D3.2 Guidelines and specifications for the implementation of the QUANTUM labelling mechanism

as foreseen in the legislation for the development of HealthData@EU, article 78

Nuno Cruz (SPMS)
Sara Marques (SPMS)
João Santos (SPMS)
Enrique Bernal-Delgado (IACS)

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Author(s)/Organisation(s)	Nuno Cruz, Sara Marques, João Santos (SPMS) Enrique Bernal-Delgado (IACS)
Contact Email	nuno.cruz.ext@spms.min-saude.pt sara.marques.ext@spms.min-saude.pt ebernal.iacs@aragon.es
Contributor(s)	Monica Jones; Eva Garcia; Truls Korsgaard; Siri Laronningen; Cátia Pinto; Peter Rijnbeek; Jaques Demotes; Jeroen Belien; Claudio Mercuri; Ana Prada; Jan-Willem Boiten; Maria Ryan; Giuseppe Davenio; Metka Zaletel; Tina Zupanic; Francisco Estupiñan Romero
Reviewer(s)	Valentine Facque; Lorentz Dolanski-Aghamanoukjan; Carlos Silvestre
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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	D3.2 aims to broach sustainability and transferability topics of the developed QUANTUM Data Quality, Utility and Data Holder Maturity label, issuing recommendations for the major stakeholders involved in its implementation (Data Holders, HDABs and the EC). These recommendations were developed through identification of key sustainability issues from previous work from Tasks 3.1-3.3, and surveys sent to HDABs and Data Holders in task 3.4. Through discussion with a dedicated Task Force, a first set of recommendations were outlined, to be validated and refined through two separate validation exercises based on a hybrid Nominal/Focus Group approach. Therefore, the document presents the consensual recommendations for the

	transfer and sustainability of the QUANTUM label resulting from T3.4 consensus exercises, concluding with proposals for future work, and open questions to be considered in the future.
Keywords	Sustainability; Transferability; Data Quality; Maturity; Recommendations; HealthData@EU

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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
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17	ECRIN	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	FR
18	BFARM	BUNDESINSTITUT FUR 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
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30	INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	FR

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QUANTUM

THE HEALTH DATA QUALITY LABEL

Developing a data quality and utility label for the European Health Data Space.

Project number: 101137057

Call: HORIZON-HLTH-2023-TOOL-05

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Executive Summary

This Deliverable aims to broach sustainability and transferability topics of the developed QUANTUM Data Quality, Utility and Data Holder Maturity label, issuing recommendations for the major stakeholders involved in its implementation (Data Holders, Health Data Access Bodies and the European Commission). These recommendations were developed and validated via consensus methods, built upon previous work from Tasks 3.1-3.3, and surveys sent to HDABs and Data Holders in Task 3.4.

From the consensus exercises performed by Task 3.4 (**Section 4**), a comprehensive list of recommendations was drafted for each stakeholder group (**Section 5**) and then further condensed into condensed into its key ideas, omitting more granular implementation details, and set to a timeline in accordance with the EHDS implementation timeline (**Section 6**):

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

A list of these key ideas and their timing for implementation is presented below for ease of consultation:

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

Mid-term:

1. Extended controlled implementations along the whole data life cycle
2. Procedures in place for the improvement of the QUANTUM specification, tool and supporting materials
3. Development and testing of the fitness-for-purpose (F4P) technical specifications
4. Implementation of the F4P assessment
5. Setting up a community of practice for the adequate implementation of the data quality and utility and Data Holders' (DHs) maturity label
6. Data intermediation entities set up to support DHs duties

7. DHs should have data governance, data quality and assessment frameworks in place, 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

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List of Abbreviations and Acronyms	
CoP	Community of Practice
DH	Data Holder
DQ	Data Quality
DQA	Data Quality Assessment
DQ&U	Data Quality and Utility
DQF	Data Quality Framework
DQMS	Data Quality Management System
DU	Data User
Dx.x	Deliverable (number)
EC	European Commission
EDIC	European Digital Infrastructure Consortium
ERIC	European Research Infrastructure Consortium
EHDS	European Health Data Space
EHDS2	European Health Data Space for the secondary use of health data
F4P	Fitness-for-purpose
HDAB	Health Data Access Body
HDIE	Health Data Intermediation Entity
HIQA	Health Information and Quality Authority, Ireland
HDRUK	Health Data Research UK
MS	Member-State
NGT	Nominal Group Technique
RIs	Research Infrastructures
SG	Subgroup
Tx.x	Task (number)
WP	Work Package

Glossary

Term	Definition as per TEHDAS2 Joint Action[1] and QUANTUM[2]
Data controller[1]	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 holder[1]	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 processor[1]	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 Quality[1]	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-purpose[2]	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-use[2]	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)
HDIEs[1]	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)
Maturity[2]	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 seeks to develop a common data quality, utility and data holders' maturity label, as laid out in Article 78 of the European Health Data Space (EHDS) Regulation [1]. 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 beforementioned 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 [2], 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.

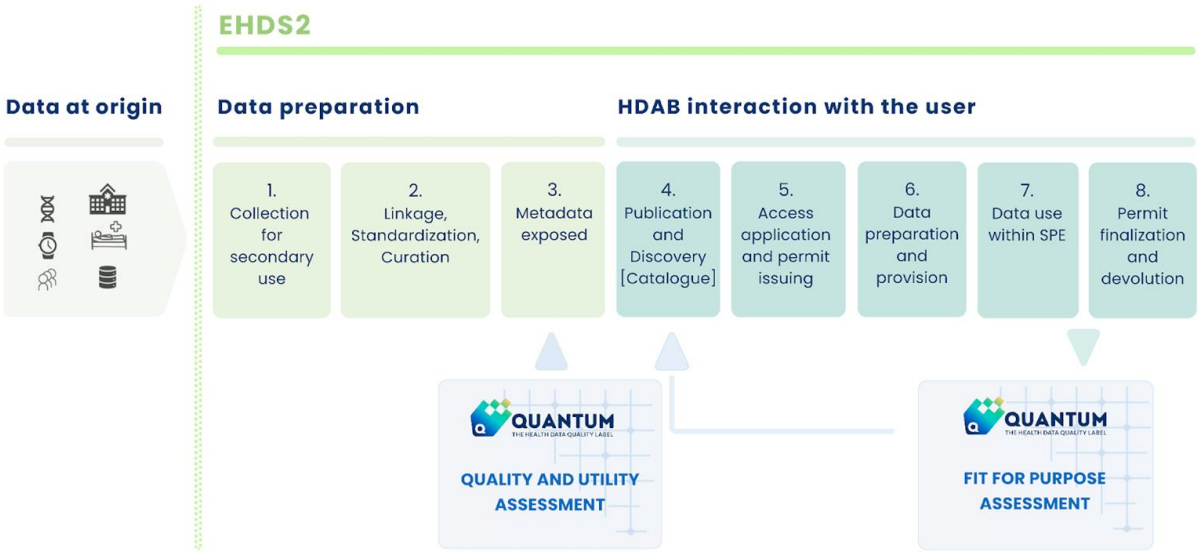

Figure 1. EHDS2 Data life cycle, QUANTUM is a part of the metadata exposed to the Data User during Discovery, and the Fit-for-Purpose assessment creates a user feedback cycle.

The establishment of the abovementioned label throughout the QUANTUM project was conducted by a set of technical Work Packages (Figure 2) interlinked to create the QUANTUM label while ensuring its sustainability and making stakeholders aware and capable of employing this label.

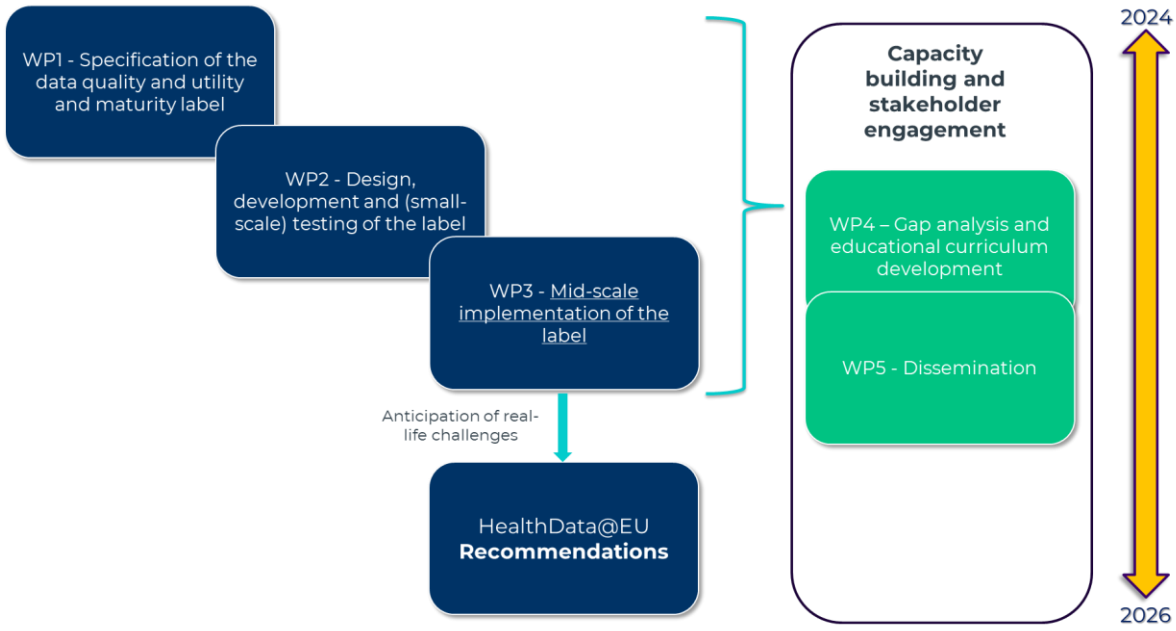

Figure 2. "Critical path" of the technical Work Packages of the QUANTUM project.

In QUANTUM Work Package (WP) 1 “Specification of the data quality and utility and maturity label” work in developing the specifications and establishing the dimensions of data quality and utility, and data holders’ maturity for the label was performed. These specifications encompass 12 dimensions and 15 metrics for Data Quality and Utility, and 10 dimensions for Data Holder Maturity [3,4]. A QUANTUM labelling tool was created in WP2 “Design, development and testing of the label”, aiming to streamline the process of generating the label based on those specifications (available at [5]). WP2 also tested the labelling tool in a small-scale pilot, engaging in an iterative improvement process of the tool.

As the work undertaken in QUANTUM lays the groundwork necessary to establish the Data Quality And Utility, and Maturity label that will be mandatory for all publicly funded datasets, it is important that the QUANTUM label is implemented in a sustainable fashion, guaranteeing its usefulness to EHDS stakeholders and minimizing the burden of its implementation on Data Holders and HDABs.

Therefore, once the label specifications and the labelling tool were developed, the implementation of the QUANTUM labelling tool in a diverse and representative set of data holders was tested in WP3 “Mid-scale implementation of the label”. Following an implementation plan (T3.1. “Implementation Plan”), in task T3.2 (“Mid-scale Implementation Pilot”) the QUANTUM labelling system was piloted at a larger scale than in WP2 (tested by 18 and 32 data holders, respectively, in the first and seconds rounds), while in T3.3. (“Implementation Assessment”) insights from the data holders that tested the tool were collected to assess feasibility, barriers, facilitators, institutional preparedness and governance aspects. The outputs from these tasks enabled to inform tool´s improvements, and to gather insights to issue recommendations for the transference and sustainability of the QUANTUM

label. This document contains the resulting recommendations, building upon the work in implementing the QUANTUM label in previous WP3 "Mid-scale implementation of the label" tasks. In T3.4 "Transfer and sustainability", the experience from the mid-scale pilot was leveraged, collecting implementation assessment and expert inputs to issue recommendations on the practical aspects of implementation and sustainability of the developed label and labelling mechanism.

Concurrently to the activities of WP1-3, WP4 "Capacity building, community engagement and scale up" worked to address data holders educational and training needs, building capacity and providing guidance in the best use of the QUANTUM label. Meanwhile, WP5 "Dissemination and outreach" reached outside the project's Consortium to research initiatives, patients, citizens and other HealthData@EU-building projects for dissemination and validating the Fit-for-Purpose approach.

1.1. Data Holders: Towards automating quality, utility and maturity reporting

With the application of Regulation (EU) 2025/327 establishing the EHDS [6], applicable as of March 2029, a set of specific obligations is imposed on health Data Holders (DHs) [3].

A DH is any natural or legal person, public authority, or public or private entity that processes electronic health data or makes available non-personal electronic health data in the context of healthcare delivery or health sector activities (Article 2.º (19)). This definition encompasses a wide range of stakeholders, including healthcare providers across public, private, and social care sectors, healthcare professionals, public health authorities, custodians of health registries, research organisations, and developers of digital health and wellness applications.

Among the key obligations established under the EHDS framework, DHs are required to provide a **Data Quality and Utility Label**[4] in the description of the datasets, as set out in Articles 60 and 78 of the EHDS [6]. Furthermore, DHs must provide sufficient supporting documentation to the competent Health Data Access Body (HDAB), enabling verification of the accuracy and reliability of the assigned quality and utility classification.

As such, the ability for DHs to easily report on the quality and utility of their datasets and the maturity of their institution is key to facilitate the adoption of the QUANTUM label. Data Quality reporting has been contemplated in multiple Data Quality Frameworks (DQF), documents that provide requirements, specifications and guidelines to ensure production and documentation of high-quality data.

Before the EHDS and QUANTUM, the DQF dimensions and their definitions lacked harmonization, being dependent on the institution drafting such documents. To harness this

[3] Natural persons or microenterprises are exempt from these duties (Article 50 of EHDS)
[4] Only for data holders with national or European public funding

fragmentation, QUANTUM project Deliverable 1.1 – Specification of the Data Sets' Quality and Utility Label and Deliverable 1.2 – Specification for the Assessment of Data Holders' Maturity issued standardized dimensions and definitions for reporting Data Quality and Utility, and DHs Maturity [3,4], producing the EHDS2 "de facto" standard for quality, fitness-for-use and maturity. This deliverable builds upon QUANTUM previous work, while also considering other examples of DQF [7,8] to help fuel the recommendations for DHs for the sustainability of QUANTUM.

1.2. HDAB: Towards supervising quality, utility and maturity reporting

The HDAB is the responsible entity for ensuring DHs´ compliance with the EHDS Regulation, as defined in Articles 57, d) and 78 (4). ("[…] *HDABs cooperating with and supervising health data holders to ensure the consistent and accurate implementation of the provisions on data quality and utility label in Article 78*", and "*Where a health data access body has reason to believe that a data quality and utility label might be inaccurate, it shall assess whether the dataset covered by the label meets the quality requirements forming part of the elements of the data quality and utility label (…) and, in the event the dataset does not meet the quality requirements, shall revoke the label*.") [1]. Therefore, **HDABs need sound strategies to supervise, monitor and audit the reporting of the QUANTUM label by DHs.** This auditing will, in part, be **facilitated by one of the DH duties as stated in Article 60 of the EHDS Regulation**, where it is stated that DHs shall *"provide sufficient documentation to the health data access body for that body to verify the accuracy of the label"* [1].

Official HDABs must be nominated until March 2027, so these entities as foreseen in the EHDS Regulation are not yet implemented. Guidance for HDABs to verify the accuracy of the label and to support DHs fulfilling their duties are, therefore, required. To that end, guidelines from existing data quality assurance frameworks from institutions performing similar tasks were consulted to grasp best practices and outline the recommendations present in this document.

From these it was possible to identify the importance of **creating and maintaining infrastructures to house documentation** (for traceability and auditability), of the existence of **widely available quality guidelines** (providing methods to ensure high-quality data at the source) and the need for **trained auditors** that perform their tasks based on **reference documentation** [9]. Likewise, existing quality assurance frameworks recommend including quality assessment procedures as a part of quality management, since **quality reports can be used as a basis for audits**. In that sense, the **HDAB should encourage and foster an environment of continuous quality assessment in DHs**, providing **clear quality indicators** (the QUANTUM label) and making sure they are understood by DHs so these can output relevant documentation [10]. The need for cooperation between HDABs and DHs to ensure that the latter produce high-quality quality reports has been also reported, along with the need of reinforcing **quality at every step**, employing **proper quality assurance measures in a continuous fashion**, through a **multidisciplinary approach.** Existing reports in the field also

address the importance of adequate liaising between DHs and data custodians with the HDAB to **foster adherence to data quality standards** [11].

2. Scope

As a part of WP3, Task 3.4 "Transfer and sustainability" seeks 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 (Figure 3), to build guidelines and specifications for the implementation of the QUANTUM labelling mechanism in HealthData@EU. Therefore, this deliverable contains guidance and recommendations to support the transfer and long-term sustainability of the QUANTUM label.

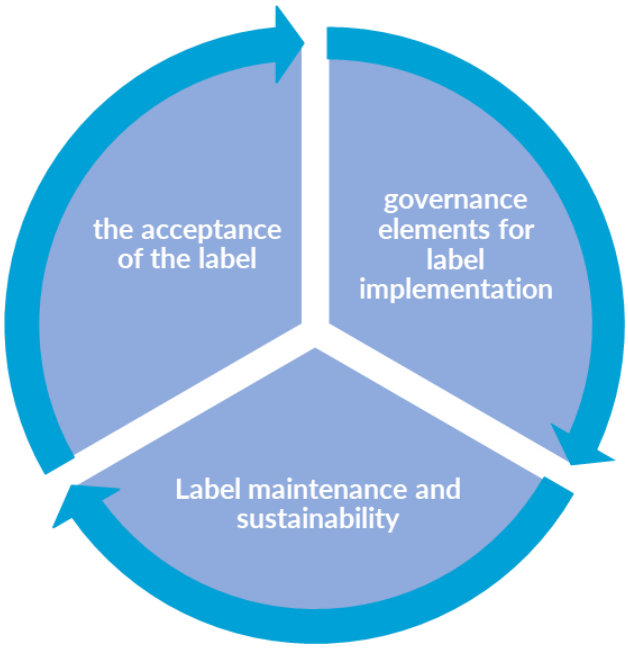

Figure 3. Core sustainability issues addressed in Task 3.4 "Transfer and sustainability" activities.

Importantly, this document will **not** prescribe specific technological solutions for label implementation and sustainability but will instead issue general **recommendations for adoption and maintenance of the label**. These guidelines will serve to support the future implementing and delegated acts relating to the Data Quality and Utility label, as foreseen in Article 78 of the EHDS Regulation [1]. Furthermore, this document will not focus on the user's experience with the datasets (i.e. Fitness-for-Purpose), as that is the purview of a separate deliverable.

In this Deliverable, the methodologies employed to arrive at the final recommendations are described, followed by an overview of WP3's results to provide context for the proposed recommendations. The recommendations section (section 5) covers all QUANTUM-relevant EHDS stakeholders: DHs, HDABs and the European Commission (EC).

3. Methodology

To generate guidelines and specifications for the long-term sustainability of the QUANTUM label, the utilization of consensus methodologies was necessary, maximizing the impact of expert insights. These methodologies have a history of utilization in several fields, including health research and the development of clinical guidelines. Commonly used consensus methods count among them the Nominal Group Technique (NGT), the Delphi method, RAND/UCLA Appropriateness Method, and Focus Groups, each with their own advantages and disadvantages [12–14].

Considering the tasks timeline, goals, and the topics to broach, the strategy adopted was the combination of the Focus Group and Nominal Group techniques. This combination was chosen since it allowed to flow from the rich outputs from a focused group discussion to the structured problem-solving and prioritization of the nominal group method [15,16].

Before activating the Focus Group, surveys were sent to HDABs and DHs within the QUANTUM Consortium, to obtain their insights and gauge consensus on various key sustainability topics. These questionnaires (Annexes I and II) leveraged the results from the pilot implementation (T3.2 and T3.3) of the labelling tool developed in WP2 “Design, development and testing of the label” to formulate the key questions to be answered. Specifically, the narrative feedback responses were directly leveraged to help construct the surveys sent by T3.4 to DHs and HDABs. These surveys covered the current status of DHs quality, utility and maturity assessments, and their needs to comply with the QUANTUM label, as well as multiple governance aspects relating to the HDAB duties, such as auditing, supervision and the real-life application of the QUANTUM label. After obtaining and processing the answers to the surveys, a document with a first draft of the recommendations was shared with the Focus Group members. This group **consisted of a task force of eight experts within the project Consortium**, with whom several topics related to the long-term implementation and sustainability of the QUANTUM label were addressed in four meetings, conducted through Microsoft Teams (Figure 4).

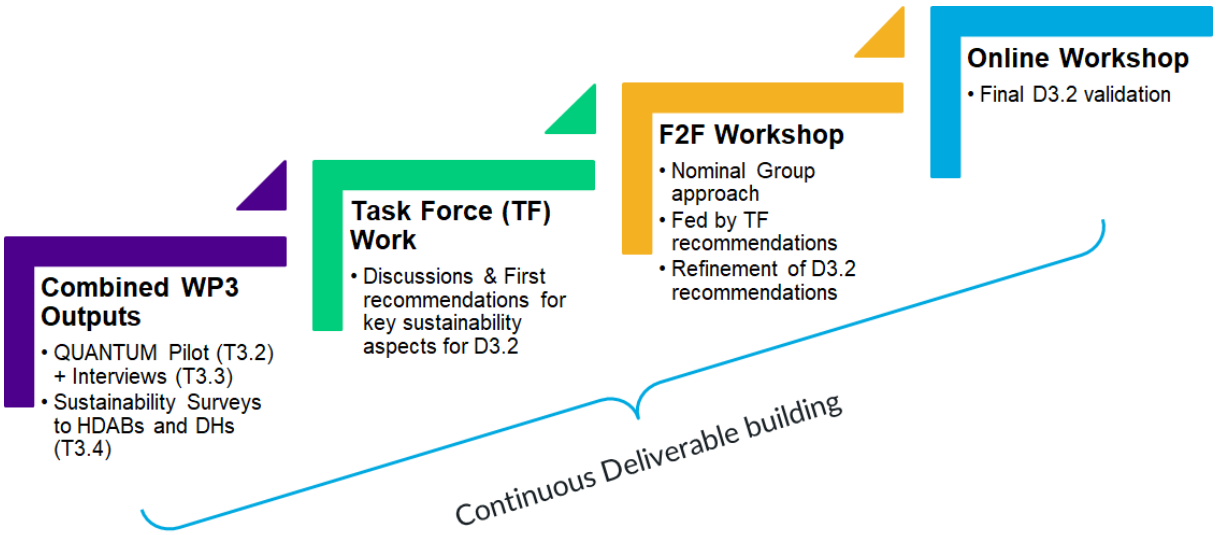

Figure 4. Roadmap to building D3.2 - Guidelines and specifications for the QUANTUM labelling mechanism.

After the Focus Group exercise conclusion, the obtained feedback regarding the first draft of the recommendations was transformed into a second version, which was **sent as preparatory material ahead of time to the Nominal Group participants, drawn from organisations that had tested the QUANTUM Label and already employed any kind of Data Quality methodology.** A face-to-face workshop hosted the Nominal Group, aiming to refine the task force's insights (second version of the recommendations) into actionable recommendations and guidelines for QUANTUM label sustainability and broad implementation on HealthData@EU. This workshop was made up of **multiple discussion sessions**, focused on certain implementation and sustainability topics of the QUANTUM label, namely:

- Recommendations for DHs on QUANTUM label application in real-life
- Recommendations for HDABs on QUANTUM label supervision and liaising with DHs
- Recommendations for the European Commission (EC) to support DHs and HDABs on the real-life implementation of the QUANTUM label

These sessions counted with a total of **21 participants** both online and face-to-face over a two-day runtime. In each session, context for each topic was provided before presenting the draft recommendations for discussion.

Once all recommendations for the current discussion topic were presented, there was a **validation phase, where participants voted via an online tool on their level of agreement with each recommendation on a 5-point Likert scale (strongly disagree to strongly agree), with the ability to provide comments via free text**. The feedback gathered during the nominal group exercise was then used to refine the third version of the recommendations. This third version was subsequently utilized to generate an **online form that allowed for an asynchronous second validation exercise** (Figure 4). For this exercise, **participants were filled in on the context of the recommendations, the methodology of the validation exercise** and had their questions

answered, before being **sent the online form.** This online form followed the same overall structure of the Face-to-Face Workshop: **participants voted on their level of agreement on a 5-point Likert scale, with the ability to provide comments via free text at the end of each section of recommendations (DHs, HDABs, EC).** The results of this final validation exercise were then used to create the final version of the recommendations present in the section 5 of this document.

4. Lessons learnt from data holders and HDABs for the implementation of QUANTUM

As one of the project's efforts, a mid-scale implementation pilot of the QUANTUM label was performed (T3.3), gathering HDABs and DHs to test the QUANTUM labelling tool. The testers group covered multiple organizations, such as academic institutions, hospitals, repositories, data hubs and others, aiming to maximise representativity. The data types used by the participants also covered multiple health data types (tabular, non-tabular, images, populational, etc.). The participants were interviewed not only on their experiences with the tool (T3.2), but also on the implementation aspects of the QUANTUM label (T3.3). These interviews therefore enables to extract insights from the DHs and HDAB points of view and have been used to inform our work in this document.

This section will cover the major lessons learnt for DHs and HDABs, coming out of the implementation exercises, as these were crucial to draft the recommendations proposed in the section 5 of this document.

4.1. Outcomes from the mid-scale pilot exercise (D3.1)

This section summarises the findings of the mid-scale pilot exercise (T3.3), providing key insights into the core sustainability issues of the QUANTUM label. The full, detailed report on the methodologies employed during the pilot, and a comprehensive discussion of its results, can be consulted in Deliverable 3.1 "Assessment report on the implementation process" [17].

4.1.1. Main Findings: the final specification in practice

After the first round of the pilot, interview sessions were held with a representative selection of test participants, focusing on topics of institutional preparedness for the label, support and resources needed, barriers and facilitators for the application of the label, and other sustainability aspects. The second round used a focus group approach to overcome the underrepresentation of academia and population health data repositories in the first round, explore topics from the first round in more detail and gauge the effect of changes to the QUANTUM labelling tool made after the feedback from the first round. The narrative feedback responses were directly leveraged to help construct the surveys sent by T3.4 to DHs and HDABs.

The structured results from the pilot first round interviews, addressing topics such as barriers and facilitators, experience with the tool, and institutional preparedness, among other, were filtered by T3.4 to identify topics directly related to the sustainability, transferability and governance for the implementation of the QUANTUM label. The main points identified to be addressed in T3.4 are presented in Tables 1 to 3.

