# Integration of CEN ISO/TS 82304-2 for Existing Health Authorities' App Assessment Frameworks: A Comparative Case Study in Catalonia

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## *Abstract*

**Background:** Health apps are increasingly being used to promote health, manage diseases, and deliver healthcare services. Still, there is scarce objective information regarding their quality beyond the required CE mark for medical apps, leading to potential risks for users. To address these challenges, several authorities have developed health app assessment frameworks. In 2017, TIC Salut Social Foundation (FTSS) in Catalonia developed its own health app assessment framework, in use since that year. The publication of CEN ISO/TS 82304-2 (abbreviated as 82304-2), an international standard for assessing health apps, and the co-creation of the related app assessment handbook and scheme provide a unique opportunity to harmonize app assessments across the EU.

**Objective:** This study aimed to perform a comparative analysis of the FTSS assessment framework with 82304-2 and explore the integration of 82304-2 in Catalonia. The goal was to identify shared concepts and context-specific concepts. Our broader aim was to provide this methodology for health authorities in other regions and countries to consider a similar integration.

**Methods:** For the comparative analysis, a mixed-method approach was used, combining a qualitative case study with a quantitative analysis of the two frameworks. The analysis covered five key areas: framework characteristics, governance, workflows, quality aspects, and quality requirements (criteria). To support a quantitative analysis, the 120 FTSS requirements and 74 quality aspect-related 82304-2 requirements were translated into 97 concepts. A scoring system was applied to identify matches of the frameworks with these concepts, with scores ranging from 0 (no match) to 1 (full match). Integration was evaluated considering a series of scenarios, including using the 82304-2 related assessment scheme, adopting 82304-2 requirements, adapting the requirements to local needs, and maintaining the current FTSS framework.

**Results:** The main difference between the frameworks was its app usage-based assessment (FTSS) versus evidence- and app usage-based assessment (82304-2). Overall, a 48% (47/97) match between the frameworks' concepts was found, with an additional 39% (37.5/97) specific to 82304-2 and 13% (12.5/97) to FTSS. The 82304-2 only concepts were found to be relevant to FTSS. Thus, FTSS decided to integrate all eighty-one 82304-2 requirements. Five FTSS-specific requirements were included in the app assessment handbook for 82304-2, while another 4 rigor-enhancing, 1 scope-expanding and 1 context-specific requirement will be assessed on top.

**Conclusions:** The integration of 82304-2 in Catalonia offers a more structured, comprehensive, standardized approach to health app assessment. Once the 82304-2 assessment framework is put in practice, and 82304-2 quality labels are issued, the evolved handbook will achieve 93% (81/87) of the FTSS assessment, reducing the assessment workload specific to Catalonia to only 7% (6/87). FTSS encourages other authorities to perform a similar process or to wait until the L2E handbook is in practice to adopt it in full.

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## Original Paper

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**Keywords:** mHealth; Mobile health, Health apps; Mobile applications; ISO; Assessment; Certification; Criteria; Quality; Regulatory; Comparative analysis

# Introduction

## Background

Health apps refer to apps designed for managing, maintaining or improving the health and wellbeing of individual persons or the delivery of care, and thus include both medical and wellness apps [1,2]. A great number of health apps are already being used by millions of people, and several reports have pointed out the potential of these apps and digital technologies to deliver the right information to the right people at the right time. Health apps can enhance the safety, effectiveness and efficiency of care by promoting health, contributing to the prevention and treatment of diseases, facilitating patients' equal access to personalized health care, and engaging patients in their own care. They can also respond to unmet patient needs, enable better coordination of care, exploit the possibilities of remote health promotion and remote care, and strengthen the resilience and sustainability of health systems [3–5]. However, not all health apps provide sufficient evidence to support their claims, putting users at risk and calling into question their quality [6]. This creates a need for robust evaluation and regulatory oversight [3,4].

The European Union (EU) Medical Device Regulation (MDR) mandates a conformity assessment and related CE mark for all medical devices, including software, and is therefore applicable to medical apps [7–9]. However, while the MDR ensures patient safety, it does not include the issuance of a quality report, only the CE mark. Additionally, Notified Bodies are only involved in the evaluation of class IIa, IIb and III medical devices. Wellness apps, on the other hand, fall outside the scope of the MDR, and digital marketplaces do not require robust evaluations [10]. As a result, health apps available on the market largely lack essential quality information apart from the user star ratings in app stores, which are known to be a poor indicator of quality [11]. To address this situation, several countries and regions in Europe and worldwide have developed assessment frameworks for health apps [12]. These frameworks assess characteristics beyond the MDR, such as data privacy, and provide more assessment information than a CE mark to support decision-making. The TIC Salut Social Foundation (FTSS, Catalan abbreviation), within the Ministry of Health of Catalonia (Spain), was in 2017 one of the first European health authorities to develop such an assessment framework [13,14]. With the emergence of more frameworks, lack of cross-country harmonization has been introduced, leading to a significant duplication of app assessment efforts for manufacturers and healthcare systems, causing confusion among app users [2]. In addition, despite the widespread interest in the use of health apps across Europe, even authorities with relatively well-established frameworks encounter challenges with efficient implementation [12].

The World Health Organization (WHO) has called on health authorities and researchers to establish a common methodology for evaluating health apps, highlighting the need for these evaluations to become a standard practice rather than an exception [3]. Founded upon the premise that international,

cross-border regulations could highly benefit the integration of apps in healthcare systems [2], the European Commission commissioned the European Committee for Standardization (CEN) to develop a Technical Specification (TS) for quality and reliability of health and wellness apps, which was achieved in collaboration with the International Organization for Standardization (ISO). CEN ISO/TS 82304-2 “Health software – Part 2: Health and wellness apps – Quality and Reliability” (henceforth referred to as 82304-2) was published in 2021 [1,2]. As a next step, the EU-funded Label2Enable (L2E) project, initiated in 2022, has been dedicated to facilitating the adoption of this TS as the common assessment framework within the EU and potentially beyond. The project has iteratively co-created the Label2Enable handbook for app assessment with 82304-2 and the Label2Enable Certification Scheme [15].

