



Deliverable 6.2

Project Data Management Plan

QUANTUM - Quality, Utility and Maturity Measured; Developing a Data Quality and Utility Label for HealthData@EU

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Abstract:	<p>This document contains the Data Management Plan for the QUANTUM project. This relates to <i>Task 6.1: project coordination and strategic management</i>, which pertains to QUANTUM WP 6 - <i>Coordination, evaluation, and management</i>. The goal of this task, led by the Health Science Institute in Aragón, Spain (IACS), is to create a document that covers what kind of data will be collected or generated in QUANTUM and how it will be handled, processed and shared.</p> <p>This document contains the QUANTUM DMP version 1.0 delivered in month 06 according to the QUANTUM Description of the Action. The project DMP is a live document that will be reviewed and updated periodically to ensure it remains up to date.</p>

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QUANTUM CONSORTIUM			
#	Short Name	Organisation Name	Country
1	IACS	INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD	ES
2	Sciensano	SCIENSANO	BE
3	Health Data Hub	PLATEFORME DES DONNEES DE SANTE	FR
3.1	HOSPICES LYON	HOSPICES CIVILS DE LYON	FR
3.2	HOSP TOULOUSE	CENTRE HOSPITALIER UNIVERSITAIRE DE TOULOUSE	FR
3.3	CHU Bordeaux	CHU HOPITAUX DE BORDEAUX	FR
4	I-HD	THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA	BE
5	UCSC	UNIVERSITA CATTOLICA DEL SACRO CUORE	IT
6	BBMRI-ERIC	BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM	AT
7	DIGITALEUROPE	DIGITALEUROPE AISBL	BE
8	GÖG	GESUNDHEIT OSTERREICH GMBH	AT
9	UPV	UNIVERSITAT POLITECNICA DE VALENCIA	ES
10	HEALTH-RI	STICHTING HEALTH-RI	NL
11	EUHA	EUROPEAN UNIVERSITY HOSPITAL ALLIANCE	BE
12	AP-HP	ASSISTANCE PUBLIQUE HOPITAUX DE PARIS	FR
13	VIB	VIB VZW	BE
14	CIPH	HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO	HR
15	HUS	HUS-YHTYMA	FI
16	THL	TERVEYDEN JA HYVINVOINNIN LAITOS	FI
17	ECRIN	ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK	FR
18	BFARM	BUNDESINSTITUT FÜR ARZNEIMITTEL UND MEDIZINPRODUKTE	DE
19	HIQA	HEALTH INFORMATION AND QUALITY AUTHORITY	IE
20	ISS	ISTITUTO SUPERIORE DI SANITA	IT
21	CESSDA ERIC	CESSDA ERIC	NO



21.1	KNAW	KONINKLIJKE NEDERLANDSE AKADEMIE VAN WETENSCHAPPEN - KNAW	NL
21.2	EKKE	ETHNIKO KENTRO KOINONIKON EREVNON	EL
22	e-helse	DIREKTORAT FOR E-HELSE	NO
23	U.PORTO	UNIVERSIDADE DO PORTO	PT
24	SPMS	SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE	PT
25	NIJZ	NACIONALNI INSTITUT ZA JAVNO ZDRAVJE	SI
26	ERASMUS MC	ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM	NL
27	EDHA	EUROPEAN DIGITAL HEALTH ACADEMY GGMBH	DE
28	HDR UK	HEALTH DATA RESEARCH UK	UK
29	UESSEX	UNIVERSITY OF ESSEX	UK
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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Type of Action: Horizon-CSA
Start Date of Project: 01 January 2024
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Table of Contents

Introduction	6
1. Data summary	7
1.1 Data Flow	7
1.2 Purpose of the data collection/generation. Relation to the objectives of the project	9
1.3 Types, formats and size of data generated and collected	10
1.4 Data origins	14
2. FAIR Data	15
2.1 Making data findable, including provisions for metadata	15
2.2 Making data accessible	15
Repository	15
Data	15
Metadata	15
2.3 Making data interoperable	15
2.4 Increase data re-use	16
3. Other research outputs	17
4. Allocation of resources	17
5. Data Security	18



6. Ethics	19
7. Other	21
7.1 PMO and DPO	21
8. Next steps	21
Annex I QUANTUM Project Management Repository	22
Annex II QUANTUM SURVEYS Consent form template	24
Annex III QUANTUM RECORDED EVENT consent form template	26
Annex IV Non-Disclosure Agreement for the External Advisory Board	28
Annex V Conflict of Interest form for QUANTUM External Advisory Board members	33



Introduction

The Data Management Plan (hereinafter “the project DMP”) is a mandatory deliverable by the European Commission (EC) that outlines what kind of data will be collected or generated and how it will be handled, processed and shared. The project DMP considers: overview of the project data flow, compliance with Open Science and FAIR sharing and Ethics Requirements as required by WP7.

This deliverable is based on the guidelines on data management provided by the European Commission ([HE programme guide](#)) and the template of DMP for Horizon Europe projects.

This document is QUANTUM DMP version 0.1 delivered in month 06 according to the QUANTUM Description of the Action.

