptions and limitations underlying that assessment. The quantitative analysis focuses primarily on the effort required for health data holders to prepare initial dataset descriptions and for HDABs to check them.

The assessment is subject to important limitations. No complete and validated EU-wide inventory is available of the dataset descriptions that will be provided under Article 77 of the EHDS Regulation, and metadata maturity varies across Member States and health data holders. The available quantitative evidence primarily supports an estimate of the unit cost of preparing and checking an initial dataset description. The annual number of descriptions for newly added datasets and the effort required to verify or update existing descriptions cannot be aggregated reliably on the basis of the available evidence. Structural and system-level costs and the expected benefits are not monetised. Aggregate figures are therefore illustrative order-of-magnitude estimates and should not be interpreted as forecasts of actual future costs. Costs that cannot be quantified are not assumed to be zero.

The impact assessment accompanying the Commission proposal for the EHDS Regulation (SWD (2022) 131 final) [2] assessed the broader impacts of the EHDS framework, including the secondary-use framework and dataset catalogues. It did not assess in detail the incremental costs associated with the specific metadata elements and their characteristics, as those costs depend on the requirements established by the implementing act. This SWD complements that impact assessment without reopening the policy choices already made by the Union legislator.

To inform the cost assessment, the Commission used a targeted external expert assessment on metadata requirements and indicative onboarding effort. This work compared cumulative analytical metadata profiles of increasing completeness and

[1] Regulation (EU) 2025/327, OJ L, 2025/327, 5.3.2025, ELI: http://data.europa.eu/eli/reg/2025/327/oj

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52022SC0131

estimated the effort required to prepare and check an initial dataset description. The profiles are used solely as cost proxies for the measures included in the implementing act. They are not regulatory options and do not mechanically reproduce the legal requirements.

For the purposes of the cost analysis, the relevant functional roles are the preparation of dataset descriptions by health data holders and their checking or management by the competent catalogue authority. Where authorised participants, Union institutions, bodies, offices or agencies, or the Union health data access service perform comparable functions, similar categories of costs may arise. Separate aggregate estimates are not provided for those actors because the available evidence does not provide a basis for estimating the corresponding workload or volume of dataset descriptions.

The methodology, assumptions and limitations of the assessment are set out in Annex III. The relationship between the analytical metadata profiles and the measures included in the implementing act is presented in Annex IV. The standard Better Regulation cost tables and the assumptions used for administrative burden reporting are presented in Annex VI.

1.2. Legal empowerment under Article 77(4) of the EHDS Regulation

The legal empowerment for the implementing act is laid down in Article 77(4) of the EHDS Regulation. That provision empowers the Commission to adopt implementing acts setting out the minimum elements that health data holders are to provide for datasets and the characteristics of those elements.

This empowerment must be read together with Articles 77(1), 77(2) and 60(3) of the EHDS Regulation. Article 77(1) requires HDABs to make publicly available, through standardised and machine-readable dataset catalogues, descriptions in the form of metadata of the datasets available for secondary use. The description of each dataset must include information concerning the source, scope, main characteristics and nature of the electronic health data in the dataset, as well as the conditions for making those data available.

Article 60(3) requires health data holders to communicate a description of the datasets they hold to the relevant HDAB and to verify, at least annually, that their dataset descriptions are accurate and up to date. Article 77(2) also provides for a dataset catalogue for Union institutions, bodies, offices and agencies, to be provided by the Union health data access service.

The implementing act lays down a harmonised regulatory minimum for those dataset descriptions. It requires the minimum metadata elements to be expressed using the definitions, structure, cardinalities and controlled vocabularies set out in HealthDCAT-AP[3]. HealthDCAT-AP provides a health-specific, machine-readable application profile

[3] HealthDCAT-AP latest version

based on DCAT-AP and supports the consistent implementation and interconnection of national dataset catalogues and catalogues of authorised participants into the EU dataset catalogue referred to in Article 79 of the EHDS Regulation.

1.3. Scope and limits of the implementing act

The implementing act applies to dataset descriptions concerning datasets falling within the scope of Chapter IV of the EHDS Regulation, datasets containing personal and/or non-personal electronic health data relevant for secondary use. It applies to the minimum metadata elements provided by health data holders and, where relevant, to authorised participants in HealthData@EU when providing dataset descriptions in accordance with the EHDS Regulation.

The authorised participants referred to in Article 75(4) and (5) of the EHDS Regulation comprise health-related research infrastructures or similar infrastructures whose functioning is based on Union law, and which support the use of electronic health data for research, policymaking, statistical, patient-safety or regulatory purposes. Subject to the conditions laid down in Article 75(5), third countries or international organisations may also become authorised participants. Where Union institutions, bodies, offices or agencies hold electronic health data falling within Chapter IV, their dataset catalogue is provided by the Union health data access service in accordance with Article 77(2).

The implementing act establishes a binding minimum set of catalogue-level metadata. Information on dataset structure and variables may indicate, where applicable, whether a dataset follows a predefined structure and identifies the main variables, fields or coding systems it contains or uses. It does not require the publication of individual records, data values or a complete data dictionary. Health data holders and authorised participants may provide additional metadata elements supported by HealthDCAT-AP on a voluntary basis.

The publication of a dataset description in a dataset catalogue does not imply that access to the underlying dataset has been granted or that the dataset is openly or publicly available. Access to the underlying electronic health data remains governed by the EHDS Regulation, including the rules on data access applications, data permits and secure processing environments. The implementing act does not require restructuring of databases, full semantic harmonisation of the underlying datasets or complete standardisation of national data models and coding practices.

The costs assessed in this SWD concern compliance with the metadata requirements established by the implementing act. They are distinct from the costs underlying any fees that may be charged under Article 62 of the EHDS Regulation for making electronic health data available for secondary use.

2. RELATIONSHIP WITH THE IMPACT ASSESSMENT SUPPORTING THE EHDS PROPOSAL AND PROPORTIONALITY OF THE ANALYSIS

2.1. Matters already assessed in the impact assessment supporting the EHDS proposal

This SWD builds on the impact assessment accompanying the Commission proposal for the EHDS Regulation, SWD (2022) 131 final. That impact assessment examined the broader need for Union action in the field of digital health and health data and the expected impacts of the EHDS framework. This included the secondary-use framework, HDABs, HealthData@EU and dataset catalogues, as well as the Union added value, subsidiarity and proportionality of action at Union level.

Those broader policy choices were subsequently made by the Union legislator and are not reassessed in this SWD.

The impact assessment did not examine in detail the cost implications of the specific minimum metadata elements and their characteristics, as these requirements were to be laid down through the implementing act under Article 77(4) of the EHDS Regulation. This SWD addresses that more limited evidence gaps in relation to the requirements established by the implementing act.