Table 1. Outcomes from T3.3 relevant for T3.4 work on the topic of organizational aspects on data governance.

Outcome 1 - organizational aspects on data governance	
Sub-themes	**Description**
Over-seeing body and organisational co-ordination	Without an over-seeing body that co-ordinates the filling out of tool on a yearly basis its implementation is not possible. Roles and responsibilities need to be determined.
Organisational co-ordination required	Participants see the need for different parts of their organisation to coordinate well.
Technical and legal support requirement	Participants required legal support as well as technical support such as interpretation of questions from similar colleagues.
Coordination across the organisation	Co-ordination between IT systems and owners of different datasets or a central co-ordinating authority is necessary for transferability to different datasets
Quality vs. Maturity dimensions	Participants found the Quality Aspect of the tool easier to answer on their own in comparison to the maturity aspect of the tool, for which they required help. Only one user experienced no difference.
Mandatory data knowledge and expertise	Participants felt the need for a field level technical knowledge and involvement with the dataset to be prepared to implement the tool. Two different individuals must fill the data quality and maturity aspect.
Time and designated resources	Participants highlighted that designated time and resources towards new roles were mandatory for the sustainability & transferability of the tool.
Metadata	Participants encountered a lack of metadata in their databases or documentation needed to assess the label.
Lack of information on governance	Participants lacked knowledge regarding data governance practices and suggested that seniors might have a better idea of it.
Existing approval and audit cycles	Organisations had potential approval, audit and feedback loops in place.

Regarding data governance, the narrative feedback pointed toward a need for data quality and governance frameworks, with defined roles and responsibilities to assess quality and maturity for the QUANTUM label. To achieve this, cross-coordination within the organisation (between technical experts and governance experts), with data providers and with the HDAB is required. Clear audit and approval cycles were also identified as crucial.

Table 2. Outcomes from T3.3 relevant for T3.4 work on data quality improvement and technical preparedness of institutions.

Outcome 2 - organizational aspect on data quality improvement	
Sub-themes	**Description**
Allocation of resources	Organisations require proper data quality improvement roles and investment in resources.
Quality data	A wish to improve data quality may be a facilitator to the implementation of the tool.
Bench-marking tool	The tool must state comparison scores, or suggestions to improve scores in order to improve data quality in organisations.
No major initiatives	Participants had expected a similar data quality score as estimated by tool, and that did not lead to any quality enhancement initiatives

Outcome 3 - organizational aspect on technical preparedness	
Time-consuming	Participants found the process of filling out the tool slow and time-consuming. One participant disagreed.
Organisations were pre-prepared	Organisations were pre-prepared and found it easy to enter data into the tool as they had utilized OMOP common data model recently.
Potential future change of processes	Because of QUANTUM, organisations consider changes in their processes (tool integration, documentation practices, assignment of roles and teams, ...).
Data quality improvement practices	Participants highlighted the importance of data quality. Some organisations had quality improvement strategies in place, whereas others hoped to have standard practices in place in the future.
Future support/resources	Data governance teams and AI technologies may be able to provide support for filling out the tool in the future.

Interviewees expressed that the QUANTUM labelling tool should encourage its users (DHs) to improve their data quality, suggesting benchmarking features. The idea of implementing strategies to encourage data quality improvement as a way to improve the implementation of the QUANTUM labelling tool was also expressed. As for the technical aspects of tool utilisation, interviewees expressed worry about the scalability of the tool, suggesting automatization wherever possible, and reinforced the notion that institutions that already employ Common Data Models like OMOP are better prepared to fill in the tool.

Table 3. Outcomes from T3.3 relevant for T3.4 work on the topics of promoting data sharing and training needs of stakeholders.

Outcome 4 - Promoting data sharing	
Sub-themes	**Description**
Lack of incentives	Organisations lack the initiative of sharing data unless they are offered incentives such as co-authorship.
Reluctance to share data	Data holders and physicians are reluctant to share data within and among organisations. This is a huge barrier.
Outcome 5 - Training needs	
Expertise dependent	The usability of tool is dependent on the user's level of expertise and experience in this field
Mandatory knowledge of QUANTUM	Participants need some knowledge about QUANTUM to be able to assess the label.
Training needed	N/A

Table 3 gathers the outcomes related to data sharing promotion and stakeholder training needs, where interviewees expressed that training on QUANTUM is key to ensure the labelling tool users can perform quality, utility and maturity assessments in accordance with QUANTUM standards. Furthermore, they noted that users need to be familiar with the intricacies of data quality and institutional maturity to perform QUANTUM labelling tasks. Finally, interviewees expressed worry about the incentives to data sharing: due to the time and manpower investment required in creating datasets and their descriptions, organisations are typically interested in being the primary beneficiary of the data; this creates a barrier to data sharing.

The Focus Group exercise conducted in T3.3 upon the second round of the mid-scale pilot reiterated most of the findings of the first-round interviews, but a few new points were brought

up, particularly on governance aspects:

- **Lack of continuity:** it is common in less mature DHs that the individuals that have deep knowledge of the datasets, their data models and methods do not transfer that knowledge before leaving their position, generating a loss of expertise and creating difficulties in performing the QUANTUM assessment.
- Less mature institutions faced higher difficulties performing QUANTUM assessments due to lacking the expertise to perform such an evaluation and lack of adequate governance frameworks: the QUANTUM labelling should also be accessible to less mature organizations, as those results will become useful as a tool to strengthen institutional maturity.
- **Maturity heterogeneity:** in some institutions a maturity assessment at the organization level does not accurately depict the maturity of the processes applied to the gathering and construction of the dataset. This happens due to heterogeneity in the institution's approach to different data types, or in the workflows of different departments. For these cases, it was suggested the possibility of issuing a "dataset level" maturity label in the QUANTUM labelling system.
- **Transferability:** Interest was shown in including the QUANTUM label into HealthDCAT-AP metadata, and assurance of FAIR machine actionability to increase interoperability.
- **Comparability and objectivity:** for the label to work as intended, the responsibility of the HDAB in ensuring that the labels issued by DHs reflect reality will be crucial to garner trust and maintain comparability and objectivity.

4.2. Outcomes from T3.4

The feedback collected during T3.3. provided key context to guide T3.4 work in the recommendations for the implementation of the QUANTUM label. As previously mentioned in the Methodology (section 3), to expand on the governance topics reported on during the pilot and obtain deeper insights from DHs and HDABs, T3.4 sent questionnaires to these stakeholder groups. Below the resulting collected insights are summarized.

4.2.1. Data holders – surveys to capture needs

Surveys (Annex I) were responded to by 8 data holders from Belgium, Spain, France, Ireland, Italy, Netherlands, and international organizations not directly affiliated with any single Member State. The survey aimed to answer key questions in DH general needs for QUANTUM implementation, gauge the current state of DH data quality assessments and gather insights on their plans to comply with the QUANTUM label. Table 4 presents a summary of the survey findings.

Table 4. Summary of T3.4 Data Holder Survey results.

Key Question	Survey Results
	Data Quality Assessment
Data Quality Assessment status	75% of respondents perform DQA, using a mix of (semi) automatic tools, data quality improvement workflows, implementation of data quality (DQ) frameworks and methodological procedures. Most of these (83%) have data storage solutions for DQ evaluation documentation, **but costs are a burden**.
Barriers to DQA	• Lack of knowledge (33%) • Resourcing/financial challenges (33%) • For a Data Holder that depends on a single agent, with datasets distributed across sites, sometimes the responsibility is not site or is delegated to the data provider (33%)
Certification	Certifications are not always employed (50%), and when they are, they differ from institution to institution.
Label compliance by Data Holders	
Label compliance strategies	100% of respondents accompany QUANTUM developments, and are incorporating/planning to incorporate QUANTUM into their workflows
DH needs for compliance	• Documentation on DQ assessments, reporting and templates • Training on label application and governance best practices
Desired features for the QUANTUM labelling tool	• **Versioning of quality assessments** • **Bulk assessment actions** • **RDF importing and exporting functions** • **Step-by-step built-in guides**
Health Data Intermediation Entities (HDIEs) as supporting agents	Responses revealed average interest (3 in a 5-point scale) in HDIEs as agents to help reduce administrative burden, despite mounting worry about the workload necessary to perform QUANTUM labelling operations.

4.2.2. HDABs – surveys to capture needs

Surveys (Annex II) were responded by 7 HDABs/HDAB implementing entities from Belgium, Germany, Luxembourg, Finland, France, Netherlands and Slovenia. This survey aimed to gather insights on key questions regarding governance: supervision of DHs' labels, certification of the label and auditing, and real-life application of the label. Table 5 presents a summary of the collected insights.

Table 5. Key insights derived from the survey directed to (future) HDABs.

Key Question	Survey Result
Governance – Data Holders supervision and support	
HDAB DQ supervision status	1 out of 7 (14%) respondents oversees DQ reporting by other institutions, employing (semi) automatic auditing tools.
How should oversight of QUANTUM label application be performed in each MS? What tools will be required?	Some (50%) HDAB implementers believe this task will need a dedicated body (like a dedicated HDAB), others (50%) believe that it is too early to decide. To fulfil this task, the responsible body would require dedicated DQ Officers and (semi) automatic tools. Despite this, most respondents are not planning to employ dedicated DQ teams, stating that alternative solutions depend on national legislative developments and QUANTUM having fully developed label criteria.
How will HDABs inform Data Holders of their duties, and the tools available for them to fulfil them?	Most (71%) respondents already have employed or planned dissemination and training strategies for Data Holders.
Governance – Certification and Auditing	
Is certification of the label by a third-party necessary, particularly for high-quality labels?	This is a contentious issue, and there is a 50% division on whether the label could be audited by the HDAB in all cases, or if a third-party validation is necessary for higher quality labels.
Avoiding conflicts of interest: can HDABs that are also Data Holders properly audit the DQ labels they emit?	All respondents are of the opinion that segregation of duties in the HDAB is sufficient to prevent conflicts of interest.
Standardization:	71% of respondents believe that receiving standardized documentation from Data Holders will be useful, and that guidelines for auditing this documentation are helpful. 29%

• Standard templates on label support documentation for data holders • Guidelines for auditing this documentation	disagree, believing that auditing guidelines are not useful, and that standardization is not viable.
Governance – Application of the label	
DQ and Maturity Label for datasets sourced from multiple Data Holders: How to implement?	Data Quality: the institution generating the label should be responsible for the Data Quality part of the label. Maturity: there is a trade-off between granularity in Maturity evaluation (since maturity varies intra and inter-institutionally) and the associated burden to Data Holders in performing these evaluations. Some suggestions were presented: • Apply the lowest maturity on the composite dataset as the final maturity score • Use the average maturity as the final maturity score • Display the individual maturity levels of Data Holders and the resulting average
How to spread the QUANTUM label to non-mandatory datasets?	Only 50% of respondents plan to spread the QUANTUM label to non-mandatory datasets, with only 50% of those institutions having plans to perform this dissemination. These plans range from supporting Data Holders with workshops, communication materials, training and templates, and direct contact with relevant stakeholders and private data holders. The respondents that gave a negative answer did so chiefly due to uncertainty in the national legislation, or due to a lack of influence over non-public datasets.

4.2.3. Consensus exercises to validate recommendations

As detailed in section 3, recommendations were drafted based on cumulative work (Figure 4): first insights on DHs and HDABs needs were collected from T3.3 results and T3.4 surveys. These insights then resulted in a set of recommendations drafted together with a dedicated task force. These were submitted to two rounds of validation.

The first validation exercise took place in a hybrid format. Twelve participants representing DHs and (future) HDABs that are part of the QUANTUM Consortium joined both in person and online. In this event, each recommendation was voted in a 5-point Likert scale (Strongly Disagree to Strongly Agree), and free-text comments were taken in after each voting session, allowing participants to describe aspects requiring modification in the drafted

recommendations. This exercise allowed to gauge the level of consensus (Tables 6 to 8 and Annex III) and refine the recommendations towards the version used in the final validation stage.

Out of the 59 recommendations that were put up to vote, 49 (83%) exhibited high levels of consensus (considering the frequency charts with the distribution of votes, the median of results and its IQR, and average and respective standard deviation) and only 1 recommendation (1,7%) was considered fully rejected (average score <3), not moving to the second validation exercise. The free-text comments provided critical insights into the more contentious recommendations and helped find points of improvement for non-accepted recommendations, towards their paraphrasing into acceptable versions. The free-text comments were also considered for recommendations for which there was a high level of agreement, to change their content into more mature and agreeable versions.

The second and final validation exercise extended the pool of participants to cover multiple stakeholder groups across the QUANTUM Consortium. This exercise involved 17 participants, with a good representativity of all relevant stakeholders (DHs, HDABs, Research Institutions), and of the countries represented in the Consortium (10 out of the 16). This exercise was done via an online form, following a similar methodology: each recommendation was voted on the level of agreement in a 5-point Likert scale, with the possibility of submitting free-text comments to suggest alterations, improvements or provide justification for negative votes. The responses (Tables 9-11 and Annex IV) were used to obtain the final version of the recommendations, as presented in Section 5.

In this second exercise, out of the 91 recommendations that were put up to vote, 86 (95%) exhibited high levels of consensus (IQR<2), and 5 (7,7%) were considered non-consensual (IQR≥2). Beyond the IQR analysis, two additional recommendations were considered as non-consensual when considering the frequency charts with the distribution of votes, average values and respective standard deviation, and the feedback received, for a total of 7. Out of these 7, 3 were revised to meet the written feedback provided, and 4 were completely rejected. For all recommendations, the written feedback provided by all respondents was invaluable to reword and refactor the recommendations into improved, more agreeable versions. Furthermore, whenever necessary, these comments were used to add recommendations to the appropriate sections.

To note, some comments highlighted concerns regarding the heavy resource cost (human, financial or otherwise) of implementation of the QUANTUM label on DHs, HDABs and the EC, which will have to be considered for the long-term sustainability of the QUANTUM label.

First Validation Exercise Analysis

Table 6. Analysis of results from the first validation exercise for the Data Holder Recommendations.

DHs	***Quality Assessments***								
		Rec. 1	**Rec. 1.1**	**Rec. 1.2**	**Rec. 1.2.1.**	**Rec. 1.2.2.**	**Rec. 1.3**	**Rec. 1.4**	**Rec. 2**	**Rec. 3**
	Median (IQR)	5.00(1.00)	4.00(1.00)	5.00(0.00)	5.00(0.25)	4.00(1.00)	3.00(0.50)	5.00(0.00)	5.00(0.25)	5.00(0.00)
	Avg±SD	4.42±1.16	4.17±0.94	4.83±0.39	4.58±0.90	4.25±0.62	2.73±1.01	4.92±0.29	4.75±0.45	4.83±0.39
		Rec. 3.1.	**Rec. 3.2**	**Rec. 4**	**Rec. 5**					
	Median (IQR)	5.00(1.00)	4.00(1.25)	5.00(0.00)	4.00(1.50)					
	Avg±SD	4.55±0.69	4.17±0.83	4.75±0.62	3.82±0.98					
	Label Compliance									
		Rec. 1	**Rec. 2**	**Rec. 3**	**Rec. 4**	**Rec. 5**				
	Median (IQR)	4.50(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.25)	5.00(1.00)				
	Avg±SD	4.40±0.64	4.90±0.28	4.80±0.37	4.30±1.01	4.50±0.65				

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Table 7. Analysis of results from the first validation exercise for the HDAB Recommendations.

HDABs		**Rec. 1**	**Rec. 1.1**	**Rec. 1.2**	**Rec. 1.2.1**	**Rec. 1.2.2**	**Rec. 1.3**	**Rec. 1.4**	**Rec. 2**	**Rec. 3**
	Median (IQR)	4.00(2.00)	5.00(1.00)	3.00(2.00)	4.00(0.25)	5.00(1.00)	4.50(1.00)	5.00(0.25)	5.00(1.00)	4.00(1.25)
	Avg±SD	3.80±1.21	4.60±0.49	3.10±1.04	4.10±0.64	4.50±0.65	4.50±0.50	4.80±0.43	4.40±0.76	4.00±0.91
		Rec. 3.1	**Rec. 3.2**	**Rec. 4**	**Rec. 5**	**Rec. 6.1**	**Rec. 6.2**	**Rec. 7.1**	**Rec. 7.2.1**	**Rec. 7.2.2**
	Median (IQR)	4.00(1.00)	5.00(2.00)	4.00(1.00)	5.00(0.00)	4.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(1.50)	4.00(1.25)
	Avg±SD	4.20±0.90	4.30±0.92	4.20±1.03	4.60±0.84	4.40±0.62	4.50±0.63	4.60±1.11	4.00±1.41	3.80±1.40
		Rec. 8.1	**Rec. 8.2.1**	**Rec. 8.2.2**	**Rec. 8.3**					
	Median (IQR)	3.00(1.00)	5.00(1.00)	4.00(2.00)	4.00(2.00)					
	Avg±SD	3.30±1.14	4.60±0.62	4.00±0.96	4.20±0.86					

Table 8. Analysis of results from the first validation exercise for the EC Recommendations.

EC		**Rec. 1**	**Rec. 1.1**	**Rec. 1.2**	**Rec. 1.3**	**Rec. 1.4**	**Rec. 1.4.1**	**Rec. 2**	**Rec. 3.1**	**Rec. 3.1.1**
	Median (IQR)	5.00(1.00)	4.00(2.00)	5.00(1.00)	5.00(1.00)	4.00(2.00)	4.00(2.00)	5.00(0.00)	5.00(1.00)	4.00(1.00)
	Avg±SD	4.70±0.46	3.80±1.17	4.20±1.31	4.30±1.14	3.80±1.10	4.20±1.10	4.90±0.29	4.40±.088	4.50±0.50
		Rec. 3.2	**Rec. 3.3**	**Rec. 4.1**	**Rec. 4.2**	**Rec. 5**	**Rec. 6.1**	**Rec. 6.2**	**Rec. 7**	**Rec. 7.1**
	Median (IQR)	5.00(1.00)	4.00(1.00)	4.00(1.50)	3.00(2.00)	5.00(0.50)	4.00(1.50)	5.00(1.00)	5.00(0.50)	5.00(1.00)
	Avg±SD	4.50±0.66	4.20±0.94	3.30±1.35	3.20±1.40	4.60±0.64	4.00±0.95	4.60±0.48	4.70±0.45	4.40±0.77
		Rec. 8								
	Median (IQR)	5.00(1.50)								
	Avg±SD	4.30±0.86								

Second Validation Exercise Analysis

Table 9. Analysis of results from the second validation exercise for the Data Holder Recommendations.

DHs	***Data Quality Assessments***						
		Rec. 1	**Rec. 1.1**	**Rec. 1.2**	**Rec. 1.2.1.**	**Rec. 1.2.2.**	**Rec. 1.2.3.**
	Median (IQR)	5.00(0.00)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	4.00(1.00)
	Avg±SD	4.65±0.68	4.35±0.76	4.82±0.38	4.71±0.46	4.29±0.89	3.53±0.98
		Rec. 1.3	**Rec. 1.4**	**Rec. 2**	**Rec. 3**	**Rec. 4**	
	Median (IQR)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	
	Avg±SD	4.59±0.60	4.65±0.76	4.65±0.84	4.65±0.48	4.53±0.78	
	Label Compliance						
		Rec. 1	**Rec. 2**	**Rec. 3**	**Rec. 4**	**Rec. 5**	
	Median (IQR)	5.00(1.00)	5.00(1.00)	5.00(0.00)	4.00(2.00)	5.00(1.00)	
	Avg±SD	4.41±0.77	4.47±0.85	4.82±0.38	3.94±0.94	4.35±0.90	

Table 10. Analysis of results from the second validation exercise for the HDAB Recommendations.

HDABs		**Rec. 1**	**Rec. 1.1**	**Rec. 1.2**	**Rec. 1.2.1**	**Rec. 1.2.2**	**Rec. 1.2.3**	**Rec. 1.3**	**Rec. 1.4**	**Rec. 2**
	Median (IQR)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)	4.00(2.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)
	Avg±SD	4.47±0.61	4.65±0.68	4.65±0.48	4.47±0.78	4.65±0.59	3.59±1.24	4.53±0.78	4.41±0.77	4.00±0.84
		Rec. 3	**Rec. 3.1**	**Rec. 3.2**	**Rec. 3.3**	**Rec. 3.3.1**	**Rec. 3.3.1.1**	**Rec. 4**	**Rec. 5**	**Rec. 6.1**
	Median (IQR)	5.00(1.00)	5.00(1.00)	4.00(2.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)	4.00(1.00)	5.00(1.00)	5.00(0.00)
	Avg±SD	4.53±0.78	4.41±0.77	4.00±0.84	4.53±0.78	4.35±0.84	4.53±0.61	3.65±0.97	4.53±0.70	4.82±0.38
		Rec. 6.2	**Rec. 6.2.1**	**Rec. 6.2.2**	**Rec. 7**	**Rec. 7.1**	**Rec 7.2**	**Rec. 7.2.1**	**Rec. 7.2.2**	**Rec. 7.3**
	Median (IQR)	4.00(2.00)	4.00(1.00)	4.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(0.00)
	Avg±SD	4.06±0.80	4.24±0.88	3.53±1.09	4.76±0.42	4.47±0.78	4.59±0.60	4.71±0.57	4.65±0.59	4.82±0.38

Table 11. Analysis of results from the second validation exercise for the EC Recommendations.

EC		**Rec. 1**	**Rec. 1.1**	**Rec. 1.1.1**	**Rec. 1.2**	**Rec. 1.2.1**	**Rec. 1.2.2**	**Rec. 1.2.3**	**Rec. 1.2.4**	**Rec. 1.3**	**Rec. 1.4**
	Median (IQR)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(0.00)	5.00(0.00)	5.00(0.00)	5.00(0.00)
	Avg±SD	4.71±0.75	4.41±0.77	4.65±0.59	4.59±0.77	4.82±0.51	4.82±0.51	4.71±0.75	4.71±0.57	4.88±0.32	4.88±0.32
		Rec. 1.4.1	**Rec. 1.5**	**Rec. 2.1**	**Rec. 2.1.1**	**Rec. 2.1.2**	**Rec. 2.2**	**Rec. 3**	**Rec. 3.1**	**Rec. 3.2**	**Rec. 4**
	Median (IQR)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)	4.00(2.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)
	Avg±SD	4.82±0.38	4.59±0.49	4.65±0.48	4.71±0.46	3.88±0.96	4.59±0.49	4.76±0.42	4.76±0.42	4.64±0.59	4.41±0.69
		Rec. 5	**Rec. 6.1**	**Rec. 6.1.1**	**Rec. 6.1.2**	**Rec. 6.1.3**	**Rec. 6.2**	**Rec. 6.2.1**	**Rec. 6.2.2**	**Rec. 6.3**	**Rec. 6.4**
	Median (IQR)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.00)
	Avg±SD	4.53±0.70	4.59±0.84	4.47±0.85	4.71±0.75	4.65±0.76	4.59±0.69	4.47±0.61	4.71±0.57	4.65±0.68	4.47±0.78
		Rec. 7	**Rec. 7.1**	**Rec. 8**	**Rec. 8.1**	**Rec. 8.2**	**Rec. 9**	**Rec. 10**	**Rec. 10.1**	**Rec. 10.2**	**Rec. 10.3**
	Median (IQR)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)	5.00(1.00)
	Avg±SD	4.82±0.51	4.35±0.97	4.41±0.77	4.76±0.42	4.41±0.77	4.76±0.55	4.41±0.77	4.47±0.61	4.53±0.61	4.41±0.69
		Rec. 10.3.1	**Rec. 11**	**Rec. 11.1**	**Rec. 12**	**Rec. 12.1**	**Rec. 12.2**	**Rec. 12.3**	**Rec. 12.4**		
	Median (IQR)	5.00(1.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)	5.00(0.00)	5.00(1.00)	5.00(1.00)	5.00(0.00)		
	Avg±SD	4.59±0.49	4.65±0.59	4.12±1.23	4.82±0.38	4.71±0.67	4.47±0.85	4.65±0.59	4.76±0.42		

5. Recommendations for the long-term sustainability of the EHDS2 Quality and Utility label

In this section, insights and recommendations are presented to inform future guidelines and specifications for the implementation of the QUANTUM labelling mechanism in HealthData@EU, as foreseen in EHDS article 78.

These recommendations broach what each stakeholder is responsible for in the implementation of the QUANTUM label: for instance, HDAB responsibilities towards the DHs will be present in the HDAB section. Furthermore, the recommendations use specific language to communicate the "strength" of the recommendation, based on the RFC 2119:

- **Must** – The recommendation is believed to be an absolute requirement, something that must absolutely be done for the sustainable implementation of the QUANTUM label.
- **Should** – There may be valid reasons in particular circumstances to ignore the recommendation, but the full implications of this in the implementation of the QUANTUM label must be understood and fully weighed before taking an alternative course.
- **May** – The item is truly optional; this is not a necessity for the sustainable implementation of the QUANTUM label but was still deemed relevant enough to be presented in the recommendations.

Finally, this section closes with suggestions for future work, focusing on topics that should be addressed to extend the QUANTUM label to a full and appropriate application beyond the boundaries of article 78, as well as a section on open questions that were raised throughout the recommendation-building process and could not be answered. These open questions can also foment future work in QUANTUM sustainability and transferability.

To note, and as mentioned in the Scope (Section 2), these are 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. Data Quality covers a vast ecosystem that spans from data collection to its reuse, with QUANTUM to become a component of this ecosystem**. Therefore, the recommendations below 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 5. Figure 5 provides a **high-level overview of the recommendations** presented in this section.