The project DMP is a live document that will be updated when needed to ensure it remains up to date.



1. Data summary

Regarding the description of the frame of QUANTUM and other initiatives to which the QUANTUM project must be aligned with:

- QUANTUM project inception was the TEHDAS Data Quality Framework, available at: <https://tehdas.eu/results/tehdas-proposals-for-data-quality-and-utility-in-ehds/>
- EHDSR draft [EUR-Lex - 52022PC0197 - EN - EUR-Lex \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2022/197/oj) Chapter 4 Section 5 article 56 (Label) is the EC legislation framing our QUANTUM decisions.
- Other initiatives are shaping our project, such as DCAT extensions, interoperability testbed, etc.

The QUANTUM project's expected results are: a) A common concept of datasets Quality and Utility and Data holders' Maturity; b) Technical specifications for the label (Deliverable D1.1. and D1.2); c) A conformance checking tool that yields the label (D2.1); d) An implementation report of the label mechanism (D3.1); e) Recommendations for a large-scale implementation of the QUANTUM label mechanism (D3.2); and, f) The QUANTUM Exchange Platform and Academy (D4.2 and D4.3) as instruments for capacity building.

1.1 Data Flow

The data flow distributed among the different technical Work Packages (WP1-WP2-WP3):

- WP1 whose overarching goal is the conceptualisation of a data quality and utility, and a maturity labelling mechanism that will end up producing the specifications for its implementation.
- WP2 will design, develop and test the labelling mechanism at small-scale.
- WP3 will implement the labelling mechanism in a number of data holders anticipating real-life issues for a large-scale implementation of the label.

The conceptualisation phase in task 1.1 will translate into technical specifications (Deliverables 1.1 and 1.2) that will be the basis for the development of the QUANTUM labelling mechanism (i.e., tool) deployed at the data holders' site. The QUANTUM tool will render RDF/JSON files (i.e., the label) interoperable with HealthData@EU publication standards (i.e., DCAT).

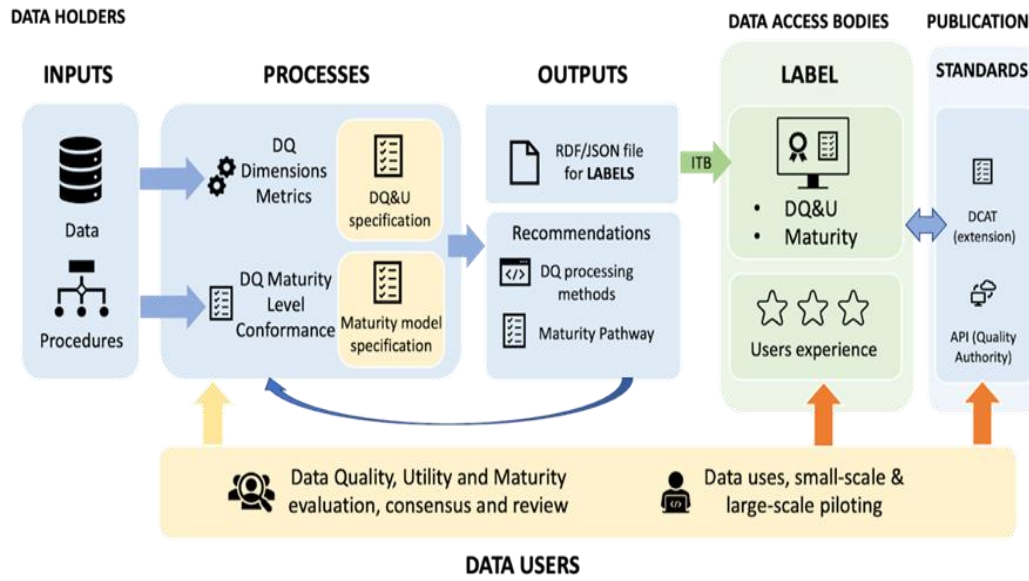


Figure 1 QUANTUM data flow



1.2 Purpose of the data collection/generation. Relation to the objectives of the project

QUANTUM will develop and implement a label mechanism that could be ideally adopted for the future HealthData@EU, a major cornerstone piece in the future European Health Data Space. QUANTUM will focus on the following objectives:

1. Conceptualise and develop a data quality and utility label in the context of the data holder maturity model;
2. Design, develop and test the labelling of the data sets' quality and utility and data holders' maturity;
3. Analyse the implementation challenges with a view to enabling the transferability and sustainability of the labelling mechanism as part of HealthData@EU and,
4. Develop a capacity building and outreach program that allows a broad engagement with the data quality professional community.

To fulfil these objectives, QUANTUM is expected to generate or collect data in the following main activities:

- (1) The QUANTUM tool will be deployed in the data holders' premises and will receive as input data quality metrics that periodically (and outside the scope of the QUANTUM project) each data holder will collect as outputs from their data quality management procedures (see details in WP2 and WP3, implementation section).
- (2) The output files yielded in implementing the QUANTUM tool (i.e., the label of quality, utility and maturity) are aggregated non-personal information.