## Objective

The objective of this study was to generate a systematic comparative analysis of the FTSS assessment framework for health apps with the 82304-2 framework. The goal was to identify new, relevant concepts–distinct evaluative elements within the frameworks’ requirements–from 82304-2, as well as Catalonia-specific concepts addressed by the FTSS framework, to adequately consider and allow proper integration of 82304-2 in Catalonia. Our broader aim was to provide this methodology to health authorities in other regions and countries to make informed decisions about the adoption and integration of 82304-2 or other evaluation frameworks.

# Methods

## Study design

The project was carried out in two parts, as depicted in Figure 1. The first part, a comprehensive comparative analysis of both assessment frameworks, is divided into 5 sections. This part aimed to identify the characteristic traits and differences of each assessment framework. The second part is divided into 3 sections and involved evaluating the integration of 82304-2 in Catalonia, considering its advantages and disadvantages, and carrying it out.

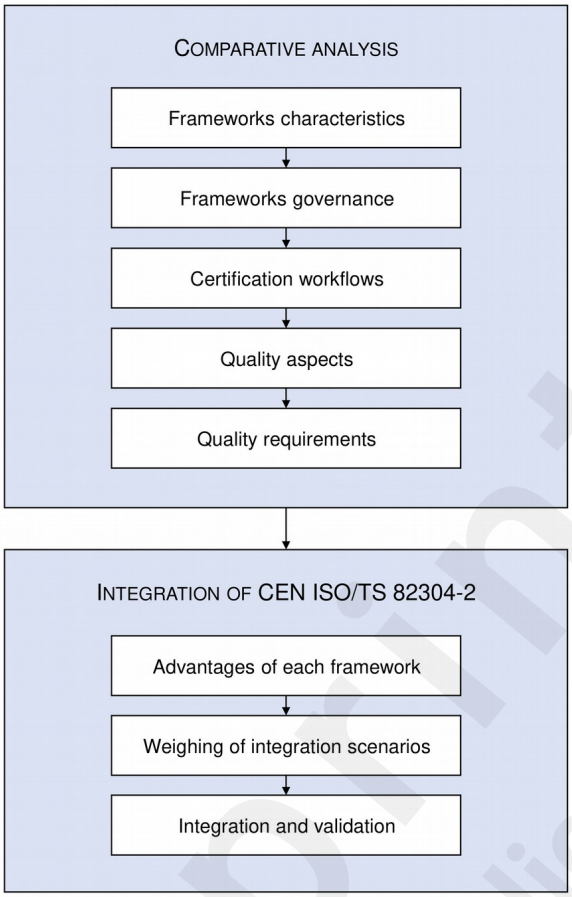


Figure 1. Overview of the methodology used in this study.

## Comparative analysis

The comparative analysis was conducted using a mixed-method approach, comprising a qualitative case study–ideally suited to capture complexity–and a quantitative analysis. This methodology [16] was adapted from a comparative analysis of assessment frameworks for sustainability [17]. The analysis addressed qualitatively and descriptively the (1) assessment frameworks characteristics, (2) assessment frameworks governance, (3) certification workflows and techniques used, (4) quality aspects and sub-aspects of each framework, and (5) quality requirements (or criteria).

To enable a quantitative analysis of the FTSS and 82304-2 requirements shared across the two assessment frameworks (5), first, the key concepts assessed in each of the 82304-2 requirements were identified and organized within the 82304-2 sub-aspects (“health requirements”, “health risks”, “ethics”, “health benefit”, “societal benefit”, “accessibility”, “usability”, “privacy”, “security”, “technical robustness” and “interoperability”). In cases where multiple requirements addressed the same overarching concept, distinctions were made to recognize when they assessed different sub-concepts. The obtained concepts were then searched within the FTSS requirements. For each common concept, the requirements of 82304-2 and FTSS were compared, considering aspects such as the intended assessment goal, the level of detail required, and any differences in scope. Three outcomes were possible: 0 = no match, 0.5 = partial match, and 1 = full match between requirements.

The process was repeated in the opposite direction, for FTSS requirements against 82304-2. In this case, concepts were extracted both from the FTSS quality requirements and from the FTSS assessment submission form. In some instances, individual requirements were broken down into two distinct concepts to account for a proper comparison. Similarly, multiple requirements were grouped under the same concept and sub-concept when necessary.

The matching in both directions was performed first as a draft (by FTSS members CPB and BLC). Concepts and sub-concepts with draft outcomes “no match” and “partial match” were discussed with the lead expert of 82304-2 (PH) to ensure content was not accidentally overlooked and concepts were adequately assigned. Consensus was reached for all concepts and sub-concepts.

Then, overall match scores were computed. The sum of all full matching concepts and partial matching concepts*0.5 was labeled “Both” (meaning that both frameworks assess this concept), the sum of all not matching concepts and partial matching concepts*0.5 applicable to 82304-2 as “82304-2 only”, and the sum of all not matching concepts and partial matching concepts*0.5 applicable to FTSS as “FTSS only”. The overall match score was calculated as the sum of all full matching concepts and partial matching concepts*0.5 divided by the total number of concepts identified in both frameworks, or each quality sub-aspect. The values were then converted to a percentage and plotted with R.

## Integration of CEN ISO/TS 82304-2

The second part consisted of an analysis of the results of the comparative analysis, to decide on integration of 82304-2 into the FTSS assessment framework. Integration would imply using the concepts identified in 82304-2 for the assessment of health apps quality in Catalonia.

First, we identified and discussed the advantages and disadvantages of each assessment framework and their certification workflow. Next, we weighed integration scenarios, whether (1) to use the L2E Certification Scheme and related handbook adding only Catalonia-specific requirements, (2) to adopt 82304-2 into the FTSS framework (using the phrasing of 82304-2), (3) to adapt 82304-2 according to our needs, or (4) to maintain the FTSS assessment framework in Catalonia.

# Results

## Comparative analysis

### *Frameworks characteristics*

Table 1 summarizes and compares the main characteristics of each assessment framework [1,2,13,15,18–24]. More detailed information can be found in Multimedia Appendix 1.