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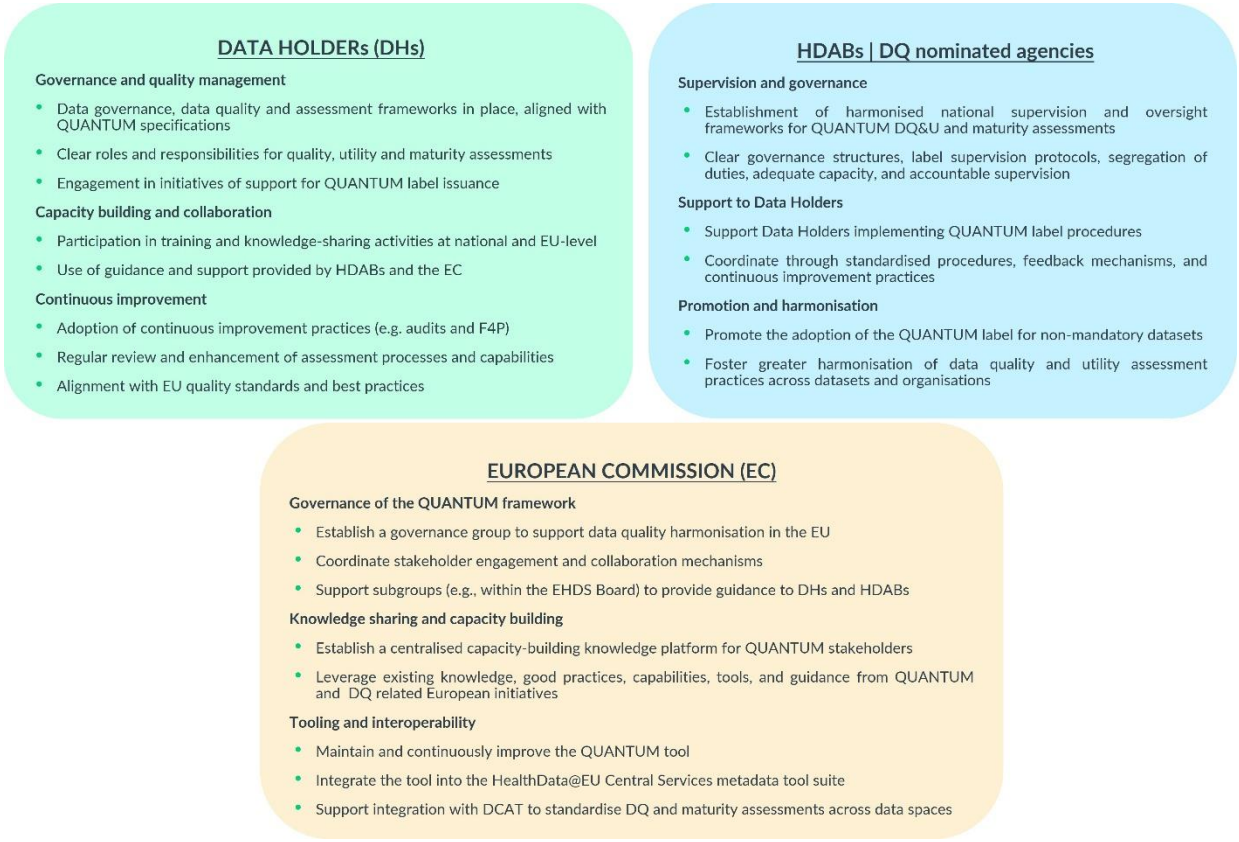

Figure 5. High-level overview of the recommendations addressed to DHs, HDABs/Data Quality nominated agencies, and the EC to support the governance, implementation, and sustainability of the QUANTUM Data Quality & Utility and maturity labelling framework.

5.1. Recommendations for DHs

Table 12. Recommendations for DHs.

ID	Description
Data Quality Assessments (DQA)	
DH 1	DHs should have data governance, data management and data quality frameworks (DQFs) in place to support the performance of DQAs and the issuance of the QUANTUM label. These should consider QUANTUM quality, utility and maturity specifications, the organisational context, and the level of maturity and the type of DH. The existence of the abovementioned frameworks will be particularly helpful in cases of DHs with decentralized data (when data is spread across sites) to clearly define the rules, roles and responsibilities and the agents responsible for performing data quality reporting and the labelling the final datasets.
DH 1.1	Roles and responsibilities to assess the quality, utility and maturity components of the QUANTUM label should be defined.
DH 1.1.1.	This should require cross-coordination within the organization (e.g. between data/technical experts/data governance experts), and with data providers and the HDAB (future supervisory authority of the DQ&U label).

ID	Description
DH 1.1.2.	DHs should ensure suitable competencies to report on DQ&U and maturity parts of the label, including competences related to data governance, data quality, metadata management and relevant domain expertise.
DH 1.1.3.	DHs should engage with supportive national and European initiatives, such as training programmes, support structures and funding for DQFs and DQAs. This is further detailed in HDAB Recommendation 3 and EC Recommendations 1 – 5.
DH 1.1.4.	DHs should engage with Communities of Practice (CoPs), knowledge-sharing platforms, and supportive and training actions to address their needs and challenges related to DQAs and DQFs. This is further detailed in HDAB Recommendation 3 and EC Recommendations 1 – 5.
DH 2	DQAs should follow agreed standards across the DH's domain and be aligned with QUANTUM specifications and guidelines, while remaining consistent with relevant implementing acts, national guidance and existing institutional frameworks where applicable.
DH 3	DHs must promote a culture of continuous improvement. To that end, audit frameworks must be established, and the feedback from data users on the errors/issues they've encountered must be collected and addressed. A fitness-for-purpose (F4P) feedback mechanism should be implemented to collect and address user-reported issues and the corrective measures implemented by the DHs. This should promote an increase of institutional maturity and encourage DHs' DQAs. Such efforts should be monitored by nominated national entities. Further details are provided in the HDAB Recommendations 1.2-1.3 and EC Recommendation 11.
DH Label Compliance	
DH 4	DHs must incorporate QUANTUM DQ standards (the specifications present in QUANTUM Deliverables 1.1 and 1.2) and guidelines into their workflows and follow QUANTUM tool and specification updates.
DH 5	DHs must assign maturity levels at a dataset level whenever significant intra-organizational heterogeneity exists. The QUANTUM tool version 1.1.0 supports this functionality[5].
DH 6	Datasets may be composed of multiple sources, compiled by a single DH, HDIE or another equivalent entity[6]. In these cases:

[5] For instance, when different data types are processed by different departments, each with its own distinct level of maturity, these differences should be correctly represented in the maturity label.
[6] For example, a publicly funded national vaccination record compiling information from multiple public hospitals (DHs).

ID	Description
DH 6.1	DQ&U labelling: The entity generating the label for the composite dataset should be responsible for issuing the DQ&U part of the label and the corresponding supporting documentation.
DH 6.2	Maturity labelling: From T3.4 outputs, it has been agreed upon that a simple average score is not sufficient, since each DH maturity score will impact the composite dataset, and that is important information to have. The most consensual strategy from this task's outputs is to display the individual maturity levels of DHs and the resulting average. This would provide maximal information, allowing Data Users to better understand the provenance of the dataset. However, this strategy will require clear traceability of data provenance and lineage, and the scores will not reflect the maturity of the processes for creating the final composite dataset. The application of this strategy should be revised in the context of real-life implementation.
DH 7	DHs should be supported by HDABs and the EC during the implementation phase to obtain accurate DQ&U and maturity label, and the respective support documentation (in URL). This is further detailed in HDAB Recommendation 3 and EC Recommendations 1–6.
DH 8	The DH's desired additions to the QUANTUM labelling tool (previously described in Table 4, section 4.2.1) identify clear points of improvement that should be considered upon the end of the QUANTUM project. This is further detailed in EC Recommendation 6.2.1 and 7.

5.2. Recommendation for HDABs

Table 13. Recommendations for HDABs.

ID	Description
HDAB 1	**Supervision:** national regulation and frameworks should be established in accordance with a common EU framework. This should reflect whether the DQ&U supervision role will lay on the HDAB or may be delegated to HDIEs or specific independent agencies/third parties specialized in data quality assessments established at national level.
HDAB 1.1	Guidelines to support HDAB (or a national agency nominated for DQAs supervision) tasks for overseeing DH's DQ reporting should be available.
HDAB 1.2	Supervision tasks should include i) conducting plausibility checks (i.e. on the reported DQ&U and maturity reported scores), and ii) verifying whether the DHs have provided URLs for the assessment documentation and have followed QUANTUM specifications.
HDAB 1.2.1	The supervisor needs to have staff trained and acquainted with the data to better assess whether the provided DQ&U scores are plausible.
HDAB 1.2.2	Strong Supervisor-DH relationships are needed to facilitate "plausibility checks" and speed up procedures. Guidance should be provided by HDABs to support DHs producing DQ&U and maturity label documentation. These guidelines should be aligned with recommendations on this at EU level, whenever available. **The QUANTUM Consortium produced a set of DQU Guidelines that should serve as a basis** [18].
HDAB 1.3	HDABs should have SOPs to conduct supervision activities – this should be developed. Moreover, user feedback usage must be in place: if Data Users report discrepancies (i.e. inaccurate labels), these should motivate auditing/reviewing activities to strengthen the overall quality and maturity of the system. **The Fitness-for-Purpose work developed during QUANTUM should be leveraged to this end [19].**
HDAB 1.4	Support for HDABs is required. This is further addressed in the EC section (Recommendations 1-6).
HDAB 2	**Oversight**: each MS must establish its own oversight strategy (i.e. assigning this role to a dedicated oversight nominated institution/HDAB *vs.* oversight by the coordinator HDAB); regardless of the strategy, **dedicated staff capable of performing oversight duties is required and must be ensured to perform such tasks.**
HDAB 3	HDABs should employ dissemination and training strategies for DHs, to support them on the application of the QUANTUM label. Some HDAB-specific recommendations follow:

ID	Description
HDAB 3.1	HDABs (or another relevant nominated national agency) should liaise with DHs, supporting them filling in DQ&U and maturity fields of the QUANTUM label. Workshops, seminars and other opportunities to allow DHs to obtain "hands-on" experience with the QUANTUM label will be invaluable for a smooth adoption, and must be provided to DHs, as these need early support. A channel for DHs to request for HDAB's support may be considered.
HDAB 3.2	A national portal, as a part of the national transparency portal, to list high quality datasets and high maturity DHs may be considered as a strategy to further encourage data quality improvements.
HDAB 3.3	If HDIEs are implemented, DHs must be informed on their potential to offload some of DH burden, since HDIEs could provide invaluable support to less mature DHs, which might lack the infrastructure and organizational maturity to perform QUANTUM labelling operations at scale. HDABs might facilitate DHs connection with HDIEs whenever needed.
HDAB 3.3.1	In case HDIEs are not implemented, the HDABs should provide this support to DHs that do not have the capacity to perform QUANTUM operations at scale.
HDAB 3.3.1.1	The QUANTUM Maturity Model will be a valuable tool to enlighten HDABs on which DHs need the most support.
HDAB 4	HDABs that are also DHs need, at the very least, **a clear segregation of duties**: a department that performs HDAB data quality-related tasks **cannot** also be involved in DH tasks, and vice-versa. This level of functional, structural and operational segregation must be ensured and audited. Clear workflows must be in place to ensure this segregation, namely to ensure that no conflict of interests in Data Quality occur, for example, when handling fitness-for-purpose feedback on DQ&U and maturity labelling. This is further explored also in recommendation 10 of the EC section (section 5.3).
HDAB 5	The QUANTUM label will be mandatory for all datasets generated via public funding. To support its application to non-mandatory datasets, HDAB involvement is necessary. It is recommended:
HDAB 5.1	National legislation support, based on the future EHDS regulation Implementing and Delegation Acts, to strengthen the legal support for application of the QUANTUM label in each MS.
HDAB 5.2.	Foster widespread dissemination to DHs and Data Users by HDABs:
HDAB 5.2.1.	**A clear value proposition should be presented**: the utility of the QUANTUM label should be clearly presented for i) data users for datasets discovery, and ii) DHs for data quality and institutional maturity improvements. Increasing the visibility/discoverability of the data is an opportunity for increased recognition and funding, an opportunity to boost DHs' research activities.

ID	Description
HDAB 5.2.2.	**QUANTUM's data-type agnosticism should be leveraged**: since the QUANTUM label can be applied to any kind of dataset, examples and use cases for a wealth of datatypes should be provided, extending coverage across the health data landscape.
HDAB 5.3	Training materials should be provided (see EC Recommendations 1 and 2).

5.3. Recommendations for the EC

Table 14. Recommendations for the EC.

ID	Description
Capacity Building and Knowledge Sharing	
EC 1	The EC should maintain, coordinate and continuously update a centralized EU-level capacity building knowledge-base platform to support DHs. This should contain training materials, guidance, methodologies, implementation resources and support tools related to QUANTUM, Data Quality, Data frameworks, DH Maturity and the various aspects of the EHDS and of Data Quality. Integration into the EU Academy should be considered to ensure sustainability and long-term maintenance.
EC 1.1	The educational and training materials and support documentation (metrics assessment, reporting, templates) provided by the QUANTUM project (Academy and D4.3) should be leveraged and maintained by the EC in this centralized EU-level platform and disseminated by the EC to HDABs and DHs to support their tasks.
EC 1.2	This platform's materials should provide best practice examples on data governance and on data quality across different types of DHs, reducing discrepancies in interpretation of the QUANTUM DQ&U and maturity dimensions. Early support in line with the QUANTUM 12 DQ&U dimensions should be provided to DHs.
EC 1.2.1	Practical tools and guidance for the technical data quality reporting, tailored according to maturity and data type of DHs, should be part of these materials.
EC 1.2.2	Relevant data quality and data framework related materials made available in the QUANTUM Academy and in other relevant EU-funded data quality initiatives should be leveraged and provided in this centralized platform. Their continued improvement and maintenance by the EC are recommended.
EC 1.3	These materials should be leveraged by HDABs to provide support to DHs.
EC 1.4	Annual Internal and External Validation procedures for all training materials should be conducted to ensure materials remain relevant and updated. A systematic review process should be established to ensure consistency and guarantee the alignment with evolving EHDS requirements and best practices.
EC 2	The EC should promote QUANTUM label related training initiatives (e.g. hands-

ID	Description
	on workshops, webinars), leveraging the existent QUANTUM Academy materials. These should demonstrate the value of intra-organizational coordination to perform the QUANTUM evaluation. Examples and use cases should also cover all aspects of the label, both DQ and Maturity.
EC 2.1	These initiatives should be tailored to multiple data types (tabular, images, non-tabular, structured) and cover multiple levels of expertise and maturity.
EC 3	The EC should support the establishment of a network of Data Quality Officers at national level, linked to an EU-level coordination network, to support bottom-up and top-down learning and convergence of best practices across the EU.
EC 4	The EC alongside the HDABs should ensure strategies to inform DHs on how their existing DQ methodologies can be leveraged to fill in the QUANTUM label.
EC 5	To build capacity among EHDS stakeholders on organizational and governance aspects, the EC should support:
EC 5.1	The creation of a Data Quality dedicated subgroup within the EHDS Board to continue and expand the efforts of the current Subgroup 2 of the EHDS2 Community of Practice to support DHs, creating a consolidated base of knowledge and best practices.
EC 5.1.1	This group should host sessions with stakeholders working on documenting processes and other DQ relevant issues, so that their work can be leveraged for future guidelines.
EC 5.1.2	Guidance, policies and existing documentation on institutional best practices on data governance and DQF (e.g. documentation on data governance from HIQA and on data quality and utility frameworks from HDRUK) should be addressed in these groups. Since best practices are not yet fully established across contexts and maturity levels, this should be a topic to be addressed by these SGs to support implementation across different types of DHs and levels of maturity in a harmonized way.
EC 5.1.3	Likewise, existing knowledge, tools and capacities of European Research Infrastructures (RIs) and digital networks, such as EDICs and ERICs, on data quality and data governance should be leveraged by these SGs. Therefore, their liaising with European RIs and digital networks, to enable a community-based layer of quality and utility assessment should be promoted.
EC 5.2	Creation of national or EU-level CoPs/peer-to-peer learning experiences and/or support initiatives to assist HDABs in establishing their plausibility check SOPs and gathering trained staff for QUANTUM label supervision. The EC capacity building materials on DQ&U can be leveraged for HDABs training and must be properly disseminated through HDABs and updated as needed.
EC 5.2.1	These support initiatives will benefit from the presence of institutions (HDABs, DHs and other equivalent entities) with high levels of maturity and data quality, to share best practices and knowledge with less mature institutions. Existing RIs and digital networks should be leveraged due to their experience in data management and governance.

ID	Description
EC 5.2.2	Active involvement of the EC in EU-level knowledge-sharing initiatives is recommended, to avoid the spread or replication of incorrect practices.
EC 5.3	Establishment of a data governance supporting task force/subgroup of the EHDS Board to guide and support EU and national developments. Providing this level of data governance support from the beginning is key to ensure institutions develop robust DQFs that align with the EHDS requirements.
EC 5.4	The abovementioned subgroups must:
EC 5.4.1	Have a clearly defined scope and framework to avoid institutional fragmentation and duplication of governance structures of participating Member States.
EC 5.4.2	Be supported by dedicated platforms, that allow for example, compilations of relevant materials and dedicated forums for questions to be submitted and answered by qualified experts, ensuring structured support and guidance.
EC 5.4.3	Be supported by a formalized network of Data Quality Officers to ensure existing experiences are leveraged and Data Quality views are harmonized.
Tooling	
EC 6	QUANTUM tool must remain an open-source solution and the EC should assume custodianship over it. The tool must be included in the HealthData@EU Central Platform in upcoming releases, alongside the HealthDCAT-AP Dataset Description Assistant. Therefore:
EC 6.1	Future implementing and delegated acts must ensure continuous improvement of the tool and the label itself to meet stakeholders' needs, ensuring sustainability.
EC 6.2	A similar update structure to the Central Services Releases should be followed for the QUANTUM tool (i.e. as currently occurs of the HealthDCAT-AP dataset description assistant), with clear communication of an update roadmap to ensure stakeholders can adapt to changes to the label.
EC 6.2.1	These updates must allow the tool to evolve alongside the ever-changing nature of the health data landscape, including the addition of the QUANTUM tool functionalities requested by DHs (Section 4.2.1, Table 4), such as versioning for quality assessments, bulk actions, RDF importing and exporting functions, and comprehensive step-by-step built-in guides.
EC 6.3	Future versions of the QUANTUM tool manual should provide definitions, examples and practical use cases to properly support consistent application by DHs. The EC should ensure that further case studies across different DHs are developed to improve applicability and clarity.
EC 6.4	The EC should ensure the establishment of a QUANTUM label technical support team to provide a "helpdesk" service for the application of the label, answering questions regarding compliance with QUANTUM standards or other related topics.
EC 7	The EC should consider including the capacity to filter datasets in the HealthData@EU central platform's Catalogue via QUANTUM average score and dimension-specific score to further facilitate discovery of high-quality, fit-for-

ID	Description
	use datasets by Data Users.
EC 8	EC should promote the inclusion of QUANTUM quality and maturity specifications into DCAT, leveraging QUANTUM's data-type agnosticism. This would allow to expand QUANTUM's reach to harmonize data quality and institutional maturity across data spaces, not just health data. **The QUANTUM Consortium has developed a report on the RDF Template for the QUANTUM label, and should be used as basis for this integration** [19].
Governance and Operationalization	
i) Trustworthy management	
EC 9	Standardization of the support documentation to be provided by DHs to HDABs, and of the auditing process performed by HDABs was considered crucial. To achieve this, the EC should:
EC 9.1	Ensure that guidance on how DHs should prepare their label support documentation is made available. This guidance, when available, should be included in the QUANTUM training materials for DHs.
EC 9.2	Ensure that Standard Operating Procedures (SOPs) exist for HDABs to conduct auditing on the accuracy of the information in the QUANTUM label (DQ&U + Maturity). For example, there needs to be a clear workflow that covers response to feedback submitted about a dataset in the EU Catalogue: this should trigger an HDAB audit to evaluate if the Data Holder needs to perform any changes in the label. This is fundamental for the harmonized and trustworthy implementation of the QUANTUM label in the HealthData@EU.
EC 10	EC must ensure that conflicts of interest in Data Quality and Maturity evaluation are avoided: HDABs that are also DHs need, at the very least, a clear segregation of duties; the department that performs HDAB tasks cannot also be involved in DHs tasks, and vice-versa. This must be explicitly present in the article 78 related implementing acts. To that end:
EC 10.1	The EC must oversee the Member States' establishment of dedicated bodies to audit HDAB's segregation of duties. These bodies must enforce the requirements established by the Commission.
EC 10.2	The future HealthData@EU compliance framework for HDABs must entail audit requirements to verify whether measures to prevent conflicts of interest in data quality are in place and are sufficient.
ii) Data Quality Improvement	
EC 11	The EC, or a European initiative should develop a common tool for User feedback and complaints, allowing Data Users the option to report on label accuracy and dataset fitness-for-purpose.
EC 11.1	This tool should be based on the recommendations present in the QUANTUM F4P document [20]. Future work in this is required (See Section 5.4).
EC 12	The EC should foster data quality improvement: the creation of a DQ&U improvement environment across EHDS stakeholders elevates their institutional maturity. To aid building this environment some recommendations follow:

ID	Description
EC 12.1	The EC should develop governance frameworks for the EHDS2 DQF and QUANTUM.
EC 12.2	The EC should encourage periodic monitoring by HDABs. This should entail periodic Data Quality reports delivered by DHs to HDABs, which result in a summarized public report issued by the HDAB compiling results on national DQ levels.
EC 12.3	The EC should conduct periodic monitoring, collaborating with HDABs to track the effect of the QUANTUM label on DQ and Maturity across Data Holders in the EHDS.
EC 12.4	Recommendations 12.2 and 12.3 can be satisfied using dashboards akin to the EHDS2 HDAB and Member State Maturity Model.
EC 12.4.1	This must help informing the EC on the need of i) support actions for countries facing higher challenges in implementing the QUANTUM label, ii) label updates.
iii) Funding	
EC 13	Labelling costs' support: the infrastructure and resource investment to build up and maintain the capacity for dataset labelling operations is currently explicitly excluded from applicable fees related with data access applications and data requests ("(…) costs related to the creation, updating, and maintenance of the metadata (…) including quality labelling (…) are out of scope (…)" [21]). Consequently, the EC should ensure that:
EC 13.1	For future datasets (not existing ones), the labelling costs can be included in the funding provided to create them, so there is no need for extra financial support.
EC 13.2	For legacy datasets (datasets that were created before the EHDS) that still see current use but do not have funding for their maintenance can be covered by a system that allows DHs to apply for public funding to create the QUANTUM label for these datasets.
EC 14	The EC should include clear information in future national and funding calls (such as future HORIZON calls) regarding the expectation or obligation for publicly funded datasets to adhere to the QUANTUM label.
EC 14.1	Also, the EC should provide a competitive advantage for the call in case applicants either utilize datasets that follow the HealthDCAT-AP and QUANTUM standards, or present a feasible roadmap to achieve compliance with these standards during the project, to further encourage their use. This incentive should be clearly disclosed in the text of the call.

5.4. Other recommendations to the EC

In case the future work needed for the implementation of the QUANTUM label and for its sustainability (recommendation 7, section 5.3) is not assured by the EC , a follow-up project, continuing the work conducted in QUANTUM is strongly recommended, to assist the EC in bridging the QUANTUM label efforts with other European initiatives on Data Quality and addressing pending issues or identified gaps. Nevertheless, further research and implementation activities in this field should be actively supported by the EC, building on the work of the QUANTUM and ensuring progress across different contexts and levels of maturity. Some of the identified gaps and areas for further work follow:

- F4P report implementation is lacking, despite recommendations for future work were issued during QUANTUM [20]; follow-up activities to implement this are needed and should be assured;
- Likewise, the discussions of the future Implementing Acts on Article 78 and on the final version of TEHDAS2 guideline on data user duties [1,22] should address the inclusion of the F4P report in the Data User duties foreseen in Article 61 of the EHDS regulation.
- It is necessary an extended pilot for the QUANTUM labelling system, to extend generalisability and obtain QUANTUM-specific best practices in broader scenarios. This exercise is an opportunity to develop case studies, explore implementation across different levels of maturity, revise metrics for specific data types and apply the label across different types of DHs.
- Standardization of methodologies surrounding QUANTUM compliance models and case studies for assessing compliance, as well as training needs analysis, coordination and management aspects are needed.
- Several points were also identified in the EOSC EHDS workshop that need to be addressed, such as:
  - Fostering a harmonised approach to interoperability, data quality, and FAIR data practices;
  - Reducing fragmentation across initiatives by enhancing coordination among European health data–driven Research and Digital Infrastructures active in both spaces;
  - Leveraging EOSC capabilities for data hosting, discoverability, accessibility, processing, and research output reuse in support of EHDS deployment [23].

5.5. Open Questions

- Should the EC consider a certification framework for entities working as HDIEs? Or should this be left to Member States discretion (with no harmonization on the requirements to be an HDIE for the tasks related with data quality labelling).

- How will HDAB supervision and oversight duties be operationalized when multi-HDABs exist at national level? How will this be operationalized for EDICs, ERICs, and cross-border

registries? EOSC-EHDS have started considering this point [23].

- How can the use of the QUANTUM label be promoted for non-mandatory datasets, namely by the private sector? How can private sector concerns regarding description of the datasets protected by trade secrets, be addressed?

6. Implementation Plan for the Recommendations

In Section 5, recommendations for the 3 stakeholder groups chiefly responsible for the implementation of the QUANTUM labelling mechanism were presented, in accordance with the methodology and results obtained throughout WP3's work. In this section, a high-level vision of the same recommendations is provided, condensing the main points and omitting specific details on the implementation, as such details are present in Tables 12-14.