Other activities/outputs:

- (3) Landscape analysis with consolidated data quality dimensions, their definitions, their alignment with the EHDS regulation and additional comments (WP1);
- (4) Quantitative survey using DELPHI methodology (WP1) and qualitative interviews with key stakeholders to validate DELPHI survey results (WP1);
- (5) Nominal group on the specification of the quality and utility metrics (WP1);
- (6) 2 Focus groups on the maturity model (WP1);
- (7) Survey to understand the scopes and uses, as well as current data quality practices of data holders in Europe, to compile information about the tools and methodologies used by QUANTUM partners and to capture the desires and expectations of relevant stakeholders, including the future Label users on the QUANTUM tool (WP2)



- (8) Interviews with the implementers (WP3);
- (9) Collection of qualitative data on QUANTUM tool implementation through a Focus Group (WP3);
- (10) 2 workshops on transfer and sustainability (WP3);
- (11) Survey to harvest valuable insights, needs, and expectations from relevant stakeholders within the health data ecosystem to deliver a capacity needs assessment (WP4)
- (12) Publicly accessible online platform and repository containing guidelines, templates, checklists and initial QUANTUM labelling experiences (WP4)
- (13) Training materials: Online training courses and workshops for different stakeholder groups (WP4)
- (14) QUANTUM consortium mailing lists (WP5)
- (15) QUANTUM Projects Forum, QUANTUM Citizens and Patients Forum, HealthData@EU building initiatives Forum (WP5)
- (16) The different documents produced as intermediate or final achievements of QUANTUM, including Milestones and Deliverables such as Public Reports, recommendations, etc;
- (17) Any scientific manuscripts produced as a consequence of the project;
- (18) Any relevant link to repositories and related initiatives.
- (19) Personal information for QUANTUM administration/management
- (20) QUANTUM dissemination-related materials (WP5)



1.3 Types, formats and sizes of data generated and collected

The expected types and formats are the following:

- **QUANTUM tool and output files:**
 - a. Types: standalone open source software
 - b. Formats: RDF/ OWL/JSON files
 - c. Reference “activity” section 2.1 above (1), (2).
 - d. Expected Size: Few MBs

- **Documents produced as intermediate or final achievements of QUANTUM:**
 - a. Types: reports, brochures
 - b. Formats: Plain text – Word files – PDF Files
 - c. Reference “activity” section 2.1 above (3), (16)
 - d. Expected Size: Few MBs

- **Surveys:**
 - a. Type: replies to the survey.
 - b. Format: structured tables.
 - c. Reference “activity” section 2.1 above (4), (7), (11).
 - d. Expected Size: Few MBs

- **Workshops/Interviews/Focus Groups/Nominal Groups/Forums /... with key stakeholders:**
 - a. Type: opinions/exchange on different issues.
 - b. Format: video recordings.
 - c. Reference “activity” section 2.1 above (5), (6), (8), (9), (10), (15).
 - d. Expected Size: Few GBs



- **Training Materials produced as intermediate or final achievements of QUANTUM:**

- a. Types: reports, brochures, audiovisual materials
- b. Formats: Plain text – Word files – PDF Files - Webinars - HTML
- c. Reference “activity” section 2.1 above: (12), (13)
- d. Expected Size: GBs

- **QUANTUM mailing lists Consortium:**

- a. Types: list
- b. Formats: outlook .pst files
- c. Reference “activity” section 2.1 above (14)/ All activities needing a specific mailing list
- d. Expected Size: KBs

- **Scientific manuscripts produced as a consequence of the project:**

- a. Types: reports, manuscripts
- b. Formats: Plain text – Word files – PDF Files
- c. Reference “activity” section 2.1 above (17).
- d. Expected Size: Few MBs

- **Any relevant link to public scientific repositories and related initiatives:**

- a. Types: links
- b. Formats: HTML links –Digital Object Identifiers/DOIs
- c. Reference “activity” section 2.1 above (18).
- d. Expected Size: KBs

- **QUANTUM Project Management repositories:**

- a. Types: staff salaries, timesheets, transcripts and notes,...
- b. Formats: Excel, Google Sheets
- c. Reference “activity” section 2.1 above: (19).
- d. Expected Size: KBs



- **QUANTUM Dissemination-related materials:**
 - a. Types: Website/Newsletter/QUANTUM PPT deck slides, 1 pager, pictures taken during conferences, workshops and seminars;...
 - b. Formats: html,ppt, pdf, jpg, ...
 - c. Reference “activity” section 2.1 above: (20).
 - d. Expected Size: MBs



1.4 Data origins

- a. Re-use: Any relevant link to repositories and related initiatives; ex. landscape analysis on existing EHDS Data Quality Frameworks
- b. Produced during the project development: ex. outcomes from interviews and surveys with relevant stakeholders.
- c. Data from data holders to be ingested by the QUANTUM tool (software)



2. FAIR Data

2.1 Making data findable, including provisions for metadata

QUANTUM will integrate standardised data management and analysis methods and protocols to ensure FAIR (Findability, Accessibility, Interoperability, and Reusability) is integral to the process.

2.2 Making data accessible

Repository

Relevant QUANTUM data will be deposited in ZENODO and GitHub repositories with persistent IDs.