Table 1. Comparison of the main characteristics of each assessment framework.

| | FTSS assessment framework | CEN ISO/TS 82304-2 |
|---|---|---|
| **Year of publication** | 2017 | 2021 |
| **Scope** | Catalan Healthcare System | Europe/International |
| **Consensus** | Relevant stakeholders in Catalonia | Key stakeholders mostly European |
| **Product information** | Obtained from the FTSS assessment submission form | 1 aspect:<br>• Product information |
| **Quality aspects** | 4 aspects:<br>• Clinical contents and functionality<br>• Usability, accessibility and design<br>• Security and privacy of data<br>• Technological robustness | 4 aspects:<br>• Healthy and safe<br>• Easy to use<br>• Secure data<br>• Robust build |
| **Quality requirements** | 120 | 74 within the 4 quality aspects (81 with the additional 7 in Product information) |
| **Score-impacting requirements** | Maximum 120 | Maximum 67 |
| **Structure of each requirement** | Affirmative sentence with:<br>• Description<br>• Levels of obligatoriness | Question with:<br>• Condition<br>• Purpose<br>• Response options<br>• Evidence<br>• Notes |
| **Assessed apps** | 20 for testing, 55 for assessment, 23 as smoke test | 11+24 for testing |
| **Certified apps** | 14 out of 55 | 0 (given testing phase) |
| **Results communication** | Certification seal + Internal report | Quality label + Quality report |

## Frameworks governance

Both FTSS and L2E have a stakeholders and expert organization to help approve, maintain and improve their framework. FTSS applies a 2-to-3-year maintenance cycle; L2E intends to maintain the scheme annually and more frequently if needed. Both have defined a similar methodology of maintenance, with many steps overlapping. L2E has 3 unique steps (steps 5, 6 and 9 of Figure 3).


Figure 2. Methodology of definition and maintenance of each quality aspect within the TIC Salut

Social Foundation (FTSS) assessment framework.

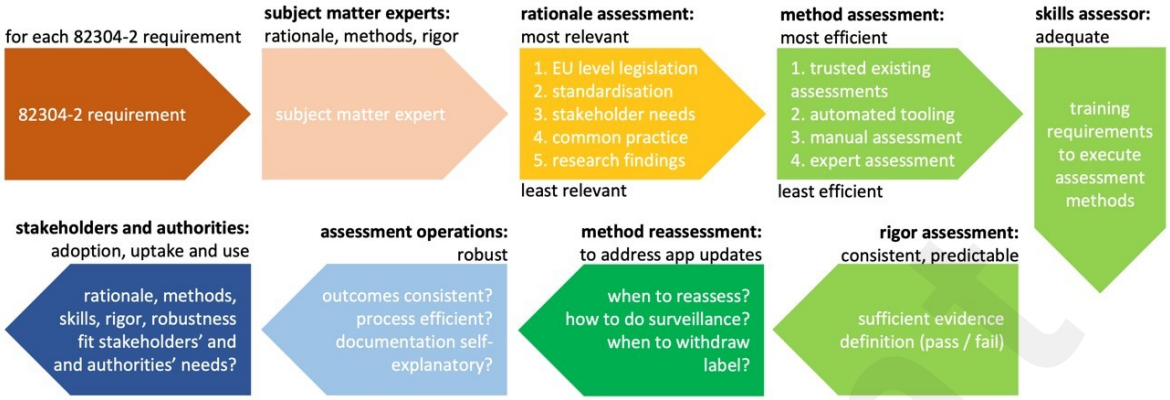


Figure 3. Methodology to co-create the handbook app assessment for CEN ISO/TS 82304-2 (abbreviated as 82304-2).

Some remarkable steps in Figure 2 and Figure 3 are (1) L2E focuses specifically on each quality requirement, while FTSS divides the maintenance process in quality aspects. (2) L2E relies on subject matter experts and key stakeholders for the maintenance, while FTSS is supported by health societies, among others [25]. (3) The rationale for requirements is, for both L2E and FTSS, a result of consulting legislation, stakeholder needs and common practice, but L2E additionally considers standardization and research findings to inform the scheme. (4) L2E evolves the assessment from expert to manual, automated and trusted existing assessments. (5) L2E considers based on the assessment methods the needed skills of the assessor and its training, which is not contemplated by FTSS as their assessors have previous experience and knowledge. (6) L2E defines the specific evidence needed to pass or fail each requirement, which lacks in the FTSS assessment framework and would provide more objective results. L2E also establishes which requirements are mandatory to qualify for the quality label, which can be reviewed over time. This step is comparable to step 5 of FTSS. (7) L2E explores the "compatibility" with what key stakeholders and authorities consider useful (and appropriate). This is not evaluated by FTSS *per se*, but the FTSS framework was built by considering its impact.

A broader explanation of each governance process can be found in Multimedia Appendix 2.

## Certification workflows

As can be observed in Figure 4, the certification workflows of FTSS [20] and 82304-2 (as defined by Label2Enable) are quite comparable. The main difference between the two is that the FTSS assessment is mostly app usage-based, while the Label2Enable assessment is evidence- and app usage-based. In FTSS, assessors use the app and analyze its content and functionalities to decide on pass or fail of each requirement. In L2E, the manufacturer must supply evidence for each quality requirement that they claim to meet. Subsequently, assessors employed by a Conformity Assessment

Body assess the evidence to determine the pass or fail, also checking the app.

