



QUANTUM
THE HEALTH DATA QUALITY LABEL

D5.10 Recommendations for the maintenance and upgrade of the QUANTUM labelling mechanism

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QUANTUM summary	QUANTUM aims at developing and implementing a label mechanism that could be ideally adopted in the future HealthData@EU. QUANTUM builds on 5 technical work packages (WPs). WP1 conceptualises and provides technical specifications for a data quality, utility, and maturity label. WP2 designs and tests, at small-scale, the label. WP3 implements the labelling mechanism in a number of data holders. WP4 engages the data quality users' community; and, WP5 outreaches other interested parties, including other initiatives building HealthData@EU.
Deliverable abstract	D5.10 reports on the dedicated session at the last QUANTUM meeting with the Advisory Board members aimed to discuss on the sustainability and transferability topics of the developed QUANTUM Data Quality, Utility and Data Holder Maturity label, issuing recommendations for the maintenance and upgrade of the QUANTUM labelling mechanism, based in Deliverable 3.2 "Guidelines and specifications for the implementation of the QUANTUM labelling mechanism as foreseen in the legislative regulation EHDSR article 78".
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QUANTUM CONSORTIUM			
#	Short Name	Organisation Name	Country
1	IACS	INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD	ES
2	Sciensano	SCIENSANO	BE
3	Health Data Hub	PLATEFORME DES DONNEES DE SANTE	FR
3.1	HOSPICES LYON	HOSPICES CIVILS DE LYON	FR
3.2	HOSP TOULOUSE	CENTRE HOSPITALIER UNIVERSITAIRE DE TOULOUSE	FR
3.3	CHU Bordeaux	CHU HOPITAUX DE BORDEAUX	FR
4	I-HD	THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA	BE
5	UCSC	UNIVERSITA CATTOLICA DEL SACRO CUORE	IT
6	BBMRI-ERIC	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM	AT
7	DIGITALEUROPE	DIGITALEUROPE AISBL	BE
8	GÖG	GESUNDHEIT OSTERREICH GMBH	AT
9	UPV	UNIVERSITAT POLITECNICA DE VALENCIA	ES
10	HEALTH-RI	STICHTING HEALTH-RI	NL
11	EUHA	EUROPEAN UNIVERSITY HOSPITAL ALLIANCE	BE
12	AP-HP	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	FR
13	VIB	VIB VZW	BE
14	CIPH	HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	HR
15	HUS	HUS-YHTYMA	FI
16	THL	TERVEYDEN JA HYVINVOINNIN LAITOS	FI
17	ECRIN	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	FR
18	BFARM	BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE	DE
19	HIQA	HEALTH INFORMATION AND QUALITY AUTHORITY	IE
20	ISS	ISTITUTO SUPERIORE DI SANITA	IT
21	CESSDA ERIC	CESSDA ERIC	NO
21.1	KNAW	KONINKLIJKE NEDERLANDSE AKADEMIE VAN WETENSCHAPPEN - KNAW	NL
21.2	EKKE	ETHNIKO KENTRO KOINONIKON EREVNON	EL

22	e-helse	DIREKTORAT FOR E-HELSE	NO
23	U.PORTO	UNIVERSIDADE DO PORTO	PT
24	SPMS	SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE	PT
25	NIJZ	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	SI
26	ERASMUS MC	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	NL
27	EDHA	EUROPEAN DIGITAL HEALTH ACADEMY GGMBH	DE
28	HDR UK	HEALTH DATA RESEARCH UK	UK
29	UESSEX	UNIVERSITY OF ESSEX	UK
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Developing a data quality and utility label for the European Health Data Space.

