XpanDH

Expanding Digital Health through a pan-European EHRxF-based Ecosystem

D2.3 – (D2.3) Technical requirements for quality labelling

WP2 – Standards and Technical Artefacts

DRAFT Candidate Version 2

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What did this document aim to achieve?	Provide a comprehensive overview of the various aspects of quality labelling. Among others, by using existing standards and previous European Commission projects. By starting at a high level and providing more details based on a specific domain and use case, this document aims to provide a generic framework focussing on real-world applicability.
Present the main methodological approaches in bullet point format	1 This Deliverable makes use of a qualitative approach consisting of desk research following the following the following steps: 1.1 Providing an overview of applicable standards, frameworks and their relevance to this Deliverable and XpanDH as a whole; 1.2 Providing an overview of previous European Commission projects and their relevance; 1.3 Describing applicability on a high/generic level; 1.4 Applicability on domain specific level; 1.5 Applicability on a use case specific level; 1.6 (Self) Assessment; 1.7 Further development and providing input for WP4.
What were the main findings or take-away messages? What implications does it have for the XpanDH project?	Overview of applicable standards, frameworks, and their relevance in terms of Quality labelling Formalisation of a quality framework used for quality labelling of Digital Consumer Health Products (DCHPs) With respect to the XpanDH project, the quality frameworks support a trusted use of the EEHRxF for exchanging data between consumer products and EHRs/Laboratory systems, etc.
Which project stakeholder group would benefit the most from the document and why?	**Healthcare Professional**: Rely on and trust quality labelled digital tools, that are scope of 2.3 **International Adherence Network/Initiative**: Rely on and trust quality labelled digital tools, that are scope of 2.3 **Investors and Funding**: Rely on the quality of digital tools invested on, that are scope of 2.3 **Patient Organization**: Rely on and trust quality labelled digital tools, that are scope of 2.3 **Patient/Caregiver**: Rely on and trust quality labelled digital tools, that are scope of 2.3 **Pharma (Marketing&Sales/Medical Dept./R&D)**: **Public Authority or Policymaker**: Rely on, trust, and recommend quality labelled digital tools **Regulatory body**: Availability of framework to identify quality in digital tools, that are scope of D2.3 **Standardization Body/ Open-Source Network Researcher/Academic**: Take the resulting quality framework and render it standard/technical specification, maintaining it. **Statutory Health Insurance Company**: Rely on and trust quality labelled digital tools, that are scope of 2.3 for insurance purposes **Technology & Service Provider**: Know beforehand the quality criteria to which their solutions must adhere, so they can focus on innovation and their own specific added value. **Other**
List any relevant organizations or social media accounts for wider visibility	

Revision History			
Version	**Date**	**Editor**	**Description**
0.1	01/03/2023	Hans Gille	Initial setup, introduction and scope, discussion of existing standards and previous projects.
0.2	02/05/2023	Pier Angelo Sottile	Inserted info on Label2Enable, EN ISO 13131 and more info on 82304-2
0.3	02/06/2023	Hans Gille	X-eHealth relevance
0.4	30/09/2023	Pier Angelo Sottile, Hans Gille	Label2Enable relevance, Description of standards
1.0	31/10/2023	Pier Angelo Sottile, Hans Gille	Final version 1, taking into consideration XpanDH internal review process
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2.2	10/05/2024	Pier Angelo Sottile	Draft Final version2. General, major update. Added sections regarding data quality and interoperability including text and criteria on the IEC/ISO 25000 series, ISO 23903, the AIDAVA project. Annex 2 has been extended with Data Quality criteria. Annex 3 with definitions has been added.
2.3	31/05/2025	Pier Angelo Sottile, Hans Gille	Finalization of D2.3 V2

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Deliverable Abstract

T2.3 concerns itself with the creation of a framework used for quality labelling of Digital Consumer Health Products (DCHPs). This Deliverable focuses on reusing existing standards and frameworks while reusing aspects from previous European Commission projects such as Label2Enable, X-eHealth and DigitalHealthEurope. The DCHP quality labelling framework has been drafted drawing inspiration from the existing 82304-2 Technical Specification regarding quality and reliability of health and wellness apps and labelling, ISO 13131, ISO 10377, and ISO 13485, and existing data quality standards. By providing sufficient guidelines to be used in the actual assessment of the quality criteria listed, this widely applicable standard is also of use for more detailed use cases or alignment of (local) regulations. For means of feasibility, this Deliverable has followed a three-layered approach starting to gradually explore the application of quality labelling. It starts with a generic level (Digital Consumer Health Products in general), continues with the domain level (Digital Consumer Health Products and Electronic Health Record systems) and finalizes with detailed use case specific level (Digital Consumer Health Products and Laboratory results). It concludes with further development and its relation to the usage of AI in healthcare.

Key Words: Digital Consumer Health Products, Quality Criteria Framework, Quality Labelling.

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List of abbreviations / definitions

Acronym	Description
EHR	An **electronic health record** (**EHR**) is the systematized collection of patient and population electronically stored health information in a digital format.
EHR system	A collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes
Xt-EHR	Xt-EHR to enhance the cooperation among Member States regarding the interoperability and exchange of healthcare data, contribute to the preparation of the foundations for the improved primary use of electronic health data, the upcoming new regulation for the European Health Data Space, and empower individuals to control their health data.
XpanDH	Expanding Digital Health through a pan-European EHRxF-based Ecosystem
X-eHealth	European project on the EEHRxF
XShare:	XShare "expanding the EEHRxF to share and effectively use data in the EHDS" is European Union funded Project promoting the vision that "everyone can share their health data in EEHRxF with a click-of-a-button". To realize this vision, xShare will: a) demonstrate the xShare button across continuity of care, clinical research, and population health scenarios, b) build the European EHRxF Standards and Policy HUB sustainable by design, c) Explore feasibility of the xShare industry label indicating capability to work with EHRxF data.
ISO	International Organization for Standardization
EEHRxF	European Electronic Health Record Exchange Format
EHDS	European Health Data Space A health specific ecosystem comprised of rules, common standards and practices, infrastructures, and a governance framework for primary and secondary use of data
European EHRxF specifications	Synonym for the common specifications in Article 23 of the EHDS proposed regulation
HCP	Health Care Professional - an individual or organisation responsible for providing care
PII	Personally Identifiable Information
PGHD	Patient Generated Health Data - Medical data generated or provided by a patient
DCHP(s)	Digital Consumer Health Product(s)
SDO	Standards Development Organisation (e.g., CEN, ISO, HL7)

Executive summary

The main purpose of T2.3 is to identify the general technical requirements for quality labelling of Digital Consumer Health Products, considering also digital health tools, EHR systems (i.e. the component parts of the EHR which address the Consumer or assisted citizen) and corresponding data. A first version (i.e. Version 1 of this Deliverable) has been released and published in October 2023. Apart from further refining all topics and particularly the quality criteria, this second version of the deliverable details the quality criteria itself, to the extent possible, with respect to the interaction and interoperability requirements that adhere to or should be supported by the infrastructure prescribed by the EEHRxF.

This Deliverable has focused on reusing existing standards and frameworks in combination with the knowledge and structures created by previous European Commission projects such as Label2Enable[1], X-eHealth[2] DigitalHealthEurope[3], QUANTUM[4], ASSESS-DHT[5] and AIDAVA[6]. while also collaborating with Work Packages 5 “Growing Digital Health ecosystems” and 6 “Sustainability and Future Action”.” and linking with the upcoming Joint Action 09 and the recently awarded xShare project and other relevant projects started over the course of the development of XpanDH.

Using and extending the existing 82304-2 Technical Specification regarding quality and reliability of health and wellness apps, and their quality labelling process, this deliverable proposes a framework applicable to the wide range of Digital Consumer Health Products (DCHPs). By providing sufficient guidelines to be used in the actual assessment of DCHPs through the quality criteria listed, this widely applicable framework is also of use for more detailed use cases. As the actual data forms the foundation of the usefulness and mutual trust with respect to the exchange of data between DCHPs (interoperability), data quality also takes an important place in this Deliverable.

For means of feasibility, this Deliverable follows a three-layered approach starting by gradually exploring the application of quality labelling in terms of the definition of a quality criteria framework. The definition of the framework starts at a generic level (Digital Consumer Health Products in general), continues with the domain level (Digital Consumer Health Products and their interaction with Electronic Health Record systems) and concludes refining the framework on the basis of a more detailed use case (Digital Consumer Health Products showing Laboratory results). The findings could function as input for Work Package 4 which focusses on “Feasibility and Experimentation” by the use of pilots and demonstrators in actual working environments.

1 https://label2enable.eu/
2 https://www.x-ehealth.eu/
3 https://digitalhealtheurope.eu/

https://cordis.europa.eu/project/id/101137057
5 https://assess-dht.eu/
6 https://www.aidava.eu/

The Deliverable concludes with further developments on the quality labelling framework including its relevance for the increasing use of AI in healthcare.

1 Introduction

Background

In X-eHealth, a previous project financed under European Commission's Horizon 2020 funding, a recommendation has been drafted for the creation of a framework for the European Electronic Health Record Exchange Format and its role in facilitating development. The framework of X-eHealth included the Patient Summary, medical imaging, discharge letters, laboratory results and rare disease registries. The Commission Recommendation of 6.2.2019 on a European Electronic Health Record exchange format recommends further development of the European Electronic Health Record Exchange Framework (EEHRxF) by engagement of member states and stakeholders. The building blocks of the EEHRxF should be expanded upon by identifying and reviewing innovation and keep moving forward in the further development of the development of the long-term exchange of electronic health records.

In XpanDH, the framework shaped by X-eHealth will be expanded upon, among other objectives, by including the quality indicators to further strengthen its usage and the added value for health care informatics.

The purpose of T2.3 is to identify the technical requirements for quality labelling of Digital Consumer Health Products, considering also digital health tools, EHR systems (i.e. the component parts of the EHR which address the Consumer or assisted citizen) and corresponding data. A first version, i.e. Version 1 of this Deliverable, has been released and published in October 2023. Apart from further refining all topics and especially the quality criteria, this second version of the deliverable details the quality criteria itself, to the extent possible, with respect to the interaction and interoperability requirements, including data quality requirements, that adhere to or should be supported by the infrastructure prescribed by the EEHRxF. Obtaining and maintaining trust and confidence in the accuracy of the shared data is paramount for the long-term success of EEHRxF implementations.

