



D5.8 PROJECT FORUM

FINAL REPORT

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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	This deliverable reports on the objectives, implementation and results of the QUANTUM Project forum. The Project forum served as a key engagement platform for external stakeholders in the project. Four interactive online forums were organised to present and validate QUANTUM key deliverables with external stakeholders. The sessions included presentations, discussions and feedback gathering via interactive tools. The content and results of all four forum sessions are reported in this deliverable, as well as the impact they had on the QUANTUM work. The stakeholders highlighted, among other things, the need to manage data quality and utility label's implementation burden especially on less mature organisations, to balance between excessive complexity that might undermine uptake and providing clear value for data users, and to balance standardisation with context-specific notions of fitness for purpose.
Keywords	Project forum Stakeholder engagement Data quality and utility label European Health Data Space (EHDS)

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QUANTUM CONSORTIUM			
#	Short Name	Organisation Name	Country
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2	Sciensano	SCIENSANO	BE
3	Health Data Hub	PLATEFORME DES DONNEES DE SANTE	FR
3.1	HOSPICES LYON	HOSPICES CIVILS DE LYON	FR
3.2	HOSP TOULOUSE	CENTRE HOSPITALIER UNIVERSITAIRE DE TOULOUSE	FR
3.3	CHU Bordeaux	CHU HOPITAUX DE BORDEAUX	FR
4	I-HD	THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA	BE
5	UCSC	UNIVERSITA CATTOLICA DEL SACRO CUORE	IT
6	BBMRI-ERIC	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM	AT
7	DIGITALEUROPE	DIGITALEUROPE AISBL	BE
8	GÖG	GESUNDHEIT OSTERREICH GMBH	AT
9	UPV	UNIVERSITAT POLITECNICA DE VALENCIA	ES
10	HEALTH-RI	STICHTING HEALTH-RI	NL
11	EUHA	EUROPEAN UNIVERSITY HOSPITAL ALLIANCE	BE
12	AP-HP	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	FR
13	VIB	VIB VZW	BE
14	CIPH	HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	HR
15	HUS	HUS-YHTYMA	FI
16	THL	TERVEYDEN JA HYVINVOINNIN LAITOS	FI
17	ECRIN	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	FR
18	BFARM	BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE	DE
19	HIQA	HEALTH INFORMATION AND QUALITY AUTHORITY	IE
20	ISS	ISTITUTO SUPERIORE DI SANITA	IT
21	CESSDA ERIC	CESSDA ERIC	NO
21.1	KNAW	KONINKLIJKE NEDERLANDSE AKADEMIE VAN WETENSCHAPPEN - KNAW	NL
21.2	EKKE	ETHNIKO KENTRO KOINONIKON EREVNON	EL
22	e-helse	DIREKTORAT FOR E-HELSE	NO
23	U.PORTO	UNIVERSIDADE DO PORTO	PT
24	SPMS	SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE	PT
25	NIJZ	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	SI
26	ERASMUS MC	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	NL
27	EDHA	EUROPEAN DIGITAL HEALTH ACADEMY GGMBH	DE
28	HDR UK	HEALTH DATA RESEARCH UK	UK
29	UESSEX	UNIVERSITY OF ESSEX	UK
30	INSERM	INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE	FR

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List of Abbreviations and Acronyms

DCAT	Data Catalog Vocabulary
DQV	Data Quality Vocabulary
EDICs	European Digital Infrastructure Consortia
EHDS	European Health Data Space
F4P	Fit-for-purpose
HDAB	Health Data Access Body
HealthDCAT -AP	The HealthDCAT Application Profile
PROV-O	The PROV Ontology
RDF	Resource Description Framework

1 Introduction

This deliverable reports on the design, implementation and results of the QUANTUM Project forums, the project's main structured mechanism for engaging external stakeholders in the development of a Union data quality and utility label and a maturity assessment framework for data holders under the European Health Data Space (EHDS) Regulation. Over four online sessions held between March 2025 and February 2026, the forums brought together a diverse community of EHDS-related initiatives, Health Data Access Bodies (HDABs), data holders and data users to discuss, test and refine key QUANTUM outputs, including the technical specification of the datasets' quality and utility label, the maturity model for data holders, the mid-scale pilot of the Data quality and utility labelling tool and the emerging fit-for-purpose (F4P) strategy.

Situated within QUANTUM's broader mandate to translate EHDS Article 78 requirements into a practical, scalable labelling mechanism for HealthData@EU - the infrastructure designed to enable the secondary use of health data within the EHDS framework - the Project forums were conceived not as dissemination events, but as co-creation and validation spaces where stakeholders could provide targeted feedback on draft deliverables and explore their feasibility in real-world settings. Each forum combined focused presentations with interactive methods (e.g. Mentimeter, Wooclap and post-meeting surveys) and follow-up opportunities via a dedicated Microsoft Teams workspace and QUANTUM project's helpdesk, ensuring that input could be captured both during and between sessions and fed back into the project's technical and policy work.

The deliverable documents the forums' objectives, membership, methods and main discussion themes, and analyses how stakeholder contributions influenced the evolution of QUANTUM's labelling specification, maturity model, piloting approach and F4P concept, as well as their positioning within the wider EHDS and HealthData@EU implementation pathway. In doing so, it provides evidence that structured, iterative stakeholder engagement can enhance the clarity, usability and legitimacy of data quality and utility frameworks intended for EU-wide adoption, while also surfacing critical issues such as burden on less mature data holders, granularity of quality information and the design of meaningful user-driven fit-for-purpose assessment model.

2 Background and scope

2.1 Purpose and objectives of the Project forum

The QUANTUM Project forum's purpose was to serve as a key platform for stakeholder engagement in QUANTUM project, where stakeholders—particularly research projects and initiatives—could learn about the QUANTUM project and provide valuable feedback on its progress. This feedback was planned to primarily focus on key parts of public deliverables, such

as the technical specification of the data quality and utility label, the results of its implementation, and recommendations to support the deployment of this labelling mechanism within HealthData@EU. The forum was not only intended for dissemination purposes but rather for constructive input on the project's evolving work. Engagement was planned to occur through online forum sessions or workshops where key points of the deliverables and ongoing work were shared, and feedback was solicited using interactive tools.

The objectives of the Project forum were to:

- Ensure QUANTUM deliverables are clear, feasible, and aligned with stakeholder needs;
- Support the effective deployment of the labelling mechanism in the HealthData@EU, and;
- Provide a structured process for feedback integration.

2.2 Methods

The Project forum acted as an engagement platform with the aim to bring stakeholders together with the QUANTUM experts. At its core were interactive Project forum online sessions, but communication between the sessions was also enabled. Over the course of the project, four Project forum online sessions or workshops were hosted, strategically aligned with the release of key deliverables to ensure that stakeholder input is integrated into the project's development.

Forum sessions were organised in Microsoft Teams and they were not recorded, as a confidential atmosphere was wanted for the forum discussions. Interactive tools were used either during the forum sessions or after them to gather feedback and input for the work from the members. In addition, a closed workspace was created for the forum in Teams, where all the materials were shared after the sessions.

2.2.1 Project forum session structure

Each Project forum event included presentations and dialogue. Some forum sessions were more workshop-like with active feedback gathering, and others focused more on presentations and discussions. All four sessions except for the first one included a structured way to collect feedback, either during the session or after it via Mentimeter, Wooclap or EUSurvey virtual tools.

Key elements of the forums included:

1. **Presentation of QUANTUM work or deliverables:** A detailed walkthrough of the relevant deliverables, emphasising specific areas for feedback.
2. **Interactive discussions:** Either free or guided discussions by prepared questions and facilitated by moderators.
3. **Real-time or post-workshop feedback collection:** Tools like Mentimeter and Wooclap

gathered input during sessions, and also EUSurvey was used to gather information and feedback after the session.

2.2.2 Collecting feedback outside the forum events

Forum members also had the opportunity to provide input outside of the organized online forum sessions. A closed Teams workspace was set up for the forum members, where materials, notes of the discussions and feedback gathered via interactive tools were shared, and a possibility for further communication was provided.