2.2. Analytical focus of this Staff Working Document

The primary quantitative focus of this SWD is the administrative and adjustment effort associated with the metadata requirements established by the implementing act, in particular the effort required to prepare and check initial dataset descriptions.

However, those costs cannot be interpreted in isolation from the function of the metadata requirements. To the extent necessary to assess their proportionality, the SWD also considers qualitatively their expected contribution to dataset discoverability, comparison, catalogue federation and implementation feasibility.

This limited qualitative assessment does not reopen the broader policy choices made in the EHDS Regulation and does not compare alternative regulatory options. The analytical metadata profiles used in the cost modelling serve solely as proxies for estimating the effort associated with the requirements included in the implementing act.

2.3. Proportionate approach to evidence and quantification

Given the technical and implementing nature of the initiative and the evidence available, the analysis combines indicative quantitative modelling with qualitative assessment.

The analytical baseline is the EHDS Regulation, which already establishes the obligations to provide dataset descriptions, to establish dataset catalogues and to verify at least annually that dataset descriptions are accurate and up to date. The SWD therefore distinguishes, as far as the available evidence allows, between costs associated with the specific content and characteristics of the metadata requirements established by the implementing act and the broader costs of implementing the EHDS dataset catalogue framework.

The quantitative model estimates the unit effort required to prepare and check an initial dataset description using the analytical profile that provides the closest available cost proxy for the requirements included in the implementing act. It does not provide a forecast of the total future cost of EHDS dataset catalogues.

No complete and validated EU-wide inventory is available of the dataset descriptions expected to be provided under Article 77 of the EHDS Regulation. The cost model therefore focuses primarily on the estimated unit cost per dataset description. Illustrative volume assumptions and sensitivity scenarios are presented in the methodological annexes for transparency. The additional central assumption used in Annex VI is intended solely to provide an order-of-magnitude input for administrative burden reporting and should not be interpreted as a validated inventory or forecast.

The quantitative analysis focuses on the initial effort required to prepare and check a dataset description. Recurrent costs associated with newly added datasets and with the annual verification and updating of existing descriptions are acknowledged but cannot be reliably monetised on the basis of the available evidence. Their treatment is set out in Section 6.2 and Annex III.

Broader structural and system-level costs, such as the development and operation of national catalogue platforms and the wider HealthData@EU infrastructure, arise principally from obligations already established by the EHDS Regulation. They are therefore not attributed in full to this implementing act. To the extent that technical adaptation to the HealthDCAT-AP-based requirements may entail additional system-level effort, the available evidence does not allow that incremental component to be quantified separately, and this is treated as a limitation of the assessment.

Expected benefits are assessed qualitatively, as the available evidence does not provide a sufficiently robust basis for monetising improvements in dataset discoverability, comparability, catalogue usability or reductions in downstream clarification exchanges. The absence of monetised benefit estimates does not imply that such benefits are absent.

3. IMPLEMENTATION ISSUE ADDRESSED BY THE IMPLEMENTING ACT

The EHDS Regulation already establishes the obligation to provide dataset descriptions and make them available through standardised and machine-readable dataset catalogues. The narrower implementation issue addressed by the implementing act is to determine the minimum metadata elements and their characteristics so that those legal obligations are implemented consistently across the Union.

3.1. Risk of inconsistent dataset descriptions

Existing metadata practices for health datasets differ in their level of detail, terminology, structure, machine-readability and use of controlled vocabularies. They also differ in the availability of information concerning the scope, structure, coding systems and provenance of datasets.

Without a harmonised minimum, health data holders and catalogue operators could interpret differently what constitutes a sufficiently complete dataset description. This would reduce the comparability of descriptions across national catalogues, catalogues of authorised participants and the EU dataset catalogue.

Metadata cannot determine conclusively whether a dataset is relevant for a particular secondary-use purpose, as relevance will depend on the intended use and on the circumstances of each application. However, dataset descriptions should provide enough information to allow health data users to make an informed preliminary assessment before submitting a data access application.

3.2. Need for an informative and proportionate minimum

The implementing act therefore needs to establish a minimum that is sufficiently informative without imposing disproportionate onboarding effort.

A very limited metadata set would reduce the initial effort required from health data holders and catalogue authorities but could provide little more than basic registration of a dataset. Conversely, requirements for exhaustive dataset documentation, complete data dictionaries or extensive semantic mapping could require substantial manual work and technical expertise.

This consideration is particularly relevant because datasets covered by the EHDS Regulation are heterogeneous. Their documentation and metadata maturity may vary according to the type of health data holder, clinical or public-health domain, data structure, coding practices, territorial coverage and level of standardisation.

The implementing act therefore establishes requirements that go beyond basic identification and technical validity, while remaining limited to the catalogue-level information needed to identify, understand and compare potentially relevant datasets.

3.3. Practical consequences of an under-specified minimum

An under-specified minimum would limit the practical usefulness of dataset catalogues. Health data users might be able to identify that a dataset exists but lack the information needed to assess its potential relevance, for example information on its time span and geographical coverage, structure, main variables, coding systems or provenance.

This could result in more exploratory or unsuitable applications and additional clarification exchanges with HDABs and health data holders. It could also impair catalogue federation, as cross-border search, filtering and comparison require sufficiently consistent and machine-readable metadata.

4. OBJECTIVES

The implementing act has the following specific objectives:

- To lay down the minimum metadata elements and their characteristics that health data holders are to provide for dataset descriptions in accordance with Article 77(4) of the EHDS Regulation.
- To ensure that those elements can be represented consistently and in machine-readable form across national catalogues, catalogues of authorised participants and the EU dataset catalogue.
- To support preliminary dataset discovery and comparison before a data access application is submitted.
- To support catalogue federation through HealthData@EU while limiting the mandatory requirements to proportionate, catalogue-level information.

5. MEASURES INCLUDED IN THE IMPLEMENTING ACT

This section describes the measures included in the implementing act. It does not present alternative regulatory options. The analytical metadata profiles used for cost modelling are described in Annex III and compared with the measures included in the implementing act in Annex IV.

The implementing act lays down a harmonised minimum set of metadata elements and their characteristics for dataset descriptions. The mandatory elements cover the principal categories of information needed to identify, understand and compare datasets:

- identification and responsibility information, including the title, identifier, publisher, custodian and contact point;
- thematic and contextual information, including the relevant health category and health theme;
- information on the scope and coverage of the dataset, including geographical coverage and time span and, where applicable, the number of records or individuals;
- governance and access-related information, including applicable legislation and access rights;
- structural and technical information, including whether the dataset is structured and, where applicable, information on variables, code values and coding systems;
- provenance-related information.

The Annex to the implementing act determines which elements are mandatory and which apply only where relevant or under the conditions specified there. Health data holders and authorised participants may provide additional metadata supported by HealthDCAT-AP where relevant and feasible.