The data should, as far as possible, adhere or should be supported by the infrastructure prescribed by the EEHRxF while adhering to the principles of the FAIR Guiding Principles for scientific data management and stewardship[7] meaning that data should be made *findable*, *accessible*, *interoperable,* and *reusable*.

To promote harmonization, interoperability, and objectivity of the results, it is beneficial to make use of the products of previous projects, existing standards/frameworks, or initiatives, even those with no specific role in health informatics. This includes input from Deliverables from previous projects financed by the European Commission, ongoing innovation projects and accepted international standards (CEN, ISO and HL7).

[7] https://www.nature.com/articles/sdata201618

Digital Consumer Health Products

In general, "Consumer Health" encompasses a broad range of direct-to-consumer, products, including over the counter, nutritional, personal care, and patient care products. Before the digitalization of Consumer Health Products, this implicitly meant non-prescription or "wellness" products. The addition of the term "Digital" brings into play, among others, "health and wellness apps", if not also "health software", and "health software product" [8].

In the EHDS regulation, references are made to "wellness apps" which, as described in the previous paragraph, results to be a category falling under the topic of Digital Consumer Health Products. Therefore, this definition will be used for means of understanding: "*Wellness application' means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data specifically for providing information on the health of individual persons, or the delivery of care for other purposes than the provision of healthcare.*"

While traditional (digital) health care products or systems are meant to be used by health care professionals, Digital Consumer Health Products (DCHPs) are aimed at the consumer or patient[2]. Using these products, patients can monitor their own health status to a certain extent, keep track of their progress of recovery, perform basic measurements and view test/lab results produced by health care professionals. This can be done, for example, via wearables such as smart watches, smartphone/desktop applications or web applications. The increasing use of such products by patients can address patient's needs without direct engagement with health care professionals thus lowering the workload for those health care professionals. However, the exponential growth in DCHPs will also increase the need for regulation and standardization to prevent misinformation, misdiagnosis, or actual harm. Due to the fact that these products are directly aimed at consumers, they are often not subject to most standards and regulations for medical products[3]. This stresses the need for quality labelling for Digital Consumer Health Products, especially that these products/services are likely to mature and solidify their position in the digital health care ecosystem.

Scope and Objectives

By identifying the relevant quality labelling and criteria, a significant step is set towards enhanced transparency concerning the quality and reliability of Consumer Health Products, EHR-systems, and Medical Devices. Quality labelling will allow consumers, patients, health care professionals and other relevant actors to make informed decisions concerning usage, recommendation and financial support based on accurate and trustworthy data.

In the XpanDH Grant Agreement, the title of the Deliverable and its description mention the full spectrum of both Consumer Health Products and EHR systems. However, to set the correct expectations for this Deliverable and its outcome, it is sensible to provide clear directions on its scope and objectives. Taking the set timelines and resources into consideration, it does not

[8] The definitions of these terms are, for the scope of this document, taken from CEN-ISO 82304-2 "Quality and reliability of health and wellness apps" and copied in Annex 3 for the convenience of the reader.

appear feasible to attempt to cover such entire spectrum in this task. Therefore, this task will provide guidance and handholds on a general level, making use of what is already there, such as CEN and ISO standards and projects such as Label2Enable and X-eHealth, and discuss more details based on a realistic use case. By focussing the efforts on a specific use case in the spectrum, the quality of the Deliverable will be as high as possible.

As already stated, T2.3 shall thus identify the technical requirements for quality labelling of digital consumer health products, considering also digital health tools, EHR systems (i.e. the component parts of the EHR which address the Consumer or assisted citizen) and corresponding data. This has been carried out in version 1 of the Deliverable D2.3 released in October 2023.

In this version 2 of the Deliverable, apart from further refining the identified quality criteria, the Deliverable itself and the criteria has been detailed, to the extent possible, with respect to the interaction and interoperability and data quality requirements that adhere to or should be supported by the infrastructure prescribed by the EEHRxF, having analysed a specific XpanDH use-case.

The results of the task have the objective of obtaining and maintaining trust and confidence in the accuracy of the shared data, which is paramount for the long-term success of EEHRxF implementations.

The realistic use case that has been used in version 2 of this Deliverable, as an example, comes from XpanDH work and regards the possible interaction between Consumer Health Products (e.g., apps) and EHR-systems. Due to the vast range of Consumer Health Apps and their (often less than) suboptimal integration with other systems, such as Electronic Health Record systems, the current level of interoperability and quality of the information exchanged is low. Therefore, this domain will be an excellent demonstrator of the potential when quality labelling could support in facilitating the exchange of information between those applications and systems.

On an even more detailed level, one of the subjects covered by the EEHRxF (for example laboratory data initially meant to be the final use case) could serve as future use case and provide enough room for expansion of the quality labelling criteria focusing not only on interoperability but security and robustness as well.

Relation with other Deliverables

Across the XpanDH project, T2.3 has made use of the products and Deliverables of Work Packages 5 “Growing Digital Health ecosystems” and 6 “Sustainability and Future Action” in order to create consistency across the project and its various Deliverables. The work described in this task has also been provided as input for Work Package 4 “Feasibility and Experimentation”, which will demonstrate its real-world applicability by possibly putting the suggestion into practice and starting pilots in the actual working field via the network of the consortium.

2 Existing standards and products

As described in the previous chapter, this task and Deliverable will try to make use of existing standards on quality labelling in the domain of health informatics, medical devices, and medical

software. By making use of established and validated standards, discussions concerning actual content of the standards will be limited to a minimum therefore making it possible to focus on the actual applicability and their benefits in terms of quality, interoperability, and robustness.

The following list is not exhaustive, and the task members have continuously looked for further input criteria.

Existing standards

2.1.1 CEN-ISO 82304-2 – Health software – Part 2: Health and wellness apps – Quality and reliability

Description

This technical specification[9] provides quality requirements for health and wellness apps and defines a health app quality label to visualize the quality and reliability of health apps. By doing so, all relevant individuals and organizations would be able to make informed decisions concerning the usage of the application based on transparent and understandable information. The overall objective was aimed to create a useful, globally applicable, trustworthy, and usable framework to assess health app quality. The 82304-2 standard lists an elaborate list of quality indicators and assesses the use and (scientific) basis of the app.

Quality requirements

ISO 82304-2 groups its quality requirements in five sections; one section on 'Product information' and four aspects of quality. The questions are listed in Annex 1. After testing with people with low health literacy, these quality criteria were identified:

1. Product information:
    - Basic information on operating systems support;
    - Name of the application;
    - Icons;
    - Used and supported languages;
    - Provided/available instructions;
    - Details on the manufacturer;
    - Representative and contact on behalf of the manufacturer.
2. Healthy and safe;
    - Health requirements:
    - Health risks:
    - Ethics:
    - Health benefit;
    - Societal benefit;
3. Easy to use
    - Accessibility;
    - Usability;

[9] https://www.iso.org/standard/78182.html

4. Secure data;
    - Privacy;
    - Security;
5. Robust build;
    - Technical robustness;
    - Interoperability.

Assessment and certification process

The final quality assessment framework includes 81 questions, 67 (83%) of which impact the scores of 4 overarching quality aspects. The scoring mechanism enables communication of the quality assessment results in a health app quality score and label, alongside a detailed report. Unstructured interviews with stakeholders revealed that evidence and third-party assessment are needed for health app uptake.

A strength of CEN-ISO/TS 82304-2's health app quality assessment framework is its third-party assessment of more than the evidence that is publicly available. Having a third-party assessment involves costs. Apart from the app manufacturer, the widespread adoption of the TS, or otherwise increasing the benefits for app manufacturers, would assist in tackling this issue. Alternatively, having the stakeholders that benefit most from the deployment of health apps pay or contribute seems a plausible solution.

The TS can also be used without third-party assessment. App manufacturers may use the TS to determine what should be addressed in the development of a particular app. Health care providers, guideline committees, and insurers may use it as a vocabulary to formulate the requirements for the inclusion of a specific type of app in care pathways, clinical guidelines, or care contracts. We expect that these requirements for adoption and more assessments with the TS will result in further fine-tuning of the evidence required and, in time, of the scoring mechanism. The quality requirement questions are also expected to evolve, as assessment frameworks are known to do. Practical experience, including the certification scheme being developed in Label2Enable, will evolve and inform the regular revision process of the TS as mandated by ISO.

To obtain the label for a specific health app, app manufacturers must provide supporting evidence for all the requirements they claim to be compliant with. This evidence will be assessed by contracted/licensed conformity bodies using the 82304-2 EU certification scheme that the EU H2020 Label2Enable project is currently developing. More on Label2Enable can be found in §2.2.2

The description of the study aimed to develop the 82304-2 TS, with relevant stakeholders, to obtain a useful, trustworthy, and usable health app quality assessment framework with the potential to become the preferred European and global framework can be found in [1].

Relevance for XpanDH

CEN-ISO TS 82304-2 is an elaborate technical specification that focuses on the functionality, benefits and consultation of health care professionals when developing and promoting the usage of the application.

CEN-ISO TS 82304-2 is extremely relevant for XpanDH also -and especially- regarding this Task 2.3 – Technical requirements for quality labelling of consumer health products. The TS, in fact,

provides a conformance assessment framework and quality label that has served as inspiration for -and that can be expanded/extended to cover- the assessment and labelling framework of DCHPs, considering also patient facing components of EHRs.

For more information on TS 82304-2 and its relevance for XpanDH see section 2.1.9.

2.1.2 ISO 13131 – Telehealth services – Quality planning guidelines

Description

Following preliminary work by experts from Canada and the Netherlands, developed further with input from Australia, ISO/TC 215 published ISO/TS 13131:2014 - Health informatics -- Telehealth services -- Quality planning guidelines. Following systematic review, this was updated and published as a full international standard, ISO 13131:2021[10] - Health informatics -- Telehealth services -- Quality planning guidelines. In 2022, this updated standard was directly adopted by CEN and in Australia and is used in many other countries.

ISO 13131 defines a telehealth service as a healthcare activity supported at a distance by information and communication technology service(s). Telehealth services have been referred to in different jurisdictions as virtual care, telecare, and telemedicine.

ISO 13131 is a generic, risk-based standard which provides health provider organizations and healthcare professionals with quality characteristics and risk management processes needed to realize desired quality in their delivery of telehealth services. Examples of essential quality procedures, objectives and use cases are also given.