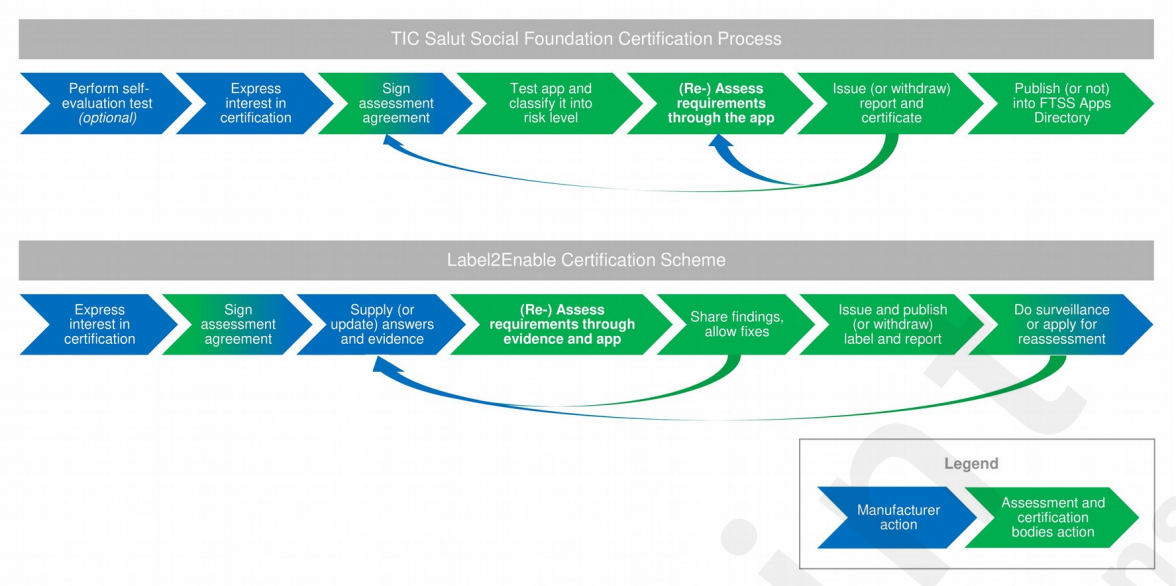


Figure 4. Overview of certification workflows of TIC Salut Social Foundation (above) and Label2Enable Certification Scheme (below).

Other differences are that FTSS includes an optional self-evaluation test [26] and publishes certified apps in the FTSS directory. Label2Enable intends to provide a verification service of the label it supplies. The current project did not include the provision of a directory, which has been recommended to explore in a separate article (Hoogendoorn et al., upcoming). For more detail, see Multimedia Appendix 3.

## *Quality aspects*

The FTSS and the 82304-2 assessment frameworks both contain four overarching quality aspects [2,19]. Based on the semantics of each aspect and the concepts assessed in each, a match between the aspects of the two frameworks was observed. On a more detailed level, differences in distribution applied. See Figure 5 for the specific matches of aspects and sub-aspects.

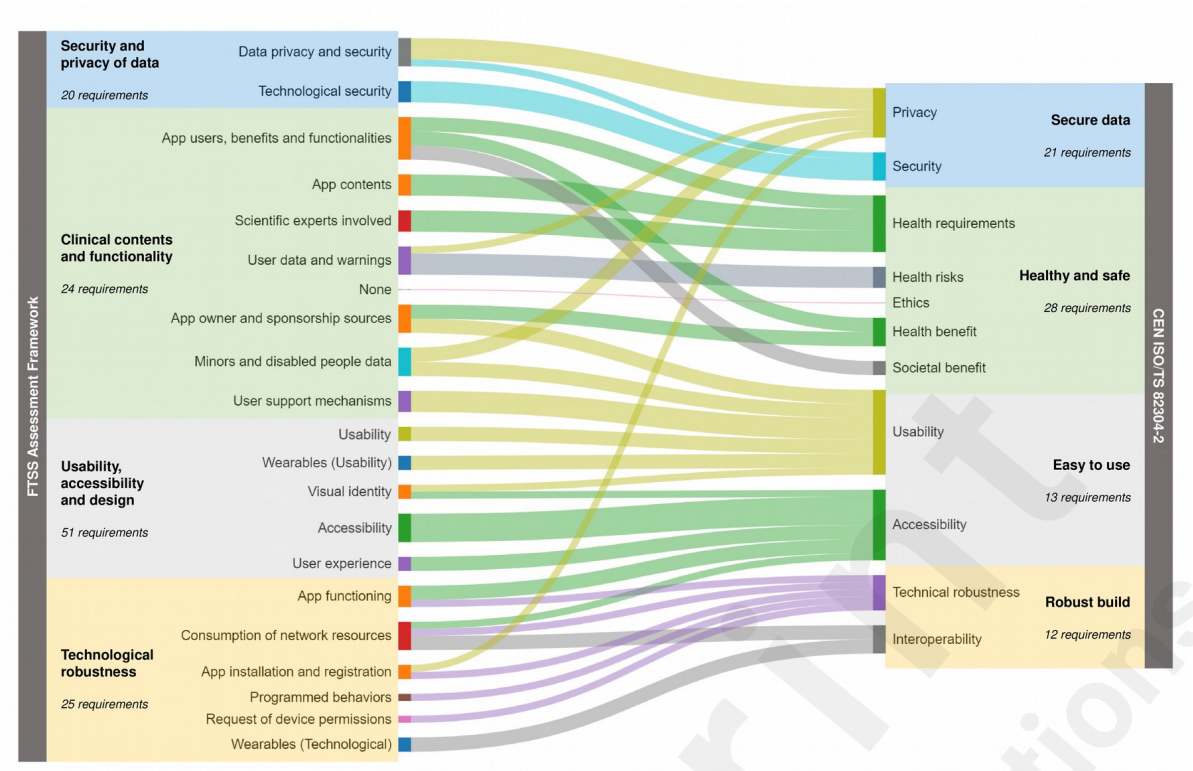


Figure 5. Matches found between the four quality aspects of TIC Salut Social Foundation (FTSS) assessment framework and CEN ISO/TS 82304-2, represented with the same background color (blue, green, grey and yellow); and main connections between the different sub-aspects of both frameworks. Connections were found when the concepts assessed in the requirements were similar. Note that this is a qualitative analysis; thus, the thickness of the connection lines is not numerically representative.

FTSS' quality aspect Clinical contents and functionality domain is broader than 82304-2's Healthy and safe, with many of FTSS' sub-aspects connecting to 82304-2's Easy to use and some to Secure data. Technological robustness is also broader than Robust build. The organization of 82304-2 seems a bit more logical, FTSS has some scattered requirements; however, concepts assessed are fairly common in both frameworks.