HealthDCAT-AP was chosen as the technical reference framework because it builds on DCAT-AP, the common European application profile for data catalogues, while adding properties and vocabularies tailored to health datasets. It therefore supports both

alignment with broader Union data-catalogue practices and the health-specific information needed for dataset discovery under the EHDS Regulation.

The legally binding minimum is established by the implementing act. HealthDCAT-AP provides the corresponding technical structure, property definitions, cardinalities and controlled vocabularies needed for machine-readable implementation. Subsequent technical evolution of HealthDCAT-AP cannot, by itself, create additional mandatory legal requirements.

The measures remain limited to catalogue-level metadata. Information on dataset structure, variables, coding systems or provenance does not require publication of individual records, data values or a complete data dictionary, nor does it require restructuring or semantic harmonisation of the underlying dataset.

For cost-modelling purposes, the measures included in the implementing act are closest to the extended analytical metadata profile described in Annex III, because they include structural, technical and provenance-related metadata. They do not mechanically reproduce that profile: some elements examined in the analytical profiles are not mandatory, while others were refined, added or made conditional to reflect the HealthDCAT-AP structure, the scope of Article 77(4), and input received during preparation of the implementing act.

The extended analytical profile is therefore used as the closest available proxy for the likely onboarding effort associated with the measures included in the implementing act. This does not imply that the analytical profiles were regulatory options.

6. AFFECTED STAKEHOLDERS AND ASSESSMENT OF IMPACTS

The main impacts of the implementing act concern the effort required to prepare and manage harmonised dataset descriptions and the expected effects on dataset discovery, catalogue usability and interoperability.

6.1. Affected stakeholders

Health data holders, which will prepare or complete dataset descriptions containing the mandatory metadata elements. This group includes SMEs and smaller public or non-profit organisations where they qualify as health data holders under the EHDS Regulation. Their effort will depend on existing documentation, metadata-management capacity, catalogue systems and the extent to which information can be reused or generated automatically.

HDABs, which will receive, process and make available dataset descriptions and may check their conformity with the applicable metadata requirements before publication.

The Union health data access service, which provides the dataset catalogue for Union institutions, bodies, offices and agencies in accordance with Article 77(2) of the EHDS Regulation. Where it performs checking or management tasks comparable to those performed by HDABs, similar cost categories arise.

Authorised participants in HealthData@EU, which may incur costs where they provide or manage dataset descriptions. The applicable cost category depends on whether they perform a function comparable to that of a health data holder or a catalogue authority.

Health data users, including researchers, innovators, regulators, public authorities, health technology assessment bodies and policymakers, which are expected to benefit from more complete, consistent and searchable dataset descriptions.

The public and patients, which are not subject to obligations under the implementing act but may benefit indirectly from greater transparency and more effective secondary use of electronic health data.

6.2. Compliance costs: initial onboarding and recurrent effort

Initial onboarding effort

The principal directly quantifiable costs are one-off compliance costs associated with preparing and checking an initial dataset description.

For health data holders, these comprise direct administrative costs associated with entering and submitting information that is already known or readily available, and direct adjustment costs associated with extracting, structuring and aligning existing technical or semantic documentation with the metadata requirements.

For HDABs, the relevant cost is the administrative effort required to check or validate the submitted description.

Stakeholder group	Cost category	Estimated effort under the closest cost proxy
Health data holders	Preparation of the dataset description and completion of mandatory metadata elements	28 hours per dataset description
Health data access bodies	Checking and basic validation of the dataset description	3 hours per dataset description
HealthData@EU / EU dataset catalogue layer	Catalogue federation and system-level implementation	Not quantified as an incremental administrative cost of this implementing act
Health data users, citizens and patients	No compliance obligation	No administrative cost

Where the Union health data access service performs tasks comparable to those of health data access bodies in relation to dataset descriptions, similar categories of administrative costs may arise. These costs are not quantified separately, as the available evidence does not provide a basis for estimating the corresponding workload or volume of dataset descriptions.

The closest available cost proxy therefore gives an estimated total unit cost of EUR 1 681.25 per initial dataset description.

Some elements, such as the title, identifier, publisher, contact point, access rights or health category, are likely to require limited effort where the information is already

known. Other elements may require more work where a health data holder needs to identify the structure of a dataset, its main variables, coding systems or provenance.

No separate aggregate estimate is provided for the Union health data access service because the available evidence does not identify the number of Union-level dataset descriptions for which it would perform comparable checking or management tasks. Its exclusion from the aggregate calculation should not be interpreted as meaning that no such cost will arise.

The costs assessed in this SWD concern compliance with the metadata requirements established by the implementing act. They are distinct from the costs that may underlie fees charged under Article 62 of the EHDS Regulation for making electronic health data available for secondary use.

Recurrent effort

The preparation of a description is a one-off activity for each individual dataset. Similar costs may nevertheless arise over time when descriptions are prepared for newly added datasets. The estimated unit cost can be used as an indicative proxy for each such description, but the annual aggregate cannot be calculated because no reliable evidence is available on the number of datasets that will be newly added each year.

Recurrent effort may also arise from the obligation in Article 60(3) of the EHDS Regulation to verify at least annually that dataset descriptions are accurate and up to date. This obligation derives directly from the EHDS Regulation. The effort needed for annual verification will depend on whether a description remains unchanged or requires substantive updates.

The available evidence does not allow the average time needed to review an existing description, the proportion of descriptions that will require substantive updates each year, or the incremental share of that effort attributable specifically to the level of metadata detail established by the implementing act to be estimated reliably.

These costs are therefore acknowledged but not monetised. Their non-quantification should not be interpreted as an estimate of zero.

Structural and system-level costs, such as developing or operating national catalogue platforms or the wider HealthData@EU infrastructure, are also not attributed in full to the implementing act, as they arise principally from obligations already established by the EHDS Regulation. Any incremental technical adaptation specifically attributable to the metadata requirements could not be isolated on the basis of the available evidence.

6.3. Digital and interoperability benefits

The implementing act is expected to support digital interoperability by establishing a common, machine-readable minimum for dataset descriptions and by using HealthDCAT-AP as the technical reference framework.

More consistent metadata should facilitate cross-border search, filtering, comparison and federation across national catalogues, catalogues of authorised participants and the EU dataset catalogue. It should also reduce the risk of catalogues using incompatible

structures or providing substantially different kinds of information for comparable datasets.

These effects concern the metadata and catalogue layer. The implementing act does not require adoption of a single underlying data model, full semantic harmonisation of datasets or mapping of every data element to a common terminology.

The interoperability assessment carried out for the implementing act is addressed in Section 8.3.

6.4. Process and catalogue usability benefits

More complete and standardised dataset descriptions should help health data users identify potentially relevant datasets and make a preliminary assessment of their relevance before submitting a data access application.