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Glossary

Term	Definition as per TEHDAS2 Joint Action ¹ and QUANTUM ²
Data controller¹	A data controller is a person or organisation that determines the purposes and essential means of the processing of personal data. The role of the data controller can be shared by several people or organisations. In that case, they are defined as joint controllers. The controller is accountable and responsible for establishing a lawful data processing workflow and observing the rights of data subjects. (GDPR Article 4(1)(7)).
Data holder¹	Any person, organisation or public body involved in healthcare, care services, health-related products, wellness apps or health(care) research, that has the right to process data for health care provision or for public health purposes, reimbursement, research, policy making, official statistics or patient safety. This includes, for example, hospitals, insurers, research institutes and EU institutions. For a more detailed definition: EHDS Regulation, Article 2(2) point (t))
Data processor¹	The data processor should handle data exclusively in the manner prescribed by the controller. A data processor acts under the detailed instructions of the data controller only, by processing personal data on their behalf. (GDPR, Article 4(1)(8))
Data Quality¹	Data quality means the degree to which the elements of electronic health data are suitable for their intended primary use and secondary use; (EHDS Article 2 (2)(z))
Fitness-for-purpose²	Utility of an accessed dataset according to the objective of the health data request. The information necessary to evaluate fit-for-purpose depends on the user's experience. This information needs to be added to the description of a dataset as fit-for-purpose metadata.
Fitness-for-use²	A dataset's "potential" utility, typically information that describes the dataset in a standard manner, such as source, provenance or lineage, content, distribution, etc.
Health data access body (HDAB)¹	Member state-designated authority that facilitates the secondary use of electronic health data. HDABs assess the information provided by the health data applicant and decide on health data requests and access applications, authorise and issue data permits, obtain data from data holders and make data available in secure processing environments. HDABs systematically track the data request and data access applications

¹ as defined in the TEHDAS2 Joint Action - <https://tehdas.eu/>

² as defined in D3.1 – Assessment report on the implementation process.
<https://doi.org/10.5281/zenodo.19662256>

Term	Definition as per TEHDAS2 Joint Action ¹ and QUANTUM ²
	received and the data permits issued. (EHDS Article 55 and Recital 52)
HDIEs¹	A legal person that may be established by national law for the purpose of fulfilling the obligations of certain categories of health data holders and that is able to process, make available, register, provide, restrict access to and exchange electronic health data for secondary use provided by health data holders. (EHDS Regulation, Article 50 (3) and Recital 59)
Maturity²	A feature at the data holder level. It refers to the level of automation of data and data quality management procedures.

1. Introduction

QUANTUM is a Horizon Europe funded project kicked off in 2024 that has developed a common data quality, utility and data holders' maturity label, as laid out in Article 78 of the European Health Data Space (EHDS) Regulation. The main goal of this label is to empower secondary use by making data discovery – the process through which researchers, policymakers, healthcare professionals and other data users find relevant data for their work – more meaningful. Figure 1 represents the data life cycle in EHDS for secondary use (EHDS2), depicting where QUANTUM fits in this life cycle. The before mentioned Article 78 makes the QUANTUM label mandatory for all publicly funded datasets (i.e. all datasets collected, processed or otherwise generated using national or EU funds). Thus, QUANTUM label is part of the metadata fields present in the future EHDS metadata standard, HealthDCAT-AP, and part of the datasets description and discovery. Meanwhile, the Fitness-for-Purpose Assessment introduces a user feedback mechanism at the end of the data use step that further empowers Data Users in data discovery by identifying datasets that are a good fit for their purposes.