Relevance for XpanDH

The quality objectives listed in ISO 13131 can be used as an addition to the criteria proposed in CEN-ISO 82304-2 as described in the previous section. This will especially be relevant in the self-assessment which will be the mechanism for certification. Furthermore, this methodology could be used to monitor the effectiveness of implementation during the pilots conducted in XpanDH's Work Package 5.

Besides a description of the quality criteria, ISO13131 also describes a methodology to evaluate and further develop the quality criteria to improve their applicability and usefulness. This is done by following a PDCA (Plan, Do, Check, Act) cycle which also nicely fits in the iterative collaborative approach to come an efficient and useful quality labelling.

The standard also describes quality plans and its relation to risk management, differentiating three elements aspects which could be included in the DCHP-framework for quality labelling:

1. Quality characteristics – describing which quality characteristics are affected if a risk occurs.
2. Quality objectives – what is the intended purpose of including the quality criteria?
3. Quality procedures – which procedures are in place to achieve the objectives?

[10] https://www.iso.org/standard/75962.html

2.1.3 ISO 10377 – Consumer product safety – Guidelines for suppliers

Description

This standard[11] provides guidelines for suppliers to assess and manage the safety of their products which includes documentation of performed risk assessments and measures for mitigation. This standard is written in generic terms without being specifically designed for health informatics.

Relevance for XpanDH

Even though this standard is not specifically designed for health informatics, ISO 10377 provides interesting input for generic consumer product safety which can be applied to this Work Package of Quality Labelling. It provides the producing/manufacturing organization with a framework to improve the processes concerning consumer product safety including a PDCA-methodology as referenced as well in ISO13131. Furthermore, it addresses the possibility of potential foreseeable or unforeseeable misuse of the product. With the abundance of personal identifiable information, the potential misuse of Digital Consumer Health Products can certainly be considered a risk. Therefore, the risk-based approach, as referred to in ISO 13131, would be a fitting addition to address this risk.

2.1.4 ISO 13485 – Quality Management systems – Requirements for regulatory purposes

Description

ISO 13485[12] is an internationally recognised standard on the requirements for a quality management system with a focus on medical devices. A quality management system is a set of procedures, rules and policies that support an organization in attaining its goals. In the situation of medical devices, or in our situation DCHPs, providing health benefits or support for health care related processes in a trustworthy sense. The standard describes the procedures to come to a quality system which aims to monitor and uphold the quality of the medical device from its initial design, development and throughout its full lifecycle including decommissioning. The quality management system should focus on the continuous improvement of the product or service to best serve the interest of the various involved stakeholders (e.g., patients, health care professionals, manufacturers). As mentioned before in this document, the PDCA-cycle could be used for such purposes which is also the case for ISO13485.

This standard focuses on the requirements for quality management systems set for regulatory purposes. Due to the fact the regulations differ from country to country, the standard is providing the user with the possibility to include or exclude certain sections of the quality

11 https://www.iso.org/standard/45967.html
1212 https://www.iso.org/standard/59752.html

management system. By doing so, the standard is widely applicable regardless of the size of the organization.

Relevance for XpanDH

While other standards mentioned in this document focus on the medical device or DCHP itself, the specific attention provided for the quality management system and the aspect of regulatory purposes, makes this standard and interesting addition to the foundation laid out by ISO 82304-2. Including these aspects in the framework for DCHP will broaden and further strengthen the framework.

2.1.5 ISO 27269:2021 – International Patient Summary

Description

ISO 27269:2021 – International Patient Summary is providing a non-exhaustive overview of the data elements and associated business rules relevant for the content the international patient summary (IPS). The IPS provides, as the name suggests, a summarized overview of patient's health care related information for planned or unplanned care. By providing the most relevant information in a standardized format which is understandable for health care professionals even across borders, planned and unplanned care can be accommodated for timely.

ISO 27269:2021 lists both required data blocks as well as optional data blocks containing additional information. The required data elements are the following:

1 Patient Attributes;
2 Allergies and Tolerances;
3 Medication Summary;
4 Problems;
5 Provenance;
6 Cross Border.

These required data blocks can be expanded upon with additional information; Advance Directives, Functional Status, History of Pregnancy, History of Past Problems, Plan of Care, Social History or Vital Signs.

A patient summary will be considered an IPS document when it includes a number of specific data blocks:

1 Healthcare Provider (Attribute Collection);
2 Patient's Address Book (Attribute Collection);
3 History of Procedures;
4 Immunizations;
5 Medical Devices;
6 Results.

Relevance for XpanDH

The IPS standard (ISO 27269:2021) provides several handholds that might be interesting to take into consideration during the development of a quality labelling framework for Digital Consumer Health Products. Firstly, it lists several data blocks that can be considered relevant when

exchanging health care related information so adherence to the standard might result in a higher level of interoperability. Ensuring completeness of medical data including some of the required meta data will strengthen its overall value and its reusability by other parties in the healthcare system. Furthermore, the IPS contains a specific optional section on Medical Devices "*implanted in the patient and external medical devices and equipment that the health status depends on*". Looking at the increasing number of Digital Consumer Health Products such as wearables, it could be argued that these should also be taken into consideration.

2.1.6 EN ISO 23903 Health informatics - Interoperability and integration reference architecture - Model and framework

Description

This standard enables the advancement of interoperability from the data/information exchange paradigm to knowledge sharing at decreasing level of abstraction, starting at IT concept level (semantic coordination) through business domain concept level (agreed service function level cooperation), domain level (cross-domain cooperation) up to individual context (skills-based end-user collaboration).

The document defines a model and framework for a harmonized representation of existing or intended systems with a specific focus on ICT-supported business systems. The Interoperability and Integration Reference Architecture supports ontology harmonization or knowledge harmonization to enable interoperability between, and integration of, systems, standards, and solutions at any level of complexity without the demand for continuously adapting/revising those specifications.

The approach can be used for analysing, designing, integrating, and running any type of system.

For realizing advanced interoperability, flexible, scalable, business-controlled, adaptive, knowledge-based, intelligent health and social ecosystems need to follow a systems-oriented, architecture-centric, ontology-based, and policy-driven approach.

Relevance for XpanDH[13]

Interoperability and semantic knowledge are of paramount importance for the XpanDH project. Interoperability, in particular, has been highlighted as an extremely important category of the Quality Criteria Framework defined in Tak 2.3.

The European XpanDH project promises, in fact, crucial contributions the European Health Data Space by developing, experimenting, and adopting the EEHRxF. The digital health ecosystem integrates and interrelates actors from different domains using their own languages and ontologies based on their specific contexts, objectives, education, and skills, frequently using different terms and data for the same concept and vice versa (the same data and terms for different concepts). Therefore, the correctness of integration and interoperability is less decidable when the related representation style is more restricted to a special structure and therefore having less generative power (see figure below). For multi-disciplinary, context-

[13] Reference for the discussion can be found in [5].

sensitive domains, we must advance from the data focus to the knowledge focus, not just exchanging growing amounts of data but knowledge. Based on a Pan-European Health Knowledge Space, we can then correctly exchange any use-case specific data instances for establishing the intended xHealth (eHealth, dHealth, …) systems.

Meeting the Challenge

For meeting this challenge, multi-disciplinary interoperability and integration solutions including life sciences, natural sciences, technology, legal and social sciences, etc., require an architecture-centric systems approach to the domains of discourse represented by their ontologies, so enabling the formalization of systems representation and integration including ontology mapping, supported by appropriate tools.

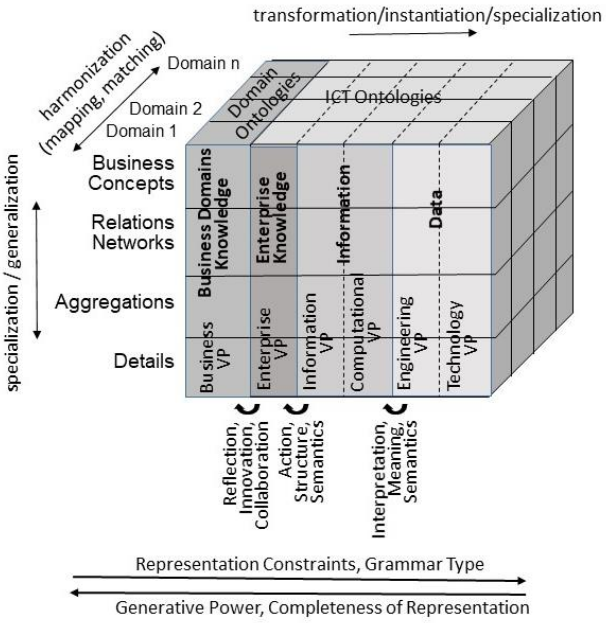
Solution

Flexible, scalable, business-controlled, adaptive, knowledge-based, intelligent systems must follow a systems-oriented, architecture-centric, ontology-based, and policy-driven approach. Such approach is standardized in ISO 23903:2021 Health informatics – Interoperability and Integration Reference Architecture, which is deployed in a series of ISO, IEC, CEN, OMG, IEEE and HL7 standards.

With respect to the Quality Criteria Framework, this translates into adding criteria to guarantee that when interoperability is involved, the criteria includes that where interoperability is knowledge, a systems-oriented, architecture-centric, ontology-based, and policy-driven approach is followed.

Practical Deployment

While the following approach is not relevant for the definition of the Quality Criteria Framework, it is useful for the XpanDH Consortium as a whole to highlight way to proceed in using the 23903 standard to achieve (semantic) interoperability. The first thing to do is modelling the components of the business view of the ecosystem and their relations for all domains/sub-domains involved in the considered use case, represented using the domains ontologies. Thereafter, we must transform the resulting model into all the other viewpoints (Enterprise, Information, Computational, Engineering and finally Technology Views) according to the software development process standardized in ISO/IEC 10746 Reference Model Open Distributed Processing, where the latter two views are represented through data. That way, we receive the use-case-specific representation of the corresponding data and their relations to be used.



2.1.7 Quality of data - The UNI CEI ISO/IEC 25000:2023 series

2.1.7.1 Quality and context

The context of the quality of systems and data cannot ignore the quality of the organization that generates, uses, and governs them. The goal is the pursuit of complete quality that connects the software, data, and applied services to the real environment. The pursuit of product quality in general and of data in particular is achieved not only by adhering to the respective quality models and frameworks, but also by considering the necessary presence of an organization capable of harmonizing the various common and interacting aspects of laws and technical standards.