Users should be better able to understand what datasets exist, the topics and health categories they cover, their time span and geographical scope, applicable access conditions, whether they are structured, and their main variables, coding systems and provenance, where relevant.

This information cannot determine definitively whether a dataset is suitable for a particular use, but it can reduce uncertainty at the discovery stage.

For HDABs and health data holders, more informative descriptions may lead to more targeted applications and fewer ad hoc clarification exchanges concerning the scope, content or potential relevance of a dataset.

These expected effects are assessed qualitatively. They cannot be monetised because there are no validated Union-wide baseline data on dataset searches, user search time, exploratory applications, clarification exchanges or the administrative cost of handling those exchanges.

Information generated during implementation may be used in future evaluation or review exercises relating to the EHDS framework.

6.5. SMEs and smaller data holders

SMEs and smaller public or non-profit organisations are affected where they qualify as health data holders. The onboarding effort may be proportionally greater for organisations with limited metadata-management capacity, fragmented documentation or less mature information systems.

For the standard Better Regulation tables, the private-sector uplift is divided on the working assumption that 50% concerns SMEs and 50% concerns large companies or other non-SME private actors. This assumption is used for calculator purposes only. No reliable Union-wide evidence is available on the distribution of dataset descriptions between SME and non-SME private health data holders.

The effect on smaller health data holders is limited by several features of the implementing act:

- The requirements concern catalogue-level metadata.
- Elements apply conditionally where specified in the Annex to the implementing act.
- The act does not require publication of the underlying electronic health data.
- It does not require complete data dictionaries, full semantic harmonisation or restructuring of datasets.
- Common specifications, documentation and validation support can facilitate reuse and reduce avoidable manual work.

6.6. Fundamental rights and data protection

The implementing act does not provide a legal basis to access personal electronic health data or modify the conditions for issuing data permits, the safeguards applicable to secure processing environments or the rights and obligations established by Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.

The required metadata describe datasets rather than the individuals whose data may be included in them. Elements such as whether a dataset contains personal data, its variables, coding systems, geographical coverage or time span are intended to support catalogue-level discovery and relevance assessment.

The implementing act may have a positive effect on transparency by making it easier to identify which categories of datasets exist and the conditions under which access may be requested.

At the same time, dataset descriptions must be prepared so as not to disclose information that could indirectly identify individuals or reveal protected information. Particular care may be needed for very small cohorts, rare diseases or highly specific datasets.

Health data holders, HDABs, the Union health data access service and authorised participants remain responsible for complying with applicable Union and national law, including rules on data protection, confidentiality, intellectual property and trade secrets.

6.7. Social and environmental screening

The implementing act is not expected to generate significant direct social or environmental impacts beyond those associated with the EHDS framework.

It does not require new collection of electronic health data, modify the conditions for access to those data or reduce the applicable safeguards. Any incremental effects associated with adapting catalogue and metadata-management systems are expected to be limited.

6.8. Uncertainty and limitations of the estimates

The cost assessment is subject to the following limitations:

- No complete and validated Union-wide inventory is available of the dataset descriptions expected to be provided under Article 77.

- Dataset granularity and metadata maturity differ across Member States, sectors and health data holders.
- Actual costs will depend on existing documentation, automation, reuse of metadata, staff profiles and national implementation models.
- The extended analytical profile is the closest available cost proxy but is not identical to the measures included in the implementing act.
- The annual number of descriptions for newly added datasets is unknown.
- Annual verification and update costs cannot be quantified or separated reliably from the obligation already established by Article 60(3).
- System-level costs and the separate volume of work performed by the Union health data access service cannot be isolated.
- Expected benefits cannot be monetised on the basis of the available evidence.

The unit cost and aggregate assumptions should therefore be interpreted as indicative order-of-magnitude estimates rather than forecasts.

7. ASSESSMENT OF THE MEASURES INCLUDED IN THE IMPLEMENTING ACT

This section assesses the effectiveness, efficiency, coherence and proportionality of the measures included in the implementing act.

7.1. Effectiveness

The measures are expected to be effective because they establish a common metadata layer that goes beyond basic registration of a dataset.

The mandatory and conditional elements support identification of datasets and responsible entities, understanding of their scope and content, preliminary assessment of their potential relevance, machine-readable comparison and filtering, and federation of dataset descriptions across national and Union-level catalogues.

Information on thematic categories, access conditions, geographical coverage and time span, dataset structure, variables, coding systems and provenance should reduce the risk of catalogues in which users can identify that a dataset exists but cannot make a meaningful preliminary assessment before submitting an application.

The effectiveness of the measures will nevertheless depend on the accuracy, completeness and regular updating of the descriptions and on the implementation support available to health data holders and catalogue authorities.

7.2. Efficiency

The closest available proxy estimates the initial unit cost at EUR 1 681.25 per dataset description, comprising EUR 1 512.50 for preparation by a health data holder and EUR 168.75 for checking by an HDAB.

The aggregate cost cannot be forecast precisely because the number and granularity of dataset descriptions are not yet known. Recurrent verification and update costs and the annual flow of newly added datasets also cannot be aggregated reliably.

The expected benefits for discovery, comparison and catalogue federation are not monetised. It would therefore not be justified to state that the quantified costs are demonstrably offset or balanced by quantified benefits.

The available evidence nevertheless indicates that the measures are targeted at information directly relevant to catalogue usability and federation, while excluding substantially more burdensome requirements such as complete data dictionaries, restructuring of databases or full semantic harmonisation. Support tools and the possibility of reusing existing metadata may further reduce avoidable implementation effort.

On that basis, the approach is expected to use resources more efficiently than either a minimal description with limited practical value or an exhaustive documentation requirement.

7.3. Coherence

The measures are coherent with the EHDS Regulation. They implement Article 77(4), read together with Articles 60(3), 77(1) and 77(2), without modifying the legislative framework for secondary use, data access applications, data permits or secure processing environments.

They are also technically coherent with DCAT-AP and broader Union data-catalogue practices, as HealthDCAT-AP builds on the common DCAT-AP structure while adding health-specific elements.

The use of a common machine-readable application profile is relevant to the objectives of the Interoperable Europe framework. The specific conclusions of the interoperability assessment are reflected in Section 8.3 once the final assessment report is available.

The measures are also consistent with applicable data-protection, intellectual property and confidentiality requirements. They concern catalogue-level metadata and do not modify the legal conditions for processing or accessing the underlying electronic health data.

No broader conclusion is drawn regarding other digital or cybersecurity legislation where the available evidence does not identify a direct interaction with the metadata requirements.