Forum members were also offered the opportunity to comment on deliverables in the closed workspace. However, the deliverables did not receive any comments in Teams. The deliverables shared for commenting were:

- Deliverable 1.1 Specification of the datasets' quality and utility label;
- Deliverable 1.2 Specification for the assessment of data holders' maturity;
- Deliverable 4.1 Stakeholder learning needs assessment mapped to learning objectives.

Also after the third forum session, a survey was sent to the forum members to gather more insights and input on the topics presented and discussed during the forum. In addition, participants were encouraged to send possible additional questions via the [QUANTUM ticketing tool](#), from which they were to be distributed to relevant QUANTUM experts.

2.3 Project forum members

Membership to the Project forum was by invitation, determined based on synergies identified by the QUANTUM consortium partners, the funding authority, and the broader EHDS community. In addition, an opportunity to express interest in becoming a member was offered on the project's website while marketing upcoming Project forums. Project forum events were marketed, among others, on the QUANTUM project's social media channels, in the project's newsletter and on the website, and the messages delivered included the opportunity to contact and express an interest in becoming a member and participating in the forums.

A detailed list of invited member organisations, including relevant data-driven Horizon Europe and EU-funded projects, EHDS initiatives, and infrastructure projects, is provided in the annex. It should be noted, however, that the list is not a comprehensive list of members, as the list has not been fully updated with actual participants of the forum sessions or those who have expressed their willingness to participate. However, the list represents the targeted group of members.

3 Project forum implementation and results

3.1 Overview of the forums

Overview of the four forums is presented in the following table.

Table 1: Overview of the Project forums

	1. Project forum	2. Project forum	3. Project forum	4. Project forum
Date and time	March 13th, 2025 11:15 - 12.30 CET	July 1st, 2025 11:00 - 12:00 CET	October 28th, 2025 11:00 - 12:00 CET	February 12th, 2026 12:30 -14:00 CET
Main theme	Project forum kick-off meeting: QUANTUM project, label specification, Project forum concept	QUANTUM Maturity model, QUANTUM Datasets' quality and utility label	QUANTUM Data quality and utility labelling tool, Mid-scale pilot of the labelling tool, QUANTUM Academy	Workshop on QUANTUM fit-for-purpose strategy
Speakers	Enrique Bernal-Delgado (IACS), Nathan Carvalho (DIGITALEUROPE)	Enrique Bernal-Delgado (IACS), Monica Jones (HDRUK), Lorenz Dolanski-Aghamianoukjan (GÖG)	Carlos Sáez Silvestre (UPV), Claudio Proietti Mercuri (Sciensano), Carlos Telleria (IACS), Niina Eklund (BBMRI-ERIC)	Ascensión Doñate-Martínez (UPV), Carlos Sáez Silvestre (UPV), Claudio Proietti Mercuri (Sciensano), Ángel Sánchez García (UPV)
Feedback channel	Open discussion	Mentimeter, open discussion	Open discussion, post-meeting survey via EUSurvey	Open discussion, Wooclap
Organisation responsible organizing	DIGITALEUROPE & UCSC	DIGITALEUROPE & UCSC	THL & UCSC	THL & UCSC
Number of participants	37	39	31	46

3.2 Project forum contents and results

3.2.1 The first Project forum - Kick-off Meeting

3.2.1.1 Overview

The first QUANTUM Project Forum was held as an online kick-off meeting on 13 March 2025. The session marked the formal launch of the Project Forum as QUANTUM's structured stakeholder engagement mechanism and introduced the project's approach to the data quality and utility label under the EHDS framework.

In total, 37 participants attended the meeting, with an overall meeting duration of 1 hour and 18 minutes and an average attendance time of 54 minutes, indicating sustained interaction over the course of the session. The forum was organised by DIGITALEUROPE and IACS on behalf of the QUANTUM consortium. Main speakers were Enrique Bernal-Delgado (IACS, QUANTUM coordinator) and Nathan Carvalho (DIGITALEUROPE), who jointly presented the QUANTUM project, the emerging label specification and the Project forum concept, alternating between technical content and engagement-related aspects.

3.1.1.2 Objectives and role within QUANTUM

The kick-off meeting had a dual purpose: (i) to introduce QUANTUM's overall objectives and work on a Union data quality and utility label, and (ii) to launch the Project forum as a recurring platform to gather feedback on key deliverables from a broad community of stakeholders. In line with the overall Project forum concept, the emphasis was placed on collaboration and structured feedback, rather than one-way dissemination, so that QUANTUM's outputs would be clear, feasible and aligned with the needs and realities of organisations that will ultimately have to apply the label.

More specifically, the first forum aimed to:

- Present QUANTUM's interpretation of Article 78 of the EHDS Regulation and the core elements of the envisaged data quality and utility label and maturity assessment, thereby positioning QUANTUM within the wider EHDS implementation landscape.
- Explain the conceptual building blocks and dimensions of the label and how they build on TEHDAS and the EHDS2 pilot projects, to show continuity with previous EU efforts and avoid duplication.
- Introduce the Project forum's set-up (four workshops, timeline, modes of engagement) and clarify expectations for participants' contributions, including their role as "critical friends" for QUANTUM deliverables.
- Collect initial questions and concerns from stakeholders to inform the further development of the label specification, the self-assessment tool and subsequent Project forum agendas, with a view to establishing a feedback loop from this first event.

By explicitly presenting the Project forum as a co-creation and validation space rather than a dissemination channel, the meeting positioned external stakeholders as active contributors to the quality and usability of QUANTUM outputs.

3.1.1.3 Participants and stakeholder profile

The 37 participants represented a broad and heterogeneous group of stakeholders that QUANTUM intends to engage throughout the project. Attendance included: Health Data Access Bodies and national health data authorities (e.g. The Danish Health Data Authority, THL), research infrastructures and data initiatives (e.g. ELIXIR, EUCAIM, ORPHANET), EU projects and joint actions (e.g. Cancer Watch Joint Action, AIDAVA, ONCOVALUE), universities and research institutes, hospitals, and other data holders and data users.

This composition mirrored the target groups that will be affected by, or directly involved in, the future HealthData@EU catalogue and related labelling processes. From the outset, the consortium sought to involve both more and less mature data holders, in order to understand differences in capacity, burden and needs related to the implementation of the label. The attendance list, complemented by the detailed Teams report (including in-meeting duration for each participant), provides evidence that this diversity was already present at the kick-off meeting. The mix of stakeholders also allowed for cross-fertilisation between those with strong technical expertise on metadata standards and those closer to operational constraints in clinical or registry environments.

3.1.1.4 Format, agenda and methods

The meeting combined short presentations with a plenary question-and-answer segment and open discussion, allowing participants to react in real time to the conceptual and technical proposals presented. The agenda consisted of: Welcome and introductions; “What is QUANTUM and what is the QUANTUM tool?”; Q&A; “What is the Project Forum and how will it work?”; Q&A; and next steps.

At this early stage, no structured polling or interactive whiteboards were used; instead, feedback was collected live through verbal interventions and the meeting chat, which was considered more appropriate for a launch event where participants were still familiarising themselves with the project. Nevertheless, participants were informed that subsequent forums would make more systematic use of virtual engagement tools (e.g. Mentimeter, Miro) to structure input around specific deliverables, and that an online space would be established to host materials and support continuous exchange. This progression from relatively unstructured to more structured feedback methods over time was presented as part of the Project forum design.

3.1.1.5 Main content presented

Enrique Bernal-Delgado (IACS, project coordinator) introduced the QUANTUM project, explaining its links to TEHDAS and the EHDS2 pilot projects and its role in supporting the implementation of Article 78 of the EHDS Regulation. The presentation detailed how QUANTUM translates the regulatory requirements into a concrete label specification with dimensions and metrics for data documentation, technical quality, data quality management processes, coverage, access and provision, and data modifications, ensuring that each regulatory element could be assessed in a transparent and repeatable way.

The pathway towards HealthData@EU was described as an iterative process, starting from a scoping review and Delphi-based consensus process, through to a technical specification and pilots of the Data quality and utility labelling tool with diverse health data holders. This sequence was presented to reassure participants that the label had already undergone systematic conceptualisation before being tested in practice. Screens and dashboards of the self-assessment tool were briefly introduced to illustrate how data holders would interact with the label in practice, including dashboards for data quality and maturity that would provide both summary and drill-down views of their self-assessment.