2.1.7.2 The UNI CEI ISO/IEC 25000:2023 series

Developed within ISO/IEC SC7 "Software Engineering", it takes all these aspects into account. The series consists of various technical standards, among which the most used currently concern quality aspects relating to:

- Software (25010)
- Data (25012)
- Quality in use (25019)
- Evaluation (25040)

Experts are extending some of the 25000 series standards under ISO/IEC SC42 "Artificial Intelligence" to software issues (including for example algorithms and neural networks), data and datasets (in particular for Machine Learning) and to meet issues related to the evaluation of the quality achieved.

If we consider the main aspects of system quality, following the setting of the ISO/IEC 25000:2023 series of standards, it is possible that we find ourselves needing to simultaneously

coordinate the evolutions of software products, data, and IT services, while also ensuring the continuity of "quality in use" that must be guaranteed in the real environment in the post-sales phases.

Data quality model

With respect to data quality, the following characteristics are defined in ISO/IEC 25012 and 25024:

1. - Inherent quality
2. Accuracy (reflects reality)
3. Actuality
4. Completeness
5. Consistency between data and sources
6. Credibility (also of sources and provenance)
7. System-dependent quality
8. Availability Traceability
9. Portability
10. Recoverability (backup)
11. Both inherent and system-dependent quality
12. Accessibility
13. Understandability
14. Confidentiality
15. Compliant with laws (e.g. GDPR)
16. Efficiency

The 25012 standard, in the integrated vision of the 25000 series, is complementary to the ISO/IEC 25010 standard (relating to software), which from 20023 presents the new "Safety" feature of particular interest for the world of health, maintaining the previous characteristics regarding reliability, safety, efficiency, etc.

"Telescopic" data quality - Knowledge base/Semantics

The "telescopic" quality of data permeates social and territorial boundaries. The territorial localization of epidemic outbreaks is useful, for example, to limit emergency phenomena and provide targeted interventions. Until now, only few regions in EU countries have statistically monitored the territory with this telescopic approach, favouring the control and timely availability of vaccines and treatments.

To facilitate the comprehensibility of data and their use in shared and usable data spaces, tools are needed to understand the data itself and its reuse: knowledge bases to enable semantic interoperability between systems. This concept is also present in the 23903 standard.

In healthcare, traditionally, everything was based on paper: department records, prescriptions, reports, notes from the family doctor to help his memory, etc. On paper, the data is interpreted by a healthcare professional, based on the context. With digital transformation, data has become "alive" and offers the opportunity for new valuable services, to support assistance processes, managerial/executive management, and research. To handle the underlying concepts, these services rely on an autonomous discipline, semantics, complementary to computer science.

Quality as a strategic objective, both in general and especially concerning data

Producing and managing quality concerns the use of resources in the different contexts in which the objectives are placed: strategies, governance, management, process, and quality of the final product, always taking into account the needs of end users, as well as of the designers. In other words, to obtain (general) quality it is necessary to address different aspects, with the final objective of obtaining quality data which is of paramount importance for all that concerns the safety and treatment of patient.

Existing products and other projects

2.1.8 X-eHealth - Exchanging Electronic Health Records

Description

During the European Commission's innovation project X-eHealth, a framework was developed meant for (international) exchange of health data. This common framework covered medical imaging, discharge letters, laboratory results and rare diseases. Furthermore, the framework was used to facilitate data exchange between health entities across EU Member States and individual patients. This resulted into the European Electronic Health Record Exchange Format (EEHRxF) which laid the foundation for future EU projects and further innovation.

As proposed by X-eHealth, the role of the EEHRxF is to provide clinical data to patients, healthcare professionals and health institutions with improved quality, safety and efficiency. Assuring consistent data, often exchanged as clinical document, from the original system to any end-user consumer system, at the local, national and international level. One of the key aspects of the EEHRxF and its framework is the adherence to FAIR principles; by doing so data would be reusable for primary and for secondary use or for the national or European Health data space.

Relevance for XpanDH

Besides the fact that the X-eHealth has laid the foundation for the current version of the European Electronic Health Record Exchange Format, a number of specific topics from the various Deliverables of that project could be of great use for this specific Deliverable. By making use of the methodologies used in X-eHealth and the knowledge obtained via that project, the quality labelling can be structured, piloted, and implemented as effective as possible. In X-eHealth, interoperability (IOP) indicators were used to assess the degree of the interoperability of EHRs in Europa. A similar approach could be used for the implementation and pilots conducted in subsequent work packages to objectively measure the success of the implementation.

Furthermore, one of the X-eHealth deliverables stresses the need for balanced iterative approach for means of implementation finding middle-ground between a top-down and a bottom-up approach. This is meant to ensure speed of implementation and a right fit with all various players present in the health ecosystem. This requires good cooperation with both internal as well as external stakeholders. Such cooperation is most feasible, if there is enough guidance from (international) governing bodies while also leaving enough availability for the actual working field to contribute and interpret for local needs and use cases. On a more specific

level, the use case of laboratory results in X-eHealth provides a nice fit to the proposed third (detailed) level of implementation for this XpanDH Deliverable.

2.1.9 Label2Enable

Description:

The EU funded Label2Enable project; (101057522, May 2022-May 2024), currently in progress, is meant to promote the adoption of CEN-ISO/TS 82304-2 and its quality label for health and wellness apps[14]. By doing so Label2Enable aims to increase the quality level of care and create an environment for innovative, sustainable, and competitive care in the Digital Single Market. Label2Enable provides guidelines for the implementation of CEN-ISO/TS 82304-2 and the tools for assessments organisations to validate the implementation of the standards. The project Label2Enable is in fact, working on and successfully releasing a conformity assessment scheme based on the 82304-2 Quality Criteria Framework. The project includes assessment organisations that are assessing 24 apps to validate the resulting assessment conformity scheme but also to verify uniformity among the resulting assessments. Furthermore, the project provided use cases to stimulate adoption and provide stepping stones for research to lower the threshold as much as possible.

The project consists of three major pillars: Trust, Use and Adoption.

- **Trust**: the L2E Consortium will co-create and test the CEN-ISO/TS 82304-2 handbook for accredited health app assessment organizations, in ISO terminology resulting in a certification scheme according to ISO/IEC 17065. The Consortium will ensure that the handbook contains appropriate accepted assessment methodologies, aligns with EU legislation and values, produces the same consistent results regardless of the assessment organization involved, and works as well for app manufacturers who wish to carry out self-assessment. The Consortium will secure maintenance of the handbook after the project and enable accreditation of assessment organizations, while also investigating if legislation for the label is sensible and who is to pay for the assessment.
- **Use**: L2E Consortium partners will, in this pillar, investigate who consumers trust most to give them recommendations on health apps and what will also help people with low health literacy to use the quality label. They will find out what healthcare professionals need in the detailed health app quality report to be able to recommend health apps and how to display the label effectively in app stores, app libraries and trusted sources.
- **Adoption**: the L2E Consortium promotes CEN-ISO/TS 82304-2 involving stakeholders through various channels. With ''use stories'' of pilots with CEN-ISO/TS 82304-2 in Italy, Catalonia, and the Netherlands and potentially more countries or regions, the Consortium will provide insights on how to implement the assessment framework effectively. Finally, they will explore with health insurers and health technology assessment bodies how the ISO assessment framework can help in decision-making on reimbursement of health apps.

[14] Label2Enable uses the term “Health apps” to refer to both health and wellness apps. In this section “health apps” shall thus be used with same intention.

Relevance for XpanDH

The Label2Enable Project is extremely relevant for XpanDH also and especially regarding Task 2.3 – Technical requirements for quality labelling of consumer health products. The Label2Enable project is based on the CEN/ISO TS 82304-2 "Quality and reliability of health and wellness apps", providing a conformance assessment framework and quality label that can be expanded/extended to cover Digital Health Consumer Products (DCHPs), considering also patient facing components of EHRs.

It is also worth mentioning that during the assessment of apps, it has become clear to the L2E project officials and assessors that very often health and wellness apps are part of telehealth and/or teleassistance systems, in any case platforms. Thus, in some of those cases the project has faced the option of assessing more than the app itself. While the assessment of the platforms has not been actually performed, the assessment WP members have concerted that the framework can be extended and used for a broader scope.

Approval and endorsement by Lable2Enable

Due to the relevance of the Label2Enable Project and with respect to the approach that has been followed, since the start of XpanDH, it has been deemed important that representatives of that project feel aligned with the efforts on quality labelling of Digital Consumer Products in this XpanDH Deliverable. In fact, the 82304-2 health app quality label was designed to be expanded over time to a larger scope of DCHPs, similar to the EU energy label being targeted to a larger scope of household appliances and products. Label2Enable has been thus involved and provided very important feedback on the quality labelling framework. The Label2Enable project leader was one of the active participants in the organized workshop as well. She indicated her endorsement of the work done within the scope of this Deliverable and supports its further development in subsequent standardisation projects carried out in CEN and ISO, for example extending the scope of 82304-2 to cover DCHPs, and/or in further EU projects such as xShare and Xt-EHR.

2.1.10 DigitalHealthEurope

Introduction

DigitalHealthEurope[15] is an innovation project financed under the European Commission focussing on the exchange of data and the creation of the Digital Single Market Strategy in line with the European Commission's 2018 Communication on this topic. Its main objective is the development of digital solutions for person-centred integrated care and aims to achieve this by pursuing the following goals:

- Citizen's secure access to and sharing of health data across borders;
- Better data to advance research, disease prevention and personalised health and care;
- Digital tools for citizen empowerment and person-centred care.

[15] https://digitalhealtheurope.eu/

Furthermore, DigitalHealthEurope will facilitate the creation of a shared platform or multi-stakeholder communities to address the three priorities mentioned above.

Relevance for XpanDH

One other topic that is part of DigitalHealthEurope is "Digital Health Standards" which is a joint communication effort between Empirica and the European Institute for Innovation through Health Data. This collaboration actively promotes standards by providing educational information on health data standards. Standards such 82304-2 could potentially be promoted via this joint communication effort.

Solely communicating the existence of standards and their use via educational information, only covers a section of the potential for collaboration. In order to properly engage the full ecosystem of relevant organizations and stakeholders, making use of an existing platform for communication and collaboration (e.g., the platform of DigitalHealthEurope) would be sensible. This also applies to the development, performing tests in the form of pilots and actual implementation. As mentioned before, the (constant) engagement of the organizations and stakeholders that are occupied with the data/information in real world settings is important for successful implementation and further development.