7.4. Proportionality

The available evidence supports the conclusion that the measures are proportionate to the limited implementing objective pursued. The requirements:

- concern catalogue-level metadata rather than the underlying data;
- do not require publication of individual records or data values;

- do not require a complete data dictionary;
- do not require restructuring or full semantic harmonisation of datasets;
- include conditional elements where the relevant information or circumstances apply;
- allow additional HealthDCAT-AP metadata to be provided voluntarily;
- are supported by common specifications, prospective validation and guidance tools.

The estimated unit cost is not negligible, particularly for health data holders with limited existing documentation. However, the requirements giving rise to the greatest effort concern information needed to make descriptions practically useful, such as dataset structure, variables, coding systems and provenance.

The proportionality conclusion remains qualitative because aggregate volumes, recurrent costs and monetised benefits are uncertain. It should therefore be read together with the limitations set out in Section 6.8 and Annex III.

8. IMPLEMENTATION, SUPPORT AND MONITORING

The implementing act establishes the binding regulatory minimum. Consistent implementation will also depend on technical documentation, controlled vocabularies, validation tools, implementation guidance and proportionate monitoring.

These support measures do not create legal obligations beyond those established by the implementing act.

8.1. HealthDCAT-AP governance and controlled vocabularies

The implementing act identifies the minimum metadata elements and their characteristics. The applicable version of HealthDCAT-AP referred to in the implementing act provides the corresponding machine-readable structure, including property definitions, cardinalities and controlled vocabularies.

The Commission will maintain and make publicly available the relevant HealthDCAT-AP specification and associated documentation, including information on property definitions, implementation requirements and versioning.

Where HealthDCAT-AP evolves, technical updates should not create new mandatory obligations for health data holders or other actors unless those obligations are reflected in the applicable legal framework.

Controlled vocabularies support the consistent expression of metadata values across catalogues. The implementing act specifies the vocabulary applicable to the metadata element concerning health categories. Other vocabularies should be clearly identified in the applicable HealthDCAT-AP documentation, publicly accessible and appropriately maintained and versioned.

8.2. Validation and support tools

Implementation will be supported by technical tools and documentation. A validation tool is expected to support checks of dataset descriptions against HealthDCAT-AP and the mandatory metadata elements, including missing elements, incorrect formats and invalid controlled vocabulary values.

Automated checks can reduce errors and support more predictable implementation, while some qualitative elements may still require human review depending on national implementation models and dataset complexity.

Public documentation and, where relevant, additional support tools such as a dataset description assistant may help data holders prepare metadata descriptions, reuse existing metadata, pre-fill fields and reduce manual work.

8.3. Interoperability assessment

An interoperability assessment has been carried out. The assessment report will be available on the Interoperable Europe Portal.

The interoperability assessment concluded that the implementing act is compatible with the interoperability requirements applicable under the Interoperable Europe framework. In particular, the use of a common HealthDCAT-AP-based metadata specification supports semantic and technical interoperability across dataset catalogues.

8.4. Monitoring indicators

Monitoring should remain proportionate and rely, as far as possible, on information generated through normal operation of national catalogues, catalogues of authorised participants, the Union-level catalogue, validation tools and relevant workflows.

The implementing act does not establish a separate reporting obligation. Monitoring should therefore use information already generated or reasonably available through implementation of the EHDS Regulation.

Relevant information could include:

- The number of dataset descriptions published in national catalogues, catalogues of authorised participants and the EU dataset catalogue.
- The number of new descriptions added during a reporting period.
- The proportion of descriptions reviewed and, where necessary, updated in accordance with Article 60(3).
- The completeness and conformity of mandatory metadata elements.
- The frequency and type of validation errors.
- The use of optional HealthDCAT-AP elements beyond the regulatory minimum.
- Where already recorded, clarification exchanges linked to the relevance, scope or completeness of dataset descriptions.

- Where obtainable without creating a separate reporting burden, implementation evidence on the effort needed to prepare, verify or update descriptions.

The relevant information would be held by HDABs, catalogue operators, authorised participants, the Union health data access service and the Commission, according to their respective functions.

Monitoring may help identify recurring implementation difficulties and inform improvements to guidance, examples, controlled vocabularies, validation tools and technical support. Where legally and operationally appropriate, relevant information may also contribute to existing EHDS reporting, evaluation or review mechanisms.

9. CONCLUSION

This SWD assesses the costs and expected effects of the minimum metadata requirements established by the implementing act under Article 77(4) of the EHDS Regulation.

The implementing act establishes a HealthDCAT-AP-based minimum that supports consistent and machine-readable dataset descriptions across national catalogues, catalogues of authorised participants and the EU dataset catalogue.

The closest available cost proxy estimates an initial unit cost of EUR 1 681.25 per dataset description, comprising preparation by the health data holder and checking by an HDAB. Where the Union health data access service performs comparable checking or management tasks, similar categories of administrative costs may arise, but these costs cannot be quantified separately on the basis of the available evidence.

Similar initial costs will arise for descriptions of newly added datasets. Annual verification and update costs may also arise, but their magnitude and the incremental share attributable to the implementing act cannot be quantified reliably. These costs are not assumed to be zero.

The measures are expected to improve dataset discovery, preliminary relevance assessment, metadata comparability and catalogue federation. Those benefits are not monetised and are therefore not presented as quantitatively offsetting the estimated costs.

The proportionality of the approach rests on the limited catalogue-level scope of the requirements, the use of conditional elements where appropriate, the exclusion of substantially more burdensome requirements and the expected availability of common technical and validation support.

Implementation experience and proportionate monitoring should inform future guidance, technical support and relevant EHDS evaluation or review exercises.

ANNEX I - PROCEDURAL INFORMATION

The lead service is DG SANTE, Unit C1 – Digital Health.

DECIDE reference: ISC/2026/06525

The SWD accompanies the Commission Implementing Regulation under Article 77(4) of the EHDS Regulation and is processed as a standalone SWD.

Preparation and consultation

The implementing act and this SWD were prepared by the Commission services with input from:

- The Committee[4] on the European Health Data Space.
- The interservice consultation.
- Technical work on HealthDCAT-AP.
- A targeted external expert assessment on metadata requirements and indicative onboarding effort.
- Feedback received through the Commission's Have Your Say mechanism.

The Have Your Say feedback was used to identify stakeholder views, technical clarification needs and practical implementation concerns. It was not used as the quantitative basis for the cost estimates.

Evidence base and its limitations

The evidence base and methodology are set out in Annex III. The quantitative analysis is subject to important limitations, in particular the absence of a complete and validated Union-wide inventory of dataset descriptions and differences in dataset granularity and metadata maturity. The estimates are therefore intended to indicate orders of magnitude rather than forecast actual costs

Use of targeted external expert assessment

The Commission services used a targeted external expert assessment to compare cumulative analytical metadata profiles and estimate the effort required to prepare and check initial dataset descriptions. The assessment supported the cost modelling but did not constitute an impact assessment and did not determine the final content of the implementing act.