Nathan Carvalho (DIGITALEUROPE, PM) then presented the Project forum as one of QUANTUM's key engagement structures, alongside the HealthData@EU forum, the Citizens and patients forum and the advisory board, clarifying the complementarity between these channels. He explained that the Project forum would consist of four workshops aligned with major project milestones, with the kick-off focusing on initial deliverables and subsequent workshops planned to be in May 2025, September 2025 and February 2026 dedicated to more mature outputs such as the labelling tool, the mid-scale pilot results and the fit-for-purpose strategy. For each workshop, a basic framework was outlined, combining short presentations, focused review of selected sections of the deliverables and guided discussions supported by virtual engagement tools.

3.1.1.6 Key discussion points

The open discussion focused strongly on the practical implementation of the label and its implications for different types of organisations, reflecting participants' interest in how the proposed concepts would work "on the ground". Key issues raised by participants included:

- **Applicability and granularity:** Participants asked whether the data quality and utility label should be applied at Health Data Access Bodies level, data holder level, or at the level of individual datasets, and how this choice would be reflected in catalogues and metadata. The distinction was seen as critical for clarifying who would bear the reporting burden and how users would interpret the label in HealthData@EU.
- **Cost-benefit and sustainability:** Several interventions expressed concern about the effort and costs for data holders, particularly hospitals and smaller organisations, to maintain the information required for the label, and questioned how benefits for end-users would balance these efforts. Participants highlighted the risk that, without clear value for data users, the label could be perceived as an additional compliance

burden rather than a tool supporting data reuse.

- **Engagement of smaller and less mature data holders:** Stakeholders queried how QUANTUM would involve organisations without strong expertise in RDF, DCAT or metadata, and whether they would be sufficiently represented in the pilot and, later, in EHDS-wide implementation. This concern was linked to broader worries that EHDS implementation costs might fall disproportionately on hospitals and smaller providers with limited resources.
- **Use-case specificity and fit-for-purpose:** Participants underlined that dataset utility is inherently use-case specific and asked how the label would capture fit-for-purpose information, including potential ontologies of purposes or extensions to HealthDCAT-AP metadata specification. Questions were raised about how experiences from specific research projects could be fed back into metadata so that future users could see for which purposes a dataset had been successfully used.
- **Representation in HealthData@EU metadata:** The discussion touched on where the label's RDF file should "land" within the HealthDCAT-AP specification, with "certificate" mentioned as a potential candidate property. Participants stressed the importance of using an appropriate metadata field so that the label is both technically interoperable and semantically clear to catalogue users. It was also highlighted that it is important to be able to have discussions about the data with the data holder.

In response, the QUANTUM team clarified that the label is conceived as a self-assessment tool based on a structured questionnaire, where the main burden lies in documenting evidence rather than filling in the form itself. The mid-scale pilot is explicitly designed to include a variety of data holders with different levels of maturity to understand reporting burdens and refine guidance, and a third pilot round is foreseen to fill potential representativeness gaps, including small data holders that may not be present in earlier rounds.

Regarding fit-for-purpose, the team noted that this would be addressed in a complementary way to the core label, and that ongoing work (later formalised in the fit-for-purpose strategy) would explore how to reflect use cases and user experience in metadata and catalogues without overloading the label itself. Finally, on the metadata representation, QUANTUM confirmed that discussions with TEHDAS2 project (Second Joint Action Towards the European Health Data Space) are ongoing to ensure that the label's RDF file is properly embedded in HealthDCAT-AP, in a way that is consistent with other certification or qualification artefacts.

3.1.1.7 Immediate outcomes and follow-up

The first Project forum confirmed strong stakeholder interest in the data quality and utility label and validated QUANTUM's choice to use a structured, iterative engagement mechanism, rather than relying solely on internal expertise. It also surfaced several critical design and implementation questions—around costs, burden, scope and use-case specificity—that were fed back into the internal work on the label specification and the planning of subsequent forums, ensuring that concerns raised at this early stage could influence the project trajectory.

As an immediate follow-up, the team also announced the creation of an online workspace where participants could access meeting materials (slides, notes, summary and attendance overview) and continue exchanging with the consortium, thus providing continuity between live sessions. Finally, participants interested in testing the QUANTUM tool were invited to contact the coordination team, and several indicated their willingness to be involved in the mid-scale pilot, laying the groundwork for a concrete community of practice around the label and its implementation

3.2.2 The second Project forum - Advancing QUANTUM data standards: quality labelling and maturity assessment frameworks

3.2.2.1 Overview

The second QUANTUM Project Forum, titled “Advancing QUANTUM Data Standards: Quality Labelling and Maturity Assessment Frameworks”, took place online on 1st of July 2025. This session represented the first in-depth technical engagement with stakeholders on the core QUANTUM standards for data quality, utility and maturity, following the more introductory nature of the kick-off forum.

The forum was organised under the Project forum umbrella by DIGITALEUROPE together with QUANTUM partners and was hosted on Microsoft Teams. A total of 39 participants attended, with a logged meeting duration of approximately two hours and 10 minutes and an average attendance time of around one hour, reflecting sustained active participation over and beyond the formal one-hour programme (including time for logging in, informal greetings and extended discussion). Key presenters were Monica Jones (Health Data Research UK, University of Leeds), who introduced the QUANTUM Maturity model and [Deliverable 1.2](#), and Lorenz Dolanski-Aghamanoukjan (Gesundheit Österreich GmbH, Austrian National Public Health Institute), who presented the datasets’ quality and utility label as specified in [Deliverable 1.1](#), supported by the QUANTUM coordination and Project forum facilitation team.

3.2.2.2 Objectives and positioning within QUANTUM

This second Project forum was explicitly positioned as a technical deep dive into QUANTUM’s foundational frameworks for quality labelling and maturity assessment. Whereas the first forum focused on introducing the overall concept of a Union data quality and utility label and the rationale for a maturity model, the July 1 session sought to test the concrete content and structure of the relevant deliverables with an expert audience.

The specific objectives of the forum were to:

- Provide an updated overview of QUANTUM’s objectives, progress and planned outputs, situating D1.1 and D1.2 within the wider EHDS implementation pathway and

QUANTUM's overall "backbone".

- Present the methodology, dimensions, scoring logic and intended use cases of the QUANTUM Maturity model for data holders (D1.2), including how it can support both internal improvement and external transparency.
- Present the validated set of dimensions, measures and value ranges underpinning the datasets' quality and utility label (D1.1), and explain how these map to the requirements of Article 78 of the EHDS Regulation.
- Collect initial structured feedback, via interactive tools and open discussion, on the frameworks' perceived clarity, relevance, feasibility and potential application in different organisational settings.
- Stimulate forward-looking reflection on how these frameworks could inform future HealthData@EU specifications and how they might be integrated into concrete workflows for data holders, Health Data Access Bodies and data users.

By focusing on these objectives, the session acted as a bridge between work package 1's conceptual work and subsequent implementation and piloting activities in work package 2 and 3, while continuing to position the Project forum as a co-creation and validation space rather than a purely informative webinar.

3.2.2.3 Participants and stakeholder profile

The attendance report records 39 participants, representing a slight increase compared to the first forum and confirming a stable core of engaged stakeholders across the series. The composition of the group preserved the diversity sought by QUANTUM: national health data authorities, Health Data Access Bodies, EU-funded projects, research infrastructures, hospitals, disease registries, European agencies and other organisations involved in health data governance and reuse.

Participants included representatives from national public health institutes, health data platforms, university research centres, clinical and registry environments, and EU-level initiatives working on EHDS-related topics. This mix brought together:

- Individuals with strong methodological and technical expertise in data curation, metadata standards and maturity models.
- Operational staff responsible for data provision, registry management and practical implementation of quality processes.
- Stakeholders with a policy or coordination role in the broader EHDS ecosystem.

Several organisations had also participated in the first forum, which supported continuity in dialogue and allowed the group to track how QUANTUM was responding to concerns raised previously (e.g. burden on smaller data holders, clarity of concepts, granularity of the label). The presence of both newcomers and returning participants was considered valuable, as it combined fresh perspectives with the contextual knowledge gained in earlier sessions.