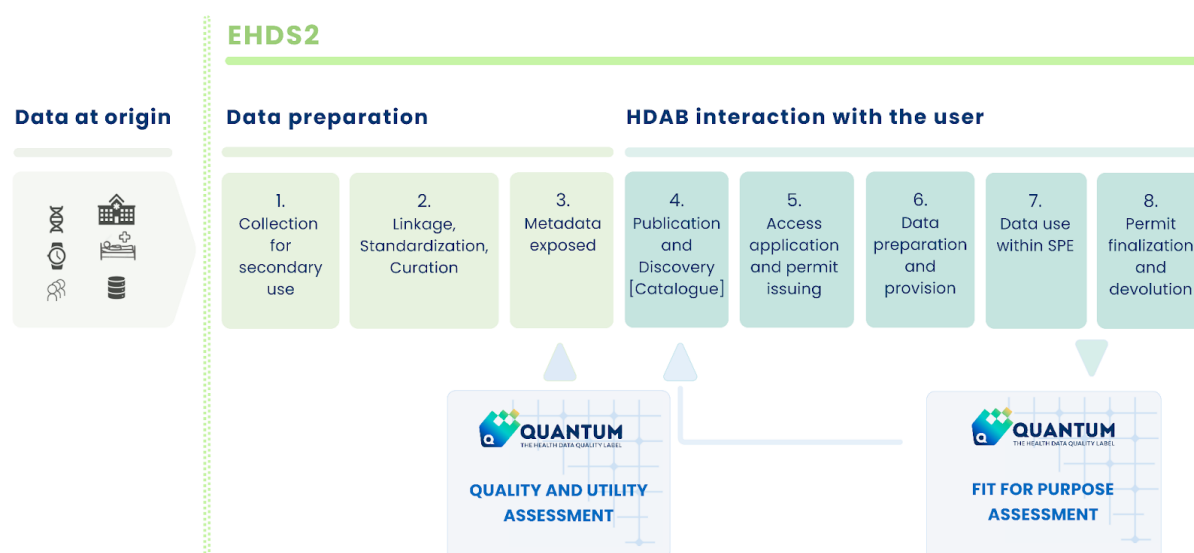


Figure 1. EHDS2 Data life cycle, QUANTUM is a part of the metadata exposed to the Data User during Discovery, and the Fit-for-Purpose assessment creates a user feedback cycle.

As a part of QUANTUM activities, a dedicated task sought to discuss the transfer and sustainability aspects for the implementation of the label of data quality and utility, and data holders' maturity developed in QUANTUM with relevant stakeholders. As a result, a set of "Guidelines and specifications for the implementation of the QUANTUM labelling mechanism as foreseen in the legislative regulation EHDSR article 78" to support the transfer and long-term sustainability of the QUANTUM label was delivered (Deliverable D3.2).

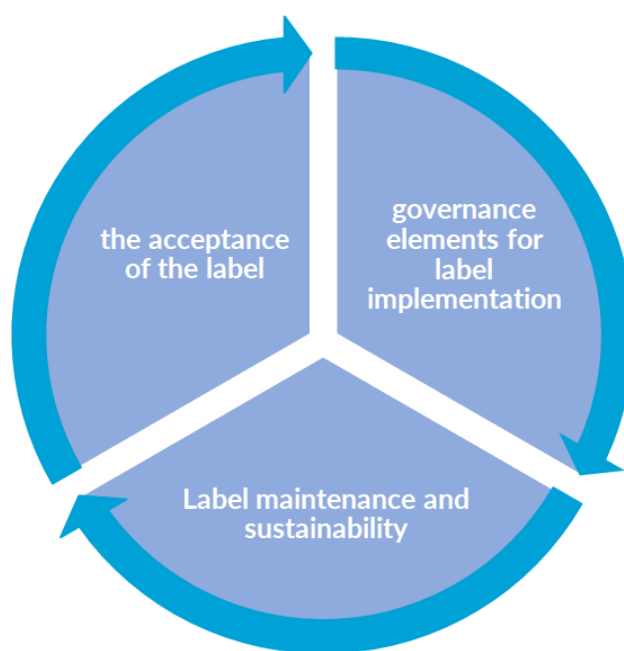


Figure 2. Core sustainability issues addressed in Task 3.4 “Transfer and sustainability” activities.

Deliverable D5.10 “Recommendations for the maintenance and upgrade of the QUANTUM labelling mechanism” summarizes the dedicated session that took place at the last QUANTUM meeting with the QUANTUM Advisory Board members (27/05/2026). This session aimed to discuss the sustainability and transferability topics of the developed QUANTUM Data Quality, Utility and Data Holder Maturity label and, in particular, the main recommendations for QUANTUM outcomes’ sustainability included in Deliverable 3.2.