Specifically, Task 4.3, Sustainable community of practice and repository of best practice resources, will standardise and index the initial resources developed in Task 4.2 in a searchable repository.

The repository will also include the compilation of data quality management and quality assurance methods, pipelines, tools (open-source) and experiences (including case studies), initially from consortium partners and later from the wider community.

Data

A QUANTUM labelling mechanism will be designed, developed, and tested to implement a TRL 7 system prototype in an operational environment among QUANTUM data holders (WP2 and WP3).

The different versions (v0.1, v0.2.x, v1.0) of the QUANTUM tool will be published and persisted in Zenodo, and the software code and documentation will be published in a GitHub repository under an open-source licence. The output of the QUANTUM tool—RDF and JSON files—is thought to complement the metadata describing a dataset or an organisation and consequently be part of the HDABs metadata catalogues.

The guidelines and specifications for implementing the QUANTUM labelling mechanism (Deliverable 3.2) will be published along with the QUANTUM tool.

Open access to generated data will be applied under the premise ‘as open as possible as closed as necessary’.



It is the intention to publish the relevant QUANTUM outputs in an open-access publication as a special issue in a peer-to-peer access journal

Metadata

With a view to facilitate the eventual use of the QUANTUM labelling mechanism in the future HealthData@EU, QUANTUM will develop controlled vocabularies and existing ontologies designed for metadata cataloguing as part of the label publication. For example, the data quality specifications (DQV) and data provenance specifications ([PROV-O](#)) in DCAT v2 or DDI, as general approaches to meta-data. Nonetheless, given the variety of data holders and data types, other standards to be considered will be: data quality vocabulary ([dqv](#)), the data quality constraints library (dqc), the data quality management vocabulary (dqm), the GDPR provenance ontology ([GDPRov](#)), the open data rights statement vocabulary ([odrs](#)), the open provenance model vocabulary specification ([opmv](#)), the provenance vocabulary core ontology specification (prov), the relations for reusing ontology ([r4r](#)), and the W3C shapes constraint language vocabulary ([SHACL](#)).

2.3 Making data interoperable

General data and metadata vocabularies, standards, formats and methodologies will be followed.

QUANTUM analyzes DCAT extensions/ontologies/vocabularies, identifying existing gaps, such as missing categories, dimensions, etc.

The QUANTUM label tool will be developed, maintained, and supported using open-source software code, which will be published in a GitHub repository, enabling public contribution and version control.

2.4 Increase data re-use

Intellectual property rights and protection will be managed using an International Attribution 4.0 Creative Commons licence (CC-BY International 4.0). This includes the specifications for data quality and utility (Deliverable 1.1), the specifications for data holder maturity (Deliverable 1.2), the QUANTUM tool (Deliverable 2.1), and the implementation report (Deliverable 3.2).

In addition, the QUANTUM online platform (Deliverable 4.4) will be using W3C standards.

QUANTUM Website

The consortium will disseminate relevant project outcomes on QUANTUM's website (quantumproject.eu). The website will be a front-end platform to disseminate knowledge developed in QUANTUM.



Zenodo

Long-term preservation of relevant QUANTUM outcomes will make use of publicly available system Zenodo digital repository (<https://zenodo.org/>). As a European Commission supported initiative, and technically supported by CERN, we trust this as the best way to ensure access to the generated data continues long after the project ends.

GitHub

The open-source software of the QUANTUM Tool will be stored in a dedicated space in the GitHub repository (<https://github.com/>).



3. Other research outputs

N/A

4. Allocation of resources

The Data Management Plan is a living document and will be updated as needed by the lead beneficiary (IACS) to support the data management lifecycle for all data that will be collected, processed and/or generated by the project.

The responsibilities of the QUANTUM project members include:

- Regular classification of the data collected and/or generated by the WP activities (to be made available on the QUANTUM Gdrive);
- Implementing the Data Management Plan.



5. Data Security

All project deliverables and data will be stored and shared in the dedicated QUANTUM Google Drive repository (see details in Annex I), which is hosted and managed by the QUANTUM Project Management Unit/PMO Team. The project consortium will have editorial access to this repository.

The QUANTUM Google Drive system is a password-protected system designed to safeguard collected data against unauthorized use. Suppose personal data is collected in a physical form (e.g., attendance lists on paper). In that case, the collector is expected to store it in Google Drive in a digitalised version as soon as possible. In case they are needed, the physical copies shall be kept in a secured place.



6. Ethics

Processing of personal data will respect the Data Protection Principles as set out: Lawfulness, fairness and transparency; Purpose limitation; Data minimisation; Accuracy; Storage limitation; Integrity and confidentiality; accountability.

The purposes of processing personal data in QUANTUM include but are not limited to, project technical execution (QUANTUM WP1-WP4), management and coordination, project outreach, communication including internal communication and dissemination activities, administration and compliance with the Grant Agreement, etc.

Such activities require the active involvement of human participants. Some non-sensitive data on individuals -mostly merely personal contact information- will be collected. The data is collected online ex. links are given to the QUANTUM partners and/or to external entities to participate in the survey.