## Quality requirements

In total, 97 different concepts and sub-concepts were extracted from the 82304-2 and FTSS frameworks combined. Overall, 48% (47/97) of the concepts of both frameworks were a partial or full match, 39% (37.5/97) 82304-2 only and 13% (12.5/97) FTSS only. The sub-aspect accessibility had the highest match, with 94% (7.5/8) of concepts assessed in both frameworks, and FTSS addressing another 6% (0.5/8); see Figure 6. Other sub-aspects such as health requirements, health risks, health benefit and usability had at least 50% of concepts covered by both frameworks. The 82304-2 requirements were found to cover most of the FTSS requirements, ranging from sub-aspects such as health benefit and societal benefit missing no concepts (0%) to technical robustness missing a maximum of 38% (5/13). The most relevant 82304-2 only sub-aspect was ethics, which is not assessed by FTSS. For other sub-aspects (societal benefit, security and interoperability), 82304-2

provided at least 50% of the concepts.

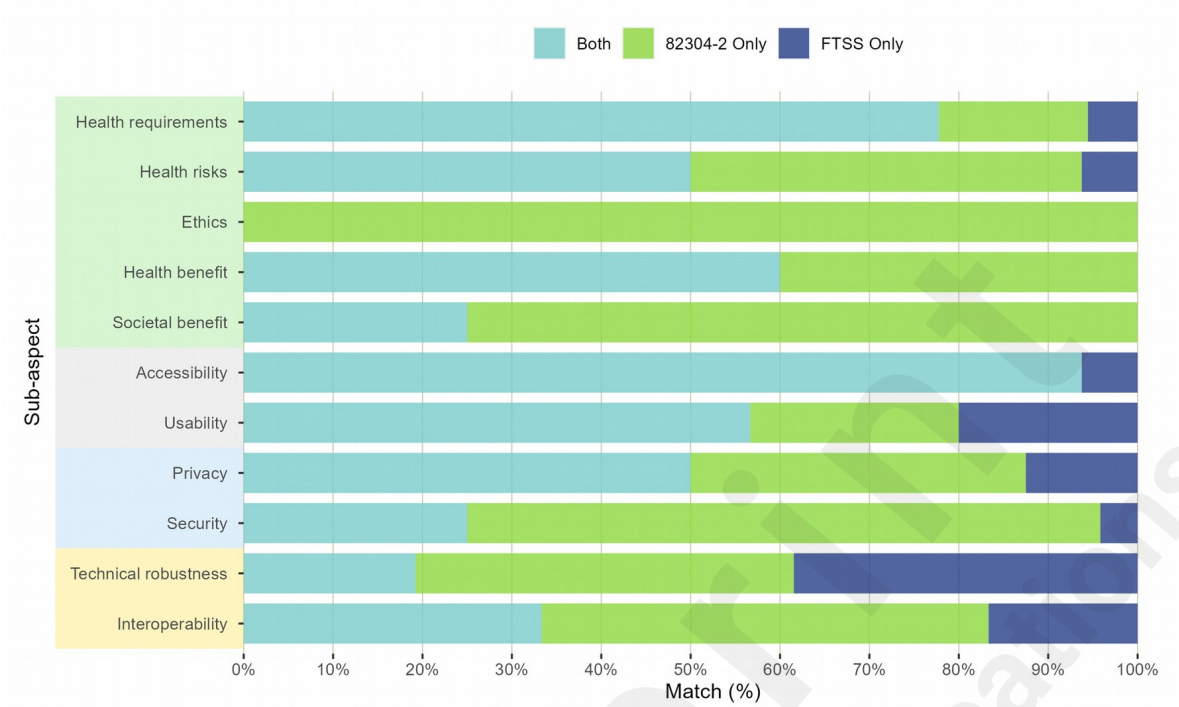


Figure 6. Percentage match of concepts between CEN ISO/TS 82304-2 (abbreviated as 82304-2) and TIC Salut Social Foundation (FTSS) assessment framework across each assessment sub-aspect.

For more detail, Table 2 provides the match scores obtained for each concept assessed in the frameworks. Please note that this comparison has been performed with the original 82304-2 rather than with the more detailed L2E handbook for app assessment, which provides standardized sub-questions to assess the 82304-2 quality requirements and thus adds more sub-concepts in the assessment.

Table 1. Scores obtained for each concept and sub-concept assessed in CEN ISO/TS 82304-2 (abbreviated as 82304-2) and/or TIC Salut Social Foundation (FTSS) assessment framework (N=97 sub-concepts extracted).[a]

| **Sub-aspect** | **Concepts extracted** | **n sub-concepts extracted** | **Concepts match (sum of sub-concepts match scores)** | | |
|---|---|---|---|---|---|
| | | | Both | 82304-2 only | FTSS only |
| **Health requirements** | | | | | |
| | Intended users[b] | 1 | 1 | 0 | 0 |
| | Age restrictions | 1 | 1 | 0 | 0 |
| | Health issues[b] | 1 | 0 | 1 | 0 |
| | Intended use[b,c] | 1 | 1 | 0 | 0 |
| | Medical device[c] | 1 | 1 | 0 | 0 |
| | Health professionals collaboration | 2 | 1.5 | 0 | 0.5[d] |