2. Summary of dedicated discussion with the QUANTUM Advisory Board

The main issues tackled:

- The importance of making the outputs and tool's underlying specifications highly visible in the QUANTUM repository so others can adapt them.
- The need to have a roadmap (with short/medium/long term actions) on how QUANTUM recommendations can be implemented to target the EC and to ensure that the recommendations find their way in the EHDS Implementation Act.
- The need to draft a 5-pages "fact sheet" to summarize how to use the project's outputs, tools, and specifications for new users who cannot read the extensive QUANTUM Deliverables.

- The need for active advocacy³ to preserve the integrity of the QUANTUM specifications. To this end the coordinator will work on that together with those partners in close relation with the Member States participating in the EU Commitology process.

3. Recommendations for the sustainability of the EHDS2 Quality and Utility label

QUANTUM general recommendations for adoption and maintenance of the label, supporting the future implementing and delegated acts relating to the Data Quality and Utility Label, as foreseen in Article 78 of the EHDS Regulation focus specifically on aspects found crucial to the implementation, maintenance and sustainability of the QUANTUM Data Quality & Utility, and DH Maturity label, not addressing broader data quality topics that fall outside this scope.

Figure 3 below provides a high-level overview of the recommendations presented by QUANTUM in Deliverable 3.2.

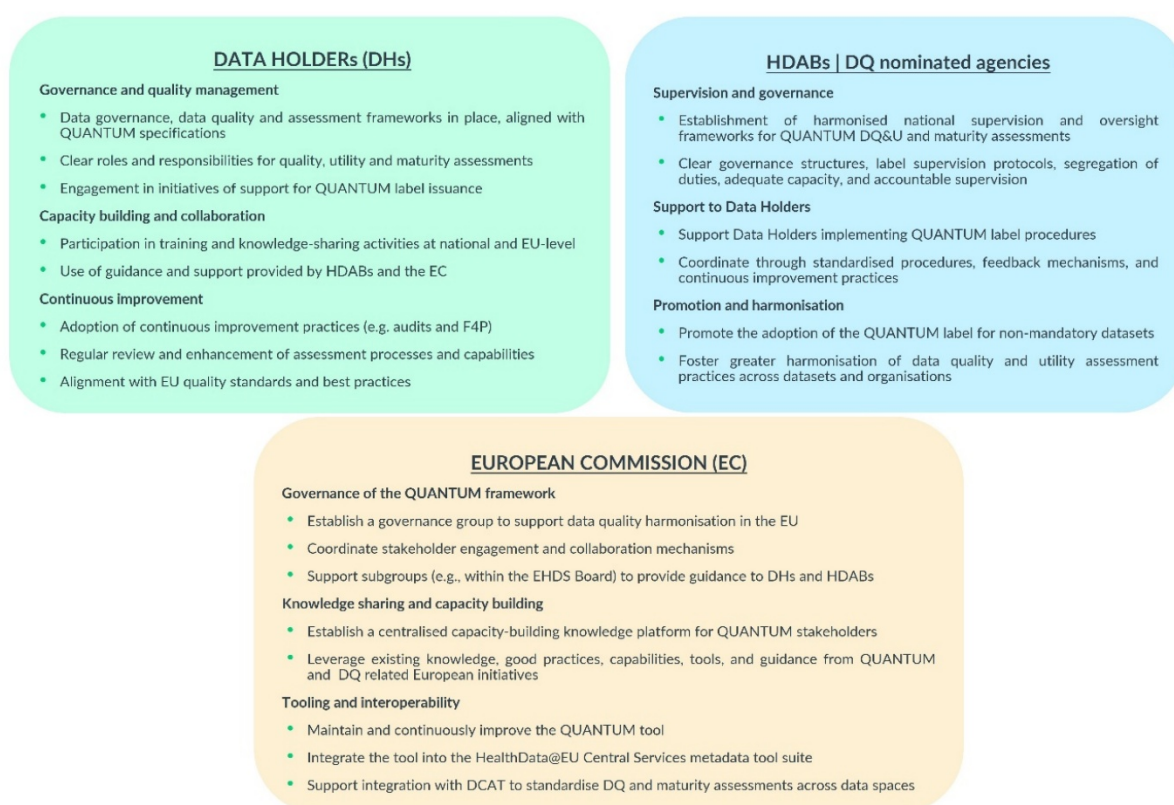


Figure 3. High-level overview of the recommendations addressed to DHs, HDABs/Data Quality nominated agencies, and the EC to support the governance, implementation, and sustainability of the QUANTUM Data Quality & Utility and maturity labelling framework.