These high-level points have been prioritised, following the EHDS Regulation implementation timelines, to **suggest 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:

ID	Description	Responsibility
ST1	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	**EC**
ST2	Integration of the tool into the HealthData@EU Central Services metadata tool suite	**EC**
ST3	Establishment of a knowledge base collating all the *Academies'* work, ready for use by all stakeholders	**EC**
ST4	Establishing the mechanism for a structured update of the quality and utility specification	**EC**

Mid-term:

ID	Description	Responsibility
MT1	Extended controlled implementations along the whole data life cycle	**DH**
MT2	Procedures in place for the improvement of the QUANTUM specification, tool and supporting materials	**EC**
MT3	Development and testing of the fitness-for-purpose (F4P) technical specifications	**EC**
MT4	Implementation of the F4P assessment	**EC**
MT5	Setting up a community of practice for the adequate implementation of the data quality and utility and Data Holders' (DHs) maturity label	**EC**
MT6	Data intermediation entities set up to support DHs duties	**HDAB**
MT7	DHs should have data governance, data quality and assessment frameworks in place, aligned with QUANTUM specification. This will support them issuing the label. Clear roles and responsibilities for quality, utility and maturity assessments.	**DH**
MT8	HDABs or data quality agencies nominated at national level and following harmonised national supervision and oversight frameworks for QUANTUM DQ&U and maturity assessments	**HDAB**
MT9	HDABs or data quality agencies nominated at national level must support DHs implementing QUANTUM label procedures	**HDAB**

Long-term:

ID	Description	Responsibility
LT1	Continuously improve the QUANTUM tool and update related materials	**EC**
LT2	Establishing a culture of continuous improvement utilizing F4P, regular audits, etc	**DH, HDAB, EC**
LT3	Promoting the adoption of the QUANTUM label for non-mandatory datasets	**HDAB, EC**
LT4	Fostering harmonisation of data quality and utility assessment practices across datasets and organisations	**HDAB, EC**
LT5	Support integration with DCAT to standardise DQ and maturity assessments across data spaces	**EC**

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Annex I – T3.4 Data Holder Survey

1. **Which country do you represent?** *

- ○ AT
- ○ BE
- ○ DE
- ○ ES
- ○ FI
- ○ FR
- ○ IE
- ○ IT
- ○ NL
- ○ NO
- ○ UK
- ○ European/International Organization

2. **Does your institution have any procedures in place to perform Data Quality assessments?** *

- ○ Yes
- ○ No

3. **Do you employ any of these methods?** *

- ☐ Dedicated DQ teams
- ☐ Automatic/Semi-automatic tools
- ☐ Data Quality improvement workflows (Tracking DQ KPIs, Regular audit reports, etc.)
- ☐ Other

4. **Do you have data storage solutions to host documentation needed to support your DQ evaluations?** *

- ◯ Yes
- ◯ No

5. **What barriers have you encountered?** *

6. **What certifications do you employ?** *

7. **Does your institution not perform DQ assessments due to (choose all that apply):** *

- ☐ Lack of guidance/knowledge
- ☐ Limited dedicated tools/software
- ☐ Insufficient data standardization procedures (e.g. inconsistent data models, undefined quality metrics, no continuous monitoring)
- ☐ Insufficient data documentation
- ☐ Resourcing/Financial challenges
- ☐ Delegation to a third party
- ☐ Other

8. **Do you employ strategies to report and document changes to the standards and data models used?** *

- ◯ Yes
- ◯ No

9. **Do you consider these strategies important to improve your data quality?** *

- ◯ Yes
- ◯ No

10. **The QUANTUM label will be mandatory for all datasets derived from publicly funded data. Does this obligation apply to your datasets? (Choose one)** *

- ◯ No
- ◯ Yes (<50% of datasets)
- ◯ Yes (>50% of datasets)

11. **What strategies will you adopt in order to comply with the QUANTUM labelling requirements?** *

12. **Pick any of the tools that you believe are relevant for compliance with the QUANTUM Label** *

Select all that apply

- ☐ Support documentation on DQ assessment/reporting
- ☐ Documentation templates to report assessments
- ☐ Training on QUANTUM label
- ☐ Training on Data Governance best practices
- ☐ Other

13. Some Data Holders hold many datasets. Each dataset will need their own DQ&U label. *

The QUANTUM labelling tool allows Data Holders to create "catalogues" for quality assessment of their datasets. This functionality allows organization of the datasets by data provider, for instance, despite each dataset requiring its own Data Quality label. Do you feel this is sufficient for management needs? What other features would be helpful?

14. **Health Data Intermediation Entities are described in the EHDS Regulation as organizations that may perform the duties of certain categories of data holders, as a way to reduce administrative burden. From Recital 59 of the EHDS Regulation: "(...) Such health data intermediation entities should be legal persons able to process, make available, register, provide, restrict access to, and exchange electronic health data for secondary use provided by health data holders."** *

If legislation was approved in your country to establish these entities, how would you rate their viability as a strategy to support Data Holders on DQ&U assessment and reporting? Consider 1 as "not viable" and 5 as "completely viable"

1	2	3	4	5

15. **In your view, what support would you require to comply with the QUANTUM label?** *

Annex II – T3.4 HDAB Survey

Supervising Data Quality & Utility, Data Holder Maturity

1. **Which country do you represent?** *

- ○ AT
- ○ BE
- ○ DE
- ○ ES
- ○ FI
- ○ FR
- ○ IE
- ○ IT
- ○ NL
- ○ NO
- ○ UK
- ○ European/International Organization

2. **Does your institution currently oversee/audit the data quality and/or maturity of other institutions?** *

- ○ Yes
- ○ No

3. **Do you employ any of these methods?** *

- ☐ Dedicated DQ Officer
- ☐ Automatic/semi-automatic auditing tools
- ☐ Other

4. **How do you envision this task to be performed in your country?** *

- ◯ By a Coordinator (and only) HDAB?
- ◯ By a dedicated HDAB (in a national organization that foresees multiple HDABs)?
- ◯ Other

5. **What do you think you would need to successfully accomplish this task?** *

- ☐ Dedicated DQ Officer
- ☐ Automatic/semi-automatic auditing tools
- ☐ Other

6. **Does your institution employ or have planned any dissemination and training strategies for Data Holders to better comply with QUANTUM values?** *

- ◯ Yes
- ◯ No

7. **Does your institution envision employing dedicated auditing teams to supervise the labels generated by Data Holders?** *

- ◯ Yes
- ◯ No

8. **What other strategies are you planning to employ?** *

Governance

Certification and Auditing

9. **Do you believe that in certain situations (e.g. high-quality label) certification of the label by an external authority may be needed? Or should labelling be in its majority performed by self-assessment? (Choose one)** *

- ◯ Self-assessment will suffice as the HDAB will audit the label
- ◯ External certification needed for higher quality labels
- ◯ Other

10. **Some HDABs will also be Data Holders. Should a third party be involved in auditing the label in these cases, or would segregation of functions inside the institution suffice? (Choose one)** *

- ◯ A third party should be involved in these cases
- ◯ Segregation of duties inside the HDAB will suffice
- ◯ Other

11. **Do you consider having guidelines for auditing the documentation submitted by Data Holders on their QUANTUM label beneficial for HDABs?** *

- ◯ Yes
- ◯ No

12. **Does your institution consider that receiving Data Holders' documentation in a standard format (e.g. dedicated template) would be useful? (Choose one)** *

- ◯ Yes
- ◯ No
- ◯ I don't think standardization is viable

Governance

Application of the Label

13. **Some datasets will be sourced from multiple Data Holders to form a final dataset (e.g. vaccination data from multiple healthcare providers)** *

Regarding the maturity part of the label, should the QUANTUM label display the maturity level of each Data Holder? Should an "average" maturity score be displayed instead? Please describe how you believe this should be addressed.

14. **Following the previous question, regarding the Quality and Utility part of the label, do you agree that the institution generating the final dataset would be responsible for generating the respective DQ&U label and producing the needed documentation?** *

- ◯ Yes
- ◯ No

15. **Please suggest how this should be approached.** *

16. **Do you foresee applying a fixed fee related to data requests/data access applications to support DQ operations?** *

For further details, consult the TEHDAS2 document: https://tehdas.eu/wp-content/uploads/2025/09/draft-guideline-on-fees-related-to-the-ehds-regulation.pdf

- ◯ Yes
- ◯ No

17. **Does your institution/country plan on encouraging the QUANTUM label use even in non-mandatory cases (i.e. non-public funded datasets)?** *

- ◯ Yes
- ◯ No

18. **What methods are planned?** *

19. **Why do you think this is not necessary?** *

20. **What strategies do you think should be in place to encourage Data User feedback on datasets' quality and utility?** *

21. **What strategies do you envision to address Data User complaints about the accuracy of the DQ label on a dataset?** *

22. **Does your country already employ strategies to encourage Data Quality improvement at the Data Holder level (e.g. National/Regional Data Quality Transparency Portal, Annual DQ Reports, etc.)** *

- ◯ Yes
- ◯ No

23. **Please specify** *

24. **What support would be required to achieve widespread application of the QUANTUM label in your country?** *

25. **What strategies would you consider to be feasible to empower the widespread application of the QUANTUM label and for DQ improvement in your country? (Select all that apply)** *

- [ ] National/Regional Data Quality Transparency Portal (i.e. a portal exhibiting the Data Holders' data quality scores, tracking improvement over time)
- [ ] Annual DQ National Reports (i.e. an annual report delivered to the HDAB by the Data Holders that results in a summarized public report on National DQ levels)
- [ ] Creation of dedicated roles in institutions, focused on DQ improvement at collection
- [ ] Other

26. **How could your institution leverage QUANTUM to encourage Data Quality improvement in your country?**

(non-mandatory)

Annex III – 1st Validation Exercise Results

In this Annex, the materials taken to the first validation exercise and the respective results are presented.

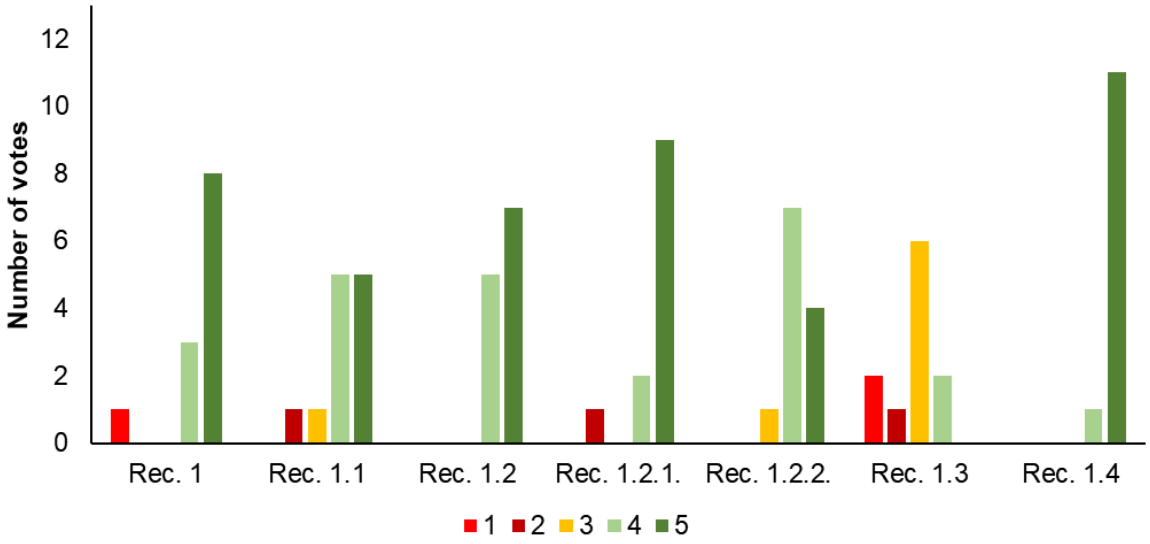
To facilitate the presentation and the gathering of participants feedback, the recommendations are organised according to stakeholder group (DH, HDAB, and EC), with further subdivision into specific sections within each group. **The DH category is divided into three sections, the HDAB category into five sections, and the EC category into four sections.**

The corresponding results are presented through frequency graphs illustrating the number of participants who selected each level of the Likert scale for each recommendation. The maximum number of responses obtained for a given recommendation was n = 13, while the minimum was n = 11, due to certain questions being non-mandatory and therefore not answered by all participants.

Recommendations for DHs

Data Quality Assessments

1. Institutions should have data quality frameworks in place to perform data quality assessments (DQA).
    1.1. Clear audits and approval cycles are needed.
    1.2. Roles and responsibilities to assess the quality and utility, and the maturity parts of the QUANTUM label must be defined.
        1.2.1. This requires cross-coordination within the organization (e.g. between data/technical experts/data governance experts), and with data providers and with the HDAB (future supervisory authority of the DQ&U label).
        1.2.2. The DH should ensure suitable profiles to report on DQ&U and maturity parts of the label.
    1.3. The existence of a data quality framework is sufficient to harmonize processes across sites even in cases of decentralized DHs.
    1.4. Training, support structures and funding are required to support DHs establishing DQFs.



#Written Comments DHs 1

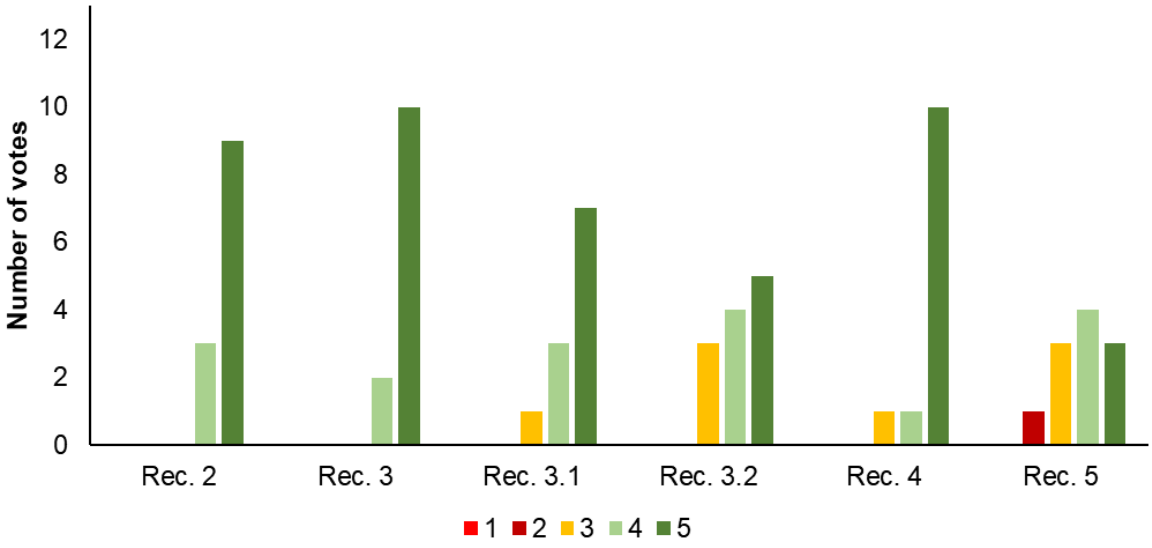
- 1.3. is not clear enough (as already discussed); and the issue of "decentralized DHs" needed to be clarified (definition?)
- The QUANTUM Label specification and the framework from which it arises is a great opportunity to set the basis of an EU standard on data governance as it provides clear signals of what is needed
- Ongoing training and support is very important for sustainability. This will lose momentum if not properly funded then it will struggle to continue to be implemented.
- Agree that organisations should have a DQF, but it'd be better if it is part of a comprehensive framework that includes data management and governance.
- Also requires clear guidance on what good governance looks like for data holders to support the development and implement a DQF
- In the recommendations it would be good to differentiate between data holders at source, data holders that prepare data for secondary use, etc tomake sure it is clear what we refer to
- DQF is essential as well as to increase the maturity of an organization. However, assuring that it will be enough for decentralized harmonization needs practicle use cases to test it.
- traininig and support are needed differentiating per type of data (tabular, images, and so on) --> Tailored training
- The DQF could serve as a standard curriculum for a certification program to third parties assisting with data governance and dataset cataloguing for the EHDS, not just training but certified capacity
- The point about DQF being sufficient is the most contentious. I agree that this will help to harmonise but DQF on its own is not sufficient.
- To note, there needs to be baseline knowledge and skills in developing and implementing a DQF. This will require enhancement of skills and capacity in line 12 dimensions - early support required

- These kind of recommendations should may be framed as a the focus of a EU Data Governance Framework facilitating secondary use of health data
- Support role related to providing both HealthDCAT-AP metadata descriptions and data quality and utility label might be needed in the organisation
- A single DQF may not be sufficient to harmonize processes. Its implementation may require additional governance mechanisms and adaptations tailored to national contexts and institutional structures
- Further clarification is needed on what the 'suitable profiles' would contain for Rec 1.2.2 is needed. We must be careful not to add to the burden for DHs
- The existence of a data quality framework may not be sufficient but is requiered in order to propose an standard where information and processes requirements are explicitly stated
- Supports need to include best practice examples across different types of data holders as large variation in interpretation of the dimensions within and across organizations.
- Many of these recommendations are a reflection of the maturity of an organisation so the maturity matrix is important for assessing the preparedness for DQF

#Oral Comments DHs 1

- DQA table needs clarification for last point (barriers and challenges): it must be made clear that the problem comes from datasets distributed across sites that depend on a central agent.
- Rec 1.3 needs to be clearer: need a better explanation of what is meant by “processes” – when data is distributed across multiple sites, the procedures to create the dataset for the central Data Holder responsible for labelling the dataset. Have roles and responsibilities attributed to the distributed sites via a DQF.
    - Also support roles, tools and guidelines for the technical data quality reporting are needed in the organisations. This should be clear in the text.
- Clarity and separation into clear recommendations present in the Menti should be reflected in the final document.
- Rec 1.2.2 needs more clarity: “profiles” should be changed to “competencies”.

2. DQAs must be performed following the agreed standards across the data holder's domain, and aligned with QUANTUM principles.
3. A culture of continuous improvement must be promoted. How:
   3.1. Feedback from data users on the errors/issues they've encountered must be collected. A system to gather and address this feedback is recommended, with reporting on the identified issues and the corrective measures implemented by the data holders. This will promote an increase of institutional data maturity and encourage data holders' DQAs.
   3.2. Implement a national portal to showcase and broadcast high quality datasets and high maturity data holders.
4. CoP/EHDS board subgroups/supportive and training actions to address data holders' needs and challenges and to provide a "knowledge sharing" platform are needed. This should be supported by the EC.
5. Financial support through fixed fees is required.



#Written Comments DHs 2

- Data holders should have at disposal a set of agreed standard to perform the DQA. These standards should be provided to them and should be tailored also to the type of data type.
- A recommendation on data preparation costs should be given. Not sufficiently clear in the wording
- Incentives essential as costs are high in terms of roles and responsibilities/costs of generating good quality data. Those really investing in generating good quality data don't want to share!
- I am not sure if all data holders should have their own tool for the feedback from data users. Shouldn't it be developed together with the fit-for-purpose labeling tool that all HDABs could use?
- To promote real QIs, a network of DQ champions is required at each level - EU, National,

Regional and local. This is essential in early days to identify best practice, standardize practice etc

- About data users' feedback shouldn't' Just be on errors and issues but also fitness-for-purpose
- The financial support is definitely needed although whether this is through fixed fees or other mechanisms should be explored
- Fixed financial support makes no sense (cont): C) Institutional burden and incentives should be focused on the reuse, and properly populating the EHDS catalogue is just a requirement for reuse
- How to address the cost of managing the storage place to host the feedbacks. And who should bare this cost.
- Fixed financial support makes no sense considering: A) burden of description and data quality assessment of a dataset may be highly heterogeneous B) Data governance is an institutional requirement
- No 5 is important, but maybe we could leave out the fixed fees or maybe say "through fixed fees or some other financial source"?
- National portal may not be needed depending on the filtering features of the EHDS portal
- Regarding the national portal, I wouldn't create a specific one for these high qua datasets. Instead, a different solution could be to somehow flag them in the national portal (avoiding fragmentation)
- National portals may differ across countries. Clear scoring thresholds and harmonized criteria are needed to ensure consistent quality levels and comparability between datasets across countries.
- 3.2: this could be a part of "transparency portal" that is quite unclear now.
- The culture of continuous improvement is a fundamental component of the maturity model. It is assumed that organisations will want to improve however this can only happen if there are benefits
- Maybe object / contend. / clarify the idea of fixed fees and adapt according to the level of maturity And the focus should always be contextual to the preparation of data sets for secondary use
- The EU portal should be the master version of the standard and the national portals must link and comply with the EU regulation
- A network through peer support would also be invaluable

 # Oral Comments DHs 2

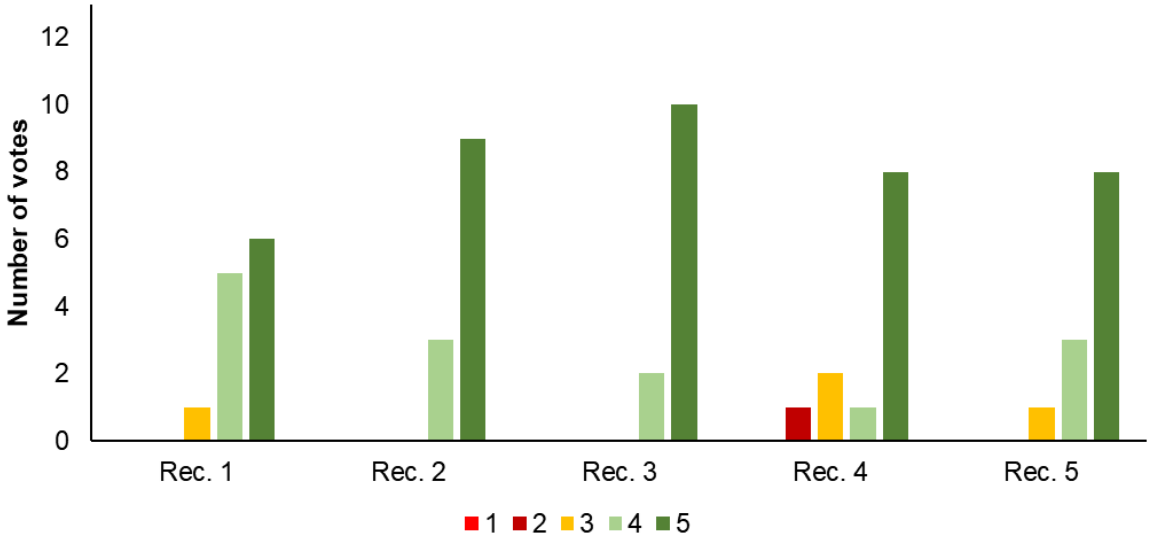
- Financing aspect is a bigger burden on HDABs than on DHs: maintaining the catalogue (HDAB responsibility) is a larger investment than issuing the label (Data Holder).
- "Data Quality Champions" as a part of a constellation of structures (European, national) where best practices and knowledge are shared.
- Issuing the QUANTUM label should already be a part of the Data Holder's budget. The focus should not be on financing but capacity building. Having financial benefits for providing data does not help the ones that really need the funding (small data holders) to overcome the barrier

of developing their economy of scale.

- Recommendation on using QUANTUM as a tool to harmonize data quality criteria between datasets across countries. Provide a roadmap for label improvements, akin to Central Services Releases, making sure everyone moves alongside the label.
    - Ensure the continuous update via the Delegated Acts
- Recommendation to include QUANTUM into the DCAT specification to increase harmonization across all data types, not just health data.
- Recommendation on filtering datasets in the Catalogue via QUANTUM: average score, specific dimension score.

Label Compliance

1. Data Holders should follow QUANTUM developments and incorporate QUANTUM DQ standards into their workflows.
2. Data Holders should be supported by HDABs and the EC during the first years to obtain accurate DQ&U and maturity label, and the respective support documentation (in URL).
3. Dedicated training materials that cover data holder needs must be available and be disseminated.
4. The QUANTUM labelling tool "wishlist" identifies clear points of improvement that should be considered in a QUANTUM follow-up project.
5. A central coordinated action to harmonize data quality and reduce administrative burden on Data Holders is required.



 # Written Comments DHs 3

- There is the opportunity to recommend that in countries where there can be no intermediary agents support, that support should be provided by the HDABs
- There is no doubt that data holders should be working towards incorporating 'standards' into work flows but further consideration for less mature organizations/countries as some will really struggle
- There is the opportunity to recommend EC to establish a certification framework and program

for any organization that wants to act as intermediary agent for supporting data quality labelling
- I'd point out that even though in this document we are not addressing its sustainability or adoption, this is very relevant as much effort was put there (as for other materials) and should be addresse
- Not related to this section :) Is it foreseen that also in the future other sector specific data spaces there will be data quality label? Maybe in the future we will have a base standard & extensions?
- Make it clearer that 'standards' in this context refers to QUANTUM deliverables D1.1 and D1.2
- Back to small/less mature data holders there is a huge need for someone doing the work - intermediary entities and instead of fixed fees starting funds
- Unless there is some avenue/clear structure to enhance less mature, and if the 'standards' are implementable in these settings, it may have a unintended consequence(strong focus on driving QI/support)
- Training materials need to targeted e.g. general, specific and expert and clear who should do which training
- At this stage, the label specification should not be maintained on a project basis but as part of DCAT AP regular procedures
- Clarification is required on how may years is covered by the 'the first years' statement in Rec 2 and what level of support is required
- There should be a platform (national level) where the DH can raise their questions or issue with compling with QUANTUM standards or how to use it. A sort of "help center"
- There should be a DQL technical support task force or help desk office at the EC/EHDS central level to assist the application of the DQL
- Especially in the first years a lot of support is needed for both metadata and quality labeling
- Features wishlist should be transferred to the EHDS portal team in terms of users' feedback on desired features
- Dedicated training materials should be incorporated to the general EU data training portal and offered as part of the digital skills portfolio for EU citizens and institutions
- Recommend that HDABs use the maturity framework to assess the level of support requiered by each of the Data Holders under their competency and prioritiitise their strategy on how to tackle the DQL
- Is the QUANTUM wishlist prioritised ? if not this could be difficult to manage and potential for scope creep is likely

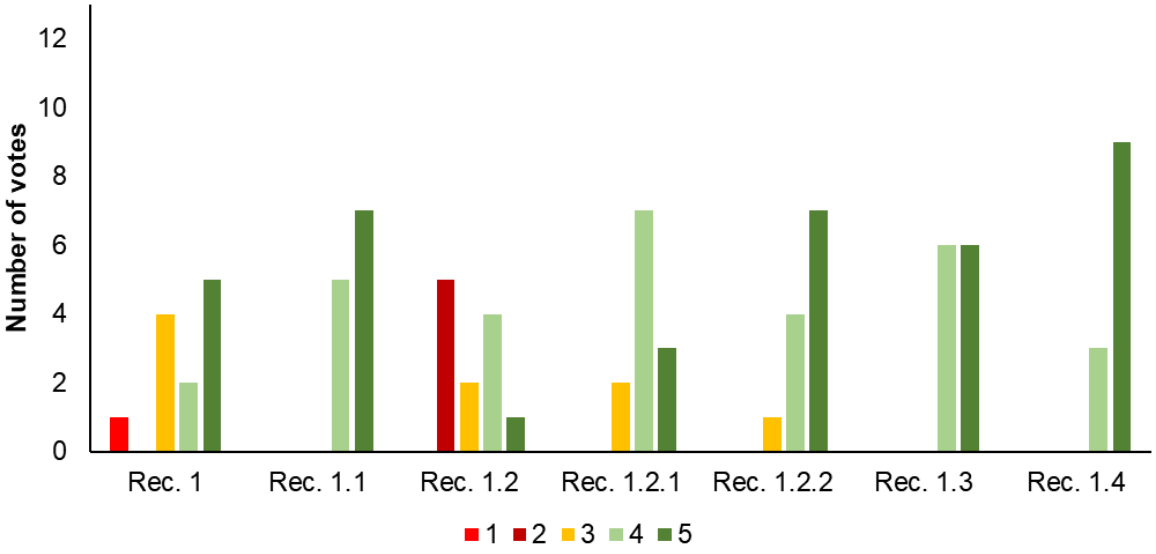
 # Oral Comments DHs 3

- Opportunity to have a recommendation for certified HDIEs.
    - If no national legislation support exists, recommend having HDABs provide this support to Data Holders.
- Reinforcement of idea to include QUANTUM in DCAT or DCAT-AP (DCAT preferred as it is the core standard).
- HDAB should use the QUANTUM maturity levels of Data Holders to help plan the level and time of support necessary.
- Reinforcement of the idea to have “digital exemplars”, entities that have high maturity and can lead by example and share their knowledge to less mature institutions.
- Possibility of including a recommendation that smaller data holders will need more support (“seed money”, training materials, capacity building initiatives)
- Opportunity to recommend to the EC certification framework for entities that want to act as

HDIEs: certification on their knowledge of the specification of HDCAT and QUANTUM.
    - Technical part can be proven via the Interoperability Test Bed (ITB), soft (governance) part via some standard like an ISO standard.
- Suggestion to establish cross-border, pan-European support structures to help overcome lower maturity of some countries: instead of focusing only on building each country up to perform the same duties, direct some of that burden to a European entity.
- Recommendation for the EC to leverage existing tools and capacities of Research Infrastructures (RIs) for Data Governance
    - Heavier focus on support rather than training: for RIs, ERICs and EDICs, some tasks are "one and done" for researchers, no need to focus on providing training in these cases.
- Suggestion to have ERICs and EDICs as "data exemplars", due to their experience in managing data.
- Training materials should be structured according to maturity

Recommendations for HDABs

1. Supervision: national regulation and frameworks must be established. This should reflect whether the DQ&U supervision role will lay on the HDAB, or may be delegated to HDIEs or specific agencies specialized in data quality assessments established at national level.
   1.1. Guidelines to support HDABs tasks for overseeing DH's DQ reporting should be available.
   1.2. HDAB supervision should be limited to i) conduct plausibility checks, and ii) verify whether the DHs have provided URLs for the assessment documentation and have followed QUANTUM specifications.
      1.2.1. HDAB needs to have staff trained and acquainted with the data to better assess whether the provided DQ&U scores are plausible.
      1.2.2. Strong HDAB-DH relationships are needed to facilitate "plausibility checks" and speed up procedures
   1.3. SOPs to conduct supervision activities are recommended. Moreover, F4P feedback usage must be in place.
   1.4. Support for HDABs is required.