For activities exclusively with Consortium members, consent won't be needed as the legal basis is based on its legitimate interest nature covered by the Grant Agreement, Consortium Agreement, labour law or employment contracts.

For third parties, personal data will be only processed when subjects have given explicit consent to process personal data for specific purposes in language and terms intelligible to the participants.

Specific consent templates are available for partners to personalise for the specific QUANTUM activities; see Annex II and Annex III.

Data processing doesn't involve profiling.

In the case of the QUANTUM tool (Tasks 2.3 and 3.2), this tool will benefit from the metrics regarding data quality that periodically (and outside the scope of the QUANTUM project) each data holder is collecting as outputs from their data quality management procedures.

Specifically, the QUANTUM tool will ingest this non-personal data. The output files yielded in implementing the QUANTUM tool (i.e., the label of quality, utility and maturity) are aggregated information.

Recruitment of External Advisory Board/EAB Members

Non-disclosure Agreements/NDA and Conflict of Interest forms have been signed by the members of the EAB; see Annex IV and Annex V.

Gender

The consortium has strived to invite diverse participants representing all genders.



Compliance with ethical principles and relevant legislation

The consortium is fully committed to adhere to the highest ethical, fundamental rights and legal standards, as recognized at the European Union and international levels. QUANTUM's activities will be carried out in strict compliance with the ethical principles and fundamental rights enshrined by:

The European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR, 1950) Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (1997).

The Directive on Privacy and Electronic Communications (2002/58/EC) UNESCO International Declaration on Human Genetic Data (2003).

The UNESCO Universal Declaration on Bioethics and Human Rights (2005).

The EU Charter on Fundamental Rights (CFREU, 2010).

The Directive on Patients' Rights in Cross-Border Healthcare (2011/24/EU)

The Helsinki Declaration, in its latest version (2013)

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).



7. Other

7.1 DPO

When necessary, the coordinator's Data Protection Officer will be involved to guarantee the individuals' rights when QUANTUM processes personal data. This includes options to withdraw consent and procedures that must be in place to deal with privacy violations in a timely manner.

8. Next steps

Review if needed to ensure it remains up to date.

Annex I QUANTUM Project Management Repository

The Project Management repositories do not store research data but project data required to manage, monitor, and control the project execution. QUANTUM intends to use these repositories to monitor and control QUANTUM project administrative, legal, financial and technical aspects providing a collaborative workspace to generate project deliverables, milestones and manage internal and external communication activities. At the same time, it aims to foster collaboration across project participants.

The QUANTUM Project Management Repository Structure is presented in Table 1.

Table1. QUANTUM Project Management Repository Structure

Top-level folder	Content
1. Project MASTER File	Master document with details from the project: contact lists, effort distribution, lists of deliverables & milestones, GANTT chart, etc. Legal documents pertaining to the project: Consortium Agreement, Grant Agreement, Description of Action, amendments, contracts, etc.
2. WPs	Working folders for the WPs
3. Deliverables & Milestones	Repository for project deliverables and milestones
4. Project meetings, Events & TCs	Details of all project meetings and events (agendas, minutes, slide presentations, etc.)
5. Periodic Reporting	Financial and periodic reports from all project partners



6. Guidance and Templates	Project handbook, containing guidance pertaining to all aspects of the project (processes, communications, management structure and responsibilities, etc.) Project templates: deliverables, milestones, agendas, minutes, slide presentations etc
7. Project Communications and Outreach Materials	Project branding & style guidelines, press releases, articles, presentations, newsletters, graphic resources, etc



Annex II QUANTUM SURVEYS Consent form template

[This template is to be adapted and embedded into their specific questionnaire for participants to be able to consent to QUANTUM consortium and third parties processing activities on the use of the personal data of survey participants PRIOR to their participation in the survey].

We are asking for your input on the survey titled [insert title of the survey], which aims at [include aim of the survey/reason to be contacted] in the context of the QUANTUM project. QUANTUM project will be developing and implementing a label mechanism that could be ideally adopted for the future HealthData@EU in the context of the Horizon Europe Coordination and Support Action (CSA) funded by the European Union (HORIZON-HLTH-2023-TOOL-05, GA Nr 101137057). You can find further information on the QUANTUM project at: <https://cordis.europa.eu/project/id/101137057>. You will be able to read about our project findings on the QUANTUM website at: <https://www.quantumproject.eu/> in due course.

The [include survey organizer] will be working with the survey service [include survey tool], which is an online survey service to [ex. create questionnaires].

[include tool,] will be authorized to process the data only for [include purposes such as administration, etc,] purposes. More information at: [include survey tool data processing conditions]

There are no risks associated with your participation in this survey. Some non-sensitive personal data on you as survey participant will be collected: [include personal data collected such as email, name, last name, position, etc.] The replies you will provide to the survey will only be used internally and in a secured way by the QUANTUM consortium carrying out the QUANTUM project and only for the objective explained above. The data will only be processed as input to obtain project outcomes, including milestones, deliverables, publications, etc. No use for commercial purposes will be made with your information.