³ A 5 pager was prepared and delivered as an input to the Commitology process.

Recommendations for the 3 stakeholder groups chiefly responsible for the implementation of the QUANTUM labelling specification, tools and supporting materials⁴, have been prioritised, following the EHDS Regulation implementation timelines, to create a simple and direct chronogram of when each recommendation group should be addressed. To wit, the considered timeframes are:

- **Short-term** – Until March 2027
- **Mid-term** – Until March 2029
- **Long-term** – After March 2029

Below follows the condensed, prioritised list:

Short-term:

1. Recognition of the label as a *de facto* standard – full introduction of the developed label specifications and related recommendations in the Article 78 implementing act
2. Integration of the tool into the HealthData@EU Central Services metadata tool suite
3. Establishment of a knowledge base collating all the *Academies* work, ready for use by all stakeholders
4. Establishing the mechanism for a structured update of the quality and utility specification
5. Development and testing of the fitness-for-purpose technical specification

Mid-term:

1. Extended controlled implementations along the whole data life cycle
2. EHDS steering board assumes Continuously improvement of the QUANTUM specification, tool and update related supporting materials
3. Implementation of the fitness-for-purpose (F4P) assessment evaluation for continuous improvements
4. Support integration with DCAT to standardise DQ and maturity assessments across data spaces
5. Setting up the community of practice and governance of the quality label
6. Data intermediation entities set up to support DHs duties
7. DHs should have data governance, data quality and assessment frameworks in place,

⁴ The QUANTUM outputs and tool's underlying specifications are available in the [QUANTUM repository](#) (QUANTUM Deliverable 4.4 due 30/06/2026).

aligned with QUANTUM specification. This will support them issuing the label. Clear roles and responsibilities for quality, utility and maturity assessments.

8. HDABs or data quality agencies nominated at national level and following harmonised national supervision and oversight frameworks for QUANTUM DQ&U and maturity assessments
9. HDABs or data quality agencies nominated at national level must support DHs implementing QUANTUM label procedures

Long-term:

1. Continuously improve the QUANTUM tool and update related materials
2. Establishing a culture of continuous improvement utilizing F4P, regular audits, etc
3. Promoting the adoption of the QUANTUM label for non-mandatory datasets
4. Fostering harmonisation of data quality and utility assessment practices across datasets and organisations
5. Support integration with DCAT to standardise DQ and maturity assessments across data spaces

In addition to these recommendations, a paper has been released and made available to several representatives of the EU Member States with the purpose of leveraging QUANTUM technical specification, tools and supporting materials in the process towards the actual implementations of Article 78. (See annex)

Annex

QUANTUM position with regard to the use of the QUANTUM technical specification and supporting material in the implementation of article 78