#Written Comments HDABs 1

- Strongly disagree with a national regulation or framework. There should be an EU framework and leave the application or implementation of the framework at national or other level but one common frame
- HDABs should check the URLs content-wise, not only if they are provided or not.
- Has regulation of regulators (HDABs) been considered? This is where an independent third party may provide added value in terms of oversight and additional/specific expertise.
- Certificates bodies could take the supervision role on behalf the HDAB for regular data holders. In the case of authorized participants the could take the role on behalf
- SOPs to conduct supervision activities should be mandatory in any case that supervision exist. However, there is no need for specific or particular supervision, rather than monitoring and

assistance

- Query if third party should also be involved in F4P feedback and follow-up...provides an independent focus on QI?
- Support for HDABs is very vague. I assume as per the previous discussions we are not talking about funding (fixed or otherwise) ?
- I don't think we can say that national regulation MUST be established. As other colleagues have said the EC framework should take precedence. National frameworks may not be required.
- General recommendations on securing the documentation attached to the DQL, can be stated as a caution for the cybersecurity responsible at the EHDS portal
- I believe that 1.2 is more about national consensus how DH and HDAB see their way of working together - so maybe HDAB could have more power.
- HDIE's role is not clear, in which article of part IV of EHDS are they mentioned?
- Agree with the first comment on national regulation or framework
- Using the term limited supervision for HBABs is misleading and contradicts the overarching recommendation in this case. Perhaps use the examples of plausibility and verification as types but not limit
- Clarify what should be supervised may be needed in the recommendation
- Are SOPs too prescriptive for supervision activities. What is the context for F4P feedback. Perhaps an example would help.
- Maybe there should be a centralised service to publish the quality documentation in an uniform manner. Then it would be easier for HDABs to check the documentation.
- it should be mandatory to check a specific document if that dimension was flagged as negative from the F4P report. So there must be a cross-checking test to flag inconsistencies
- Flexibikity of oversight is required: not all MS will have centralised, single-instititon HDABs. In case of multi-HDAB structure, oversight may be provided by the HDAB coordinator (which is a HDAB)

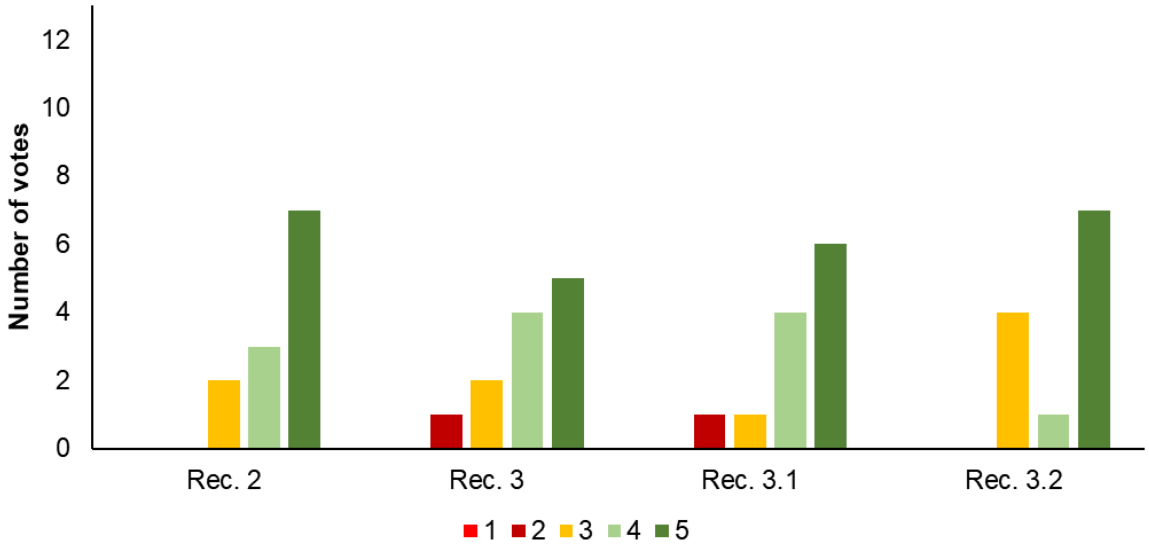
#Oral Comments HDABs 1

- Verify alignment/overlap with DGA and Data Act: data controller role overlap with Data Holder definition
    - More clarification on the EHDS roles is required
    - A footnote needs to be added stating that national law needs to align with international (European) regulations
- Suggestion of footnote regarding that HDAB recommendations assume an HDAB capable of performing certain tasks. A “lean and mean” HDAB might require distribution of those tasks to third-parties or other governance structures.
- HDAB plausibility checks should include a cybersecurity check on the URLs and associated documents provided by the DH in their label.

2. Oversight: each MS will employ their own HDAB strategies (dedicated oversight

institution/HDAB vs centralized HDAB); regardless of strategy, dedicated staff capable of performing oversight duties is required.

3. HDABs should employ dissemination and training strategies for Data Holders, to support them on the application of the QUANTUM label. Some HDAB-specific recommendations follow:
   3.1. HDABs should liaise with data holders, supporting them filling in DQ&U and maturity fields of the QUANTUM label. Workshops, seminars and other opportunities to allow Data Holders to obtain "hands-on" experience with the QUANTUM label will be invaluable for a smooth adoption, and must be provided by the HDABs.
   3.2. If HDIEs are foreseen in national law, DHs should be informed on their potential to offload some of DH burden, since HDIEs could provide invaluable support to smaller DHs that might lack the infrastructure and organizational maturity to perform QUANTUM labelling operations at scale.



#Written Comments HDABs 2

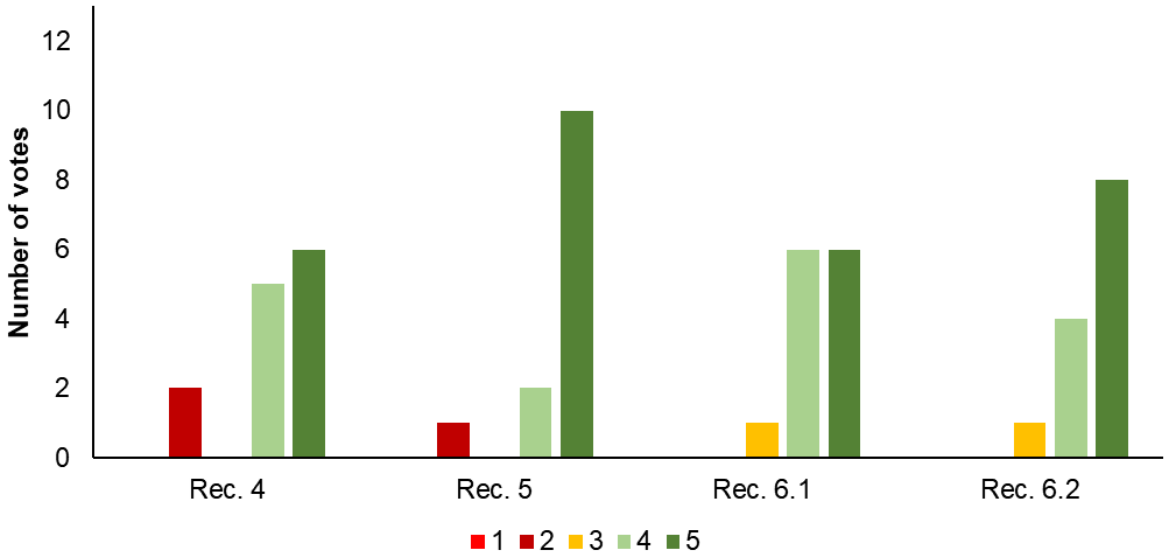
- rewording of recommendations such that for example should in 3.2 has to be MUST
- In addition to HDAB, EC should also be involved in producing dissemination and training strategies for DH on the application of the QUANTUM label. The aim is to reduce the burden for HDAB
- take into account the different implementations of HDABs between countries: from lean&mean to one full swing large single organisation
- Rec 3.2 needs to be reworded as discussed. Using the term 'foreseen' doesn't explain what we mean here. If HDIEs exist nationally then the DH must be informed.
- oversight must be at the coordinating HDAB (if in line with EU EHDS)
- There are national and EU orgenisation whose business is capacity building Suggestion to outsource not for HDAB to play this capacity building role
- I still think that smaller countries will not be able to establish an HDAB but do agree that some oversight at national level may be required.
- We can recommmend regular data-thons or waves as a way to operationalise the capacity

building at data holder levels for the adoption of the DQL (attached to the recommendation on the relationship)
- On addition to training, data holders and data reusers should be exit from operational services
- Oversight should incorporate users' feedback about the vappropriateness of the label information
- In case of multi-HDAB structure, should the HDAB coordinator play a relevant part on ovversight?
- Dedicated staff capable of performing the oversight duties should be present in the HDABs with specific responsibilities regardless of the internal organization of the HDABs in a Member State
- 3.2 DHs should be not only informed, but they should facilitate the connection with those HDIEs
- Agree with not being too prescriptive - each country needs flexibility to define the governance and oversight that works best, particularly for smaller/less mature counties - building capacity is key
- Criss border solutions should be promoted to ensure HDAB expertise
- also for 3.1) EC should be invested in supporting HDAB to accomplish such a role.
- A strong relationship based on SOPs and clear governance structures must be encouraged and supported both in terms of ensuring data application and data request processing & improve data quality
- Oversight may also be provided by another statutory body/agency (regulator) - providing vital support for the HDAB in terms of expertise and capacity
- We need to be careful that not too much oversight is disseminated to HDABs. Ultimate responsibility still lies with EC.

#Oral Comments HDABs 2

- For multi-HDAB structures, regardless of the delegation of duties, the capacity to perform HDAB activities needs to exist.
    - The Coordinator HDAB should perform oversight activities to harmonize the final results
- Reinforce the idea of having an EC Recommendation on cross-border solutions such as “middleware” entities (like HDIEs) that can perform tasks for smaller Data Holders, or HDABs of smaller/less mature countries
    - These can leverage cross-border solutions instead of relying on national expertise
- F4P and reports on the accuracy of the label as motivators for deeper supervision and oversight

4. For the initial implementation phase, we recommend against employing third-party certification even for high-scoring labels. A gradual development of the QUANTUM standard is recommended instead, increasing the level of certification as successful implementation grows.
5. Conflict of interest avoidance: HDABs that are also Data Holders need, at the very least, a clear segregation of duties: a department that performs HDAB tasks cannot also be involved in Data Holder tasks, and vice-versa.
6. Standardization of the support documentation provided by Data Holders, and of the auditing process performed by HDABs was considered crucial. To achieve this, we recommend:
   6.1. Guidelines are required on how to produce support documentation, informing DHs on how they should report on the QUANTUM dimensions.
   6.2. Standard Operating Procedures (SOPs) must be in place in case the information in the QUANTUM label (DQ&U + Maturity) isn't accurate: establishment of auditing processes conducted by HDABs are needed.



#Written Comments HDABs 3

- Please, consider rewording "guidelines" to "guidance" in REC 6.1
- How is this going to work in practice? How/Who is going to check this segregation is properly stablished? What if this is not the case?
- Not sure that SOPs MUST be in place but can recommend that they SHOULD be provided.
- Rec. 5: HDAB that are also DH can face resource limitations, due to separation of duties. Is the EC willing to provide support?
- Auditing processes are another overhead that will create a burden on HDABs to be aware of. Can they mark their own homework ? probably not. EC should provide the audit requirements
- Concerned on COI for smaller organisations - how do we separate functions if these individuals work closely?

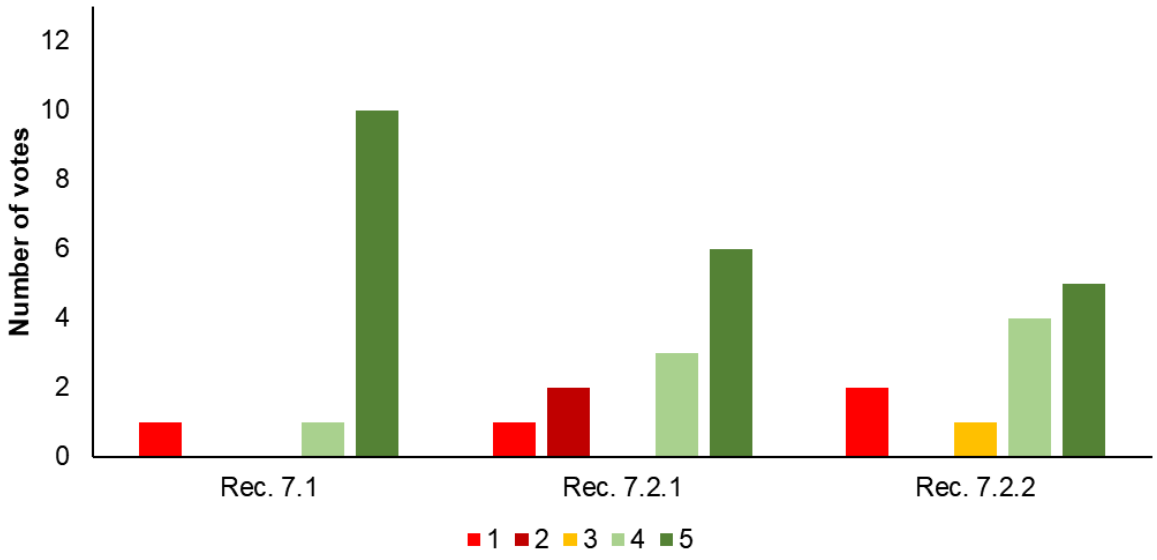
- HDABs should integrate feedback mechanisms and institutional learning processes, so that cases of inaccurate labels contribute to strengthening the overall quality and maturity of the system
- Recommendation for International certification entities
- At 6.2 as discussed make clear that the SOPs might need to cover the entire process/flow from EU-portal to DH and anything in between
- Functional, estructural and operational segregation must be ensured and audited between data holding and processing and access processing
- Finnish Findata (functioning currently as HDAB) is part of Finnish Institute for Health and Welfare (THL), who is a big data holder. Findata is working really separately from THL. Could be looked at
- Involving EC to help HDAB in producing such guidelines on how to produce supporting documentation for DH.
- Guidelines should support/facilitate complex organisational structures (e.g. certain universities have various levels of data management, like at university level, at department level, at PI-group)
- In REC 6.1 an somehow easy guidance can be provided in available open source tools or platforms providing the level of detailed documentation required for the label
- Recommendation on certifying institutions as early as possible in the implementation process
- The économic model (feed to access data) of HDABs may lead to CoI with DH or intermediation entities
- Recommendation should be issued on the use of the QUANTUM label guidelines both for reporting and supervision purposes - this ensures common rules
- Certification is a difficult matter and is hard to achieve. We careful what is expected and the effort needed to police this. It is definitely gradual to implement if at all.
- If the HDAB is a data holder, should the F4P feedback be managed by an independent third party or at least the oversight of findings?
- iSome conflict of interest can arise also in case of separation of duties. The HDAB staff may know the personnel of the DH part of the same institution, and that could bias HDAB's decisions
- Is there a sperate governance/oversight structure needed if HDAB and DH are within the same organization?
- at 5 make clear given discussions that this recommendation is about conflict of interest on the DQ&U and maturity labels only.

#Oral Comments HDABs 3

- Rewrite “Conflict of Interest” into “Conflict of Interest in Data Quality”.
- Recommendation 4 is bimodal; this is relevant to keep in mind since the average skews the view.
    - Disagreement on the “initial phase”: recommendation should focus on not making third-party certifications mandatory at all at any stage of implementation.
- Rec 6.1 should be in the EC section.
- Reinforce in Rec 5 that this segregation regards only Data Quality
    - This recommendation should also be moved to the EC section.

7. For datasets composed of multiple sources:
   7.1. Data Quality and Utility: The institution generating the label for the composite dataset should be responsible for issuing the Data Quality & Utility part of the label and the corresponding supporting documentation.
   7.2. Maturity labelling: Two possible strategies are recommended:

Strategy	Advantages	Disadvantages
7.2.1. Display the individual maturity levels of Data Holders and the resulting average	Provides maximal information, allowing Data Users to better understand the provenance of the dataset	If the composite dataset undergoes higher maturity DQ processes during its creation, these are not reflected in the scores
7.2.2. Display a maturity score that reflects the maturity of processes utilized to create the composite dataset	Reflects cases when the composite dataset undergoes high maturity processes during creation	Results in a maturity score that is very granular: it reflects the maturity of processes employed for the individual dataset creation, and not the maturity of the data holders themselves; Much harder to audit



#Written Comments HDABs 4

- Three mandatory measures could be: Individual Institutional Maturity Level; Weighted Aggregate Dataset Maturity Level; and an Inter-Institutional Heterogeneity Indicator (variability process)
- 7.2.1 higher maturity DQ processes are not reflected, but should be specified in the documentation
- Some real examples shall be presented in recommendations / guidelines to enable DH to understand how to compile any of 7.2.1 or 7.2.2
- If the composite dataset is made with data of the same type (e.g., in federated datasets), it is probably not useful for the end user to know the maturity level of each DH institution

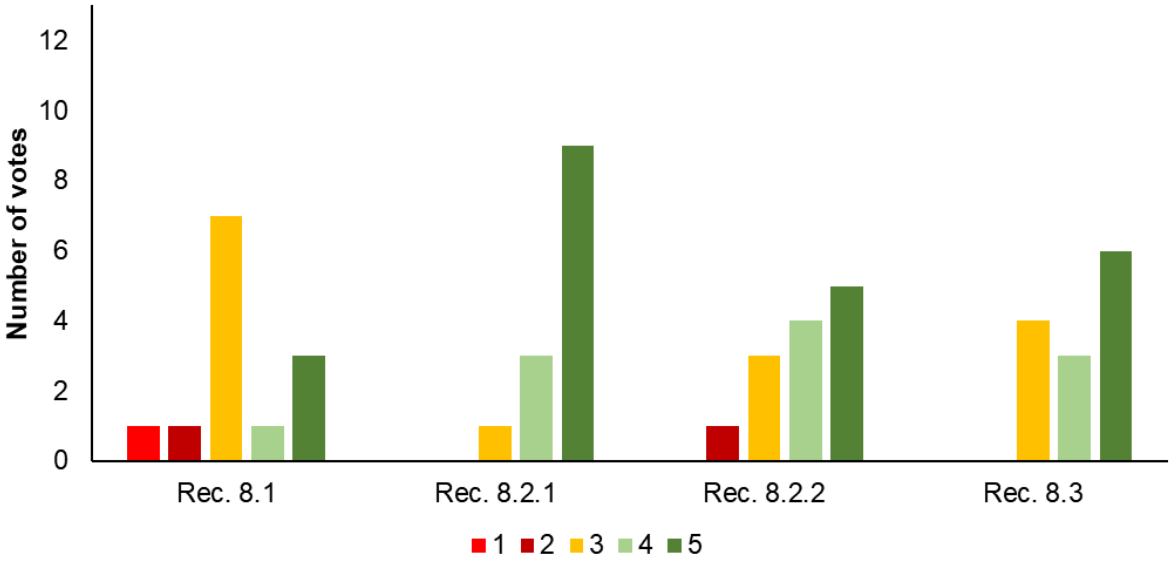
- Makes no sense to assess the maturity at institutional level in composite datasets if and only if data lineage (provenance) is stated or linked to the original sources, and they are EHDS or publica
- could we start pushing a conditional attribute: ask is anything changed then ask for additional maturity
- We could include both 7.2.1 and 7.2.2 strategies as they are not mutually exclusive
- There is an opportunity to recommend not on the maturity assessment of these composites but on the reproducibility of the processes to compose them/generate them
- The critical information for composite data sources in terms of maturity is provenance, lineage and processing
- It is important to know both / all of the contributing organisations maturity to a composite dataset. This will bring provenance and opportunities for improvement.
- we should make clear that if datasets are processed when combining then the maturity information of the one processing is very relevant. if only combing then there is hardly any extra info for user
- In many cases I think the dataset will be a small part of the organisation's data and wouldn't affect that much the whole maturity label level
- Important for data holder to be able apply the maturity for individual datasets as there is significant difference in maturity across datasets within data holders (choosing the maturity for composite)
- Expectations in terms of data quality vary according to the users (e.g. A cohort study, a comparative effectiveness trial, a registration trial). How is the need of reusers captured ?
- Providing as much detail as is available - individual scores and average, as well as scoring if additional processing occurred to the composite score
- Data source may have their own governance. If the last data holder is in charge of combining sources, maturity should reflect its Data QualityManagenent maturity. Difficult report in others' maturity
- If an organization has multiple maturity assessment for different datasets, they should be able to choose the relevant score for the dataset being included in the composite dataset

#Oral Comments HDABs 4

- Rec 7.1 requires a footnote explaining that the generator of the composite dataset can be any data controller, a DH or an HDIE.
- For the different strategies, clarify that they are not mutually exclusive.
    - Contextualize the strategies with an example of a composite dataset to increase clarity, and then explain the results of each strategy regarding the example.
    - Make clear that these rules apply to publicly funded datasets only: the maturity report is only mandatory if the composite dataset is publicly funded as well.
    - Combination without curating the data would only require 7.2.1.
    - Curation of data during combination would benefit from 7.2.2.
- No weighing should be applied for maturity level reporting, that would complicate matters too much.
    - Provenance information helps cover that gap.
- Suggestion to expand the "optional, recommended, mandatory" levels with "conditional": applying to cases such as the maturity strategies, where if the composite dataset had data curation processes applied to it, Strategy 7.2.2 would be mandatory.

- Suggestion that Strategy 7.2.2 is redundant: if you have the data provenance information and the maturity of each data holder, reporting on the maturity of the composite dataset is unnecessary.

8. The QUANTUM label will be mandatory for all datasets generated via public funding. To support its application to non-mandatory datasets, we recommend:
   8.1. Robust national legislation support, based on the future Implementing and Delegation Acts. This legislation should be built on the EHDS Regulation to strengthen the legal support for application of the QUANTUM label in each MS.
   8.2. Foster widespread dissemination to Data Holders and Data Users:
      8.2.1. Present a clear value proposition: demonstration of QUANTUM utility for data discovery (Data Users) and data quality and institutional maturity improvements (Data Holders).
      8.2.2. Leverage QUANTUM's data-type agnosticism: provide examples and use cases for a wealth of datatypes, extending coverage across the health data landscape.
   8.3. Robust templates and training materials (see EC Recommendations).