You will have the opportunity to access the data collected in this survey as you will receive an email with your replies to the survey [make sure the survey is set to send a copy of the responses via email to the email address provided].

Your responses, including your reply to consent to participate in this survey and its declared processing of personal data, will be kept in the IACS password-protected QUANTUM Google Drive platform for a maximum of 5 years after the QUANTUM project ends (i.e., June 2031).

In accordance with the European Union's Regulation on Personal Data Protection ([GDPR 2016/679](#)), you have the right to access, modify, object, and erase your personal data. If you want to exercise this right, you can contact the QUANTUM Project Management Office at: pmo@quantumproject.eu



Consent

This consent form is made pursuant to the relevant national, European and international data protection laws and regulations as well as personal data treatment obligations. Specifically, this consent form complies with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

By providing your consent, you agree to participate in this survey and its processing of your personal data.

I consent to participate in this survey

YES NO



Annex III QUANTUM RECORDED EVENT consent form template

[This form is to be used by the event owner to be adapted to your specific event and then used/embedded in your online registration process; once filled in by the participants, the resulting table, including the consent (Y/N), is to be uploaded in the QUANTUM google drive relevant folder]

Event name:

Event Date(s):

[include QUANTUM beneficiary that acts as main event organizer] is organising [include name of the event] and we will collect some personal data on you as event attendee.

Specifically: [ex. personal contact information, personal data collected such as voice, video and/or photograph of presentation, name and last name in connection with the videos and/or photographs, etc] hereinafter referred to as your information. No use for commercial purposes will be made with your information from QUANTUM Consortium.

The QUANTUM consortium will process your information in the context of the QUANTUM project, which is developing and implementing a label mechanism that could be ideally adopted for the future HealthData@EU in the context of the Horizon Europe Coordination and Support Action (CSA) QUANTUM project funded by the European Union (HORIZON-HLTH-2023-TOOL-05, GA Nr 101137057). You can find further information on the QUANTUM project at: <https://cordis.europa.eu/project/id/101137057>

The data will be processed to work as input to obtain QUANTUM project outcomes, including milestones, deliverables, publications (including in the context of QUANTUM dissemination and outreach efforts), etc. You will be able to read about our project findings and dissemination efforts on the QUANTUM website at: <https://www.quantumproject.eu/>

[choose below the purposes of your event]

PROCESSING PURPOSE 1:

I understand that [include organizer] will be working with the videoconferencing service [include videoconferencing tool, ex. Zoom], which is an online videoconferencing service to stream the presentations to an online audience.

[include videoconferencing tool, ex. Zoom] will be authorized to process your information only for event planning, organisation and administration purposes. More information at: [include videoconferencing tool data processing conditions, ex. Zoom at <https://explore.zoom.us/en/trust/privacy>]

PROCESSING PURPOSE 2:

I understand that the QUANTUM project is working with the cloud storage system of Google, which is authorised to process your information to provide QUANTUM with the online service to store, share and collaborate on files and folders. More information at: <https://cloud.google.com/privacy/gdpr>



**PROCESSING PURPOSE 3:**

Regarding [interviews/ focus groups/...] they will be recorded for the sake of opinion retrieval , stored at QUANTUM Google Drive and used for further analysis to achieve QUANTUM deliverables and milestones.

PROCESSING PURPOSE 4:

Regarding [workshops/...] in addition to the activities stated in purposes 1 and 2, the following personal information will be disclosed [choose: only for those participants who have registered for the event/publicly/...] at [choose: QUANTUM Google Drive/QUANTUM website/...]:

The QUANTUM password-protected Google Drive is managed by IACS (Instituto Aragonés de Ciencias de la Salud) and used by the QUANTUM consortium carrying out the QUANTUM project for the objectives explained above. Your information, including your reply to consent to participate in this event and its declared processing of personal data, will be kept in this IACS QUANTUM Google Drive platform for a maximum of 5 years after the QUANTUM project ends (i.e., June 2031).

In accordance with the European Union's Regulation on Personal Data Protection ([GDPR 2016/679](#)), you have the right to access, modify, object, and erase your personal data. If you want to exercise this right, you can contact the QUANTUM Project Management Office at: pmo@quantumproject.eu

Consent

This consent form is made pursuant to the relevant national, European and international data protection laws and regulations as well as personal data treatment obligations. Specifically, this consent form complies with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

By providing your consent, you agree to participate in [include name of the event] and its declared processing of personal data.

I consent to participate

YES NO



Annex IV Non-Disclosure Agreement for the External Advisory Board

Instituto Aragonés de Ciencias de la Salud ('IACS') and the organisations shown in the Annex to this Agreement (the "Consortium") are participating in the project entitled Quality, Utility and Maturity Measured; Developing a Data Quality and Utility Label for HealthData@EU "QUANTUM" (the "Project"), funded by the Horizon Europe – the Framework Programme for Research and Innovation (2021-2027).

The Consortium welcomes you as a member of the External Advisory Board ("EAB"). Participation as a member of the EAB will involve you receiving and/or participating in Project discussions/presentations concerning information produced and/or acquired by the Consortium members either as part of the Project ("Foreground") or before/outside the Project ("Background").