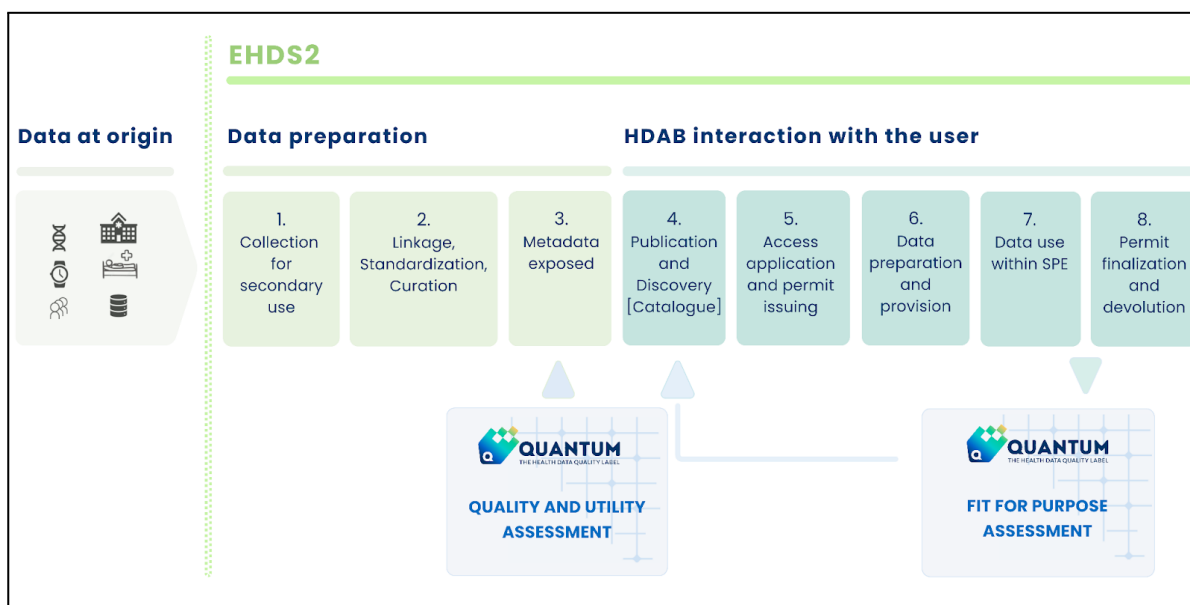
The QUANTUM project was granted to provide a technical solution supporting article 78 on the description of Datasets Quality and Utility in Healthdata@EU. The project held its final general assembly on May 27th, unofficially coming to an end. The project has already delivered the expected outcomes, concurrently with the start of the Commitology towards the drafting of the implementing act on article 78.

Scope

QUANTUM label has been thought as a self-assessed description of the quality and utility of the datasets **once datasets are prepared and made available for secondary purposes**. It does **not pursue labelling data sources but datasets** prepared for the purposes foreseen in article 53.

The logic of this decision is mainly based on:

- 1) a wide **agreement on what should be the data life-cycle for secondary purposes, and where the quality and utility label should fit** (see figure);
- 2) the **experience of secondary use champions** such as Findata, HDH, BIGAN-Aragon (ES), Health data Research UK, Darwin EU® or European Research and Digital infrastructures in the area of health such as BBMRI-ERIC, GDI or EUCAIM;
- 3) the **burden for data holders of medical records, highly dynamic (streaming) or non-structured data (natural language annotations)** to document the technical quality of the data.



QUANTUM's position with regard to the implementing act: there is a need for more specification on the scope of the label, clarifying that it applies to datasets intendedly prepared for secondary purposes, while recognising that the QUANTUM label has to input the Healthdata@EU catalogue.

Conceptual approach and QUANTUM solution

The QUANTUM specification builds on five restrictions:

- 1) As derived from recital 84, the label has to inform, beyond the general description of a dataset, on the specific quality and utility of a dataset, **to be exposed in the HealthData@EU Catalogue** (article 77) using the DCAT-AP vocabularies on the field.
- 2) Article 78 required the label to provide information on several elements encompassing technical data quality, potential utility (fitness-for-use), and data holders' maturity; the first **two at dataset level and the last at data holder level**.
- 3) **Maturity** is a property at **data holder level**; however, letter 3.c and 3.f requires maturity to be attached at dataset level.
- 4) **As quality is a concept linked to a specific purpose** and there may be as many purposes as users⁵, QUANTUM had to assume a **general approach, agnostic to purpose**.
- 5) In addition, the label has to describe the quality and utility of a wide variety of datasets (i.e., data categories) as in article 51, where technical quality

⁵ Purposes in article 53 are very generic from a data quality and fit-for-use perspective.

assessment may differ from one to another. QUANTUM had to **assume an agnostic approach to data categories**.