| | | | | | |
|---|---|---|---|---|---|
| | Literature used | 2 | 1.5 | 0.5 | 0 |
| **Health risks** | | | | | |
| | Risks analysis | 1 | 0 | 1 | 0 |
| | Risks control | 2 | 0 | 2 | 0 |
| | Professional approval before use[b] | 1 | 0.5 | 0.5 | 0 |
| | Risks communication | 1 | 1 | 0 | 0 |
| | Contraindications and limitations | 2 | 1.5 | 0 | 0.5[d] |
| | Safety concerns and incidents | 1 | 1 | 0 | 0 |
| **Ethics** | | | | | |
| | Ethical challenges | 1 | 0 | 1 | 0 |
| | Approval from ethics board | 1 | 0 | 1 | 0 |
| **Health benefit** | | | | | |
| | Health benefit[b] | 1 | 1 | 0 | 0 |
| | Health interventions | 1 | 0 | 1 | 0 |
| | Financial cost for users | 1 | 0 | 1 | 0 |
| | Need of health professional support | 1 | 0.5 | 0.5 | 0 |
| | Evidence for health benefit | 2 | 1.5 | 0.5 | 0 |
| | Maintenance of health information | 1 | 0.5 | 0.5 | 0 |
| | Sources for health information | 1 | 1 | 0 | 0 |
| | Funding | 1 | 1 | 0 | 0 |
| | Advertising | 1 | 0.5 | 0.5 | 0 |
| **Societal benefit** | | | | | |
| | Societal benefit | 1 | 0.5 | 0.5 | 0 |
| | Evidence for societal benefit | 1 | 0 | 1 | 0 |
| **Accessibility** | | | | | |
| | Perceptibility | 2 | 2 | 0 | 0 |
| | Operativity | 2 | 2 | 0 | 0 |
| | Understandability | 2 | 2 | 0 | 0 |
| | Robustness | 1 | 0.5 | 0 | 0.5[d] |
| | Age appropriateness | 1 | 1 | 0 | 0 |
| **Usability** | | | | | |
| | Design taking users into account | 2 | 1.5 | 0 | 0.5[d] |
| | Users involved in design | 1 | 0 | 1 | 0 |
| | User-centered evaluation | 1 | 0 | 1 | 0 |
| | Measures to avoid misuse | 3 | 2 | 0 | 1[e] |
| | App information communication | 3 | 2 | 0.5 | 0.5[d] |
| | Instructions for use | 2 | 1.5 | 0 | 0.5[d] |
| | User support when experiencing problems | 1 | 1 | 0 | 0 |
| | Mechanisms for network and systems problems avoidance | 1 | 0.5 | 0 | 0.5[d] |
| | Usability research for improvements | 1 | 0 | 1 | 0 |
| **Privacy** | | | | | |
| | Processing of personal data[b,c] | 1 | 0.5 | 0.5 | 0 |
| | Processing of personal health data[b] | 1 | 0 | 1 | 0 |
| | Data minimization | 1 | 1 | 0 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| | Data retention policy | 2 | 1.5 | 0 | 0.5[f] |
| | Privacy statement for users | 1 | 1 | 0 | 0 |
| | Data processing of minors and severely disabled people | 1 | 0.5 | 0 | 0.5[d] |
| | Secure contracts with data processors | 1 | 0 | 1 | 0 |
| | User approval for data use and opt-in default | 2 | 1.5 | 0 | 0.5[d] |
| | Data protection officer | 1 | 0 | 1 | 0 |
| | Security incident response procedures | 1 | 0 | 1 | 0 |
| **Security** | | | | | |
| | Security Management implementation | 1 | 0 | 1 | 0 |
| | Information Security Risk Assessment | 1 | 0 | 1 | 0 |
| | Secure by design process | 1 | 0 | 1 | 0 |
| | Security of third-party software | 1 | 0 | 1 | 0 |
| | Security of source code | 1 | 0.5 | 0.5 | 0 |
| | Organizational measures for legitimate processing of data | 1 | 0 | 1 | 0 |
| | Security with user authentication | 2 | 1.5 | 0 | 0.5[d] |
| | Encryption of data stored | 1 | 1 | 0 | 0 |
| | Management of security vulnerabilities | 1 | 0 | 1 | 0 |
| | Regular testing of app security | 1 | 0 | 1 | 0 |
| | Security policy for users | 1 | 0 | 1 | 0 |
| **Technical robustness** | | | | | |
| | Product requirements | 1 | 0 | 1 | 0 |
| | Software development with standards and methods | 1 | 0 | 1 | 0 |
| | Secure coding standard | 1 | 0.5 | 0.5 | 0 |
| | Configuration management plan | 1 | 0 | 1 | 0 |
| | Dealing with increase in demand | 1 | 1 | 0 | 0 |
| | Validation and verification plan | 1 | 0 | 1 | 0 |
| | Release and deployment process | 1 | 0.5 | 0.5 | 0 |
| | Maintenance process | 1 | 0.5 | 0.5 | 0 |
| | General functioning | 2 | 0 | 0 | 2[d] |
| | Functioning with device events | 1 | 0 | 0 | 1[e] |
| | Use of device resources | 1 | 0 | 0 | 1[e] |
| | Use of network resources | 1 | 0 | 0 | 1[e] |
| **Interoperability** | | | | | |
| | Functioning with wearables | 2 | 1 | 0 | 1[g] |
| | Guides and specifications for all APIs | 1 | 0.5 | 0.5 | 0 |
| | Guides and specifications for terminologies | 1 | 0 | 1 | 0 |
| | Validation of data | 1 | 0.5 | 0.5 | 0 |

| | | | | | |
|---|---|---|---|---|---|
| | transferred via APIs | | | | |
| | Export of app data | 1 | 0 | 1 | 0 |

[a] Concepts and sub-concepts of each requirement in each assessment framework have been extracted and organized according to 82304-2 sub-aspects but include both 82304-2 and FTSS requirements.
[b] This concept is not score-impacting in 82304-2.
[c] This concept is not score-impacting in the FTSS framework.
[d] This FTSS only concept is now included in the sub-questions of the L2E handbook.
[e] This FTSS only concept is now partially included in the sub-questions of the L2E handbook. This means that the concept is included, but with a lower level of detail. For example, the L2E handbook checks whether measures to avoid misuse are in place, but not all measures that FTSS assesses have been included. In most cases, the L2E Consortium considered this level of detail not relevant.
[f] This FTSS only concept is context-specific for Catalonia or Spain. It is not for 82304-2 uptake.
[g] This FTSS only concept is scope-expanding, that is, it goes beyond the definition of a health app assessment framework, at least for 82304-2. Currently, it is not for 82304-2 uptake.

Both for the 82304-2 only and the FTSS only concepts, it is important to consider that these concepts may not be relevant or be of lesser importance in the other assessment framework. Of the initial 13% (12.5/97) FTSS only concepts, 7% (7/97) were in the meantime included in the sub-questions of the 82304-2 assessment handbook as considered relevant, 1% (1/97) was scope-expanding and thus was not for 82304-2 uptake, and 1% (0.5/97) was related to specific Catalan and Spanish regulations, also not for 82304-2 uptake. The remaining 4% (4/97) FTSS only concepts were specific to app usage-based assessment of the technical robustness of the app (mainly)–rigor-enhancing concepts– and not included in the L2E handbook as the evidence-based assessment was considered sufficient.