Key references

- 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) 2024/2847, OJ L, 2025/327, 5.3.2025.

[4] C131500

- Impact Assessment Report accompanying the proposal for a Regulation on the European Health Data Space, SWD (2022) 131 final.
- HealthDCAT-AP, latest applicable version.
- Committee on the European Health Data Space - Comitology Register.
- European Health Data Space - dataset descriptions, Have Your Say feedback initiative.

ANNEX II – SUMMARY OF STAKEHOLDERS' FEEDBACK (HAVE YOUR SAY)

1. Context of the feedback mechanism

A draft implementing act and its Annex were published on the Commission's Have Your Say website for a four-week feedback period from 14 April to 12 May 2026.

2. Overview of stakeholders

A total of 64 contributions were received: 14 from academic or research institutions (22%); 9 from non-governmental organisations (14%); nine from respondents registered under the category "EU citizens" (14%); eight from public authorities (13%); six from companies or businesses (9%); five from business associations (8%); one from a trade union (2%); and 12 from respondents selecting "other" (19%).

No coordinated campaigns were identified and no feedback was discarded. Attachments were submitted by 32 stakeholders.

Almost all contributions came from the EU: 11 from the Netherlands; nine from Belgium and nine from Germany; six from France; five from Spain; four from Sweden and four from Austria; two from Finland, two from Ireland, two from Poland and two from Portugal; and one from Czechia, one from Italy and one from Malta. These represented 59 of the 64 contributions (92%). Five contributions came from outside the EU: three from Norway, one from Switzerland and one from the United States.

Among the eight public authorities, one selected an international scope, five a national scope and two a regional scope. Among the six companies or businesses, two were large companies, one was a small company and three were micro-enterprises. Among the academic or research institutions, ten were large organisations, two were medium-sized organisations, one was small and one was a micro-organisation.

3. Overview of feedback

Stakeholders generally supported improving the discoverability, comparability and interoperability of health datasets through a common metadata framework. Several respondents welcomed the use of HealthDCAT-AP and a harmonised minimum set of metadata elements.

A first group of comments concerned the practical usefulness of catalogues. Stakeholders stressed that descriptions should provide enough information to allow users to make a

preliminary assessment of potential relevance before submitting an application. These comments supported the inclusion of information on dataset scope, structure, variables, coding systems, provenance, time span, geographical coverage and access conditions.

A second group concerned technical clarity and implementation. Stakeholders requested clearer specifications and guidance, validation and conformance tools, transparent versioning of HealthDCAT-AP and clearer explanations of how mandatory elements should be represented. Several comments concerned the relationship between the implementing act, its Annex and the HealthDCAT-AP specification.

A third group concerned the scope and granularity of dataset descriptions. Respondents requested further guidance on what constitutes a dataset for catalogue purposes and how dynamic datasets, registries, data series or data held across several systems should be described.

A fourth group proposed additional or more detailed metadata, including information on data quality and update frequency; versioning; sample size or population coverage; rights statements, intellectual property and trade secrets; access restrictions and legal bases; data-protection status; anonymisation or pseudonymisation; access modalities and federated access capabilities; clinical context; suitability for artificial intelligence or machine learning; and more detailed variable-level metadata.

A fifth group raised proportionality and implementation-capacity concerns. Smaller organisations and health data holders noted that preparing metadata could require significant effort where documentation was incomplete, fragmented or not machine-readable. They requested guidance, reusable components, validation support, phased implementation or clarification that certain elements applied only where relevant.

4. How feedback was considered

The feedback supported the need for a harmonised and machine-readable framework that remains limited to catalogue-level metadata.

It informed clarification of the relationship between the implementing act and HealthDCAT-AP, the role of controlled vocabularies, the importance of information on dataset structure, variables, coding systems and provenance, and implementation support and validation need.

Comments concerning examples, conformance testing, versioning and implementation guidance are primarily addressed through HealthDCAT-AP documentation, validation tools and implementation support. They are not all included in the implementing act, as this establishes the binding regulatory minimum rather than a complete technical implementation manual.

Some proposed elements were not made mandatory where they would go beyond the empowerment in Article 77(4), require publication of substantially more detailed documentation, imply restructuring or full semantic harmonisation of underlying datasets, or create disproportionate onboarding effort. Such information may still be supported as optional metadata in HealthDCAT-AP where relevant and feasible.

Comments concerning access to the underlying data, data-permit procedures, secure processing environments or broader EHDS governance were outside the scope of the implementing act.

The feedback was not used as the quantitative basis for the cost estimates.

ANNEX III - METHODOLOGY AND ANALYTICAL APPROACH

1. Purpose and scope of the methodology

This Annex describes the methodology used to assess the incremental costs and expected effects of the metadata requirements established by the implementing act. The analysis combines indicative quantitative modelling of the initial effort required to prepare and check a dataset description with qualitative assessment of recurrent effort, benefits, interoperability, implementation feasibility and methodological limitations.

2. Evidence sources and role in the analysis

- The analysis draws on the impact assessment accompanying the Commission proposal for the EHDS Regulation; the EHDS Regulation, in particular Articles 60(3), 75, 77 and 79; the HealthDCAT-AP specification and related technical work; a targeted external expert assessment of metadata requirements and onboarding effort; input from the Committee on the European Health Data Space and the interservice consultation; and stakeholder feedback received through Have Your Say.
- Each source was used for a distinct purpose. Stakeholder feedback and committee input informed technical refinement and implementation feasibility but did not provide the quantitative basis for the cost estimates.

3. Analytical metadata profiles used for cost modelling

The targeted external expert assessment compared three cumulative analytical profiles:

A minimum analytical profile, covering basic identification and governance metadata.

A medium analytical profile, adding contextual and selected structural information.

An extended analytical profile, adding richer structural, technical and provenance-related information.

These profiles were developed solely for analytical and cost-modelling purposes. They were not regulatory options or draft legal texts.

The measures included in the implementing act are closest to the extended profile in expected onboarding effort because they include information on structure, variables, coding systems and provenance. The implementing act does not reproduce the profile mechanically. Annex IV presents the detailed mapping.

4. Cost model

The cost model estimates the compliance cost of preparing and checking an initial dataset description.

The unit of analysis is a **dataset description**, understood for modelling purposes as a discoverable unit of description in a catalogue. This modelling assumption does not prejudge the legal interpretation of what a "dataset" is under the EHDS Regulation.

The model distinguishes between preparation or completion of the description by a health data holder and checking or basic validation by an HDAB. Where the Union health data access service performs comparable checking or validation tasks, similar categories of administrative costs may arise. These costs are not quantified separately because the available evidence does not provide a basis for estimating the corresponding workload or volume of Union-level dataset descriptions.