2.1.11 Extended EHR@European Health Data Space

Introduction

Joint Action 09 (JA09) or Extended EHR@European Health Data Space is another European Commission project focussing on the further development of the exchange of Electronic Health Records and the European Health Data Space. The project is still in its initial phase but due to its relevance to the topic of the XpanDH project its development will be of interest.

Relevance for XpanDH

One of the work packages of this project will be dedicated fully to the certification and labelling framework for Electronic Health Records and its corresponding data. Therefore, a joint effort of the XpanDH project and the Extended EHR@European Data Space will be beneficial. The expected start date of the JA09 will be autumn 2023, therefore a part of the XpanDH project will run parallel. In order to align the work that is being done in both projects, communication and collaboration where possible will be undertaken by involved organizations. Providing the established framework, as discussed below, to JA09 could be an excellent way to further increase the support for the DCHP quality labelling framework and its added value in creating consistency and standardization.

2.1.12 xShare

Introduction

The xShare project will commence at the start of 2024 and can be considered a follow-up project based on the results of X-eHealth and the XpanDH projects. The xShare project will make use of

the foundation laid by the other projects and aims to further specify, among others, the required infrastructure, structures, governance and used standards. By providing handholds for the community, consisting both of governing bodies as well as commercial organizations, to use the threshold for implementation and further involvement will be lowered as much as possible.

These handholds consist of business case and requirements registries, a single point of information on applicable standards, a sandbox for testing and information and structures for communities of experts. During this project, the actual users will be actively involved to make sure that the developments are actually in line with real-life expectations and add value to the safety of patients, increase efficiency and the exchange of data for secondary (e.g., research) purposes.

Just like the Extended EHR@European Health Data Space (JA09) mentioned above, this project will start after the XpanDH project is well under way. Therefore, instead of XpanDH making use of the work that has already been carried out, this project will provide input for those two projects. The intended direction of JA09 and xShare, will help shape decisions and directions for the XpanDH project.

2.1.13 QUANTUM

Introduction

The Horizon Europe QUANTUM project, started January 1st, 2024, and will focus the coming 2.5 years on the creation of a label for secondary use of data. It is intended that this label could be easily adopted in the HealthData@EU project. QUANTUM's overall objective is to provide guidance on the health data quality and utility label for the secondary use of health data in the EU. This common label system used within Europe will allow its use for scientific and health innovation purposes, enabling researchers to use data with a notion of quality and utility ensuring that their research and innovations are effective and provide value to society.

Relevance for XpanDH:

The interconnection between XpanDH and QUANTUM is critical, not only because they complement each other's focus areas – XpanDH on project quality and QUANTUM on data quality – but also due to the integral role that high-quality data plays in enhancing the efficacy and reliability of digital consumer health products. High-quality data underpinning these products ensures more accurate health insights and better patient outcomes.

By connecting between both projects, XpanDH and QUANTUM can foster a culture of continuous improvement and innovation in the health technology sector. This synergy will ultimately facilitate the creation of more robust and effective digital health solutions that are rooted in trustworthy data, thereby contributing to the advancement of global health standards and patient care.

To foster cooperation and ensure the longevity of the results of this Deliverable, communication has been established between the two projects.

2.1.14 ASSESS-DHT

Introduction

ASSESS-DHT aims to consolidate methods and tools for approval of innovative Digital Health Technology (DHT) and develop a generic assessment framework in line with the EHDS proposal. A generic assessment framework will foster a coherent digital single market giving patients, citizens, healthcare providers and health systems access to a large Pan-European innovative market of DHTs. It will also give the industry the possibility to scaling up within Europe as its marketplace. The project consists of four pillars further detailing the work: 1) Consolidation and Preparation, 2) Toolkit Development, 3) Testing and Validation and 4) Uptake and sustainability.

The first pillar will consolidate and build on existing assessment methodologies starting with a taxonomy and mapping of the existing and future DHTs. A gap analysis between the frameworks and methods and the scientific evolutions and assessment needed for different kinds of DHTs will provide criteria sets for the different use-cases (telehealth, digital health applications, AI based digital health applications and AI based tech used in radiology). The criteria shall cover data protection, cybersecurity, data quality, data bias and metadata labelling and shall assess their compliance with EHDS, GDPR, AI ethics and regulation, MDR, IVDR and EU act. The toolkit development pillar will deliver a general methodological framework and standardised approach for the assessment of DHT. Tailored to the different families of DHT the framework will also take into account the different stages of the lifecycle. Testing and validation are the third pillar, testing the robustness of the developed methodologies on the said use-cases. The final pillar focusses on the wide stakeholder's agreement. The stakeholders and experts from industry, policy makers, regulators, clinical experts, patients, and citizen representatives continuously will ensure throughout the project that the standardised framework cover their concerns and needs. The final assessment framework for DHT, including the criteria, pathways, flowcharts, accompanying guides and tools for HTA assessors and DHT developers will be hosted in an online repository.

Relevance for XpanDH:

Because ASSESS-DHT is still starting up, its products will probably not be used in the XpanDH project. However, the Quality Labelling Framework proposed in this Deliverable could be used as input for the generic framework. By doing so, the Quality Labelling Framework could be integrated in a sustainable fashion. By doing so, the framework and its criteria will not be a standalone topic and more easily integrated in current assessment and validation processes.

2.1.15 AIDAVA - AI powered Data Curation & Publishing Virtual Assistant

Description

AIDAVA aims to deliver a universal semantic representation of an interoperable and reusable patient longitudinal health record that is curated from multiple heterogeneous data sources and that can be reused for multiple purpose, by the patients and their treating physicians in clinical care or shared – with the consent of the patient – for clinical research. To ensure the data's

reliability and insightfulness, AIDAVA developed a data quality framework employing robust data quality instruments, underpinning the quality of the health records. These instruments encompass:

- Data quality dimensions;
- Instruments of data quality (e.g., data lifecycle, metadata, data quality checks, and data quality label);
- Objectives of data quality;
- Cost of non-quality.

By upholding these specific data quality instruments, AIDAVA ensures that the resulting longitudinal health record is both trustworthy and insightful, thereby enhancing its usability and impact in clinical settings and research activities.

Relevance for XpanDH

Within the AIDAVA project, the Data Quality Checks and Data Quality Label are crafted to align with specific use cases, ensuring relevance and direct applicability. XpanDH enhances this approach by focusing on the development mechanisms and categorization of these checks and labels, as detailed in Deliverable 4.6 of the project. This analysis not only examines the methodologies employed to assess and improve data quality but also to refine these frameworks for broader application across diverse health data systems.

The strategy around the Data Quality Label in AIDAVA is particularly innovative. It goes beyond simplifying complex quality metrics into easily interpretable visuals. It highlights the continuous enhancements made at each phase of the data lifecycle. This visual articulation of data quality fosters transparent communication among all stakeholders and support informed decision-making.

From the XpanDH standpoint, we focussed on the Data Quality Checks and the Data Quality Labels proposed in Deliverable 4.6 of the project to extend the Quality Framework with Data Quality Criteria.

3 Proposed framework for quality labelling of DCHPs

Approach

As described in section 2.1.1, paragraph “Relevance for XpanDH”, the framework described in CEN-ISO TS 82304-2 “Quality and reliability of apps” provides a solid foundation to build the quality criteria upon.

This approach is based on the following considerations:

1. CEN-ISO TS 82304-2 “Quality and reliability of apps” has already been used as basis and foundation/inspiration for the same purpose -and in the same way- in the Telehealth

domain[16], proving the fact that such framework's scope can be extended to cover a broader range of digital products.

2. According to the common understanding of Digital Consumer Health Products described at the beginning of this deliverable, health and wellness apps fall under such definition, consequently the task members have verified the applicability of the framework to DCHPs and actually reused it this Deliverable.
3. As mentioned in section 2.2.2, the Label2Enable project, while assessing apps according to the 82304-2 conformity assessment scheme defined within such project, has found itself facing the fact that health and wellness apps are part of platforms, like Telehealth platforms. The assessors of the relevant WP of the project have thus faced the relevant question of assessing the complete platforms. While that would have been out of the scope of the L2E project, it has become clear that the framework itself can be extended used to cove a broader scope.

The proposed framework will also provide attention to the actual usage of the Digital Consumer Health Products and its benefits. The assessment and corresponding audit and certification will thus not merely be a technical exercise. Including this aspect of quality labelling is also done in "ISO 13131:2021 Health informatics - Telehealth services - Quality planning guidelines".

Due to the vast range of products and services that can be considered Digital Consumer Health Products, it is necessary to include sufficient handholds for usage. Otherwise, there would be a risk that the generic framework covering the entire range of DCHP is not clear or accurate enough. Therefore, it was deemed useful to include corresponding notes to indicate the evidence required per section of the framework. For example, for generic (factual) information such as contact details of the supplier and the supported operating systems, plain text should suffice. However, when discussing the potential risks associated with the development and usage of the DCHP, official risk analysis reports might be requested. It should be clear that this framework should not re-evaluate previously performed risk analysis, rather document them as evidence and quality criteria. The assessment through the framework, in other words, should just validate the fact that the risk analysis has been performed and has been based on recognised frameworks and/or methodologies.

Optionally, a 'notes' field could be included to elaborate upon the criteria, its fulfilment, and the provided evidence. This can be done for two distinct reasons; 1) the organizations that carries out the assessment will be provided with the opportunity to provide additional information and 2) to provide insights in the train of thought followed when carrying out the assessment. While the first is specifically useful for those who's DHCP is being assessed, the latter can be used to further improve the framework during the pilot stage.

[16] In Mission 6, Component 2, Line of intervention 1.3.2, sub intervention 1.3.2.4 of the National Recovery and Resilience Plan, the Italian MoH is responsible for the construction and deployment of a national platform capable of promoting the culture and the spread of use of telemedicine, guaranteeing the governance of services, as well as validating and exhibiting telemedicine solutions in line with national standards. Such responsibility includes the currently ongoing development of a Showcase/Publication catalogue of validated telemedicine solutions. The more mature solutions are identified through dedicated assessment using well-identified quality criteria, taken and extended from by CEN-ISO TS 82304-2 Quality and reliability of health and wellness apps.