As the Consortium members have pre-existing obligations with respect to the confidentiality of such Foreground and Background, you will be required to keep confidential, as indicated below, any Foreground or Background that may be disclosed to you as a member of the EAB. In this agreement, any information disclosed to you relating to Foreground and/or Background shall be collectively referred to as "Confidential Information", and the Consortium member owning or holding rights to such Confidential Information who shall be entitled to enforce the obligations contained herein, shall be referred to as the "Discloser".

All Confidential Information disclosed by the Discloser, and any and all copies that may have been made thereof, remain in the ownership of the Discloser.

By signing below, you agree to the following:

- a) to take all reasonable steps to ensure that all Confidential Information disclosed to you as a member of the EAB remains confidential during the Project and for a period of five (5) years after the end date of the Project;
- b) not to become involved in any commercial, manufacturing, scientific, literary or any other exploitation of the Confidential Information, whether alone or in conjunction with another party (by licence or otherwise), or use Confidential Information otherwise than for undertaking your duties as a member of the EAB without the written consent of the Discloser;
- c) not to disclose the Confidential Information either directly or indirectly to any Third Party without the written consent of the Discloser.
- d) to remain liable for compliance by your staff and/or any other person in your service in any capacity whatsoever with these confidentiality obligations. In particular, you shall take all necessary measures to prevent such persons from disclosing any of the Confidential Information to Third Parties;



e) if in spite of all precautions one or more documents or media containing Confidential Information, or the Confidential Information itself, were to disappear or be disclosed, to immediately inform the Discloser upon discovery of their/its disappearance or disclosure.

In addition, you agree that the above obligations of confidentiality and non-use shall not apply in the following circumstances:

(i) when any such Confidential Information is public knowledge through previous publication, or when following disclosure to you as a member of the EAB, becomes general or public knowledge either through no fault of yourself or following further written agreement between you and the Discloser;

(ii) when any such Confidential Information can be shown by yourself to have been in your possession prior to disclosure under this agreement, except when such Confidential Information was supplied by the staff, students or agents of the Discloser;

(iii) when any such Confidential Information is received by yourself from a Third Party without restrictions or breach of a similar obligation of confidentiality of the Discloser;

(iv) when you can reasonably demonstrate that any such information has been previously developed by yourself without reference to, or without prior benefit of, the Confidential Information or

(v) when disclosure was required in order to comply with applicable laws or statutory regulations or pursuant to a binding court or administrative order. Nevertheless, in the latter cases, you still may be held liable if any of the following conditions are not met:

You shall, to the extent it is not prohibited by law, first inform the disclosing Party in writing of its obligation to disclose the Confidential Information in such a way that the said Party has enough time to object or to limit the scope of such disclosure, unless such information is forbidden by applicable laws;

You must confine such disclosure to what is strictly necessary for it to meet your obligations.

At any time and at the request of the Discloser, as well as following the end of the Agreement, you agree to, within ten (10) days of receiving such a request:

at the Discloser's discretion, return or destroy all original copies of documents, equipment, electronic or other medium containing the Confidential Information or their summaries in its possession;

issue a formal written statement certifying that you have not retained any Confidential Information and/or copies of the said Confidential Information on any medium whatsoever,



with the exception of a single copy that you may retain in statutory archives with a view to monitoring your commitments under this Non-Disclosure Agreement;

This Non-Disclosure Agreement is entered into intuitu personae. Consequently, it is personal, non-transferable and non-assignable.

This Non-Disclosure Agreement is governed by Belgium law.

This Non-Disclosure Agreement constitute the entire agreement between the parties to this agreement with regard to its purpose and supersede any and all prior oral or written statements, negotiations, representation, communications, acceptances, understandings and agreements between the parties in connection with the discussions and the provisions to which this Non-Disclosure Agreement applies or stipulates. It may only be amended by means of an amendment signed by the parties.

In consideration of the invitation to participate as a member of the EAB, I accept the conditions set out within this agreement.

Electronic Signatory of EAB Member

{insert here name}

Electronic Signatory of Authorised signatory

Enrique Bernal Delgado

(as authorised Member of IACS Staff on behalf of the QUANTUM Consortium)