3.2.2.4 Format, agenda and methods

The session followed a tightly structured one-hour programme, complemented by additional time before and after for joining and extended discussion. The concept note defined the session structure as follows:

- Introduction: Overview of the session, its objectives, and explanation of the interactive format.
- Presentation 1 – Deliverable 1.2: Monica Jones presenting background, methodology, maturity model matrix and key findings of the QUANTUM Maturity Model.
- Interactive discussions via Mentimeter – Part 1: Word cloud capturing participants' understanding of "maturity model", and polls on perceived usefulness and potential application areas.
- Presentation 2 – Deliverable 1.1: Lorenz Dolanski-Aghamanoukjan presenting insights from Deliverable 1.1 on the data sets' quality and utility label.
- Interactive discussions via Mentimeter – Part 2: Follow-up engagement using short polls or rating scales focused on the label's dimensions and measures.
- Open discussion and Q&A: Facilitated discussion and audience questions, allowing more nuanced or context-specific contributions.
- Conclusion: Summary of key insights, reflection on the interactive format, and outline of immediate next steps and future Project forum sessions.

Compared with the first Project forum, this second session embedded interactive methods at multiple points in the agenda rather than relying primarily on open Q&A. The use of Mentimeter enabled the facilitation team to:

- Quickly gauge participants' baseline understanding and perceptions.
- Visualise diversity of views through word clouds and aggregated ratings.
- Trigger more focused follow-up questions in the plenary discussion.

In addition, the team highlighted the existence of QUANTUM collaboration spaces (including a shared Microsoft Teams space and a helpdesk platform) as ongoing channels for commenting on deliverables and sharing written feedback outside the time-limited forum. Participants were explicitly encouraged to use these channels to submit more detailed or project-specific comments that could not be fully elaborated during the live session.

3.2.2.5 Main content presented

The introductory segment revisited the QUANTUM project's mandate to support EHDS implementation by developing a Union data quality and utility label and a maturity assessment framework for data holders, anchored in Article 78 of the EHDS Regulation. The presentation recalled key regulatory elements relating to secondary use of data (Chapter IV), the role of datasets made available through Health Data Access Bodies, and the requirement for publicly funded datasets to carry a data quality and utility label. It also restated QUANTUM's backbone: a common concept for dataset quality and utility, a common concept for the maturity of data holders, piloting and implementation in real settings, translation into

recommendations for HealthData@EU, and capacity-building through the QUANTUM Academy.

Monica Jones (HDR UK) led a presentation on Deliverable 1.2 and then introduced the QUANTUM Maturity model in more detail. She first recalled the background and rationale: the increasing recognition of the value of health data; the absence of a standardised, evidence-based mechanism for assessing data holders' readiness to manage data quality for secondary use; and the need for a structured, comparable approach that could support both local improvement and system-level benchmarking. Monica referenced relevant frameworks, including the Capability Maturity Model, and explained how QUANTUM adapted and extended such models to the context of health data quality and utility.

The methodology behind the maturity model was then summarised:

- Two focus groups with experts were organised in May–June 2024 to discuss key processes for data quality management, sustainability, and organisational features, resulting in a preliminary set of maturity dimensions and descriptions of levels.
- An online survey was conducted to validate and refine this initial structure; participants rated maturity dimensions on a numerical scale, and results showed relatively high agreement for most dimensions while highlighting areas where wording or scope required clarification.

On this basis, a maturity matrix was finalised, comprising ten dimensions with defined levels from 1 (initial) to 5 (optimised), together with guidance on scoring and interpretation.

Monica explained that the model is intended to:

- Provide a structured, evidence-based approach for assessing organisational readiness to manage data quality and utility.
- Enable data holders to benchmark themselves over time and against peers.
- Feed into the broader QUANTUM labelling mechanism by situating dataset-level quality and utility within the context of organisational processes and capabilities.

Following this, the first Mentimeter segment invited participants to share, via word cloud and polls, how they currently understood the “maturity model” in the context of QUANTUM and where they saw the greatest potential use (e.g. internal quality improvement, compliance preparation, external transparency, prioritisation of investments). This interactive part served both as an ice-breaker and as a quick diagnostic of expectations and potential misconceptions.

Lorenz Dolanski-Aghamanoukjan (GÖG) then presented key aspects of Deliverable 1.1 on the datasets' quality and utility label. He summarised the problem statement: while the EHDS Regulation defines categories of data and purposes of secondary use, and existing standards such as HealthDCAT-AP, DQV and PROV-O provide building blocks, there had been no integrated, agreed-upon mechanism for assessing and communicating dataset quality and utility across diverse data types and contexts. Lorenz described the multi-step methodology employed in QUANTUM:

- Gathering and harmonising definitions from standards, existing quality frameworks and a scoping review, resulting in an initial pool of hundreds of definitions.
- Conducting a Delphi process to select and prioritise dimensions, followed by a nominal group technique with experts from organisations including Health Data Access Bodies, data holders and data users.
- Converging on a set of twelve validated dimensions and fifteen measures, with defined value ranges and thresholds, aligned with the elements listed in Article 78 (data documentation, technical quality, quality management processes, coverage, access and provision, data modifications).

He illustrated how the label is designed to be generic (agnostic to specific data types and purposes), while still providing enough structure to support comparability and a 5-star rating system. A key message was that the label does not claim to answer all questions about “fitness for a specific purpose” directly but aims to provide a transparent, standardised description of quality and utility characteristics on which such judgements can be based.

The second Mentimeter segment then asked participants for first impressions of the label and its dimensions, inviting them to rate aspects such as perceived relevance, completeness, feasibility of data collection and clarity of the rating approach. This set the stage for the open discussion, where participants could elaborate on their answers, share concrete experiences from their own datasets and raise questions about edge cases or non-traditional data types.

3.2.2.6 Key discussion points

In relation to the maturity model, participants were encouraged to reflect on:

- How intuitive the proposed maturity levels and dimensions were, given the diversity of their organisational contexts.
- Whether the model captured the right balance between technical and organisational aspects of data quality management.
- How the results of a maturity assessment could be communicated internally and externally, e.g. to management, funders or regulators.

The Mentimeter word cloud on “maturity model” surfaced a variety of interpretations (e.g. process improvement, readiness assessment, compliance tool), which the presenters addressed, clarifying that the QUANTUM model is intended both as a developmental tool for organisations and as an input into the wider EHDS governance framework.

Participants were also asked to identify areas where the model might need further contextualisation (e.g. for small vs. large organisations, or for registries vs. hospital systems), feeding into future refinement and guidance material. For potential barriers of implementation, the participants raised lack of understanding and implementation guidelines, lack of commitment of responsible people in the organisations, organisations not seeing the value and benefit or not wanting to be open in their assessment, and resources.

For the datasets' quality and utility label, the interactive polls and ensuing discussion focused on first impressions and perceived strengths and weaknesses. Themes that were explored included:

- The practicality of collecting the information required for the dimensions and measures, particularly for data holders with limited resources or complex legacy systems.
- The extent to which the star-rating system and underlying value ranges would be understandable and useful for different audiences (data holders, data users, governance bodies, funders).
- The flexibility of the label in accommodating non-tabular or non-standard data, without diluting the standardisation benefits for more common data types.
- The need for support for data holders.

As ways to increase the usefulness of the model for data users, the participants raised having training materials and workshops, having more technical specifications, possibility to see feedback of fit-for-purpose and examples of use from earlier users, and also potential to interact with them.

These discussions built on concerns raised in the first Project forum about costs, burden and fit-for-purpose and allowed participants to express, in a more evidence-based way, where they saw the frameworks working well and where potential adjustments might be needed. The presence of organisations with different levels of maturity and different data types ensured that both “front-runner” and “resource-constrained” perspectives were heard.

Across both topics, cross-cutting issues emerged that are central to QUANTUM's long-term impact: ensuring that the frameworks are implementable by less mature organisations; avoiding excessive complexity that might undermine uptake; and ensuring alignment and interoperability with existing standards and with future HealthData@EU metadata requirements. The forum thus helped to validate QUANTUM's general direction while highlighting areas where further clarification, guidance or simplification might be beneficial.