The external assessment used standardised daily-rate proxies converted into hourly rates based on an eight-hour productive day: administrative support: EUR 31.25 per hour; researcher or data steward: EUR 43.75 per hour; senior or domain expert: EUR 56.25 per hour. These are analytical proxies and should not be interpreted as actual staffing or remuneration structures.

Task / component	Actor	Hours	Cost	Classification	Rationale
Entry of known administrative / governance metadata, e.g. title, publisher, contact point, rights	Health data holder	1h	EUR 31.25	**Direct administrative cost**	This is the part closest to "providing information" / registration-type obligation.
Structural and technical description, e.g. code values and technical metadata, including information derived from existing data dictionaries where available	Health data holder	3h	EUR 131.25	**Direct adjustment cost**	This is not simple data entry; it involves extracting, formatting and aligning technical information to the metadata framework.
Semantic / expert processing, e.g. coding systems, provenance, lineage, mapping to terminology	Health data holder	24h	EUR 1 350.00	**Direct adjustment cost**	This component captures the expert effort modelled in the extended analytical profile for coding systems, provenance and terminology alignment. It should not be understood as implying a requirement for full semantic mapping under the implementing act.
Checking / validation of the dataset description	HDAB	3h	EUR 168.75	**Direct administrative cost for administrations**	This is the public authority / HDAB effort to check or validate the submitted metadata.

The resulting unit-cost classification is:

Category	Cost
Business / data holder direct administrative cost	EUR 31.25
Business / data holder direct adjustment cost	EUR 1 481.25
Public administration / HDAB direct administrative cost	EUR 168.75
Total one-off compliance cost	EUR 1 681.25

Cost sensitivity across analytical profiles:

Metadata profile	Data holder effort	HDAB checking effort	Estimated unit cost per dataset
Minimum benchmark	1 hour	0.25 hours	EUR 39.06
Medium benchmark	4 hours	1 hour	EUR 206.25
Extended benchmark	28 hours	3 hours	EUR 1 681.25

The extended profile is used as the closest available proxy for the measures included in the implementing act.

The model does not monetise recurrent costs. Descriptions of newly added datasets will entail an initial onboarding cost for each new description. However, the annual number of such descriptions is unknown.

The annual verification obligation in Article 60(3) may entail recurrent review and update effort. The available evidence does not establish the average effort, the proportion of descriptions requiring substantive updates or the incremental amount attributable to the implementing act. No recurrent amount is therefore calculated. This does not imply that the recurrent cost is zero.

5. Dataset volume assumptions

No complete and validated Union-wide inventory is available. Dataset granularity may differ substantially between catalogues.

The external assessment developed the following illustrative scenarios: a documented-source scenario of 4 728 descriptions; an overlap sensitivity range of 4 536 to 4 921 descriptions; and a higher-fragmentation scenario of 6 522 descriptions. These scenarios are not forecasts.

For the standard Better Regulation tables, a separate working assumption of 9 456 descriptions is used: the documented-source scenario of 4 728 plus a private-sector uplift of 4 728. The private-sector uplift addresses the fact that private-sector datasets are not reliably captured in the documented-source scenario. It is an assumption for administrative-burden reporting only.

For the SME subset, the private-sector uplift is divided equally: SMEs: 2 364 descriptions; large companies or other non-SME private actors: 2 364 descriptions. Dataset descriptions in the documented-source scenario are not attributed to the SME subset.

The corresponding checking cost is 9 456 × EUR 168.75 = EUR 1.596 million.

Calculator assumption	Dataset descriptions	Data holder one-off compliance cost	Data holder direct administrative cost
Documented-source scenario, reported under businesses for table purposes	4 728	EUR 7.151 million	EUR 0.148 million
Private-sector uplift – SMEs	2 364	EUR 3.576 million	EUR 0.074 million
Private-sector uplift – large companies / non-SME private actors	2 364	EUR 3.576 million	EUR 0.074 million
Total businesses line	**9 456**	**EUR 14.302 million**	**EUR 0.296 million**

6. Treatment of benefits

Benefits are assessed qualitatively because no validated Union-wide baseline data are available for monetisation. The assessment considers potential improvements in dataset discoverability, preliminary relevance assessment, comparability of descriptions, catalogue federation, interoperability of the metadata layer and reduction of avoidable clarification exchanges. No claim is made that the estimated costs are quantitatively offset by those benefits.

7. Main limitations

The methodology is limited by uncertainty over the number and granularity of descriptions; variation in metadata maturity and documentation; use of standardised personnel-cost proxies; differences between the analytical profile and the final legal requirements; absence of robust data on recurrent verification and update effort; absence of a separate volume estimate for the Union health data access service; and absence of monetised benefits.

ANNEX IV - ANALYTICAL METADATA PROFILES AND THE MEASURES INCLUDED IN THE IMPLEMENTING ACT

The table maps the three analytical profiles against the measures included in the implementing act.

Legend

M = included as mandatory in the analytical profile

✓ = retained as mandatory in the implementing act

* = retained where relevant or under the conditions set out in the technical specification

Metadata property	Analytical profile 1: minimum	Analytical profile 2: medium	Analytical profile 3: extended	Measures included in the implementing act
Access rights	M	M	M	✓
Access URL			M	
Analytics			M	
Applicable legislation		M	M	✓*
Code values		M	M	✓*
Coding system			M	✓*
Contact point	M	M	M	✓
Conforms to				✓*
Creator			M	
Custodian	M	M	M	✓
Description	M	M	M	✓

Distribution				✓*
Geographical coverage		M	M	✓*
Has personal data	M	M	M	✓
Health data access body	M*	M*	M*	✓*
Health category	M	M	M	✓
Health specialty			M	
Health theme	M	M	M	✓
Identifier	M	M	M	✓
Is structured				✓
Keyword		M	M	✓
Language			M	✓
Max typical age			M	
Min typical age			M	
Number of records	M	M	M	✓*
Number of unique individuals		M*	M*	✓*
Population coverage		M	M	
Provenance			M	✓*

Publisher	M	M	M	✓
Publisher type			M	
Purpose			M	
Temporal coverage				✓*
Title	M	M	M	✓
Type				✓
Variables				✓*
Was generated by				✓*

The profiles are cumulative: the medium profile builds on the minimum profile, and the extended profile builds on the medium profile.

The mapping confirms that the implementing act is closest to the extended profile in terms of expected onboarding effort but does not reproduce it mechanically. The extended profile is therefore used only as a cost proxy.

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ANNEX V – WHO IS AFFECTED AND HOW?

This Annex presents the costs and benefits of the measures included in the implementing act.

The baseline is Regulation (EU) 2025/327, including the obligations to establish dataset catalogues and to provide dataset descriptions. The costs presented below, therefore, concern only the incremental costs linked to the minimum metadata elements and related characteristics specified in the implementing act under Article 77(4).