Annex 1 NDA QUANTUM Consortium parties

1. INSTITUTO ARAGONES DE CIENCIAS DE LA SALUD (IACS), PIC 998462032, established in AVENIDA SAN JUAN BOSCO 13, ZARAGOZA 50009, Spain as Coordinator.
2. SCIENSANO (Sciensano), PIC 906160809, established in JULIETTE WYTSMANSTRAAT 14, ELSENE 1050, Belgium.
3. PLATEFORME DES DONNEES DE SANTE (Health Data Hub), PIC 895824586, established in 9 RUE GEORGES PITARD, Paris 75015, France.
4. THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA (I-HD), PIC 923112723, established in MEREBAAISTRAAT 10, OOSTERZELE 9860, Belgium.
5. UNIVERSITA CATTOLICA DEL SACRO CUORE (UCSC), PIC 999915771, established in LARGO GEMELLI 1, MILANO 20123, Italy.
6. BIOBANKS AND BIOMOLECULAR RESOURCES RESEARCH INFRASTRUCTURE CONSORTIUM (BBMRI-ERIC) (BBMRI-ERIC), PIC 946597878, established in NEUE STIFTINGTALSTRASSE 2/B/6, GRAZ 8010, Austria.
7. DIGITALEUROPE AISBL* (DIGITALEUROPE), PIC 952919756, established in RUE DE LA SCIENCE 14, BRUXELLES 1040, Belgium.
8. GESUNDHEIT OSTERREICH GMBH (GÖG), PIC 928836208, established in STUBENRING 6, WIEN 1010, Austria.
9. UNIVERSITAT POLITECNICA DE VALENCIA (UPV), PIC 999864846, established in CAMINO DE VERA SN EDIFICIO 3A, VALENCIA 46022, Spain.
10. STICHTING HEALTH-RI (HEALTH-RI), PIC 887782025, established in JAARBEURSPLEIN 6, UTRECHT 3521 AL, Netherlands.
11. EUROPEAN UNIVERSITY HOSPITAL ALLIANCE (EUHA), PIC 883641774, established in RUE MONTAGNE AUX HERBES POTAGERES 2, BRUSSEL 1000, Belgium.
12. ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP), PIC 999645432, established in 55 BOULEVARD DIDEROT, PARIS 75012, France.
13. VIB VZW (VIB), PIC 999651931, established in Suzanne Tassierstraat 1, GENT 9052, Belgium.
14. HRVATSKI ZAVOD ZA JAVNO ZDRAVSTVO (CIPH), PIC 998128255, established in ROCKEFELLEROVA 7, ZAGREB 10000, Croatia.
15. HUS-YHTYMA (HUS), PIC 999483830, established in STENBACKINKATU 9, HELSINKI 00029, Finland.



16. TERVEYDEN JA HYVINVOINNIN LAITOS (THL), PIC 996697893, established in MANNERHEIMINTIE 166, HELSINKI 00271, Finland.
17. ECRIN EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK (ECRIN), PIC 948646712, established in 30 BD SAINT-JACQUES BATIMENT B, PARIS 75014, France.
18. BUNDESINSTITUT FUR ARZNEIMITTEL UND MEDIZINPRODUKTE (BFARM), PIC 998293931, established in KURT GEORG KIESINGER ALLEE 3, BONN 53175, Germany.
19. HEALTH INFORMATION AND QUALITY AUTHORITY (HIQA), PIC 928703221, established in GEORGE COURT, GEORGE LANE, MAHON CITY GATE UNIT 1301, Ireland.
20. ISTITUTO SUPERIORE DI SANITA (ISS), PIC 999978821, established in Viale Regina Elena 299, ROMA 00161, Italy.
21. CESSDA ERIC (CESSDA ERIC), PIC 904940937, established in SOLHEIMSGATEN 16, BERGEN 5058, Norway.
22. DIREKTORAT FOR E-HELSE (e-helse), PIC 920094665, established in VERKSTEDVEIEN 1, OSLO 0277, Norway.
23. UNIVERSIDADE DO PORTO (U.PORTO), PIC 999894916, established in PRACA GOMES TEIXEIRA, PORTO 4099-002, Portugal.
24. SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE (SPMS), PIC 950932323, established in AVENIDA DA REPUBLICA, 61, LISBOA 1050 189, Portugal.
25. NACIONALNI INSTITUT ZA JAVNO ZDRAVJE (NIJZ), PIC 948891346, established in TRUBARJEVA CESTA 2, LJUBLJANA 1000, Slovenia.
26. ERASMUS UNIVERSITAIR MEDISCH CENTRUM ROTTERDAM (ERASMUS MC), PIC 999988424, established in DR MOLEWATERPLEIN 40, ROTTERDAM 3015 GD, Netherlands.
27. EUROPEAN DIGITAL HEALTH ACADEMY GGMBH (EDHA), PIC 886608907, established in MOHNBLUMENWEG 1, ABENSBERG 93326, Germany.

Associated Partner number:

28. HEALTH DATA RESEARCH UK, PIC 892849596, established in 215 EUSTON ROAD 000, NW1 2BE, LONDON (UK)
29. UNIVERSITY OF ESSEX, PIC 999856989 established in WIVENHOE PARK, CO4 3SQ, COLCHESTER (UK)
30. INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE, PIC 999997833, established in RUE DE TOLBIAC 101 000, 75654, PARIS (FR)



Annex V Conflict of Interest form for QUANTUM External Advisory Board members

The avoidance of any perception that members of the QUANTUM (GA 101137057) External Advisory Board (EAB) may be biased in some fashion is important for the credibility of the feedback provided by the EAB and for the integrity of the project.

Possible competing interests should be disclosed. In many cases simple disclosure up front should be sufficient. Otherwise, the (potential) EAB member should remove the conflict or stop participating in the EAB.

No, I have no competing interest to declare

Yes, I have competing interests to declare (please provide details below)

I agree to treat all project documentation, data and discussions as confidential and I have signed the QUANTUM Non-Disclosure Agreement.

Electronic Signatory of EAB Member

{insert here name}