3.2.2.7 Immediate outcomes and follow-up

The second Project forum achieved its aim of deepening shared understanding of QUANTUM's core technical deliverables and generating targeted feedback on both the maturity model and the datasets' quality and utility label. The structured use of Mentimeter, combined with open discussion, provided the WP1 team with a set of qualitative and quantitative signals on clarity, usefulness and feasibility, which were fed back into the ongoing refinement of D1.1 and D1.2.

Insights from this forum were to be used explicitly to revise and contextualise the maturity model and to fine-tune guidance on its application in different organisational settings, supporting more grounded and applicable tools for project monitoring and development. The forum also reinforced the value of the Project forum as a standing mechanism for iterative engagement: participants were reminded of the collaboration spaces (Teams and helpdesk

platform) where they could continue to provide feedback on deliverables and share use cases between meetings.

Finally, the coordination team signalled that the third Project forum would build on the foundations laid in this session by shifting focus from static specifications to the design, development and testing of the interactive labelling tool and mid-scale implementation, while continuing to reference and apply the maturity model. In this way, the second forum created a shared reference point for subsequent practical work, ensuring that implementation activities would remain anchored in a set of standards co-developed and validated with the stakeholder community.

3.2.3 The third Project forum - the QUANTUM Data quality and utility labelling tool

3.2.3.1 Overview

The QUANTUM project organized the third Project forum on October 28th 2025 as an hour long online event. The third Project forum session focused on exploring the [QUANTUM Data quality and utility labelling tool](#) in depth. The tool is developed in the QUANTUM project to be used by data holders to assess the quality of their datasets and the maturity level of their organisation's data quality management, and thus provide the data quality and utility label. In addition, a short pitch on QUANTUM training materials and data quality capacity building was presented in the event.

The main speakers represented WP2, WP3 and WP4, and were supported by the QUANTUM coordinators and the Project forum organising team. The forum session represented moving from the more conceptual discussions to the presentation of practical applications. Altogether 31 participants participated in the forum. The meeting duration was 1 hour and the average attendance time was 58 minutes, showing the high level of commitment from the participants.

3.2.3.2 Objectives and role within QUANTUM

The main objective of the session was to present and get feedback on the concept, design principles, development process, and piloting of the QUANTUM Data quality and utility labelling tool. The aim was to provide participants an understanding of the work behind the developed tool, offer interim results of the mid-scale piloting of the tool, and also provide a practical understanding of the updated version of the tool by including a live demonstration of it, showcasing its main features and functionalities, user interface, and practical applications. Also, the aim was to offer the participants a glimpse into the QUANTUM training materials and showcase upcoming opportunities for data quality related training and community engagement, as well as request the participants to inform on capacity building materials that could be included in the QUANTUM materials.

The presented tool and its piloting are one of the important outputs of the project, and its presentation to stakeholders and receiving feedback are important for the project. The aim of the presentations and the additional feedback and input gathering after the forum via a dedicated survey were to ensure that the project's work is going in the right direction and to collect additional information from the participants to inform future work. The aim was also to raise awareness about the QUANTUM Academy and repository and to ask the participants for information about data quality training materials from other projects that could be linked from the QUANTUM Academy or the repository, and thus participate in the capacity building.

3.2.3.3 Participants and stakeholder profile

The 31 participants consisted from both external QUANTUM stakeholders and internal project members. The organisations represented a varied group of health data holders (both national authorities and organisation representatives), HDABs, data users, different project, company and authority representatives. Participants included the Danish health data authority, HUS Helsinki University Hospital, ORPHANET, IDEA4RC, EUCAIM, xShare and EMA representatives, among others.

3.2.3.4 Format, agenda and methods

The third forum consisted of four presentations and a brief open discussion. The agenda was as follows:

- Welcome and objectives
- Presentation 1: Design, development and testing of the QUANTUM Data Quality and Utility Labelling Tool – Carlos Sáez Silvestre
- Presentation 2: Demo of the QUANTUM Labelling Tool – Claudio Proietti Mercuri
- Presentation 3: Mid-scale pilot of the Labelling Tool - Carlos Telleria
- Short Pitch: QUANTUM Academy – Niina Eklund
- Open Q&A and reflections

Due to the fairly short time available and the rather extensive content, it was decided to collect structured feedback only after the forum with a dedicated survey.

3.2.3.5 Main content presented

After a short welcome and reminder of the backbone of the QUANTUM project by the forum organisers, Carlos Sáez Silvestre (Universitat Politècnica de València, UPV) presented the work done in WP2 around the design, development and testing of the QUANTUM Data quality and utility labelling tool.

The main objective has been to design a tool that allows:

- data holders to assess data quality and utility of their datasets,

- data holders to report on their organizational maturity, and
- the inclusion of health data access bodies and data users' experience on the information published.

Carlos said that in the beginning of the work a landscape analysis on data quality and utility labelling tools was done and a few tools were tested. As a conclusion a self-assessment tool and a label consisting of graphical components and a standardized RDF document using vocabularies was decided to be created. The piloting of the tool started with a small-scale pilot, consisting of seven participants covering a wide range of different data categories.

Next, Claudio Proietti Mercuri (Sciensano) gave a demonstration of the labelling tool, showing its features and how the data quality and utility label provided by the data holders' self-assessment made in the tool currently looks like. The tool and software are published in [Zenodo](#) and GitHub as open source.

The next steps in the work related to the tool were to:

- Improve the tool based on the feedback from the mid-scale pilot,
- in co-operation with other QUANTUM work packages provide labelling examples to help using the tool,
- design and provide recommendations for the fit-for-purpose inclusion, and
- align the label with the HealthDCAT-AP metadata specification.

After the presentation of the labelling tool itself, Carlos Telleria (IACS) presented the work done in WP3 on mid-scale piloting of the tool. Two or three piloting rounds with different versions of the tool will be organized. 18 organizations piloted the tool in the first round of the mid-scale pilot. The results of the first round were fairly positive, finding the clarity of the specifications of data quality dimensions an area that still needs most development. After the second round of mid-scale pilot, a new survey will be deployed, and also additional actions were to be made to get feedback to form the final conclusions and recommendations for the European Commission.

As the last speaker, Niina Eklund (BBMRI-ERIC) from WP4 gave a short pitch on the work developing the QUANTUM Academy and an open repository. The capacity building work by WP4 aims to empower stakeholders to effectively supervise, implement, and interpret the QUANTUM data quality labelling mechanism. She also presented a request for the participants to inform her on any data quality and utility educational resources or training material that could be linked from the best practices repository. The links were requested to be sent to her by email or via a survey sent after the event.

After the presentations there was time for brief discussions. The summary of the questions from the audience and the answers given by QUANTUM experts is presented below. To end the session, a survey was shared with the participants, with the aim of gaining more insights for some key questions to take the QUANTUM work forward.

3.2.3.6 The third Project forum results

3.2.3.6.1 Key discussion points

In the open discussion part, the participants asked questions related to the implementation burden to the data holders, possibility for domain specific extensions and specifications for technical data quality reporting, among others.

The questions presented were about:

- **User experiences of doing the self-assessment:** There was an interest towards the experiences about how difficult do the users find the use of the Data quality and utility labelling tool, and how much time does it approximately take to fill in the information needed for the label.
- **Domain specific quality label extensions:** A question was also raised whether there are any plans to extend the QUANTUM data quality and utility label into domain specific labels, for example a cancer specific one.
- **Specifications and guidelines for technical quality reporting:** One participant asked whether there will be specifications on technical data quality reporting, and another continued asking in which work package is the work developing the data quality reporting specifications and providing examples happening.
- **Test environment to publish the labels:** Also a question was asked about whether there will be a test environment to publish data quality and utility labels, and what will the role of the HealthData@EU Central platform be in this.

In response, the QUANTUM project experts highlighted that the user experience using the Data quality and utility labelling tool and the time that it takes to make the assessment will be obtained in the mid-scale pilot. The experience already shows that the time needed to fill out the evaluation depends on the maturity of the data holder on data management. The time required also becomes shorter when the tool becomes more familiar.

Regarding the question of extending the label to domain-specific ones, the QUANTUM experts answered that the fit-for-purpose part of the label, which the project is currently working on, is aiming to be able to provide additional information on use for specific use cases. The actual data quality and utility label provided by data holders is currently a generic one.