- 6) Finally, the label had to be technically simple, **ensuring feasible implementation** even for data holders with limited infrastructure or lower organisational maturity.

QUANTUM Solution

The absence of a framework, comprehensive enough, to cover all these needs led QUANTUM to create a **quality and utility specification (de facto standard) built on a large consensus** while grounded on existing data quality frameworks. This was not the case for the maturity part where the capability maturity model (CMM) provided sufficient knowledge base.

The technical specification for the DQ&U label includes **two independent assessments** - the **quality and utility of a dataset** (weighted dimensions and metrics) and **the maturity as the data governance workflow**, in the generation of this ++label. **While the first is covering letter a, b, d and e letters of articles 78.3; the second is covering data management maturity in letter c.** Importantly, the creation of the QUANTUM standard has used DCAT vocabularies when available or created their own definitions to be attached to DCAT properties. In the case of 78.3.c and 78.3.f, it was necessary to develop bespoke standard definitions.

Both assessments are independent in a way that **the data maturity complements the information provided but does not determine the quality and utility of a dataset.**

QUANTUM's position with regard to the implementing act: The QUANTUM specification is a de facto standard fitting the HealthData@EU needs, referred to in article 78, but also addressing the needs of article 77. This fact should be recognised keeping the specification as is, establishing a governance framework for its maintenance, update or upgrade.

QUANTUM outputs in support of the implementation of article 78

QUANTUM has developed the *de facto* standard for Healthdata@EU and the supporting material for its implementation:

1. The technical specification includes [data quality and utility dimensions](#) as well as [data holders maturity dimensions](#).
2. An open source and free [tool](#) for data holders to self-assess the quality and utility, and their own maturity, where the specification is embedded.
3. [Guidelines](#) to help data holders to better report using the tool.
4. [Training and educational materials](#) to help data holders to interpret the label.
5. An [RDF template](#) for the implementation of the quality and utility label in the Healthdata@EU catalogue.

QUANTUM's position with regard to the implementing act: QUANTUM has developed and successfully tested the technical specification and accompanying tools and material with a view to support HDAB and Data Holders in the process towards full EHDS2 implementation in May 2029. These outputs should be recognised as the reference toolbox for the implementation of article 78.

Implementation

The QUANTUM specification has been tested mid-scale in 35 different data holders⁶ and being used in broader EU initiatives, including ERICs/EDICs (BBMRI-ERIC, EUCAIM) and Joint Actions (CancerWatch, EuneCCC). A structured assessment of the implementation pilot has been released ([here](#)).

Currently, a draft document, still under internal evaluation, provides recommendations for data holders, health data access bodies and the European Commission for the transfer and sustainability of the label ([here](#)).

QUANTUM's position with regard to the implementing act: Given that implementation mid-scale pilots cover real-life situations in the future implementation of the label, the assessment and recommendations should be taken into consideration when drafting the implementing and delegated acts of article 78.

⁶ The list of data holders is [here](#)

Beyond QUANTUM scope

The consequence of assuming an agnostic approach in the development of the label specification is that datasets discovery acts as a screening on the potential quality and utility of a dataset. This brings the need for a [fitness-for-purpose](#) specification (F4P), which allows for a factual understanding of the technical quality of a dataset once accessed and used in a specific research or innovation query.

In short, the recommendation is providing data users the opportunity to report back to HDAB (and possibly to Data Holders) on the F4P of a specific dataset, attached to their specific purpose. As this would become real after running data quality assessments on the actual data, deposited in a SPE, these user's feedback could well be deemed a research outcome, that could be formally reported back to HDABs.

QUANTUM's position with regard to the implementing act: The fitness-for-purpose specification should be included in the implementation pipeline as an additional label and developed and tested before May 2029. As article 78 does not contain reference to this concept (nor it is in other articles of Chapter IV) an option would be including F4P specification as part of the users obligations in reporting research outcomes (article 61.4), and exposed in the Catalogue as a third deeper description of datasets.