## Integration of CEN ISO/TS 82304-2

### *Advantages of each framework*

In general terms, both assessment frameworks were found to be quite similar. The scope, legislation and maintenance considered in 82304-2 and L2E is broader, which makes it a more valuable framework. In addition, the 82304-2 health app quality report is expected to be useful for potential users, health professionals and health systems to increase the willingness of using health apps. It is remarkable of FTSS; nevertheless, that the assessment of their framework is supported by health societies – the Functional Experts Committee –, and that they have more years of experience in their assessment. On the other hand, L2E tested with medical societies the usefulness of the health app quality report in providing guidance on health apps. An article with the European Society of Cardiology established that 82304-2 covered all specified requirements for apps in the 4 intended uses and 3 health issues investigated [23].

Regarding the assessment itself, combining evidence- and app usage-based assessment, as defined in the L2E handbook, was shown to provide the most advantages. The objectivity of the assessment is higher in L2E, although it is valuable of FTSS that their framework calculates the risk level of the app to determine the number of mandatory requirements, which relates to L2E's decision-making on which quality requirements are needed to qualify for a label in 2025, 2026, etc. CEN ISO/TS 82304-2 has at most 67 score-impacting requirements, depending on among other intended use, and whether an app includes health information, processes personal data, and is interoperable, requirements may or may not apply. On a global level, 4 requirements are mandatory to qualify for an 82304-2 label, on an EU level more, based on an alignment with EU level legislation and values. Additionally, FTSS

has a self-evaluation (readiness) test for manufacturers, which is recommended to be implemented similarly for 82304-2.

Considering the quality requirements themselves–the most important dimension to decide on integration–82304-2 covered 87% (84.5/97) of the concepts of both frameworks (47/97 (48%) “Both” plus 37.5/97 (39%) “82304-2 only”). By having added 7 FTSS only concepts to the sub-questions, the current L2E handbook contains 100% of the EU-relevant requirements of 82304-2 and FTSS assessment frameworks. The remaining 5.5 FTSS concepts (1 scope-expanding plus 0.5 context-specific plus 4 rigor-enhancing) are specific to the FTSS assessment framework. Overall, 82304-2 and the L2E Certification Scheme provide many advantages–a broader, more objective, pan-European assessment framework, with specific terminologies (e.g., ‘intended use’, ‘intended user’) that provide an enhanced value.

### *Weighing of integration scenarios*

Given the advantages that 82304-2 proved to provide, scenario (4) was disregarded, making the remaining integration scenarios (1) to use the L2E Certification Scheme and related handbook adding Catalonia-specific additional requirements, (2) to adopt 82304-2 into the FTSS framework (using the phrasing of 82304-2), or (3) to adapt 82304-2 according to our needs.

The L2E Consortium proposes an EU-level assessment via the L2E Certification Scheme, with each country (or region) then assessing only its country (or region) specific (context-specific, scope-expanding and rigor-enhancing) requirements. For Catalonia and manufacturers involved, this would simplify and accelerate the certification process. Thus, the idea for Catalonia would be to directly use the L2E Certification Scheme (option 1) once it is put in practice and 82304-2 health app quality labels are issued.

However, as the L2E Certification Scheme has not yet been put in practice, and the Government of Catalonia needs to carry on with app assessments and is interested in already improving its framework, we decided to start by implementing 82304-2 ourselves and adapting some requirements according to our needs (mix of options 2 and 3). This allowed the L2E Certification Scheme to follow its process of implementation in Europe while updating the FTSS framework.

### *Integration and validation*

All eighty-one 82304-2 requirements were incorporated in the new FTSS framework, using different integration mechanisms based on the match scores. For unmatched 82304-2 concepts, the 82304-2 requirements were adopted as is. For full matches, FTSS subtleties were added to the 82304-2 requirements. Of the partially matched sub-concepts, 8 could be added to existing 82304-2 requirements. Next, the remaining 3 partially matched sub-concepts, the 7 unmatched “FTSS only” concepts, and 1 new concept originating from a consultation of the newest regional guidelines [27] and Catalan subject matter experts as per the methodology outlined in Figure 2, were phrased as a

question to create 11 new quality requirements.

Subsequently, 5 of these 11 requirements were included both in the L2E handbook and the FTSS framework. The 6 remaining FTSS specific requirements included 1 scope-expanding requirement (wearables), 4 rigor-enhancing requirements (additional app usage-based assessment), and 1 context-specific requirement (ensuring that apps developed within the Ministry of Health of Catalonia contain the required visual identity). The entire set of requirements was translated to Catalan using plain language.

FTSS has already developed a new online form for submitting the necessary information and evidence for assessment. Assessment results will be tested in the following months, and intent is to present the results with a quality label very similar to that of 82304-2. Once the L2E handbook is put in practice and 82304-2 quality labels are issued, option 1 will become feasible. Then, the new Catalan assessment framework would consist of the 82304-2 label with 81 requirements and its added L2E handbook sub-questions, plus 6 additional requirements assessed by FTSS. That would mean the 82304-2 label covers 93% (81/87) of the Catalan assessment, with FTSS having to assess only 7%, (6/87).

## Discussion

### Principal Findings

We successfully achieved our objective of generating a systematic comparative analysis of the FTSS assessment framework for health apps with the 82304-2 framework. We identified 97 concepts, 37.5 of these were new or partially new concepts from 82304-2, all relevant to Catalonia, and 12.5 were FTSS specific. All eighty-one 82304-2 requirements were incorporated as is in the new FTSS framework. FTSS subtleties and partially matched sub-concepts were added to the existing 82304-2 requirements where suitable. The remaining FTSS only concepts and sub-concepts were rephrased as questions to create 11 additional requirements. Of these 11 requirements, 5 were integrated in the L2E handbook for 82304-2. Once the L2E handbook is operational, the remaining 6 requirements will be assessed on top of the existing eighty-one 82304-2 requirements. Of these 6, 1 requirement is scope-expanding, 4 are rigor-enhancing, and 1 is context-specific.