The QUANTUM experts also told, that their goal is to try to provide examples and guidance on technical data quality reporting, but not force data holders to have any specific format in their reporting. They see that there are two main user groups for these reports: the HDABs as supervisors of the label, and data users. With the reports, HDABs can double check that the assessment provided by the data holder is correct. The work developing these guidelines will be a joint effort between different work packages.

It was also clarified that eventually the label will be an RDF file that can be downloaded with

the assessment. It is meant to land in the HealthDCAT-AP metadata description properties in the catalogue level. It was told that there is currently an open discussion with the European Commission Central services on how to provide this connection.

3.2.3.6.2 Post-forum survey results

After the forum session, a survey was sent to the Project forum members, the questions of which were designed in collaboration with the forum speakers.

3.2.3.6.2.1 Summary of questions

The questions covered, among other things:

- If specific data quality assessment tools or in-house code is used in the Project forum members' organisation to evaluate the quality and utility of datasets;
- If they have existing methods or practices for generating technical quality reports of datasets, which will be required in the technical data quality category of the label;
- If support in generating technical quality reports of data would be needed;
- If they would be willing to give feedback on the utility of the data for a specific use case as a data user, after they have used the data;
- Do they consider that the variety among data holder institution types, level of maturity, availability of technical staff involved, the number of datasets assessed and the types of data were enough to make the mid-scale pilot of the labelling tool valid;
- What kind of characteristics, especially specific institutions, do they possibly see missing from the pilot;
- If their project has developed data quality and data management related training material available for wider audiences, and
- Do they wish their training resources to be linked from the QUANTUM Academy.

3.2.3.6.2.2 Summary of responses

Five responses were received to the survey, so the answers cannot be considered very generalizable. The responses were forwarded to the relevant work packages so that they can be taken into account in the work. Next, the received answers are presented by theme.

Use of specific data quality assessment tools or in-house code to evaluate the quality of data

All of the five respondents' organisations had a data quality assessment tool or in-house code for assessment in use. One of the respondents' organisations used only in-house code and the others either specific data quality assessment tools or both in-house code and a tool.

The tools used were:

- EU Cancer Registry Quality Tool (JRC),
- SHACL validator for checking quality of individual personal health records,

- In-house developed tools,
- Domain-specific solutions for validating data and examining data quality,
- A tool developed within a project for specific cancer types,
- Standardised data quality assessment tools DQD by OHDSI.

Existing practices in generating technical data quality reports, and needs for external support in providing them

For technical data quality reporting the respondents reported both having existing methods and also a need to have more support and guidance. They reported having or using:

- Consistency and completeness related score generating;
- Existing domain-specific solutions to measure data quality dimensions;
- Three level data quality checks: at source data, for the whole dataset and for a selected cohort, and
- DQD by OHDSI dashboard.

Willingness to give feedback on the dataset's utility based on user experience

Giving feedback on the utility of the data for a specific use case after the data use was reported as an important and advisable direction to invest more in the QUANTUM project. Respondents also reported strong willingness to give feedback as a data user.

Views on sufficient variety among data holders participating in the QUANTUM Data quality and utility tool piloting

Regarding the mid-scale pilot of the QUANTUM Data quality and utility labelling tool, three out of five respondents reported that more variety among data holders in the pilot would be needed. Health care organisations, smaller data holders not so familiar with the EHDS, pharma companies holding clinical trial data, more academic institutes and EDICs, all the registries provided by the European Reference Networks and some of the organisations that have described their data in the EMA RWD Catalogues were raised as organisations that would be important to engage more. Also evaluation from a federated learning perspective was raised as a missing use case in the mid-scale pilot.

Two respondents reported that the variety of organisations seemed reasonable. Most of the respondents couldn't raise a specific characteristic missing from the pilot. One respondent answered that more representation from various types of organisations and combinations of characteristics, like for example academic institutes with low or medium maturity and varying types of IT-support, would be needed.

Existing data quality and data management related educational materials

Two of the respondents' projects had developed data quality or data management related training materials that are available for audiences outside of the primary project. Both of them

were keen to provide the link for the materials to be included in the QUANTUM Academy.

The training contents of these resources were about:

- Managing cancer registry data quality and consistency across Europe, and
- Training for medicines regulatory professionals who are involved in ensuring the quality of data used in regulatory decision making, based on the data quality framework for the European Medicines Regulatory Network.

3.2.3.7 Immediate outcomes and follow-up

The Project forum session included several presentations, and therefore there was not much time left for discussion. However, the questions asked highlight the participants' interest in the data holder's experiences in piloting the tool, how time-consuming the assessment is for health data holders, possibility for domain specific extensions of the label, whether there will be more precise specifications for technical reporting of data quality and about the possibilities to see the labels published in a test environment.

The post-meeting survey covering questions related to the work presented in the forum was introduced at the end of the session, and circulated to all Project forum members after the meeting via email. It was highlighted that the results can have an impact on the project's work.

The post-meeting survey results showed that there already are data quality assessment tools or in-house code in use in the stakeholders' organisations or projects. For technical data quality reporting there are both existing methods and also a need to have more support and guidance. Therefore, it can be considered an excellent thing that the QUANTUM project has decided to produce guidelines for technical quality reporting, without forcing data holders into a specific reporting format. Also the development of the fit-for-purpose part of the label was confirmed by respondents who assured that they, as data users, would be willing to provide feedback on the utility of the data for specific use cases and expressed their support for the development of this concept. It was also gratifying that projects that had developed their own data quality training were willing to share a link to their training materials to be added to the QUANTUM repository, thus enabling community capacity building on data quality.

However, there was a view among more than half of the respondents, although still comprising a small number of respondents, that the developed Data quality and utility labelling tool would need to be piloted by more varied data holders. More health care organizations, smaller data holders, pharma companies, academic institutes and EDICs, registries and a federated learning viewpoint were raised as examples of needed piloters in order to gain sufficient validity. This feedback was forwarded to the mid-scale pilot organising team to guide the future work.

The post-meeting survey didn't unfortunately gain a high response rate, but the responses can be seen as confirming the work done in the project and the planned directions, as well as encouraging the expansion of the mid-scale pilot of the tool with a few more health data holders and also the approach to build a best practices repository with links to other data

quality related training materials.

3.2.4 The fourth Project forum - workshop on fit-for-purpose for data quality

3.2.4.1 Overview

The fourth and final QUANTUM Project forum was organised on 12th of February 2026. In this online workshop, the fit-for-purpose (F4P) strategy developed under the QUANTUM project was presented, discussed and validated with external stakeholders. The fit-for-purpose assessment system is developed to complement the QUANTUM data quality and utility labelling system by providing a user-centric view on the fitness of the dataset for specific secondary use purposes.

The workshop was led by the experts behind the fit-for-purpose concept development from WP2, supported by the Project forum organizing team and QUANTUM coordinators. The speakers were:

- Ascensión Doñate-Martínez, Universitat Politècnica de Valencia (UPV),
- Carlos Sáez Silvestre, Universitat Politècnica de Valencia (UPV),
- Claudio Proietti Mercuri, Sciensano,
- Ángel Sánchez García, Universitat Politècnica de Valencia (UPV).

The workshop gained 46 participants, making it the forum session with the highest number of participants in the Project forum history. This time, most of the event was used for a participatory workshop, and therefore a slightly longer time was allocated for the forum than for the previous ones, one and half hours. The average attendance time was of 49 minutes,

3.2.4.2 Objectives and positioning within QUANTUM

The objective of this workshop was to present and validate the design features of the fit-for-purpose concept with external stakeholders. The specific objectives of the session were to:

- Give participants an overview and understanding of the fit-for-purpose strategy and its development, and
- Review and validate the refined fit-for-purpose proposal with the external stakeholders.

The fit-for-purpose concept had been developed by the QUANTUM team and validated by internal stakeholders before this workshop. In particular, the aim was to try to find consensus on the design features that had received varied responses in the previous work, and to be able to synthesize the final version of the proposal. The participants were thus offered an opportunity to actively shape the final proposal.