In addition to the foundation laid by CEN-ISO TS 82304-2, components from ISO 13131 have been also included from an early stage to further elaborate and strengthen the framework. One of the topics ISO13131 addresses, is transparency in terms of information/documentation provided. This documentation covers the intended use and scope of the Telehealth services (or in our framework; the full range of Digital Consumer Health Products). This description also includes the actors responsible for (any part of) the services including other healthcare organizations, supporting organizations, manufacturers, suppliers, and other healthcare actors such as care recipients, carers, and informal caregivers.

Having quality criteria in place and monitoring those, is not the end of the implementation of a framework. It is important that such a framework will be improved upon and will be evaluated regularly. ISO13131 calls for an evaluation of the quality criteria following the PDCA (Plan – Do – Check – Act) cycle. This methodology should have a place in the quality criteria in the framework; how does the organization aim to keep evaluating, adjusting, and improving the quality criteria in order to remain at an adequate level for its purpose and respond changes in functionality, user-feedback and legislation.

Once the basic foundation was laid out using 82304-2 and 13131, the Quality Criteria Framework has been expanded using many other standards, products, and EU projects as described in this document.

3.1.1 Validation workshop

In order to progress from the initial version of the quality labelling framework towards and more mature version that actually be operationalized, a validation workshop was organized which included experts from within the consortium as well as experts from other related projects (Label2Enable). The workshop provided an interactive setting to allow participants to provide feedback in a structured manner based around the following questions:

1. Looking at the current version, which components are missing or could be improved?
2. ISO82304-2 only covers software. However, the hardware component might also be of interest looking at the full scope of DCHP;
3. What is needed to operationalize the framework?
4. How can we integrate the framework in existing structures and processes?
5. What actions are necessary to put the framework into practice?

The workshop has led to a (partial) validation of the framework and provided handholds for further development and things to take into consideration relevant for operationalization. Some key takeaways from this workshop were:

- Clear link to the EHDS regulation and the definition of Wellness apps;
- Suggestion to include a section on hardware components;
- Relationship with the European Electronic Health Record exchange Format;
- Scope of the quality labelling framework in relation to EHR-systems;
- Further refinement of the individual quality aspects of the framework by an in-depth review.

3.1.2 Collaboration with the Label2Enable project

As the Label2Enable concerns itself with a labelling framework for health and wellness apps, a representative of this project has been asked for feedback on the quality labelling framework developed in this Deliverable. Furthermore, she attended the validation workshop described above. Among the outcomes of the workshop, having adopted the 82304-2 rationale and overall approach, the L2E project leader and personnel provided further input and refinement to the quality criteria framework for DCHPs. Such suggestions are included in the new version of the quality criteria described in Annex 2.

Among the results of such collaboration is the concept of transmitting the DCHP quality framework criteria as input to the CEN-ISO standardisation development organisations (SDOs) so that the framework can become a fully-fledged standard or technical specification and be maintained by the SDOs. The recommended modality, resulting from this Task 2.3, would be to extend the scope of the 82304-2 technical specification on the quality and reliability of health and wellness apps to cover -also in terms of labelling- what this Deliverable has been put forward in terms of a quality framework for DCHPs.

Characteristics of the quality criteria framework

3.1.3 Rationale

The rationale followed for the general quality criteria framework for DCHPs, as described in the "Approach" section, draws inspiration from CEN-ISO 82304-2 Quality and reliability of health and wellness apps and from the activities carried out in the Label2Enable project. However, the framework criteria and questions refer to DCHPs, thus –to a certain extent- can be seen as an expansion of the scope of TS 82304-2 to cover also DCHPs.

The timeline for the XpanDH Task 2.3, however, does not allow to reach the same level of detail or completeness of the Technical Specification nor the Label2Enable assessment Handbook.

The full general quality criteria can be found in Annex 2 – "Quality requirement questions for DCHPs". In the following sub-sections, we provide some insight on the quality criteria's structure and organisation.

3.1.4 Quality requirements

The quality requirement questions, as in –and for uniformity with- CEN-ISO TS 82304-2, grouped under seven sections, starting with **1.** '***Product information***' and other six aspects of quality:

2. ***Healthy and safe;***
3. ***Easy to use;***
4. ***Secure data;***
5. ***Robust build***
6. ***Continuous improvement***

The fifth and sixth item have been added after analysis of other standards/frameworks and new data quality criteria have been added in the "Robust Build" section. For each, these quality criteria have been identified:

1. Product information:

1.1 Product

- Basic information on operating systems support;
- Name of the application;
- Icons;
- Used and supported languages;
- Provided/available instructions;

1.2 Manufacturer DCHP

- Details on the manufacturer;
- Representative and contact on behalf of the manufacturer;

1.3 Transparency and accountability

- Description of the DCHP;
- Exchange of information;
- Actors involved;
- Healthcare processes involved.

2. Healthy and safe;

2.1 Health Requirements

- Intended users;
- Intended uses;
- Age restrictions;
- Which health issues are involved?
- Health professionals involved?
- Peer-reviewed literature?

2.2 Health risks

- Analyses of risks;
- Measures in place;
- Residual risks;
- Are users made aware of risks?
- Processes in place

2.3 Ethics

- Ethical challenges;
- Approval by ethics board or experts?

2.4 Health benefit

- Description and evidence of benefits;
- Awareness for users of benefits, ads, health information, forms of funding, and costs?

2.5 Societal benefit

- Description and evidence of societal benefits;
- Peer reviews available?

3. Easy to use

3.1 Accessibility

- WCAG compliance and eventual description;
- Age appropriateness

3.2 Usability

- Description and evidence of data-driven design based on understanding of users;
- Involvement of users?
- Measures to avoid user errors;
- Description and usage of product information;

4. Secure data

4.1 Privacy

- Personally Identifiable Information (PII) managed?
- Data minimization information and description;
- Availability and characteristics of Privacy statement;
- Involvement of third parties;
- Legal and regulatory compliance for Privacy.

4.2 Security

- Implementation of ISO/IEC 27001 or a recognized equivalent?
- Information security risk description and assessment processes and measures;
- Encryption and testing;
- Security policy.

5. Robust build

5.1 Technical robustness

- Documentation of product requirements
- SW development and secure coding processes;
- Configuration management;
- Validation and verification plans;
- Deployment and maintenance plans;

5.2 Interoperability

- Documentation of APIs;
- SW development and secure coding processes;
- Availability of data for users.

5.3 Data quality

- Description of data quality assessment of source data;
- Description of dataset and patient characterisation;
- Description of strategy related to handling of data quality errors;
- Description of strategy related to curation of data quality errors.

6. Continuous improvement

6.1 Operational/technical incidents/risks

- Description of operational/technical/health/... incidents and impact on the evolution/update of the risk analysis;

6.2 Evaluation and improvement

- Description how the DCHP will be evaluated with respect to the delivery of the app's health services;
- Metrics involved;

6.3 Quality system management

- Update of procedures, objectives, and use-cases

4 Generic level applicability

When healthcare actors are geographically separated, technology-enabled services can support healthcare related activities. by enabling their more effective collaboration including continuity of care, patient engagement, and the early detection of issues such as complications needing care escalation.

This care collaboration critically depends upon safeguarding the quality of the exchanged data between/from Digital Consumer Health Products and between DCHPs and EHR systems. Without this quality, DCHPs could exacerbate rather than help with continuity of care and patient safety risks. This stresses the need for a framework that could be used to assess and guard the quality of information exchanged. As is the case with the beforementioned ISO 10377, the proposed framework based on 82304-2 is widely usable and applicable.

Conformance in the context of the EHDS must now include documented evidence by the developer that an appropriately robust assessment of data quality has been made during development and testing, which includes not only the quality of the values within data elements (e.g. of the fields within tables) but of the suitability of the patients within the data set to the intended patients who will use the DCHP. The proven (i.e. tested) ability for the product to correctly import and export the EHR priority data categories specified in the EHDS Regulation, and incorporated within the EEHRxF, is also essential. This evidence may include documented internal information models and test certificates.

By formulating all criteria and comments in a generic manner, the framework can be used for all types of Digital Consumer Health Products. By choosing this generic approach, the support for potential implementation of this framework can be delivered by a broad range of manufacturers and governing organizations.

5 Domain specific applicability - Consumer Health Products and EHR-systems

As one of the driving components in the health care system, Electronic Health Records contain a significant amount of information on a single location. Unfortunately, the data in EHRs are frequently not complete, nor integrated, nor maintained properly. In some cases, patients might be able to provide useful information providing more insight for the health care professional and leading to better health care. Patient access to their own electronic health records (EHRs) is (unfortunately) very slowly, becoming an integral part of healthcare systems worldwide. This important trend has the potential to decrease healthcare provision costs, improve access to healthcare data, self-care, quality of care, and health and patient-centred outcomes [4].

However, including the input from Digital Consumer Health Products into the EHR is often not possible for patients or assisted citizens making use of those products. Leaving the potential issues arising from technical interoperability out of scope, the main threshold for including that information in Electronic Health Records is often the fact that the data provided by patients is considered less reliable. This leads to a situation that health care professionals are not inclined to include that data in Electronic Health Records. This is even the case if the data is originally provided to the patient by professional sources but has to be uploaded or provided by the individual patient [17, 18]. Therefore, manual input might pose too significant of a risk leaving (semi-)automated input as a feasible route to provide additional information to an Electronic Health Record. To, among others, provide a solution for the lack of trust in the automatically provided data, the framework on quality labelling might be fitting. By branding assessed Digital Consumer Health Products as compliant to the set quality criteria, the trust of health care professionals in such data streams can be improved.

Domain – Operationalization

The domain of EHR-systems is very complex and vastly exceeds the scope of the quality labelling framework proposed in this Deliverable. Therefore, the framework in this regard will solely focus on the sections of the EHR-system that are patient facing and, or in other words, are disclosing information to patients.

Taking this limitation in scope in mind, the question arises which specific quality requirements are necessary as addition to the generic quality labelling framework already in place. One topic would be the reference to the relevant standards that already have established themselves in the regular processes and procedures. An example of such an established standard in this domain is ISO 27789:2021 – Health Informatics – Audit trails for electronic health records.