#Written Comments HDABs 5

- check various acts what they state about public versus non-public funded data(sets) and asure all stay inline
- Need clarity on the 'Dissemination' aspect - dissemination of benefits?
- No need for National regulation/legislation supporting adoption of the label in non-mandatory datasets. There is an important opportunity to strongly recommend including EHDS clauses on mandatory cataloguing and application of the label in any public funding contract or service
- Remove the term Robust in 8.1 and 8.3 as it is not useful or adding any value to the recommendation

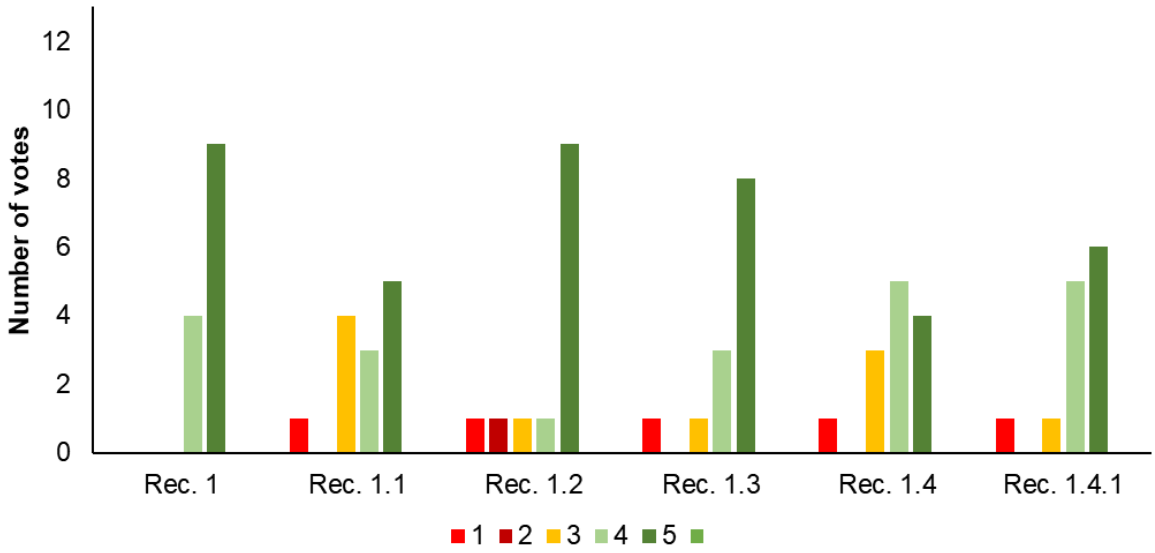
- Non-mandatory are usually those subject to intellectual property rights; incentives may come from requirements in the HTA and regulatory processes - e.g. marketing a new device
- Asking for robust national legislation support for non mandatory datasets would contribute to the overregulation in the EU legislation. The EHDS should be made as open as possible to the stakeholders
- As we are talking about non-mandatory datasets here I don't think we can use the words MUST in 8.2.1 and 8.2.2 . Change it to SHOULD support
- It's important to show the added value for researchers, not only for sharing and reusing the datasets, but also as a mechanism to boost their research activities (more visibility/recognition/funding)
- 8.3 is only as "awareness" point: all materials and guidelines should be available to all
- Maybe the best way to support the labeling is having it as a clear and usable part of the metadata and metadata generating tools: easy for the data holder to provide
- Inventives should include provisions to protect IP and commercial confidentiality.
- The wording of 8.2.2 'Leverage QUANTUM's Data-type agnosticism' could be written more clearly. It is confusing for anyone not familiar with the detail of the DQL
- May need to also offer further support (other than templates/training) to promote additional use - e.g. clinics to support the application in practice

#Oral Comments HDABs 5

- Regarding legislation: take into consideration the DGA and the Data Act.
- Expanding support to perform QUANTUM labelling on non-mandatory datasets should be present in the EC Recommendations

Recommendations for EC

1. QUANTUM material, trainings, documentation (metrics assessment, reporting, templates) need to be leveraged by and disseminated by the EC and HDABs to data holders. Leveraging existing and nascent groups that address the EHDS (the existing CoP SG2, or future SGs of the EHDS Board) will be key for this.
   1.1. Discuss existing guidance, policies and best practices from institutional documentation (HIQA; AIHW; Canada DQF). Furthermore, Data Holders should be informed on how their existing DQ methodologies can be leveraged to fill in the QUANTUM label.
   1.2. The EC should maintain and update a centralized platform where training materials covering QUANTUM, Data Quality, Data Holder Maturity and the various aspects of the European Health Data Space (EHDS) are covered.
   1.3. QUANTUM tool manual should contain extended definitions, examples and use cases to properly guide data holders.
   1.4. QUANTUM training materials should demonstrate the value of intra-organizational coordination to perform the QUANTUM evaluation. Examples and use cases should also cover all aspects of the label, both DQ and Maturity.
      1.4.1. To this effect the incorporation of QUANTUM training materials into the EU Academy, and their continued improvement and maintenance by the EC is recommended.



 # Written Comments EC 1

- if QUANTUM label is data agnostic then a general EC-platform, if only health specific then EHDS platform
- Need to strategically mange materials by updating, version controlling and streamlining. Also, materials will have to be developed for specific audiences (by maturity for example).There will be burden
- EC should maintain a central repository of contextualized knowledge regarding each of the different maintenance, implementation and communication requirements (reference materials)

- Underlining the role of intra-organizational coordination can be also counterproductive, in the sense that DHs may be nudged to change their organizational structure even if effective
- Strong networks needed to update and make sure the materials are relevant and remain fit for purpose within and across countries
- Training, capacity building and other disemination materials should be incorporated in the Data Europe Portal (EU academy) as part of the EU data and interoperability capacity building CV
- Beyond examples and materials, a dedicated platform or forum could allow questions to be submitted and answered by qualified experts, ensuring structured support and guidance.
- It is important to have both Internal Validation (INVAL) and External Validation (EXVAL) for all training materials on an annual basis. This is good practice for educational institutions
- 1.2 not necessarily a new one, but leveraging the ones that already exist (linked to 1.4.1)
- It is very important for sustainability to maintain and continually improve all the materials associated with the DQL (specification, training and support)
- In addition to training and templates, the option of hands on service provision to data holders and data users should be considered for the DH and DU with intermittent activity
- Good suggestion about capacity building by EC maybe we should reiterate this within this set of recommendations
- clear specifications on how the creation/approval process of the training materials would work when the QUANTUM project is over
- All the material and its updates should be data type sensitive. Not only is the need to provide it, but also to provide it for the different use cases.

 # Oral Comments EC 1

- This section was skipped by mistake by one person, their 0's should not be counted towards the results.
- Reinforced the idea of including the QUANTUM label in DCAT since it is data agnostic.
- Furthermore, since QUANTUM is data agnostic, the EC training platform that includes QUANTUM could be a general one instead of EHDS-specific.
- Make the wording around maintenance and update of training materials stronger.
- Intra-organizational coordination is helpful, but clearly communicate with DHs when their organizational structures are working, to avoid encouraging them to perform unnecessary restructuring.
- Feedback loops for the training materials should be in place (internal + external validation).

2. QUANTUM tool should remain an open-source solution and the EC should assume custodianship over it, including it in the Central Services Releases and perform improvements as needed.

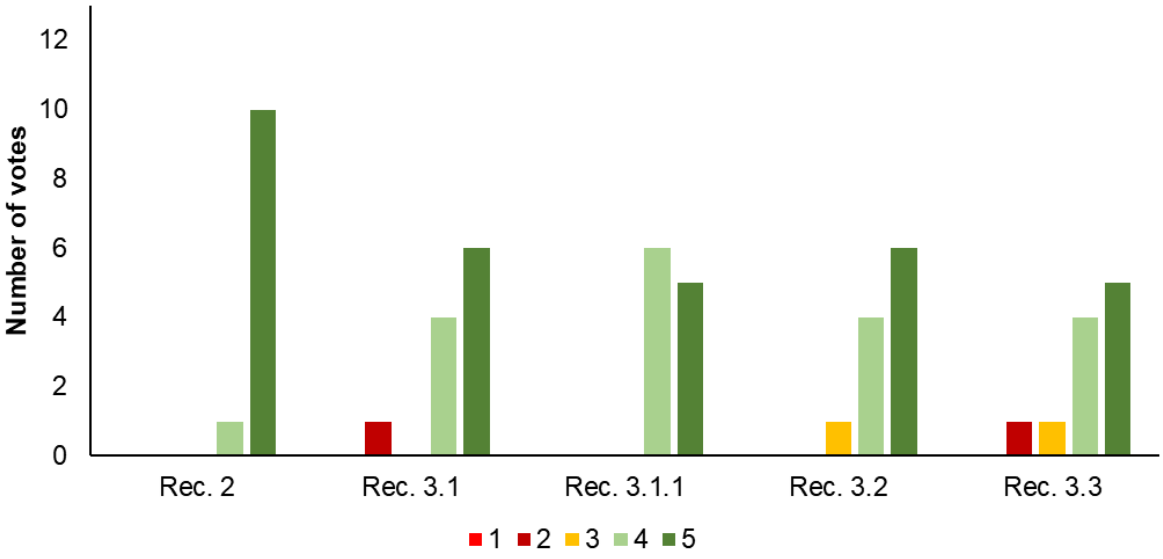
3. To build capacity among EHDS stakeholders on organizational and governance, we recommend:

   3.1. Creation of a Data Quality dedicated subgroup within the EHDS Board to continue and expand the efforts of the current Subgroup 2 of the EHDS2 Community of Practice for supporting data holders.

      3.1.1. This group should host sessions with people working on documenting processes and other DQ relevant issues, so that their work can be leveraged for future guidelines.

   3.2. Creation of national or EU-level CoPs, twinning experiences and/or support initiatives to assist HDABs in establishing their plausibility check SOPs and gathering trained staff for QUANTUM label supervision. The EC capacity building materials on DQ&U can be leveraged for HDABs training and must be properly disseminated through HDABs, and updated as needed.

   3.3. Establishment of a data governance supporting unit that can guide EU and national frameworks to have data quality requirements.



 # Written Comments EC 2

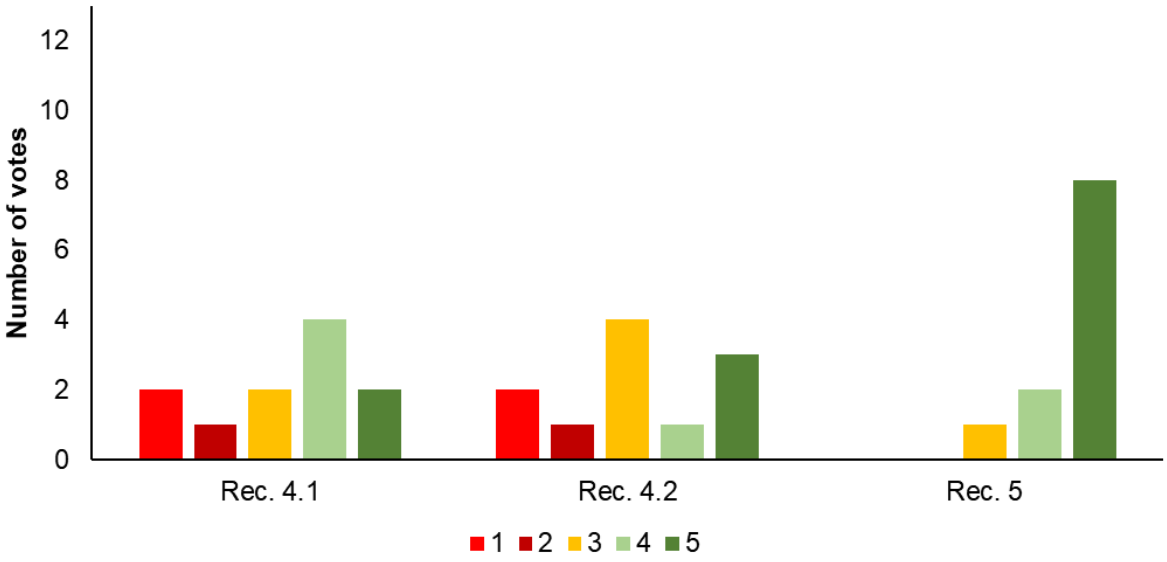
- EU or National CoPs would be a valuable space for exchange. However, EC oversight with expert support is needed to avoid the spread or replication of incorrect practices.
- reword 3.3 such that "unit" is replaced by proper framing (like a taks force of the board, a sub or special group)
- Expand 'twinning experiences' to other types of peer learning
- 3.3 needs to be an international/eu-level group on data governance
- Fully agree with the tool being open source maintained by EC. Also the fit-for-purpose part

should be involved in the tool.
- Plausibility check SOPs should be standardised across all MS. There is the risk of misalignment between HDABs
- QUANTUM specification included in the regular procedures of Health DCAT. AP updates… said elsewhere but should be EC making sure it happens
- The Subgroup should have a clearly defined scope framework to avoid institutional fragmentation and duplication of governance structures.
- Peer learning needs to cover all scenarios and build on knowledge exchange/sharing
- QUANTUM tool has been developed under a CC-BY-NC license that requires any further or derived development must by at least with no commercial purpose, so under some open source license or schema
- The suggestion of a dedicated subgroup within the EHDS Board is a good one. This governance mechanism will help to keep visibility and engagement of the DQL.
- Expand the term twinning experiences to include 'peer-to-peer' support and knowledge transfer
- We can recommend the organization of twinning or peer-to-peer support groups or particular activities such as data-thons
- If governance is not right, there will not be a robust DQFW and focus on data quality will not be a priority - support in terms of data quality (governance) is critical to success.

 # Oral Comments EC 2

- Make clear that SG stands for “Subgroup”.
- Regarding Rec 2: QUANTUM tool is licensed under Creative Commons, if the EC reuses the code, the resulting tool will remain open-source. However, if the EC decides to re-write the code “from scratch”, they can make it closed source.
- Clarify the meaning of “twinning experiences” (peer-to-peer support).
- Transform Rec 3.2 into a list of “knowledge exchange” strategies
- Rec 3.3: Make explicit how the data governance support group is meant to be international/European, and not national.
- Regarding plausibility checks (HDAB Section): SOPs should be drafted according each data type
- Reinforce the idea that getting the governance aspect of data quality right “from the start” is key for robust DQFs to exist.

4. Labelling costs' support: the infrastructure and resource investment to build up and maintain the capacity for dataset labelling operations is currently explicitly excluded from applicable fees for data access requests (TEHDAS2 M4.4.1 "(...) costs related to the creation, updating, and maintenance of the metadata (...) including quality labelling (...) are out of scope (...)").
   4.1. Despite these costs not being directly related to data access or request, the improvement of DQ before a data application should be considered a fixed fee, as it will provide higher quality data to the Data User and reduce data preparation activities upon approved applications.
   4.2. Similarly, DQ&U labelling issuance should also be considered in fixed fees, as enhanced label accuracy is crucial for improved transparency and to enable better decision-making by the data users on the adequacy of a dataset for their research purposes.
5. User feedback and complaints: Data Users should also be able to report on label accuracy in their Fit-for-Purpose reports.



 # Written Comments EC 3

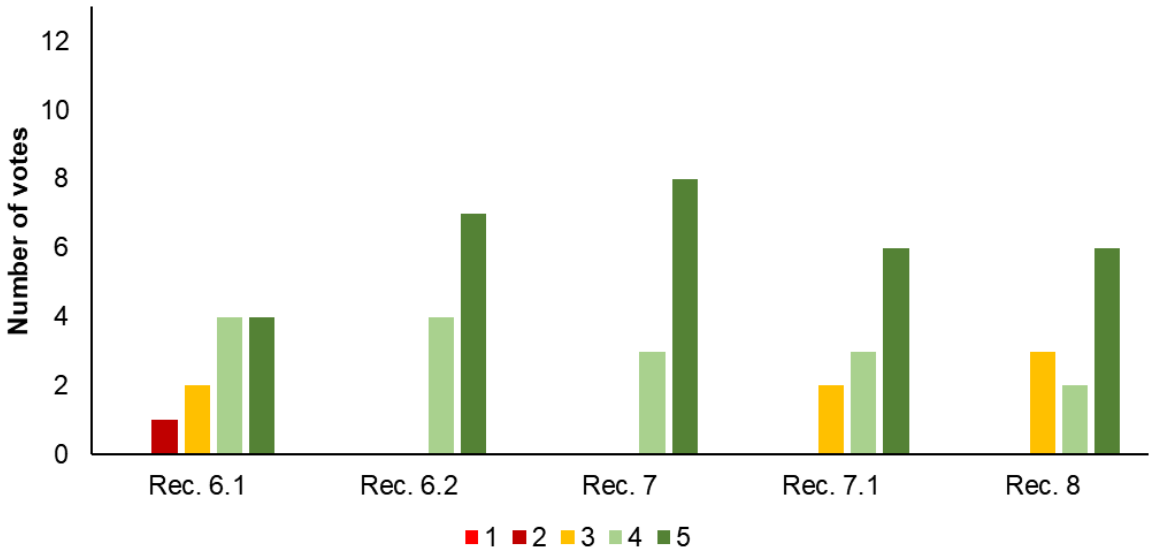
- what is paid for should be done, dont create an additional way of extra "funding"
- Use 'Overhead costs' of cataloguing and data quality labelling compliance instead of fees
- In order to make the European health data space sustainable, the cost of producion incurred by the actors (eg, the HDABs) should be covered in terms of fees for access
- EC can apply the same policy that uses to promote open science and open publications, making that kind of cost an eligible cost in public funding both for innovation and research
- Did the Commission evaluate the cost of the EHDS régulation as a whole ????
- Some incentives to help organizations get processes and structures in place for a robust DQFW (getting it right from the start) to support higher proportion of compliance
- I think it's fair that all data holders are in the same line: no fees for metadata and data quality labeling
- The wording in 4.2 would benefit from some clarification. "DQ&U labelling issuance" is a bit confusing as it is a noun not a verb

- As discussed using the term fixed fee in this context may not be appropriate. I agree that there should be some form of payment for DQ improvement activity but not necessarily as a fixed fee.
- They shouldn't evaluate the label accuracy explicitly (meaning checking it and providing feedback) but it should be reviewed if it doesn't match with users experience
- A recommendation should be done on what are the expected costs irrespective of how they are funded,
- How maintenance and update of a dataset is secured after public funds are over - recommendation on how to fund it
- Some Data Holders may have historical datasets that are still being used and refreshed so may not have public funding available anymore. In this case maybe some funding could be made available.
- Separate out complains and fitness for purpose in the recommendation
- I agree that the F4P should be reported - further considerations on the methods of how this is governed and results published

 # Oral Comments EC 3

- Rec 4.2 – Clarify what “fixed fees” are, possibly even remove the term as used in TEHDAS2
    - Remove the term “issuance”, rephrase.
- Regarding labelling operations financing: prevent the establishment of a secondary business model, a “grandfathering” system has been suggested for legacy datasets for which financing is already done.
    - Publicly financed datasets are already “paid for”, and labelling costs should not be high, institutions should simply budget for them.
- Ensure that Rec 5 is not something explicitly demanded of users, the recommendation must focus on simply providing this optional feedback avenue to data users.
    - Double-check the Data User duties in the EHDS Regulation, to prevent making demands that are out-of-scope.

6. Fostering data quality improvement: the creation of a DQ&U improvement environment across EHDS stakeholders elevates their institutional maturity. Some suggestions to aid in building this environment follow:
   6.1. Periodic evaluation by HDABs: periodic Data Quality reports delivered to HDABs by DHs, resulting in a summarized public report on national DQ levels.
   6.2. Periodic evaluation by the EC: collaborating with HDABs to track the effect of the QUANTUM label on DQ and Maturity across Data Holders in the EHDS.
7. Full transparency: we strongly recommend adding clear information about the obligation for publicly funded datasets to adhere to the QUANTUM label on future national and European funding calls (such as future HORIZON calls).
   7.1. Provide a competitive advantage for the call in case applicants utilize datasets that follow the HealthDCAT-AP and QUANTUM standards.
8. Finally, we strongly recommend a follow-up project to QUANTUM, to not only further develop the technical aspects and the implementation of the label, but also assist the EC in bridging the QUANTUM label efforts with other European initiatives on Data Quality.



 # Written Comments EC 4

- We should contextualise the reporting in the impact public reporting requirement within the EHDS regulation
- Be more specific on the evaluation type that we are referring to … eg monitoring dashboard to follow up trends in DQU and maturity
- Rather périodic évaluation by the EC to harmonise practice - national HDAB évaluation may lead to national silos
- agree, but not a Joint Action (RIs are not eligible)
- 7.1 those data holders that reluctant to share the data (and are not obliged to issue the label) could use this for preventing their data to be further reused
- Addressing the application of the label for less mature data holders/countries could be a key priority as the gaps will only become more pronounced between the highest and lowest.
- The reporting should be automated and supported by the EHDS portal

- We should reword Rec 8 to state that if the EC do not accept all the recommendations then there may be a need for a follow up project address the gaps.
- (6.1) on case of multi HDAB (sectorial) structure, should the HDAB coordinator evaluate all DH reports, or each HDAB should deal with the reports relevant to it?
- We need to keep DQ a high priority and drive the agenda. The risk if we do not identify gaps and identify additional follow-up, then the momentum will not follow.
- Highlight potential gaps (not covered or not sufficiently addressed by QUANTUM) as a subset of recommendations
- we might also provide an additional recommendations about holding back a certain percentage of the grant that will be rewarded only if the data is of certain quality and deposited in the catalague etc

 # Oral Comments EC 4

- Recommendation 8 should not be necessary if the EC accepts all of the other recommendations.
    - Make a strong recommendation for a follow-up project if the label is not yet sustainably supported by the European Commission.
- Improve wording on Rec 6.1 to prevent misinterpretation
    - Also include examples/scenarios of how this recommendation would work.
- Clarify what is meant by “evaluation” in Recs 6.1 and 6.2 (monitoring and tracking).
- Suggestion of using dashboards akin to the EC HDAB Maturity Model in the public reports.
- A “QUANTUM2” project could instead focus on standardization of data across data type, and data quality at the variable level.
    - CancerWatch as one of the projects that can be built upon.
- Provide a list with identified gaps to continue in a follow-up project
    - The QUANTUM tool “wishlist” could be included here.
    - Include both “must haves” and “nice-to-haves”.
- Clarify that Rec 7.1 is aimed for new public funding calls to create/enrich datasets.
    - Be specific on the incentives: for instance, in the Netherlands, certain funders are stating that part of the funding is only given to the applicant if their data is deposited in certain repositories with a certain level of quality.
    - If the incentive is to increase reuse of HDCAT/QUANTUM compliant datasets, be explicit on this as well.

Annex IV – 2nd Validation Exercise Results

In this Annex, the materials taken to the second validation exercise and the respective results are presented. To facilitate reading, the recommendations are separated by stakeholder group (DH, HDAB, EC), and the respective results (N=17) are presented as a frequency graph representing how many participants voted for each level in the Likert scale in each recommendation. Finally, the free-text comments for each stakeholder group's recommendations are grouped by participant and as they were submitted to the online form.

Recommendations for DHs

Data Quality Assessments

1. Institutions should have comprehensive data frameworks (including data governance, data management and data quality) in place to perform data quality assessments (DQA).

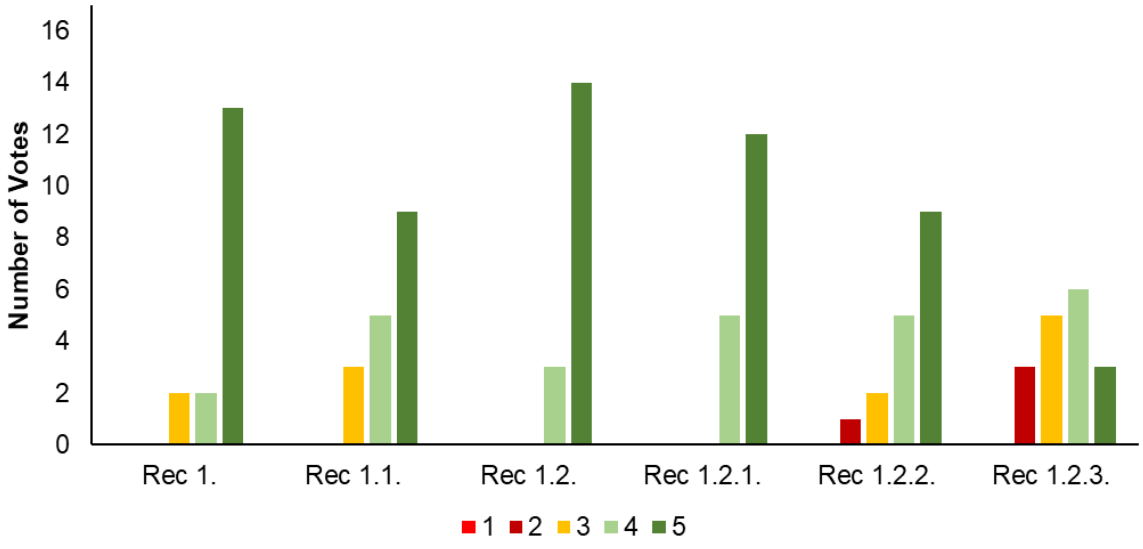
    1.1. Audit frameworks, and feedback and approval cycles are needed.

    1.2. Roles and responsibilities to assess the quality and utility, and the maturity parts of the QUANTUM label must be defined.

        1.2.1. This requires cross-coordination within the organization (e.g. between data/technical experts/data governance experts), and with data providers and the HDAB (future supervisory authority of the DQ&U label).

        1.2.2. The DH should ensure suitable competencies to report on DQ&U and maturity parts of the label.

        1.2.3. The Data Quality Framework to be implemented must be tailored to national contexts and institutional structure.

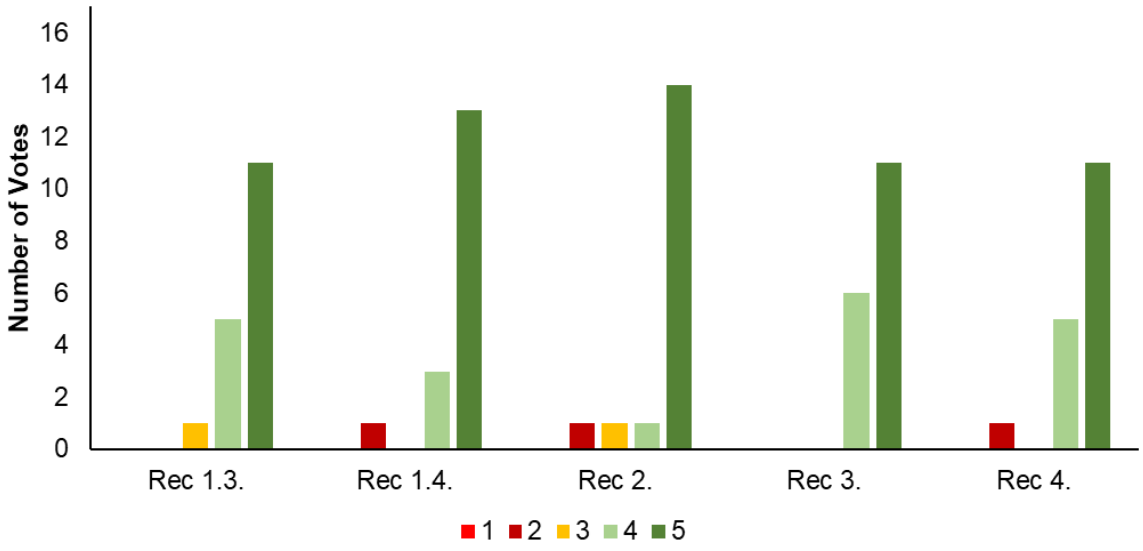


    1.3. The existence of a data quality framework (DQF) and a data management framework to harmonize processes across sites in cases of data holders with decentralized data

(when data is spread across sites) is recommended. These frameworks must clearly define the rules, roles and responsibilities to facilitate forwarding the data quality assessments tasks to agents capable of performing data quality reporting and of labelling the final datasets.

1.4. Training, support structures and funding are required to support DHs establishing DQFs. This is further addressed in the EC section.