The closest available cost proxy is the extended analytical profile. Under this profile, the estimated unit cost is **EUR 1 681.25 per dataset description**, composed of **EUR 1 512.50** for health data holder preparation effort and **EUR 168.75** for health data access body checking effort. The health data holder effort consists of **1 hour of administrative support** at EUR 31.25/hour, **3 hours of researcher/data steward effort** at EUR 43.75/hour, and **24 hours of senior expert effort** at EUR 56.25/hour. The health data

access body checking effort is estimated at **3 hours** of domain expert/senior expert effort at EUR 56.25/hour.

For the standard cost typology, the one-off data holder effort is treated as a compliance cost composed of adjustment and administrative costs. The first hour of administrative support is treated as a direct administrative cost. The remaining data holder effort is treated as a direct adjustment cost, as it concerns structural extraction, technical description, semantic mapping and provenance-related work needed to align existing dataset documentation with the HealthDCAT-AP-based metadata requirements. The health data access body checking effort is treated as a direct administrative cost for public administrations.

The cost model does not provide a validated EU-wide count of all dataset descriptions expected to be provided under Article 77. For these standard tables and the administrative burden calculator, a central calculator assumption of **9 456 dataset descriptions** is used. This consists of the documented-source scenario of **4 728 dataset descriptions** and an additional private-sector uplift of **4 728 dataset descriptions**, introduced to reflect the fact that private-sector datasets are not reliably captured in the available modelling.

This is a working assumption for administrative burden reporting purposes only. It is not a validated inventory and should not be read as a forecast of the number of dataset descriptions that will be provided under Article 77.

For the standard tables, health data holder costs are reported under **businesses**, including where health data holders are public or non-profit entities, due to the absence of a reliable EU-wide split between public and private health data holders. Health data access body checking costs are reported under **public administrations**. Citizens are not subject to obligations under the implementing act.

For the SME line, the private-sector uplift is split on a **50% SMEs / 50% large companies or non-SME private actors'** basis. This is a working assumption only, as no reliable EU-wide data are available on the distribution of dataset descriptions between SME and non-SME private health data holders.

The detailed cost classification, tariff assumptions and calculator working assumptions underlying these tables are set out in Annex III.

I. Overview of Benefits (total for all provisions)		
Description	***Amount***	***Comments***
Direct benefits		
Improved dataset findability and relevance assessment	Not quantified	Main recipients: health data users, including researchers, innovators, regulators, public authorities, health technology assessment bodies and policymakers. More complete and standardised dataset descriptions should help users identify potentially relevant datasets and assess their relevance before submitting a data access application.
Improved catalogue interoperability and federation	Not quantified	Main recipients: health data access bodies, authorised participants and actors involved in national catalogues and the EU dataset catalogue. More consistent and machine-readable metadata should support cross-border search, filtering, comparison and federation of dataset descriptions.
Indirect benefits		
Reduced downstream clarification exchanges	Not quantified	Main recipients: health data access bodies and health data holders. Better metadata may reduce exploratory or unsuitable applications and ad hoc clarification exchanges on dataset relevance, scope or content. These benefits depend on future use of catalogues and are therefore assessed qualitatively.
Greater transparency of available data assets	Not quantified	Main recipients: health data users, public authorities and citizens indirectly. Dataset catalogues should provide better visibility of available datasets without granting access to the underlying electronic health data.
Support to the effective functioning of the EHDS secondary use framework	Not quantified	Main recipients: health data users, health data access bodies, health data holders and citizens indirectly. By improving dataset discoverability and catalogue usability, the implementing act may support more effective secondary use of health data. Broader social benefits of the EHDS framework were assessed in the EHDS impact assessment.

Estimates are gross values relative to the baseline for the measures included in the implementing act. Where benefits are not monetised, this is indicated in the "Amount" column. The "Comments" column identifies the main stakeholder group receiving the benefit. No monetised reductions in regulatory costs are claimed in this table; expected reductions in downstream administrative friction are described qualitatively.

II. Overview of costs – Measures included in the implementing act							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Implementing act measures	Direct adjustment costs	0	0	EUR 14.007 million.	*Not quantified*	0	*Not quantified*
	Direct administrative costs	0	0	EUR 0.296 million	*Not quantified*	EUR 1.596 million	*Not quantified*
	Direct regulatory fees and charges	0	0	0	0	0	0
	Direct enforcement costs	0	0	0	0	0	0
	Indirect costs	0	0	0	0	0	0

Estimates are gross values relative to the baseline, which is Regulation (EU) 2025/327, including the obligations to establish dataset catalogues and provide dataset descriptions. Costs are presented for the measures included in the implementing act. Cost categories follow the standard Better Regulation typology: adjustment costs, administrative costs, regulatory fees and charges, enforcement costs and indirect costs.

*The figures use the central calculator assumption of **9 456 dataset descriptions**. This is a working assumption for administrative burden reporting purposes only. It combines the documented-source scenario of **4 728 dataset descriptions** with an additional private-sector uplift of **4 728 dataset descriptions**. It should not be interpreted as a validated inventory or forecast of actual future costs.*

*The business costs correspond to the health data holder component. The one-off data holder cost is **EUR 1 512.50 per dataset description**, composed of **EUR 1 481.25 direct adjustment costs** and **EUR 31.25 direct administrative costs**. The administration costs correspond to the health data access body checking component of **EUR 168.75 per dataset description**.*

Recurrent incremental costs are not quantified because the available evidence does not allow the annual flow of new dataset descriptions or the incremental effort associated with verification and updates to be estimated reliably. "Not quantified" should not be interpreted as zero.

III. Contribution to the administrative burden reduction targets – Implementing Act measure *Amounts are in EUR million. Figures are rounded to three decimals.*					
Administrative costs [M€]	**New recurrent costs (INs)** (nominal values per year)	**Removed recurrent costs (OUTs)** (nominal values per year)	**Net cost (INs – OUTs)** (nominal values per year)	**New one-off costs (INs)** (annualised total net present value over the relevant period)	**Removed one-off costs (OUTs)** (annualised total net present value over the relevant period)
All businesses (including public health data holders)	*Not quantified*	0	0	**EUR 0.296 million direct administrative costs**.	0
- → in which SMEs	*Not quantified*	0	0	**EUR 0.074 million**, based on the working assumption that 50% of the private-sector uplift concerns SMEs, corresponding to **2 364 dataset descriptions**.	0
Public administrations (mainly HDAB)	*Not quantified*	0	0	**EUR 1.596 million**, corresponding to the health data access body checking component under the central calculator assumption of 9 456 dataset descriptions.	0
Citizens	0	0		0	0

The table above provides non-annualised one-off cost inputs for the administrative burden calculator. The split between adjustment and administrative costs is presented in Table II. Where the calculator requires annualised values, annualisation should be carried out in the calculator based on these one-off inputs and the relevant reporting period.