[17] https://www.sciencedirect.com/science/article/abs/pii/S1386505605002145?via%3Dihub
[18] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1560697/

6 Use case specific applicability; laboratory results

As described in the previous section, trust to include (interpreted) data provided by patients in Electronic Health Records is an ongoing concern. Limiting the provisioning to an Electronic Health Record to (semi-)automatically generated data, might prove a solution. One source of patient related data that would be useful to include in Electronic Health Record systems, is laboratory results. However, the patient and their Digital Consumer Health Products might also play an important role in this exchange of information.

Imagine the situation that a patient receives laboratory results on their smartphone via a dedicated application and they would like to share that information with their General Practitioner in a standardized way. In the current situation, a GP might contact the laboratory for a copy of the results instead of relying on the data shared by the patient. Ensuring that the application on the smartphone adheres to the set-out quality criteria and for example, the data blocks set out by the IPS standard ISO 27269:2021, will incentivise the healthcare professional to directly gather the information from the client.

Use Case – Operationalization

Quality labels help to ensure that the laboratory results provided are accurate and reliable. Accurate and trustworthy labelling, including details about the method, context, and conditions under which tests are performed, significantly influence the interpretation of the results making it crucial for correct diagnosis and treatment planning.

In use case of the laboratory results, specific considerations come into play including the shared interpretation of the shared data and clarity on the calibration across the laboratories. Some tests can be measured in different ways potentially resulting in misinterpretation when established standards are not adhered or the interpretation is not shared. The applicability of specific standards or specifications are developed to a further extent in future projects such as xShare and the corresponding X-Bundles but there are a number of standards that are already identified and useful to reference:

- ISO 15189:2022: This is a broad quality standard ranging from personnel qualifications, equipment control to result reporting. This standard aims to ensure laboratory results are reliable;
- ISO 22367:2020: This risk based standard concerns itself with the data quality of medical laboratories. It mentions aspects relevant for data handling and processes which might negatively impact the quality and integrity of the laboratory data.

7 Self-assessment and certification

In order to make clear to patients, health care professionals, and other stakeholders, that the Digital Consumer Health Product they will be (potentially) using or prescribing is compliant with the proposed quality labelling framework, a form of certification is required. By doing so, potential users can make an informed decision whether they would like to make use the of a specific DCHP or look for an alternative. Taking the potential health implications into consideration, it should be clear that marking a DCHP as compliant should be done by following

a structured, validated and, mandated process. Assessing the DCHP with the DCHP quality assessment framework by the vendors/suppliers would be a potential solution.

Suppliers of Digital Consumer Health Products should verify compliance and adherence to the proposed framework on an ongoing basis. The process of ongoing assessments helps to reduce the risks for consumers to an acceptable level. Among the implementation of standards, the use of self-assessments is a common method to strengthen the level of implementation and commitment from governments and other stakeholder organizations. In Denmark, this method has also been implemented to accredit Electronic Health Record systems in hospitals[19].

Looking at the diverse ecosystem of stakeholders including public organizations as well as vendors, a framework that can be used in such a broad context would be sensible. By doing so, interested organizations can slowly move into the implementation and usage of the EEHRxF and corresponding quality labelling while using the self-assessment as an indicator for their progress. Whereas official auditing by a third party can be considered as a periodic milestone, the continuous process of self-assessment provides organizations with the opportunity and incentive for short-cyclic feedback and improvements.

However, in further implementation, organizations should be incentivized to pursue the certification by third-party auditors. By providing structured evidence in line with the criteria described in the DCHP quality labelling framework, third-party auditors can validate the implementation in an objective manner. In later stages, it would also be possible that third-party auditors would gather the evidence themselves instead of relying on the documentation provided by the vendor. This would prevent any misrepresentation of the actual situation and would further strengthen the quality labelling and certification and its value for all stakeholders involved.

8 Relation with the European EHRxF

The European EHRxF promotes standardization and the exchange of information as mentioned in Article 6 of the EHDS and reenforced in Article 31. Furthermore, Article 56 of the EHDS discusses a Data quality and utility label emphasizing the need for interoperability and mutual trust in data. A quality labelling framework on Digital Consumer Health Products (or Wellness Apps) will help build trust and confidence in the desired exchange of information. Therefore, a reference to the EEHRxF in the quality labelling framework is of significant importance.

Overall, EEHRxF and quality labelling complement each other by promoting interoperability, ensuring data quality and security, fostering trust and transparency, facilitating regulatory compliance, and driving market adoption of healthcare technology solutions. By doing so, the whole ecosystem of stakeholder can work towards a patient-centric healthcare environment fostering the exchange and reuse of data. Among other things, testing and assurance services are relevant components that are being developed under then EEHRxF. This includes functional

[19] 331-libre.pdf (d1wqtxts1xzle7.cloudfront.net)

testing, integration testing, and user acceptance testing to identify and fix issues before full-scale deployment.

As the European EHRxF is still under development, it will be an ongoing topic to manage the quality of the Digital Consumer Health Products and the corresponding data. This development in the context of the EHDS and the EHRxF, only stresses the significance of a trusted quality labelling framework that instils trust for all relevant participants.

9 Conclusions

We have proposed a useful and usable framework comprising quality criteria for DHCP quality assessment. It has the potential to become a trusted, commonly used global framework, and can be an input to the relevant SDOs for an extension of the scope during a revision of TS 82304-2. The resulting framework would help manufacturers enhance and efficiently demonstrate the quality of DHCPS, consumers, and health care professionals to make informed decisions. It would also help insurers to make reimbursement decisions on DHCPs.

This quality labelling framework is, as stated, an extension of 82304-2. However, in order to develop it further and put it in actual practice, continued standardisation efforts should be undertaken after the finalization of XpanDH, for example, in the xShare project or JA-09 (Xt-EHR), if not coherently providing the quality framework criteria as input to the CEN-ISO standards development organisations (SDOs), as anticipated in section 3.1.2, so that the framework can become a fully-fledged standard or technical specification and be maintained by the SDOs. The recommended modality would be to extend the scope of the 82304-2 technical specification on the quality and reliability of health and wellness apps to cover -also in terms of labelling- what this Deliverable has been put forward in terms of a quality framework for DCHPs.

In all cases, the activities to carry out are outlined as follows[20]:

- Further analysis of existing frameworks;
- A 2-round Delphi technique with many experts from the continents (predominantly Europe) participating in one or both rounds to be used to achieve consensus on the proposed framework for assessing DHCP quality. Aims would include identifying the maximum 100 requirement questions for the uptake of DCHPs that do or do not qualify as medical devices;
- A follow-up survey with several respondents to inform a scoring mechanism for the questions, the goal of which would be to be able to label DCHPs;
- Subsequent alignment with related standards;
- Test and fine tune the quality assessment framework with many manufacturers of various DCHPs;

[20] It is worthwhile to add that many of these activities have been carried out during the standardization process of CEN-ISO 82304-2 to reach the final technical specification and are required to consolidate the quality framework of the DCHP quality framework.

- Submit the framework and label (i.e., a revised 82304-2) to national mirror committees from the countries that participated in the SDO technical committees to comment on the working drafts and subsequently vote on the revised standard.

10 More on standardising the DCHP quality framework

Handover and consolidation of the DCHP framework

In this Deliverable and the corresponding framework (based principally and among others on 82304-2) the exchange between Digital Consumer Health Products, has been discussed in detail. However, solely adhering to the standards on quality labelling will most likely not directly result in an abundance of shared information and cooperation between DCHPs and other health care related systems such as EHR-systems.

In order to drive the exchange of health-related information and to unlock the health benefits of interoperability, standardization of data and subsequently its exchange should be done in a standardized manner while making use of a commonly used and available infrastructures. The creation of the International Patient Summary (IPS) has been a big step in the right direction for standardisation, but the benefits have not been experienced by patients to the extent that set the premise.

With the creation of the IPS and an international infrastructure for the exchange of information in the form of EEHRxF, combined with the creation of related standards such as this extension of the 82304-2 framework having the scope of assessing and quality labelling of DCHPs, the prerequisites for data sharing are put into place. The next logical step is to persuade stakeholders, health care professionals, manufacturers, and patients to actually make use of all provided tools and structures. The recently started xShare project aims to achieve that goal; Ensuring that trusted health data is shared (by the patient) in the EEHRxF-format.

Establishing a set framework on the quality labelling of Digital Consumer Health Products is a great initial first step. However, the proof of the pudding is the actual implementation into practice. For this means, ensuring appropriate and sound handover on one side towards the CEN ISO standardisation organisations in order to render it a fully-fledged standard, and on the other to EU projects like xShare, JA-09 and ASSET-DHT and other projects that will surely be started in the coming years, will be paramount for its longevity, its added value and actual success.

AI and quality labelling

Next to the usage of Digital Consumer Health Products such as smart wearables, patient portals and lifestyle tracking applications, the development of AI and its application in healthcare has significantly increased in the last few years. AI technology could be used for diagnostics support, efficient management of medical records and large-scale research. By doing so, AI enhances operational efficiency, optimizes resource allocation, and facilitates remote patient monitoring in a market with workforce scarcity. However, the usage of AI also poses risk due to potential

biases, errors in the algorithms, or a lack of transparency potentially leading to misdiagnosis, incorrect suggestions, and patient's wellbeing.

Fortunately, the European Commission, has already started developing a self-assessment list for AI since July 2020. The ALTAI[21] self-assessment tool is designed to help organization develop of AI systems that are ethical, trustworthy, and aligned with societal values. It provides structured approach for organisations to self-assess their AI applications. The approach is based on the seven key requirements of Trustworthy AI, as outlined in the European Commission's Ethics Guidelines for Trustworthy AI. These requirements are:

- Human agency and oversight:
- Technical robustness and safety:
- Privacy and data governance:
- Transparency:
- Diversity, non-discrimination, and fairness:
- Environmental and societal well-being:
- Accountability

The ALTAI tool helps organizations to identify areas where their AI systems may be lacking and take steps to improve them. By emphasizing quality assurance, healthcare providers can harness the power of AI to improve patient outcomes while minimizing risks and maintaining high standards of care.

The recently passed AI Act should also be mentioned as a legal addition in this regard. Whereas, ALTAI helps organizations self-assess their AI applications, the AI Act provides a legal framework providing the means of regulation.

Within the scope of this task 2.3 it has been possible to verify the fact that the DCHP quality criteria has much in common with ALTAI especially after the DCHP framework has been extended to cover further DATA Quality criteria so precious for the application of AI to healthcare.