The F4P part of the label is planned to complement the data quality and utility label with the information from the actual data users and therefore it is seen as an important part of the labelling. The goal of the work is to form a set of actionable recommendations to be reported in QUANTUM deliverables. The outputs of this workshop are planned to inform prospective implementation acts and align with the data quality and utility label. The main goal of the work is to advance towards efficient, effective, and safe purposes-guided secondary use of health data in the EHDS through a collaborative effort between data users, data holders and Health Data Access Bodies.

3.2.4.3 Participants and stakeholder profile

The workshop brought together external and internal QUANTUM participants from diverse roles within the EHDS ecosystem. Many project or infrastructure initiatives' representatives were present, such as EUCAIM, CancerWatch JA, xShare, AISym4Med, Phase IV AI project, among others. Also BBMRI-ERIC, EMA, the Shared services for the Ministry of Health in Portugal, and Centre for Genomic Regulation were present. The group of participants was the largest of all forums with a total 46 participants, and perhaps also the diversity of participants was higher than before. However, not all participants ultimately participated in the workshop voting exercise.

In the voting exercise of the workshop, the participants could in the beginning identify themselves as data holders, data users, HDAB representatives, or select "other". Multiple simultaneous roles were allowed. The distribution of participants included 11 data holders, 8 data users and 3 HDAB representatives. Altogether a maximum 18 participants participated in the voting exercise (QUANTUM deliverable [Towards Fitness-for-purpose assessment in HealthData@EU](#)).

3.2.4.4 Format, agenda and methods

The workshop consisted of a short welcome by the organising team, an introduction to the fit-for-purpose concept and the work done so far by QUANTUM experts, and the actual workshop part of validating the design features by giving votes of agreement and gathering qualitative free text comments on relevance, feasibility and risks via interactive Wooclap tool.

The agenda was as follows:

- Welcome and objectives
- Short introduction to the fit-for-purpose concept
- Synthesis of the work and findings so far
- Validation round by each F4P component using Wooclap tool
- Conclusions and next steps.

3.2.4.5 Main content presented

The event started with the organising team presenting a short reminder of the QUANTUM project and the purpose of the Project forum, specifically thinking of the potential new participants. It was followed by the project's coordinator Enrique Bernal-Delgado mentioning that the F4P label is not foreseen in the regulation as such, and highlighting that most of the participants of the workshop are potential data users and their views are central for the validation of the proposal.

Then followed the actual presentations and workshop lead by the team behind the F4P development from UPV and Sciensano: Presentation of the F4P concept and synthesis of the work and findings so far, and the workshop part, where participants validated and commented on the suggestions via the Wooclap tool. In addition, preliminary mock-up images of what the assessments could look like as part of the EU Dataset Catalogue in the HealthData@EU Central Platform were presented.

The experts from WP2 told, that the main objective has been to design a fit-for-purpose assessment system for EHDS to incorporate the user's perspective on the quality of datasets for specific secondary use categories. The concept has been developed and refined through bilateral meetings with selected HDABs, data holders and data users, and in a workshop within QUANTUM consortium. To finalize the concept, it was time for an external workshop to validate the refined proposal with external stakeholders. The goal of the work is to provide recommendations for prospective implementing acts complementing the QUANTUM data quality labelling system.

The areas of the proposal are divided under the headings: definition of fit-for-purpose, timing of the fit-for-purpose mechanism, and implementation strategy of the fit-for-purpose mechanism. The questions covered in the workshop included, among others, whether giving fit-for-purpose feedback should be mandatory, whether it could be given also before the data use has ended, whether more fine-grained purposes than those in the EHDS Article 53 could be assigned, whether a scoring system should be included, how the validation of the feedback should be done and how the feedback should be presented in the catalogue.

The speakers specifically presented the following questions as open questions, on which they wanted to receive feedback and discuss about:

- Regarding purposes:
 - Purposes in the EHDS Article 53 versus more fine-grained purposes (faceted lists, keywords, potentially using vocabularies such as MeSH, DUO, or newly developed one)
 - Granularity-complexity relationship.
- Regarding the obligatoriness of the F4P evaluation:
 - Mandatory versus optional
 - Tradeoff between some incentives and discrimination.
- Potential biases and conflicts of interest being data holders part of the F4P feedback validation
 - Need of control by HDABs.

- Need of resources for feedback validation and tooling maintenance.

The validation was done with the Wooclap tool where a set of ten synthetised design features were presented and the participants selected their level of agreement on a Likert scale of 1 - 7, and after that were able to give free text comments. The topics received a commendable amount of feedback and also varying views from a wide range of participants, covering both data holder, data user and health data access body representatives and perspectives.

3.2.4.6 The fourth Project forum results

A large part of the session was spent in a workshop on fit-for-purpose proposal validation. In total 18 respondents answered and gave feedback in the workshop. The results of the workshop are reported in detail in the QUANTUM deliverable [Towards Fitness-for-purpose assessment in HealthData@EU](#).

To summarise the results, it can be stated that:

- There was stronger support for using more detailed purposes in the F4P evaluation than only the purposes presented in the EHDS Art. 53.
- A structured scoring system combining purpose-specific and aggregated elements gained moderate support. However, in the open feedback there were comments of the purpose-specific score being seen as more valuable than the average score. It was commented by a few commenters that the average score that considers all purposes could be misleading.
- The proposed model combining dimension-specific scoring, structured free-text commentary, and the possibility to upload supplementary material gained fairly strong support. However, some concerns regarding moderation burden for HDABs and understandability of the data quality dimensions for the users were expressed.
- The HDAB moderation capacity was raised as a possible concern also on making the F4P evaluations visible to users in the catalogue, even though the overall support was high.
- The respondents showed moderate support for limiting F4P reporting to the moment after data use. It was also commented that it would be important to be able to report the inability to use the data for a specific purpose.
- The proposed model on feedback validation by HDABs, involving data holders before publication, gained moderate support. Several concerns about governance tensions and potential bias were raised in the open feedback.
- There was strong support for providing the F4P feedback through a dedicated, open-source tool interoperable with EHDS and reusable by HDABs. Some commentators argued that the tool should be hosted in the HealthData@EU Central Platform. Also it was questioned whether it is advisable to allow HDABs to make extensions of the tool.
- The results showed a tendency against making the F4P feedback mandatory. Several comments stressed that forced feedback tends to be of lower quality than voluntary feedback.

- The respondents supported embedding the F4P feedback in the catalogue in the way proposed, which includes among others the possibility to filter datasets by purposes, a graphical diagram presentation for the different purposes and the possibility to see all the individual feedback. However it is worth to be noted that one comment was received about how it was often unclear in this exercise what a vote means, as the proposals suggest several things but only one vote was given. Therefore, it is worth considering the support for this proposal in particular as indicative, and conducting further research into user needs.
- There was clear support for using RDF as the underlying technical background for the F4P score and feedback.
- When disaggregated by roles of the respondents (data holder, HDAB, data user), there were differences in the views related to several questions. See more in detail in the deliverable [Towards Fitness-for-purpose assessment in HealthData@EU](#).

3.2.4.7 Immediate outcomes and follow-up

Based on the results of the workshop voting part, it seems that in general the participants had a fairly high level of agreement with the proposals presented. Some differences in the views can be seen based on the respondents' roles in the EHDS community, which are reported in detail in the deliverable Towards fitness-for-purpose assessment in HealthData@EU. A lot of valuable additional information, questions and other comments were received in the open feedback, which have been taken into account in the work. However, it should be noted that one participant commented that it was often unclear what a vote meant. Therefore, it may be a good approach to look at the votes on the agreement as indicative, and pay more attention to the open feedback given. In any case, the feedback provides good guidelines for the future work. Also the high number of participants at the event indicates the high interest towards and importance of the topic.

The QUANTUM experts highlighted that the current goal of the work is setting initial design recommendations for a fit-for-purpose system, particularly those operational within the HealthData@EU. The actual score calculus and final methodology will be future work beyond the QUANTUM project. The results of the workshop will influence the QUANTUM proposals to the European Commission on how user feedback on data fitness for purpose could be taken into account in the HealthData@EU. In addition to the results being reported in a separate deliverable, they will be included in the deliverable D3.2 Guidelines and specifications for the implementation of the QUANTUM labelling mechanism.