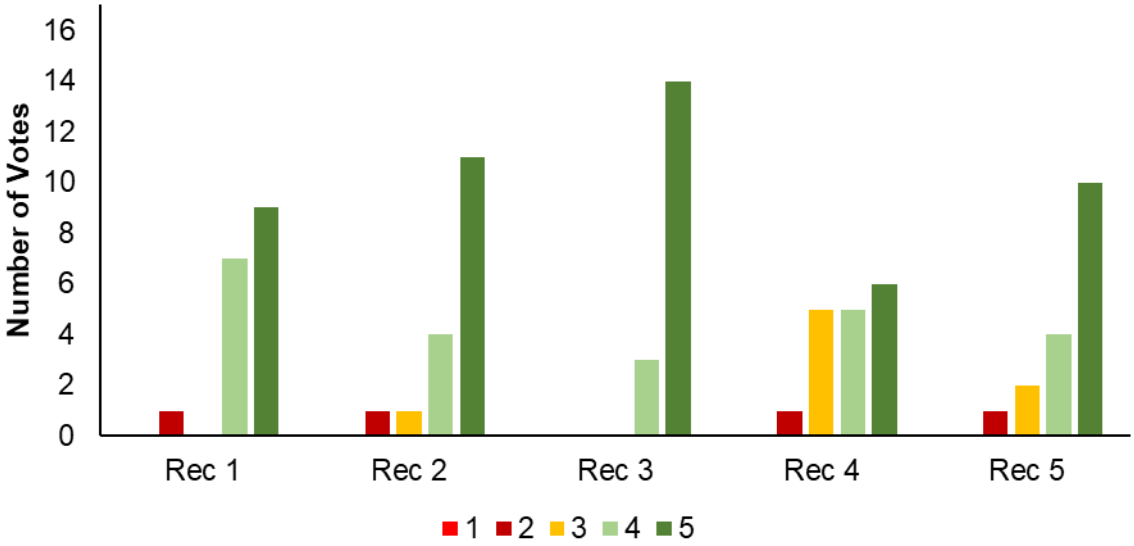
2. DQAs must be performed following the agreed standards across the data holder's domain and aligned with QUANTUM principles.
3. A culture of continuous improvement must be promoted. To that end, feedback from data users on the errors/issues they've encountered must be collected and addressed. A system to gather and address this feedback is recommended, with reporting on the identified issues and the corrective measures implemented by the data holders. This will promote an increase of institutional data maturity and encourage data holders' DQAs.
4. CoP/EHDS board subgroups/supportive and training actions to address data holders' needs and challenges at EU level and to provide a "knowledge sharing" platform are needed. This should be supported by the EC.



Label Compliance

1. Data Holders should follow QUANTUM developments and incorporate QUANTUM DQ standards (the specifications present in QUANTUM Deliverables 1.1 and 1.2) into their workflows.
2. Data Holders should be supported by HDABs and the EC during the implementation phase to obtain accurate DQ&U and maturity label, and the respective support documentation (in URL).

3. Dedicated training materials that cover data holder needs must be available and be disseminated.
4. The QUANTUM labelling tool “wishlist” identifies clear points of improvement that should be considered upon the end of the QUANTUM project.
5. A central coordinated action to harmonize data quality and reduce administrative burden on Data Holders is required.



DH Comments

#Comment 1

- Rec 4. should be addressed to EC Central Services.

#Comment 2

General Comment:

- 1. in the text of the recommendations is used sometimes "should", sometimes "must", some other times "is recommended", I would suggest to use always "should" considering these are recommendations not binding prescribtions, and to harmonise the text and the level fo details of the recommendations.
- 2. Some recommendations are really clear others not (i.e. 1.1 is very generic and not very clear). The text of all the recommendation should be harmonised at the same level of details/clarity.

About recommendations in the section 3 (Data Quality Assessments)

- - The recommendation 1.2.2 is not detailed enough to be relevant. What are the competences needed to satisfy the recommendation? Where are they listed ?
- - The recommendation 1.2.3 sounds ambiguous and possibly not needed.
- - The recommendation 1.4 is not a recommendations for the DH involving other subjects

training the DH staff, and should be removed from that section. It could be rephrased to be referred to a DH active role in demanding for training programs and other initiatives to facilitate the implementation of the DQF.

- - The recommendation 4 in section 4 (ata Quality Assessments) should be focused on a national HDAB level supported by EHDS Board.
- - The recommendation 5 of the section 5 (Label Compliance by Data Holders) is not clear.

#Comment 3

- Regarding Data Quality Assessments, Rec 1.: What if they don't? Would that impede that a less mature organisation is able to obtain a label until they have a DQF in place?. Also on Rec 1.2.2., how to ensure that, should further audit require documentation on SOPs or DQFs certification? I believe 1 and 1.3 might be merged to help manage the balance between necessity and reccomendation.
- Regarding Rec 3,. maybe add a mention to a prospective Fitness-for-purpose system.
- Label Compliance by Data Holders, Rec 4. The "wishlist" is unclear to me, it should be clarified what is it and what it can contain.

#Comment 4

- 4. Data Quality Assessment - Recommendation 2 (DQA aligned with QUANTUM principles): This would indeed be ideal. However, what with hospitals who already have a DQ framework/assessment procedure in place not aligned with QUANTUM terminology. Or with dimensions not in scope of QUANTUM due to different types of use cases. Innovative initiatives using health data is moving fast and therefore the data quality criteria are also changing quickly or need to be adjusted. QUANTUM and its principles is what a DH should provide but therefore not implemented. It is, from my perspective possible to map different DQ frameworks/assessment to the principles of QUANTUM if a dataset is uploaded. For me, the key point is the principles of documentation, this will be more important.
- 5. Label compliance by Data Holders - Recommendation 1 (incorporate QUANTUM standards in process): Same comment as above.
- 5. Label compliance by Data Holders - Recommendation 2 (HDABs should support DH): This would also be an ideal situation. But this means that each HDAB will need staff allocation/budget/data quality knowledge to address and implement this. Not sure therefore if this recommendation is feasible to reach.

#Comment 5

- '- 1.2.3. - could this point be reworded, perhaps "The data holder needs to implement a Data Quality Framework that is aligned with national and any relevant European guidance and aligned with the 12 DQ dimensions as developed by QUANTUM "
- - Each recommendation should be clear who is the targeted stakeholder e.g. 'institution' could say 'data holder'.
- - Language could be standardised and kept consistent e.g. 'data quality framework (DQF)'
- - Consideration could be given to the order of the subpoints to ensure the best flow of information - subpoints for number 1 could be re-examined to improve clarity and focus of the

points.

- - A formalised network of Data Quality Officers should be in place to support number 3 and 4 with a key contact point at a national level (similar to the Data Protection Officers for GDPR).

Label Compliance by Data Holders

- - point number 4 - lack of clarity over what the 'wish list is', to be reviewed.
- - point number 5 is unclear, does action mean network?

#Comment 6

- D1.2.3 Data quality framework - ie., data quality, utliity and maturity specifications should not be tailored to context, but how to manage the implementation

#Comment 7

- It is quite hard to be in fully disagreement with the recommendations. Nonetheless, imo they are very high level and could very well benefit from a chapter on operationalisation.
- For example: current recommendation = DQAs must follow agreed standards. To operationalise: Define minimum DQ procedures, for example with steps to take and roles and responsibilities: step 1: dataset profiling by data engineer, step 2: terminology validation by researcher/clinician, step 3: outlier detection by statistician etc.

#Comment 8

- 1.2.3 > The goal of a harmonised labeling system will be lost if national and organisational frameworks are implemented and the label becomes too specific.
- Consider rewording rec. 4

#Comment 9

Data quality assessment :

- 1.2.3 > Consider using "adapted" or "translated" instead of "tailored" to avoid a risk of heterogeneity.

Label compliance :

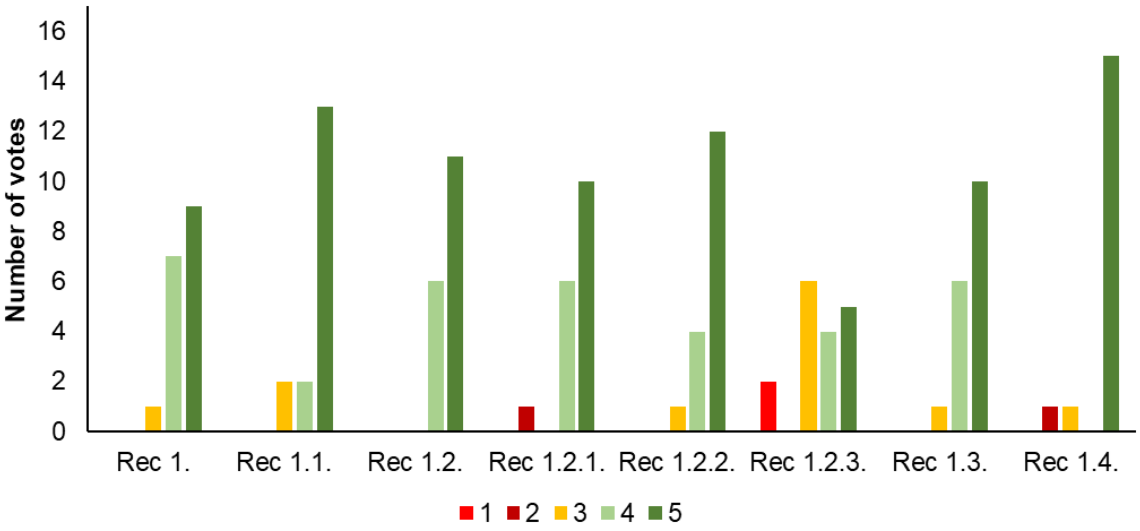
- 2 > It would be helpful to define the roles and responsibilities of the HDAB and EC in the support process.

#Comment 10

- Not all institutions might be able to have comprehensive data frameworks (for example smaller organisations not producing data primarily for research, like organisations providing data from wellness applications).
- Regarding following QUANTUM developed standards: They should be followed unless they conflict with the guidance provided by the implementing act or Commission.

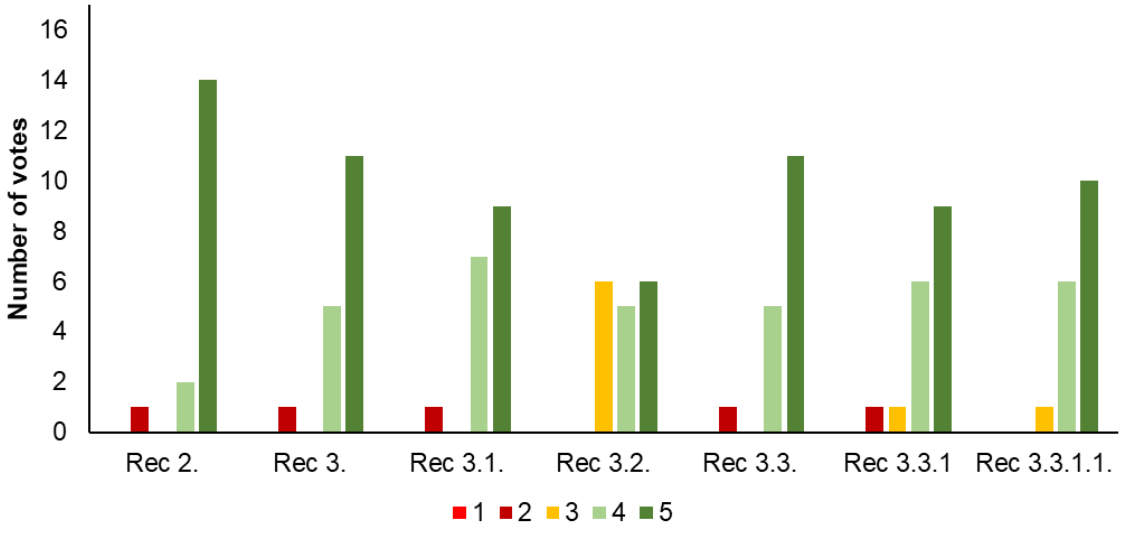
Recommendations for HDABs

1. **Supervision**: national regulation and frameworks should be established in accordance with a common EU framework. This should reflect whether the DQ&U supervision role will lay on the HDAB, or may be delegated to HDIEs or specific agencies/third parties specialized in data quality assessments established at national level.
   1.1. Guidelines to support HDABs tasks for overseeing DH's DQ reporting should be available.
   1.2. HDAB supervision tasks should include i) conducting plausibility checks (i.e. on the reported DQ&U and maturity reported scores), and ii) verifying whether the DHs have provided URLs for the assessment documentation and have followed QUANTUM specifications.
      1.2.1. HDAB needs to have staff trained and acquainted with the data to better assess whether the provided DQ&U scores are plausible.
      1.2.2. Strong HDAB-DH relationships are needed to facilitate "plausibility checks" and speed up procedures. Guidance should be provided by HDABs to support DHs producing DQ&U and maturity label documentation. These guidelines should be aligned with recommendations on this at EU level, whenever available.
      1.2.3. HDAB's URL checks must include cybersecurity evaluations for the links themselves and the documents they lead to.
   1.3. SOPs to conduct supervision activities are recommended. Moreover, user feedback usage must be in place: if Data Users report discrepancies (i.e. inaccurate labels) , these should motivate auditing/reviewing activities to strengthen the overall quality and maturity of the system.
   1.4. Support for HDABs is required. This is further addressed in the EC section.



2. Oversight: each MS will employ their own HDAB strategies (dedicated oversight institution/HDAB vs. centralized HDAB vs. oversight by Coordinator HDAB) for performing oversight tasks; regardless of strategy, dedicated staff capable of performing oversight duties is required.

3. HDABs should employ dissemination and training strategies for Data Holders, to support them on the application of the QUANTUM label. Some HDAB-specific recommendations follow:
   3.1. HDABs should liaise with Data Holders, supporting them filling in DQ&U and maturity fields of the QUANTUM label. Workshops, seminars and other opportunities to allow Data Holders to obtain "hands-on" experience with the QUANTUM label will be invaluable for a smooth adoption, and must be provided to Data Holders – early support is required. A channel for DHs to request for HDAB's support may be considered.
   3.2. Implementation of a national portal to showcase and broadcast high quality datasets and high maturity Data Holders should be considered. This could be included as a part of the national transparency portal.
   3.3. If HDIEs are implemented, DHs must be informed on their potential to offload some of DH burden, since HDIEs could provide invaluable support to smaller DHs that might lack the infrastructure and organizational maturity to perform QUANTUM labelling operations at scale. HDABs might facilitate DHs connection with HDIEs whenever needed.
      3.3.1. In case HDIEs are not implemented, the HDABs should provide this support to Data Holders that do not have the capacity to perform QUANTUM operations at scale.
         3.3.1.1. The QUANTUM Maturity Model will be a valuable tool to enlighten HDABs on which Data Holders need the most support.

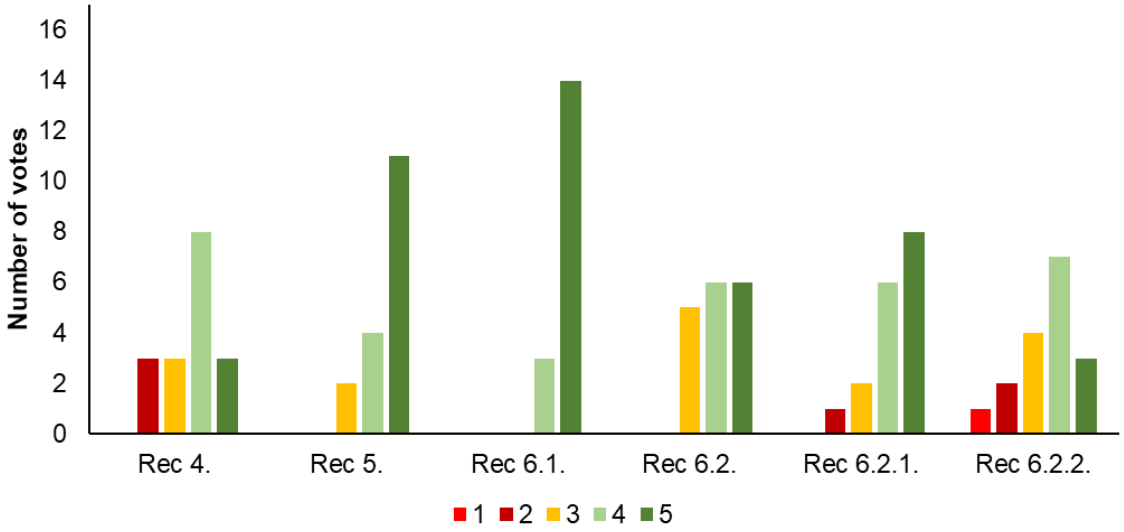


4. Employing third-party certification even for high-scoring labels is NOT recommended.
5. HDABs that are also Data Holders need, at the very least, a clear segregation of duties: a department that performs HDAB data quality-related tasks cannot also be involved in Data Holder tasks, and vice-versa. This level of functional, structural and operational segregation must be ensured and audited. Clear workflows must be in place to ensure this segregation, namely to ensure that no conflict of interests in Data Quality occur, for example, when

handling fit-for-purpose feedback on DQ&U and maturity labelling. Findata/THL model could be used as an example of this clear separation of duties.

6. Datasets may be composed of multiple sources, compiled by a single Data Holder, HDIE or another equivalent entity. For instance, a **publicly funded** national vaccination record compiling information from multiple public hospitals (Data Holders).
   6.1. **Data Quality and Utility labelling:** The entity generating the label for the composite dataset should be responsible for issuing the Data Quality & Utility part of the label and the corresponding supporting documentation.
   6.2. **Maturity labelling:** Two possible, **non-mutually exclusive** strategies are recommended:

Strategy	Advantages	Disadvantages
6.2.1. Display the individual maturity levels of Data Holders and the resulting average	Provides maximal information, allowing Data Users to better understand the provenance of the dataset	If the composite dataset undergoes higher maturity DQ processes during its creation, these are not reflected in the scores; requires clear traceability of data provenance and lineage.
6.2.2. Display a maturity score that reflects the maturity of processes utilized to create the composite dataset	Reflects cases when the composite dataset undergoes high maturity processes during creation	Results in a maturity score that reflects the maturity of processes employed for the dataset creation, and not the maturity of the data holders themselves; Much harder to audit

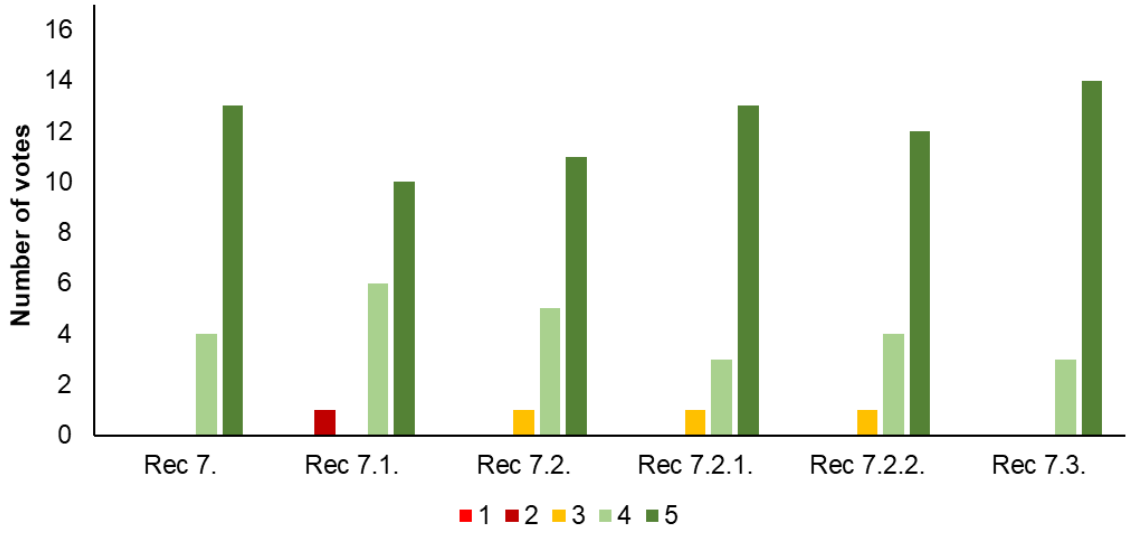


7. The QUANTUM label will be mandatory for all datasets generated via public funding. To support its application to non-mandatory datasets, HDAB involvement is necessary. It is recommended:
   7.1. National legislation support, based on the future EHDS regulation Implementing and Delegation Acts. This legislation should be built on the EHDS Regulation to strengthen the legal support for application of the QUANTUM label in each MS.
   7.2. Foster widespread dissemination to Data Holders and Data Users by HDABs:
      7.2.1. **A clear value proposition should be presented:** demonstration of QUANTUM utility for data discovery (Data Users) and data quality and institutional maturity improvements (Data Holders). Increasing the

visibility/discoverability of the data is an opportunity for increased recognition and funding, an opportunity to boost DHs' research activities.

7.2.2. **QUANTUM's data-type agnosticism should be leveraged:** since the QUANTUM label can be applied to any kind of dataset, examples and use cases for a wealth of datatypes should be provided, extending coverage across the health data landscape.

7.3. Training materials should be provided (see EC Recommendations).



HDAB Comments

#Comment 1

- HDAB Recommendations 1.3: potential mention to prospective Fitness-for-purpose system.
- 4. Need to better clarify what "third-party certification" target is.
- Rec 2. In my opinion, EC-level strategies should be defined and adopted at each MS to minimize heterogeneity and confounding for users when using datasets EU-wide.
- 6.2.2 vs 6.2.1: In my opinion, 6.2.2 is the one that fits the dataset being published itself (not 6.2.1), and it should also consider information about the maturity of each site.

#Comment 2

- There is a lot of recommendations putting extra work for HDABs. This would indeed be ideal to guide the DH and ensure maximal adoption of the label. However, this also means a lot of responsibilities for the HDABs which means the necessary investments. Would the HDABs therefore do these services as a paid service or is this a free service?
- Putting all responsibilities with the HDABs might also be restrictive. What with DH (hospital networks for example) who have a well established data quality process maybe with third parties involved.

#Comment 3

- I assumed that 6.21 and 6.2.2 was a choice. As discussed previously this is a difficult decision. My preference is for as much information as possible to be provided.

#Comment 4

- - 1 (supervision) Emphasise the value of having expertise on evaluation from an independent agency
- - 1.2, 1.2.1,1.2.2 and 1.3 refine recommendations to note that these tasks could be undertaken by a specific agency with remit in this area where appropriate
- - 1.4 - more clarity is needed regarding type of support needed.
- - References to training should be strategic, this could be focussed on in the recommendations for the EC. Is this next steps for QUANTUM 2? e.g. a training needs analysis is required
- 3.1 - this role could also be fulfilled by a relevant external agency.
- 6 - more work required, difficult to asses as this is a complex scenario. Could this be worked up further with some testing (QUANTUM 2)
- 7.2.2 dimensions and definitions should be standard but needs to be reviewed and potentially revisions required to metrics for some datasets e.g. population representative targets for a survey

#Comment 5

- 1.2.3 Although logical, this is not a recommendation derived directly from QUANTUM
- 6.2.1 We have not created nor tested this option

#Comment 6

- Here again it would be advised to add a bit more on the operationalisation of the recommendations. This requires translating the supervisory role into concrete procedures, documentation requirements, and support mechanisms. Foer example, SOPs for reviewing QUANTUM labels should include: automated checks of metadata completeness and plausibility checks of reported data quality and maturity scores. A risk-based auditing framework could be implemented, where a defined proportion of labelled datasets is reviewed annually and additional audits are triggered by user feedback or unusually high scores. An HDAB staffing model could be added to clarify what is needed on HDAB side, for example: metadata specialist (role) should be reviewing label completeness (responsibility), audit officer (role) performs (random) audits (responsibility), data scientist (role) evaluates DQ scores etc.

#Comment 7

- HDIEs are foreseen to support DHs, according to the national assessment of this opportunity. Hence, they are ad-hoc bodies that should not need an intervention by HDABs.

#Comment 8

- 1.2.3 While URL verification is important, including cybersecurity checks at the HDAB level may not be fully aligned with the core role of the HDAB, which primarily requires strong expertise in data quality assessment, plausibility checks, and support to data holders. It could be more efficient to implement a centralized platform where documentation and URLs are systematically deposited

#Comment 9

- Rec. 4: Since the label is somewhat generic and self-assessed, third party certifications could be valuable for certain types of data.
- 6.1: Should mention that "..... with the support from the source data holders"
- 7.1: Maybe first sentence is not necessary. Reads as repeating sentences.

#Comment 10

- 1.2.1 > It might be difficult to ensure that staff are fully trained and acquainted with all the diverse data an HDAB may encounter.
- 1.2.3 > This point seems more related to general internal processes rather than being specific to QUANTUM.
- 3.2 > To maintain HDAB neutrality, it might be better to use "accessible" instead of "showcase/broadcast".

#Comment 11

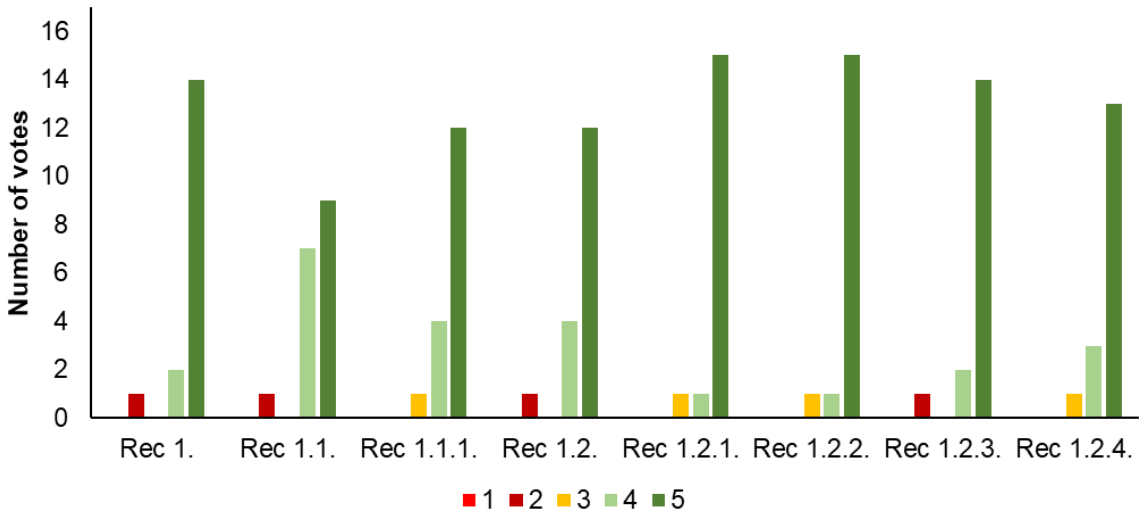
- Rec. 4: these certifications could be complementary to the DQA based on Quantum.
- Rec. 7: the points highlighted here are great, but incentives are needed, so they are not just obliged to issue the label but they do so because of the benefit it would provide to them (beyond data visibility and sharing).