[21] Assessment List for Trustworthy Artificial Intelligence (ALTAI) for self-assessment | Shaping Europe's digital future (europa.eu)

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Annexes

Annex 1 - Final quality requirement questions of EN-ISO/TS 82304-2

In this annex the final quality requirement questions of EN-ISO/TS 82304-2 are documented, including their individual purposes, whether they are a minimum requirement (R) to qualify for a health app quality label and whether they have a weight (1, 2 or 3) in the quality scoring. For each question in the EN-ISO/TS 82304-2 quality assessment framework one or more purposes may apply. These purposes include:

a. **Label content (Lc)**: information the health app quality label that communicates the results of the health app quality assessment needs, e.g., icon and name of the health app, supported platforms, health app manufacturer, and health benefit.
b. **Colour coding (Cc)**: impacts the health app quality scores communicated via the health app quality label.
c. **Requirement level (Rl)**: explores if questions apply, makes the assessment proportional, e.g., if the app does not process personal data privacy questions do not apply.
d. **Filtering (Fi)**: enables search and selection of health apps.
e. **App assessment (Aa)**: enables app assessment, that is, evaluation of the health app and evidence provided by the app manufacturer.

A coloured cell indicates the purpose applies.

Evidence requirements and further clarification text accompany each quality requirement question in ISO/TS 82304-2. The notes and other relevant content have not been included in this appendix. They are needed to operationalise the framework and can be consulted by purchasing ISO/TS 82304-2.[1]

Table S6. Final EN-ISO/TS 82304-2 quality assessment framework.

	Purposes and weight (R = Required)				
	Lc	**Cc**	**Rl**	**Fi**	**Aa**
PRODUCT INFORMATION **Product**					
5.1.1.1 Which operating systems or platforms does the health app support?	■			■	
5.1.1.2 What is the name of the health app?	■				
5.1.1.3 Provide the health app icon, if available.	■				
5.1.1.4 In which languages is the health app available?				■	

5.1.1.5 Provide instructions for access to the health app for assessment.					
App manufacturer					
5.1.2.1 What is the name of the health app manufacturer?					
5.1.2.2 Provide e-mail address and telephone number of the person who is authorized to represent the health app manufacturer.					
HEALTHY AND SAFE **Health requirements**					
5.2.1.1 Who are the intended users of the health app?					
5.2.1.2 Are age restrictions of the intended users or subjects of care made clear to potential customers and users?		1			
5.2.1.3 For which health issue(s) and/or health need(s) is the health app intended?					
5.2.1.4 What is the intended use or purpose of the health app?					
5.2.1.5 Are assessments done to establish whether the health app is a medical device or in vitro diagnostic medical device, and if applicable is regulatory approval obtained before the app is made available in each country?		3			
5.2.1.6 Are health professionals involved in the development of the health app?		3			
5.2.1.7 Is appropriate peer reviewed scientific literature used in the development of the health app?		2			
Health risks					
5.2.2.1 Are the health risks of the health app analysed?		R			
5.2.2.2 Are measures used to control the health risks of the health app?		1			
5.2.2.3 Are the residual risks of using the health app found to be acceptable?		1			
5.2.2.4 Describe when the health app requires approval from a health professional before use.					
5.2.2.5 Are potential customers and users of the health app made aware of the health risks, contra-indications, and limitations of use?		R			
5.2.2.6 Is a process to collect and review safety concerns and incidents for the health app maintained?		3			

Ethics					
5.2.3.1 Are ethical challenges of the health app assessed and documented with intended users and health professionals?		1			
5.2.3.2 Is the health app approved by an independent ethics advisor or ethics advisory board?		1			
Health benefit					
5.2.4.1 Describe the health benefit of using the app					
5.2.4.2 Are potential customers or users made aware of the health interventions applied to achieve the health benefit?		2			
5.2.4.3 Are potential customers or users made aware of all financial costs to achieve the health benefit?		1			
5.2.4.4 Are potential customers or users made aware of the need for support of a health professional to achieve the health benefit?		2			
5.2.4.5 Is evidence available to support the health benefit of using the app?		R*			
5.2.4.5.1 Does this evidence include peer reviewed research involving the use of this health app?		1			
5.2.4.5.2 Is the level of the evidence appropriate?		2			
5.2.4.6 Is there a maintenance process for the health information in the app?		1			
5.2.4.6.1 Are all sources for the health information in the health app disclosed to potential customers and users?		2			
5.2.4.7 Are all sources of funding of the health app disclosed to potential customers and users?		1			
5.2.4.8 Is the use of advertising mechanisms disclosed to potential customers and users and are advertisements clearly distinguishable in the health app?		3			
Societal benefit					
5.2.5.1 Is evidence available of a societal benefit of using the app?		1			
5.2.5.1.1 Does this evidence include peer reviewed research involving the use of this health app?		1			
EASY TO USE **Accessibility**					

5.3.1.1 Is the health app WCAG 2.1 AA or AAA compliant?		3			
5.3.1.1.1 Are reasonable measures taken to ensure that all intended users can perceive all relevant information and user interface components of the health app and related documents?		1			
5.3.1.1.2 Are reasonable measures taken to ensure that all intended users can operate all relevant user interface and navigation components of the health app and related documents?		3			
5.3.1.1.3 Are reasonable measures taken to ensure that all intended users can understand all relevant information and user interface components of the health app and related documents?		3			
5.3.1.2 Is the health app age-appropriate?		2			
Usability					
5.3.2.1 Is the health app design based on an explicit understanding of users, tasks and environment?		2			
5.3.2.2 Are intended users involved throughout design and development of the health app?		2			
5.3.2.3 Is the design of the health app driven and refined by user-centred evaluation?		2			
5.3.2.4 Are measures in place to avoid user error and reasonably foreseeable misuse of the health app?		1			
5.3.2.5 Are potential customers and users provided with adequate product information about the health app?		1			
5.3.2.6 Are instructions for use readily available for users?		3			
5.3.2.7 Are appropriate resources available to adequately help potential customers and users who experience problems with the health app?		1			
5.3.2.8 Are relevant data on the usability of the health app systematically gathered throughout its entire lifetime, in order to make regular improvements?		1			
SECURE DATA **Privacy**					
5.4.1.1 Does the health app process Personally Identifiable Information (PII)?					
5.4.1.1.1 Does the health app process health related PII?					

5.4.1.1.2 Is data minimization applied in the health app?		3			
5.4.1.1.3 Is an appropriate retention policy established to erase or review the data stored?		1			
5.4.1.1.4 Is a privacy statement readily available to potential customers and users of the health app?		R**			
5.4.1.1.4.1 Does the privacy statement start with an accessible overview in less than 150 words?		3			
5.4.1.1.5 Are contracts in place with all processors and controllers of PII of the health app and associated services to ensure the level of security controls and privacy protection are as communicated to the user?		3			
5.4.1.1.6 Is opt-in the default setting for sharing PII with third parties?		3			
5.4.1.1.7 Does the app manufacturer have a person responsible for legal and regulatory compliance of processing of PII?		1			
5.4.1.1.8 Are security-incident response procedures in place that include reporting PII breaches to the user and relevant authorities?		3			
Security					
5.4.2.1 Have the health app manufacturer and all organizations providing associated services implemented and documented the implementation of ISO/IEC 27001?		1			
5.4.2.2 Is an Information Security Risk Assessment documented?		1			
5.4.2.3 Is a secure by design process followed?		3			
5.4.2.4 Are measures in place to ensure that all third-party software libraries and other software components for the health app are reliable and maintained?		1			
5.4.2.5 Is a process to prevent unauthorized access and modifications to the health app source code in place and documented?		2			
5.4.2.6 Are organizational measures in place to ensure PII is processed in a manner that is compatible with the explicit, legitimate purposes specified in the privacy statement?		2			
5.4.2.7 Is user authentication, authorization and session management implemented to secure access to the health app?		1			

5.4.2.8 Does the health app transmit and store all PII with adequate encryption?		1			
5.4.2.9 Are security vulnerabilities reported, identified, assessed, logged, responded to, disclosed, and quickly and effectively resolved?		3			
5.4.2.10 Are the security of the health app and associated services tested on a regular basis and at major changes?		2			
5.4.2.11 Is the information security policy readily available to potential customers and users?		1			
ROBUST BUILD **Technical robustness**					
5.5.1.1 Are all the health app product requirements documented?		1			
5.5.1.2 Is the health app developed with a software development process that covers the standards, methods and tools to be used?		3			
5.5.1.3 Is a secure coding standard followed and documented?		2			
5.5.1.4 Is a configuration management plan established for the health app?		1			
5.5.1.5 Are processes in place to deal with a significant increase or spike in demand?		1			
5.5.1.6 Is a validation and verification plan documented and used for the health app?		3			
5.5.1.7 Is a release and deployment process established?		1			
5.5.1.8 Is a maintenance process established?		3			
Interoperability					
5.5.2.1 Are potential customers and users of the health app able to access the specifications and implementation guides for all the APIs?		1			
5.5.2.2 Are potential customers and users of the health app able to access the specifications and implementation guides for the terminology or terminologies used?		1			
5.5.2.3 Does the health app validate all data for the health app transferred via APIs?		1			
5.5.2.4 Can users obtain their PII by a data export to another platform?		1			

* Depending on intended use

** If the app process Personally Identifiable Information (PII)

Table S7. Weight distribution in the 'Overall health app quality score'.

Weight distribution in the 'Overall health app quality score'	**Weight**
Healthy and safe	5
Easy to use	1.5
Secure data	2.5
Robust build	1

Annex 2 - Quality requirement questions for DCHPs

[The Annex is found in “DCHP Criteria 20240510-Annex 2 of D2.3 v2.xlsx”]

Annex 3 – Definitions taken from 82304-2 "Quality and reliability of health and wellness apps"

health app

health and wellness app

app intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

[SOURCE: IEC 82304-1:2016 3.6, modified — Changed 'software' to 'app' in term and definition, 'health and wellness app' was added as a term, notes to entry deleted.]

health software

software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care

Note 1 to entry: Health software fully includes what is considered software as a medical device.

Note 2 to entry: The scope of IEC 82304-1 refers to the subset of health software that is intended to run on general computing platforms.

[SOURCE: IEC 82304-1:2016, 3.6]

health software product

combination of health software and accompanying documentation

[SOURCE: IEC 82304-1:2016, 3.7, modified — 'documents' changed to 'documentation'.]