To end the session, the organising team reminded the participants of the possibilities to contribute and engage especially via the collaboration space in the Teams environment, submitting questions via the QUANTUM ticketing tool or by contacting the key persons directly. Also the upcoming QUANTUM Final event in Brussels in May 2026 was highlighted.

4 Outcomes and conclusions

4.1 Summary of results

Across four online sessions, the QUANTUM Project forum evolved into a stable and diverse community of stakeholders representing research infrastructures and projects, related EHDS initiatives, Health Data Access Bodies, national authorities, hospitals, data holders, and data users. Different forum sessions reached slightly different participants, but also a certain recurring participant base could be seen. Building on this broad composition, the forums provided a structured setting to present and discuss key QUANTUM outputs at different stages of maturity, including the datasets' quality and utility label, the maturity model for data holders, the data quality self-assessment tool, the mid-scale pilot and the emerging fit-for-purpose strategy. Stakeholders engaged actively through presentations, plenary discussions and interactive tools, raising critical questions about regulatory interpretation, granularity of the label, implementation burden and costs, inclusion of less mature data holders, and representation of labels and F4P information in the HealthData@EU metadata. Over time, the discussions within the Project forum evolved from introductory and conceptual exchanges towards more technical and implementation-oriented dialogue, confirming both continued interest in the QUANTUM approach and growing expectations regarding its practical usability in diverse organisational contexts.

The Project forum had a tangible influence on several core dimensions of QUANTUM's work and was seen as very valuable by the QUANTUM experts presenting their work. Feedback on the interpretation of EHDS Article 78 and on the early versions of the datasets' quality and utility label informed refinements to the label's structure, measures and value ranges, particularly in relation to granularity (dataset vs. holder vs. HDAB level) and the articulation of dimensions that are meaningful to both advanced and less mature data holders. Concerns about reporting burden and sustainability led the consortium to emphasise clearer guidance materials and work towards inclusion of a broader spectrum of organisations in the mid-scale pilot. Comments on metadata representation, interoperability with HealthDCAT-AP and the positioning of the label within HealthData@EU catalogues also contributed to ongoing technical discussions with secondary use related projects and the European Commission, helping to align QUANTUM artefacts with the wider EHDS implementation ecosystem. Finally, the sustained interest in use-case specificity and user-driven perspectives on data utility provided a strong impetus for the development and positioning of the F4P strategy as a complementary layer to the core label.

The following are a few concrete examples of how the Project forum feedback was utilised in the QUANTUM work:

- **Data holder's maturity model development:** The feedback collected during the second Project forum session was incorporated into the maturity model in Deliverable 1.2. Especially the discussions concerning data augmentation and enhancement proved valuable, as these aspects had generated substantial debate during the model

development.

- **Expanding the mid-scale piloting of the labelling tool:** Regarding the comments received in the post-forum survey of the third forum, the team responsible for the mid-scale piloting of the Data quality and utility labelling tool worked to further expand the pilot. Additional outreach targeted organisations representing previously identified gaps, including a cancer-related EDIC, a research consortium, and pharmaceutical companies. Although these organisations were offered access to the tool and invited to participate in piloting activities, no formal feedback was ultimately received.
- **Identification of external training resources:** Also the WP4 received good information via the survey conducted after the third forum. The additional data quality-related educational resources identified through the survey will be incorporated into the repository developed under WP4. Also the provided input served as final validation for the WP4's approach to build a best practices repository including other educational contents, as there had been some conflicting views on the approach before.
- **Development of fit-for-purpose model:** The fourth Project forum served as an external validation workshop for the synthesised F4P design features. The resulting feedback was directly incorporated into the F4P model and its related deliverables. Validation activities deliberately focused on design features for which previous work had identified limited agreement or unresolved questions. The feedback informed revisions to the F4P specification and supported prioritisation of follow-up actions. For instance, stakeholder input helped clarify preferred configurations and necessary safeguards for governance and visibility features that had previously generated mixed views.

4.2 Conclusions

The experience of the QUANTUM Project forum demonstrates the added value of a structured, iterative stakeholder engagement mechanism in the development of EU-level data quality and utility frameworks. By involving a broad range of stakeholders throughout multiple stages of the project lifecycle, QUANTUM was able to validate key design choices, identify blind spots at an early stage, and adjust both technical specifications and implementation strategies in response to real-world constraints and expectations.

The forums also contributed to the emergence of a community of practice around data quality and utility labelling, creating channels for continued dialogue that extend beyond individual deliverables and project boundaries. At the same time, the discussions highlighted persistent challenges for EHDS implementation, including the need to manage burden for less mature organisations and HDABs, balance the complexity that might undermine uptake but also provide value for data users, and reconcile standardisation with context-specific interpretations of fitness for purpose.

These lessons are relevant not only for the future deployment of the QUANTUM label and maturity model within HealthData@EU, but also for other initiatives seeking to operationalise complex regulatory requirements through practical, widely acceptable implementation tools.

Participant engagement throughout the Project forum series further demonstrated the importance of continued collaboration and dialogue on data quality among different stakeholder groups. Overall, the forum fulfilled its intended role as a platform for structured interaction between the QUANTUM consortium and external stakeholders. At the same time, a few possible improvements were also identified by the Project forum organising team. In particular, additional mechanisms to maintain interaction between forum sessions could have been explored further. The consortium also recognised that one of the project's key outputs – Deliverable 3.2 *Guidelines and specifications for the implementation of the QUANTUM labelling mechanism* – would likely have benefited from a dedicated forum session. Although the possibility of organizing a fifth forum was considered, time constraints ultimately prevented its implementation.

Future initiatives could also benefit from a clearer differentiation of feedback according to stakeholder roles within the EHDS ecosystem, enabling concerns and expectations from data holders, data users, and HDABs to be analysed more systematically. In addition, a final evaluation survey targeting forum participants could have provided further insights regarding the practical organisation and effectiveness of the engagement process. Nevertheless, the implemented methods successfully generated extensive stakeholder feedback and diverse perspectives, which were broadly incorporated into QUANTUM outputs and recommendations.

Annex : Invited member organisations of the Project forum

The following projects, initiatives, and infrastructures have been identified as key stakeholders for the QUANTUM Project forum. This list reflects the consortium's efforts to engage a broad and diverse range of expertise within the EHDS community:

1. Data-Driven Horizon Europe and EU-Funded Projects

- IDEA4RC – Innovative Data Ecosystems for Advanced Research and Care
- eCREAM – Enabling Comprehensive Research in European Analytics and Medicine
- AIDAVA – Artificial Intelligence for Data Value Assessment
- ONCOVALUE – Advancing Oncology Outcomes through Data
- EUCAIM – European Cancer Imaging Initiative
- IDERHA – Integrated Digital European Research Health Architecture
- CancerWatch JA - Improving Quality and Timeliness of Cancer Registry Data feeding into the European Cancer Information System
- AISym4Med - Developing Platform for AI Solutions in Healthcare
- REALM - Real-world Data Enabled Assessment for Health Regulatory Decision-making
- XpanDH - Expanding Digital Health through a Pan-European EHRXF-based Ecosystem
- REDDIE - Real-World Evidence for Decisions in Diabetes

2. EHDS Key Projects and Initiatives

- DARWIN EU® – Data Analysis and Real-World Interrogation Network
- EHDEN – European Health Data and Evidence Network
- ECDC – European Centre for Disease Prevention and Control
- EMA - European Medicines Agency
- EUROSTAT – Statistical Office of the European Union
- ECRIN - European Clinical Research Infrastructure Network
- xShare – Cross-Border Health Data Sharing Initiative
- TEHDAS2 JA – Towards European Health Data Space Joint Action

3. Infrastructure Projects

- FAIR-CookBook in FAIRPLUS – Guidance on Making Data FAIR (Findable, Accessible, Interoperable, and Reusable)
- GDI – Global Digital Infrastructure for Health
- GAIAx Health – European Cloud Framework for Health Data
- ORPHANET/INSERM – Rare Disease Data Infrastructure
- PHA4GE - Public Health Alliance for Genomic Epidemiology
- CESSDA - Consortium of European Social Science Data Archives
- BBMRI-ERIC - European Research Infrastructure for Biobanking and Biomolecular Resources.