#Comment 12

- I don't strongly disagree with any recommendations, I only wonder if HDABs really will have the potential to operate in the recommended way. In many countries, funding for HDAB operations and EHDS implementation can be quite small.
- Regarding the mention of THL and Findata: Currently, Findata operates completely separately from THL, although it is part of it. Findata is legally and administratively structured to operate in conjunction with THL, while maintaining separation of THL's other activities. It seems that in many other countries, HDAB might be established within a data holder organization without such a sharp separation.

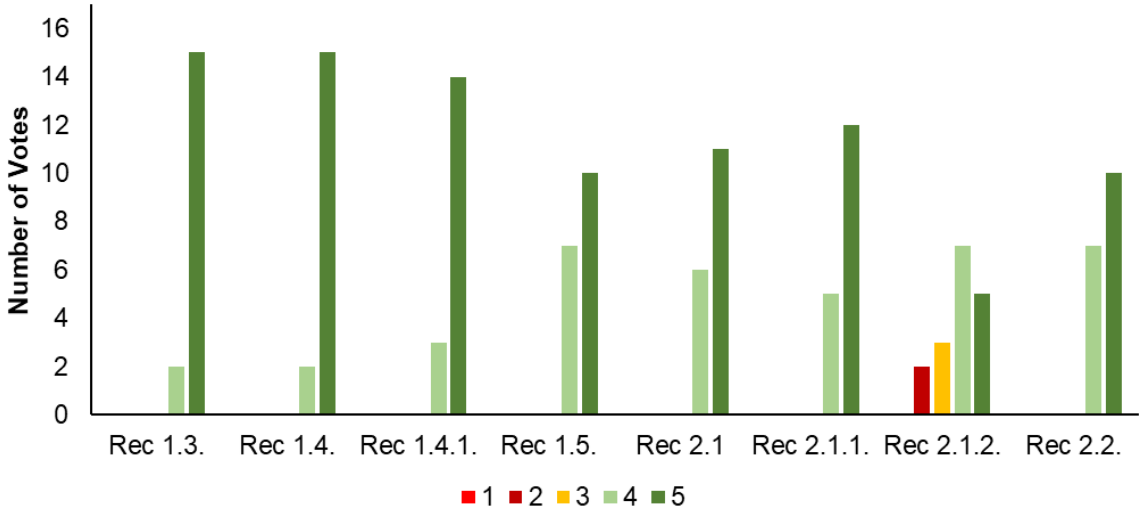
Recommendations for EC

1. QUANTUM materials, trainings, documentation (metrics assessment, reporting, templates) need to be leveraged by and disseminated by the EC to HDABs and data holders. Existing and nascent groups that address data quality and governance in the EHDS (the existing CoP SG2, or future SGs of the EHDS Board) should be leveraged for this.
   1.1. Guidance, policies and existing best practices from institutional documentation (HIQA; AIHW; Canada DQF) must be addressed in these groups.
      1.1.1. Existing tools and capacities of Research Infrastructures (RIs) EDICs and ERICs on data quality and data governance must be leveraged. Furthermore, Data Holders should be informed on how their existing DQ methodologies can be leveraged to fill in the QUANTUM label.
   1.2. **The EC should maintain and update a centralized platform** where training materials covering QUANTUM, Data Quality, Data frameworks, Data Holder Maturity and the various aspects of the EHDS and of Data Quality are covered. The incorporation of these into the EU Academy seems the most suitable approach.
      1.2.1. **Materials should include best practice examples on data governance and on data quality across different types of data holders, reducing discrepancies in interpretation of the QUANTUM DQ&U+Maturity Dimensions. Early support in line with the QUANTUM 12 DQ&U dimensions must be provided.**
      1.2.2. **Materials should include tools and guidance for the technical data quality reporting, and be tailored according to maturity.**
      1.2.3. **Relevant data quality and data framework related materials made available in QUANTUM Academy and in other relevant EU-funded data quality initiatives must be leveraged and provided in these centralized platform. Their continued improvement and maintenance by the EC is recommended.**
      1.2.4. These materials should be leveraged by HDABs to provide support to Data Holders.



1.3. QUANTUM tool manual should contain extended definitions, examples and use cases to properly guide data holders.
1.4. QUANTUM label related training initiatives (e.g. hands-on workshops, webinars) should demonstrate the value of intra-organizational coordination to perform the QUANTUM evaluation. Examples and use cases should also cover all aspects of the label, both DQ and Maturity.
1.4.1. QUANTUM training materials should be tailored to multiple data types (tabular, images, non-tabular, structured) and cover multiple levels of expertise.
1.5. Annual Internal and External Validation procedures for all training materials is recommended to ensure materials remain relevant and updated.

2. Standardization of the support documentation provided by Data Holders to HDABs, and of the auditing process performed by HDABs was considered crucial. To achieve this, it is recommended:
2.1. Guidance on how to produce support documentation, informing DHs on how they should report on the QUANTUM dimensions.
2.1.1. This could be included in the training materials for QUANTUM.
2.1.2. The TEHDAS2 data permit template can be used as inspiration for how to communicate this guidance.
2.2. Standard Operating Procedures (SOPs) should exist for HDABs for addressing cases in which the information in the QUANTUM label (DQ&U + Maturity) isn't accurate. Guidelines for establishing auditing processes to be conducted by HDABs are needed. For example, there needs to be a clear workflow that covers response to feedback submitted about a dataset in the EU Catalogue: this should trigger an HDAB audit to evaluate if the Data Holder needs to perform any changes.

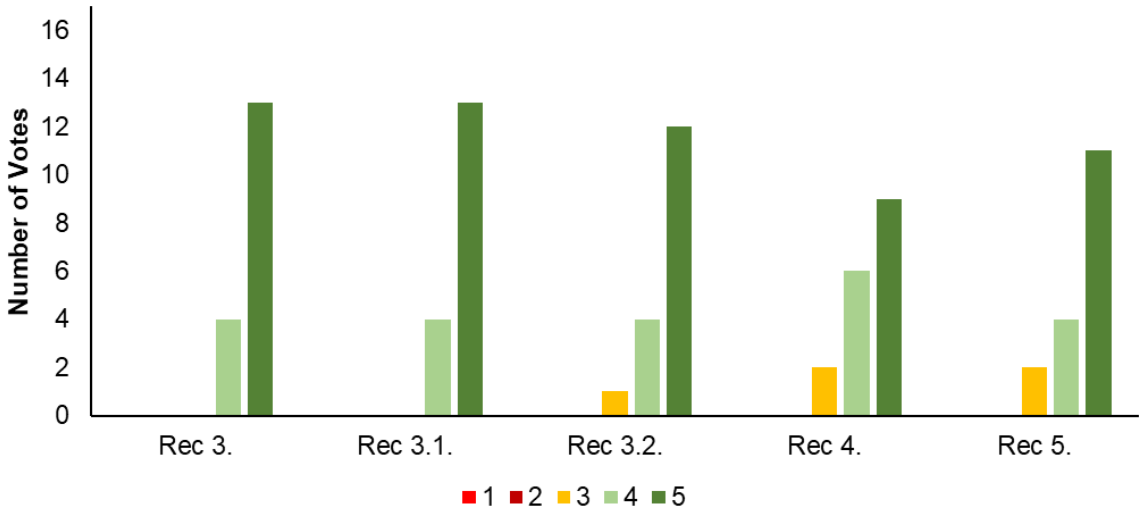


3. QUANTUM tool should remain an open-source solution and the EC should assume custodianship over it, including it in the Central Services Releases alongside the Dataset Description Assistant and perform improvements as needed.
3.1. A similar update structure to the Central Services Releases should be followed, with

clear communication of an update roadmap to ensure stakeholders can adapt to changes to the label.

3.2. Updates to the tool and the label itself should be made sustainable via the future Delegated acts, ensuring continuous improvement to meet stakeholders' needs.

4. The inclusion of the QUANTUM quality and maturity specifications into DCAT is recommended, leveraging its data-type agnosticism to harmonize data quality and institutional maturity across data spaces, not just health data.
5. Including the capacity to filter datasets in the HealthData@EU central platform's Catalogue via QUANTUM average score and dimension-specific score is recommended to further facilitate discovery of high-quality, fit-for-use datasets by Data Users.



6. To build capacity among EHDS stakeholders on organizational and governance, it is recommended:
   6.1. **Creation of a Data Quality dedicated subgroup within the EHDS Board to continue and expand the efforts of the current Subgroup 2 of the EHDS2 Community of Practice for supporting data holders.**
      6.1.1. This group should host sessions with people working on documenting processes and other DQ relevant issues, so that their work can be leveraged for future guidelines.
      6.1.2. The Subgroup should have a clearly defined scope and framework to avoid institutional fragmentation and duplication of governance structures of participating Member States.
      6.1.3. This subgroup must be supported by dedicated platforms, that allow for example, compilations of relevant materials and dedicated forums that allow questions to be submitted and answered by qualified experts, ensuring structured support and guidance.
   6.2. Creation of national or EU-level CoPs,/peer-to-peer learning experiences and/or support initiatives to **assist HDABs** in establishing their plausibility check SOPs and gathering trained staff for QUANTUM label supervision. The EC capacity building

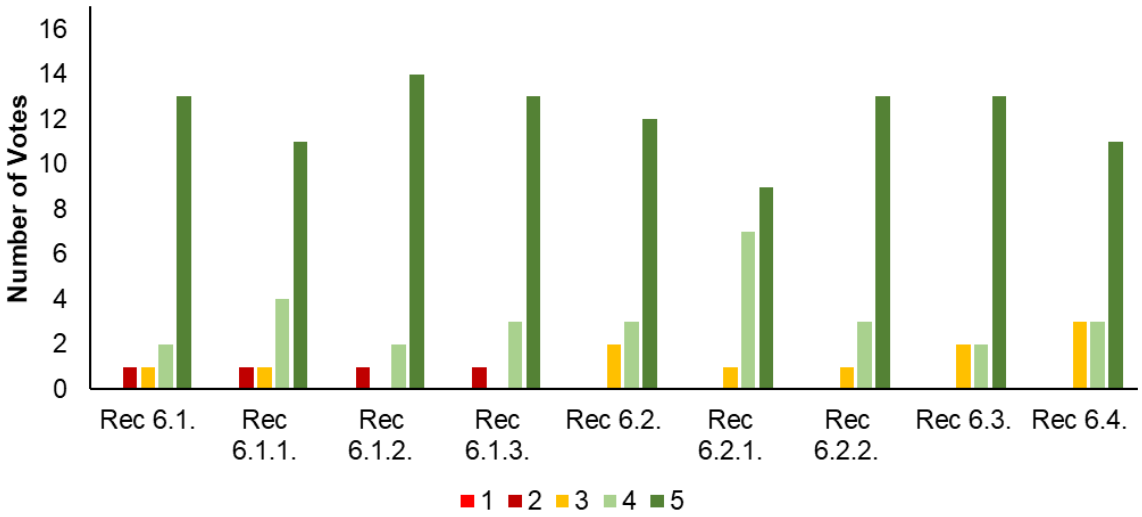
materials on DQ&U can be leveraged for HDABs training and must be properly disseminated through HDABs, and updated as needed.

6.2.1. These support initiatives will benefit from the presence of institutions with high levels of maturity and data quality, to share best practices and knowledge. ERICs, EDICs and other similar infrastructures should be leveraged due to their experience in data management and governance.

6.2.2. Active involvement of the EC in EU-level knowledge-sharing initiatives is recommended, to avoid the spread or replication of incorrect practices.

6.3. Establishment of a data governance supporting task force/subgroup of the EHDS Board that can guide EU and national frameworks to have data quality requirements. Supporting data governance from the beginning is key to ensure institutions develop robust DQFs.

6.4. Establishment of a QUANTUM label technical support team to provide a "helpdesk" service for the application of the label, answering questions regarding compliance with QUANTUM standards or other related topics.



7. **Conflicts of interest in Data Quality and Maturity evaluation must be avoided:** HDABs that are also Data Holders need, at the very least**, a clear segregation of duties:** a department that performs HDAB tasks **cannot** also be involved in Data Holder tasks, and vice-versa. This must be explicitly present in the article 78 related implementing acts.

7.1. Member states must establish dedicated bodies to audit whether this segregation of duties is being properly performed. EU level oversight at this level must be considered.

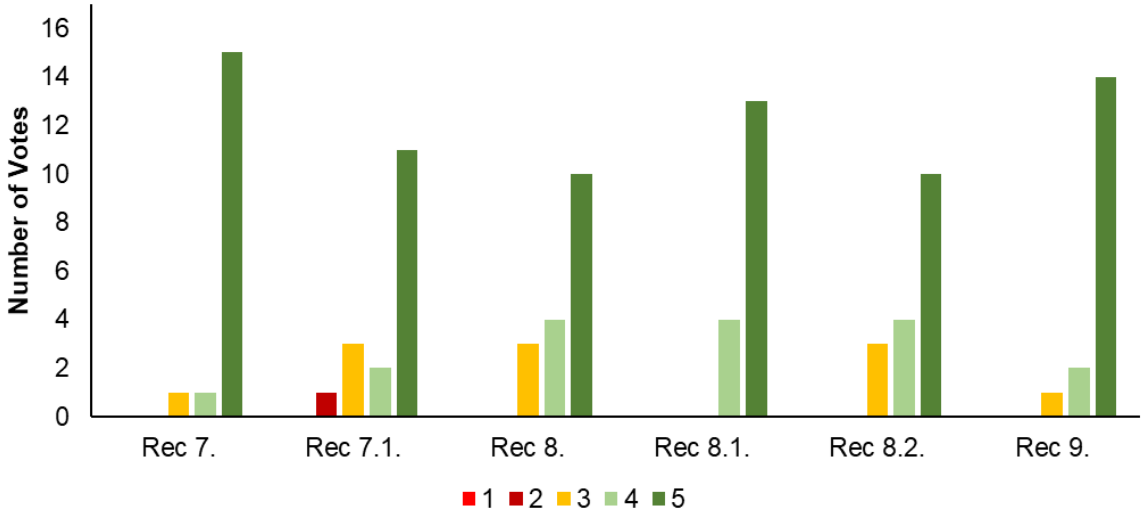
8. The EC audit requirements for HDABs must entail assessments on whether measures to prevent conflicts of interest in data quality are in place and are sufficient. Labelling costs' support: the infrastructure and resource investment to build up and maintain the capacity for dataset labelling operations is **currently explicitly excluded from applicable fees for data access requests** (TEHDAS2 M4.4.1 "(…) costs related to the creation, updating, and maintenance of the metadata (…) including quality labelling (…) are out of scope (…)").

8.1. For future datasets (not existing ones), the labelling costs should be included in the

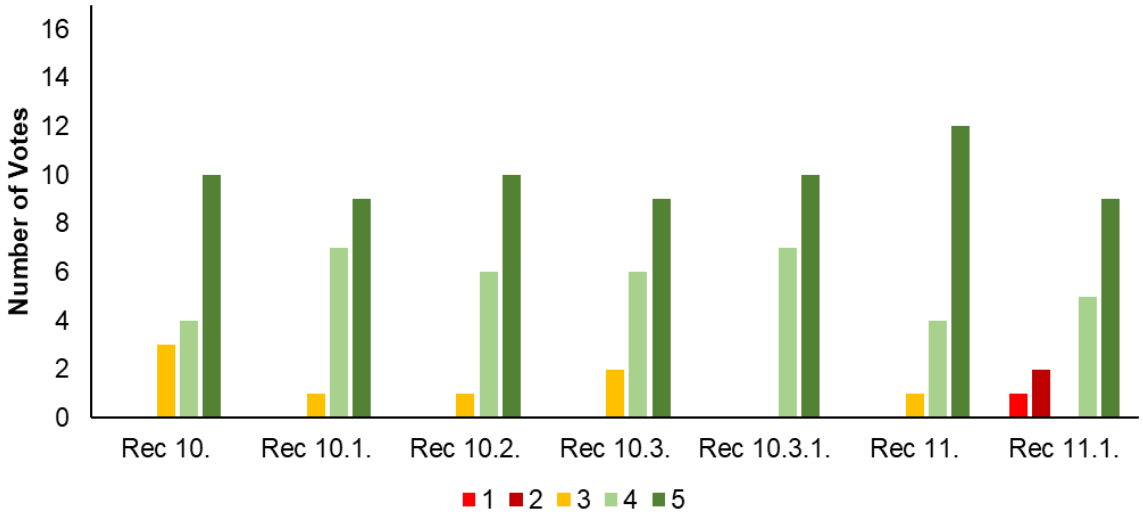
funding provided to create them, so there is no need for extra financial support.

8.2. The creation of a "grandfather" system for legacy datasets that still see current use but do not have funding for their maintenance is recommended: Data Holders should be able to apply for public funding to create the QUANTUM label for these datasets.

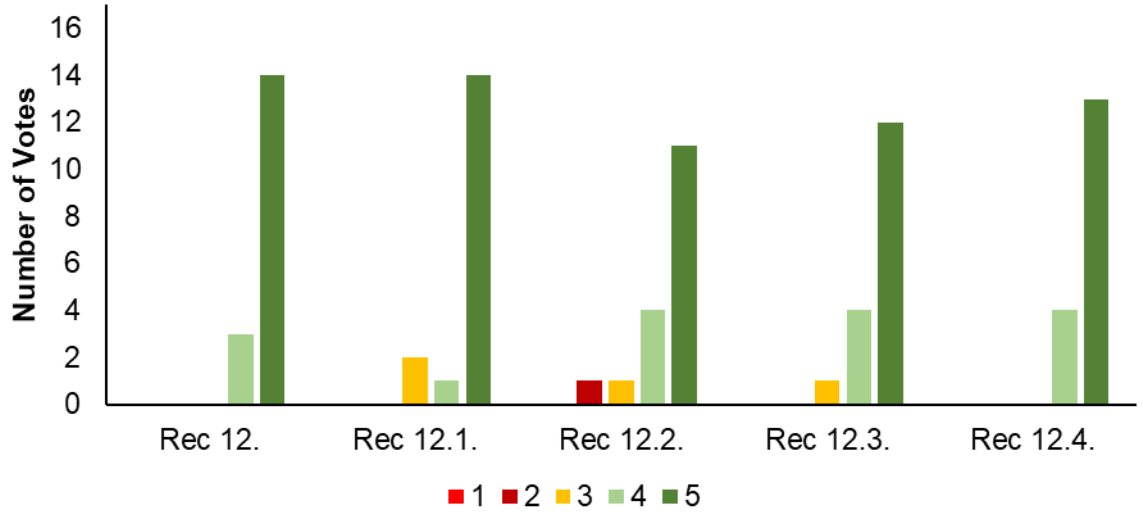
9. User feedback and complaints: Data Users should also have the option to report on label accuracy in their Fit-for-Purpose reports. The development of a common tool (akin to the QUANTUM labelling tool) either by the EC or via an European initiative to achieve this is recommended.



10. Fostering data quality improvement: the creation of a DQ&U improvement environment across EHDS stakeholders elevates their institutional maturity. Some suggestions to aid in building this environment follow:
    10.1. Periodic monitoring by HDABs: periodic Data Quality reports delivered to HDABs by DHs, resulting in a summarized public report on national DQ levels.
    10.2. Periodic monitoring by the EC: collaborating with HDABs to track the effect of the QUANTUM label on DQ and Maturity across Data Holders in the EHDS.
    10.3. 10.1 and 10.2 can be satisfied using dashboards akin to the EHDS2 HDAB and MS Maturity Model.
        10.3.1. This must help informing the EC on the need of support actions for countries facing higher challenges in implementing the QUANTUM label.
11. Full transparency: **adding clear information about the obligation for publicly funded datasets to adhere to the QUANTUM label on future national and European funding calls is strongly recommended** (such as future HORIZON calls).
    11.1. Provide a competitive advantage for the call in case applicants utilize datasets that follow the HealthDCAT-AP and QUANTUM standards to further encourage their use. This incentive should be clearly disclosed in the text of the call.



12. Finally, **in the case the QUANTUM label has not been sustainably supported by the EC**, a follow-up project to QUANTUM is strongly recommended, to assist the EC in bridging the QUANTUM label efforts with other European initiatives on Data Quality and work on pending issues or identified gaps. Some of the identified gaps follow:
    12.1. F4P report implementation (as this is not in scope of the ongoing QUANTUM project);
    12.2. Standardization of data within the same data type, across data types;
    12.3. Data Quality at the variable level, building upon projects such as CancerWatch;
    12.4. Addition of requested QUANTUM tool functionalities, such as versioning for quality assessments, bulk actions, RDF importing and exporting functions, comprehensive step-by-step built-in guides.



EC Comments

#Comment 1

- '- Rec 4. should read '(...) HealthDCAT-AP dataset description specification (...)'.
- - Rec 8.2 should provide a more detailed description of what a "grandfather" system for legacy datasets can consist of.

#Comment 2

- Rec 4: Maybe you mean Health-DCAT instead of just DCAT :)
- Excellent work. Congratulations.

#Comment 3

- Same here, a lot of responsibilties for the HDABs and now also for the commission (in sustaining all content, templates,...).
- A recommendation I am missing related to sustainability is the relation with other DQ initiatives. There is already a lot out there on data quality, how is this linked to QUANTUM? Data quality is an entire ecosystem from creation to reuse in which QUANTUM is a part off, it doesn't cover the entire spectrum. So, assuming DH need to adopt this in their internal process and HDABs therefore be the entity ensuring this adoption might be restrictive and not feasible/scalable. The recommendations are developed towards adoption and uptake of the label but this is not equal to improving data quality in the entire ecosystem. From my perspective, some recommendations should be more addressing this. Also related to the costs of implementing everything. Data holders which are low mature and who don't have the budget/staff/time to do this will rely on the HDABs who then will take the financial/time burden.
- I understand the goal of the recommendations and I am enthusiastic to see that a lot of the these recommendations are addressing aspects outside of the initial scope of the project. However, I am wondering if some of these are feasible to achieve.
- Nevertheless, thank you for this extensive work and providing me the opportunity to read and review it.

#Comment 4

- Overarching comment - to review the depth of recommendations given to the EC, there is overlap in the points, specifically around training. This work requires review, coordination and oversight of training material. A training needs analysis is required and allocation of roles and responsibilities - more research is required on this (QUANTUM 2)
- 1 - agree but think we need to add that material needs to be targeted to different types of data holders and for different levels of maturity
- 1.1 - best practice may not be yet established so should extend beyond by address generalisability of QUANTUM e.g. applying label across different types of data holders across different levels of maturity - more research is required on this (QUANTUM 2)
- 1.1.1 - a little vague, informed by whom? - more research is required on this (QUANTUM 2)
- 1.2.1 and 1.2.2 - these could be a little more specific - training materials on the application of the label for different types of data and for those at different levels of maturity. - more research is required on this (QUANTUM 2)
- 1.3 - this recommendation is important but currently needs a significant amount of work (QUANTUM 2- to develop case studies and apply across different types of data holders and across different levels of maturity)

- 1.4.1 - change text to to 'cover multiple levels of expertise and maturity'
- 2.1.1. Query, could action be for QUANTUM 2?
- 2.1.2 - a little vague?
- 2.2 - this recommendation could be stronger - e.g. methodology regarding compliance models needs to be developed and recommendations /examples of best practice provided by EU (or QUANTUM 2)
- 6.1 - suggestion to make this recommendation stronger - QUANTUM 2 needed and network of data quality experts required at each level to review, feedback and improve in a consistent way
- 6.2.1 - consideration to include all levels of maturity to make sure materials are relevant to all and change, otherwise the gap in maturities will become wider
- 6.2.2 - See suggestion for training needs analysis for this.
- 8.2 - suggest avoiding technical terms like 'grandfather system' as it could be open to interpretation.
- 9 - definitely agree to this work, methodology needs to be developed this could be work for QUANTUM 2
- 10.3.1 - agree, this is a critical recommendation, could add a point to revise the label if needed.
- 12 - this recommendation could be made stronger for example: Need also to explore implementation across levels of maturity; Revision of metrics for some data types (case-studies needed); Training needs analysis - coordination and management; Models/case study on assessing compliance

#Comment 5

- I scored rec 8 and 10 as neutral since given statements they should not be scored

#Comment 6

- 1.1.1 I would be more specific - not just leveraged but also see the way to make EDICs and ERIC systems interoperable - a 3rd layer of quality and utility that is community-based / 2.1.2 I do not see now how the permit can inspire DH documentation / 6.3. This needs further clarification - I would not say this is about developing DQFs but the governance of the EHDS2 DQF and QUANTUM specification - maybe would rephrase along the recommendations / 7.1 is not really EC but MS; maybe reallocate / 12.3, maybe add as general examples health data- based EDICs, and ERICs

#Comment 7

- As for 12.2, the question is not clear: standardization of data should be always a major target, not requiring a specific support action.

#Comment 8

- 11.1: While encouraging HealthDCAT-AP and QUANTUM standards is vital, providing a competitive advantage for pre-grant compliance creates a significant barrier. Many applicants lack the resources or finalised project scope to fully standardise datasets before securing funding. This risks penalising high-quality science. Recommendation: Replace the competitive advantage with a strong recommendation. Instead of rewarding completed compliance, evaluate the feasibility of the applicant's roadmap to achieve these standards during the project. This ensures fairness and encourages adoption without excluding promising proposals due to premature logistical hurdles.

#Comment 9

EC recommendations :

- 3.2 > It might be useful to better define "updates," as they can range from minor text corrections to the addition of entirely new dimensions.
- 8 > Regarding the format: should this section be renumbered as 7.2, and is "Labelling costs" intended to be a new paragraph?
- 12.2 > It would be helpful to clarify if the objective is broad standardization across datasets or specifically integrating the ability to address standardization within the tool itself.

#Comment 10

- Rec. 2.1.2: Maybe add the link to the TEHDAS2 template for clarity
- Rec 11.1: Encouraging the use of such datasets means that, for those DHs that are not keen to share the data (especially those for which the label is not mandatory), this would be a way to avoid further reuse of their data.