The methodology used enabled us to adequately consider and achieve proper integration of 82304-2 in Catalonia. We believe that this comparative methodology can serve as a useful model for health authorities in other regions and countries considering or seeking to integrate 82304-2 into their own assessment framework. In such cases, we expect that the comparison of the quality requirements is key. In our case, extracting the concepts of the requirements highly increased the reliability of the percentage matches obtained. The percentages obtained for each sub-aspect, as well as the final percentages, were the most useful for decision-making on 82304-2 integration.

Rogers' diffusion of innovation theory [28] acknowledges five attributes that influence rate of

adoption of an innovation. In this case, 82304-2 can be considered an innovation. The first and main attribute according to Rogers, and in our experience, is relative advantage–the degree to which 82304-2 is perceived as better than the current FTSS framework. Overall, 82304-2 has been observed to provide a positive relative advantage in comparison with the current FTSS framework, mainly due to the quality aspects and quality requirements included. Firstly, 82304-2 entails a more structured, ordered framework, with additional value-adding concepts to assess the quality of a health app compared to the FTSS framework. Secondly, 82304-2 adopts a Pan-European perspective, making it a more robust and scalable solution for app assessment across borders. This broader scope allows for the harmonization of assessment requirements, which is especially beneficial given the current lack of cross-country standardization in health app assessments. This advantage cannot be reached with a regional framework. Thirdly, 82304-2's evidence-based assessment approach on top of app usage-based assessment was evaluated favorably. For this reason, the 82304-2 requirements were incorporated in the new FTSS framework. FTSS requirements not covered by 82304-2 were maintained as additional requirements, as suggested by Frey et al. [29] and already operationalized by the Australian eHealth Agency's framework [30].

Rogers' second attribute is compatibility–the degree to which integration of 82304-2 is perceived as consistent with the existing known values, experiences and needs of Catalonia. Beyond our decisions detailed in the previous paragraphs, we propose multi-stakeholder feedback to assess compatibility. In June 2023, FTSS invited the members of the Functional Experts Committee to discuss the value of 82304-2, careers of its 8 members can be found on the FTSS website [25]. They concluded that this certification could become greatly useful if it became mandatory for all health apps in the European market, and especially if it appeared in the apps marketplaces. This way, the quality of all published health apps would be ensured, and patients, professionals, and healthcare systems would use and recommend health apps with more confidence and reliability. Additionally, in a later meeting, they valued the L2E health app quality report as a powerful tool to obtain relevant quality information of health apps and thus allow them to prescribe these apps.

Rogers' third attribute is complexity–the degree to which 82304-2 integration is perceived as relatively difficult to understand and use. Once the L2E handbook is put in practice and 82304-2 quality labels are issued, the new Catalan assessment framework would consist of the 82304-2 label plus only 6 additional requirements assessed by FTSS (7%, 6/87). A further expansion of the 82304-2 scope, as currently advocated for the upcoming 82304-2 revision, would likely eliminate the need for assessing the scope-expanding requirement by FTSS, further reducing the Catalonia-specific workload to 6% (5/87). Uptake of 82304-2 thus avoids considerable duplication of assessment efforts with similar requirements. Currently, however, as the L2E handbook was not yet available, we used an extensive analysis of 82304-2 to achieve proper integration. To operationalize the new framework, training of the assessors will be required. Although it is expected that this integration may carry more workload for assessors–at least in the beginning–, the time investment was considered acceptable in view of the enhanced value of the new framework and quality of certified apps that combined promote health app use. To end with, it will be necessary to properly decide how the quality labels are used; for instance, which scores are considered sufficient for apps to be used within the Catalan

Healthcare System.

The final two of Rogers attributes, trialability, the extent to which 82304-2 can be tested before its integration, and observability, the level to which 82304-2 integration provides tangible results, were considered of lesser importance at this stage. Taking into account that L2E has already performed tests with 24 apps, trials were considered mostly covered. However, Catalonia will test the resulting assessment framework with a minimum of 6 apps (hospital and private apps) by the end of 2024. Finally, regarding observability, we especially perceive great potential of 82304-2 in increasing the trust in and willingness to use health apps among all stakeholders, supported by recent and upcoming 82304-2 related publications [23,31]. Once certificates are issued, it will be possible to observe the actual increase in the degree of trust.

## Conclusions

The methodology presented has allowed a systematic, extensive comparative analysis of Catalonia's FTSS health app assessment framework and CEN ISO/TS 82304-2. CEN/ISO-TS 82304-2 was found to provide a more structured, ordered framework, with many additional, important concepts to assess the quality of a health app in comparison to the FTSS assessment framework. Once the 82304-2 assessment framework is put in practice through the L2E handbook, and 82304-2 quality labels are issued, the L2E handbook will achieve 93% (81/87) of the new Catalan assessment, reducing the assessment workload to 7% (6/87) Catalonia-specific requirements. FTSS highly encourages other authorities to undertake a similar process or to wait until the L2E handbook is in practice to adopt it in full.

## Acknowledgements

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## Authors' Contributions

Conceptualization – CPB (lead), BLC, PH, MVQ (supporting)
Formal analysis – BLC (lead), CPB (equal), PH (supporting)
Funding acquisition – CPB (lead), PH (equal)
Methodology – CPB (lead), BLC (equal)
Project administration – CPB
Supervision – CPB
Validation – CPB
Visualization – BLC
Writing – original draft – BLC

Writing – review & editing – BLC (lead), PH (equal), CPB, MVQ (supporting)

## Conflicts of Interest

None declared. Although TIC Salut Social Foundation was part of the L2E Consortium, the actions, findings and conclusions presented in this study have not been instructed by Label2Enable. This study has been conducted following the willingness and needs identified by the Ministry of Health of Catalonia, based on their existing knowledge on health apps assessment.

## Data Availability

Most of the data used in this study are publicly available and can be accessed or purchased online via the links provided in the references. Additional data regarding the methodology and results may be made available upon reasonable request to the corresponding author.

## Abbreviations

82304-2: CEN ISO/TS 82304-2
CEN: European Committee for Standardization
EU: European Union
FTSS: TIC Salut Social Foundation (Catalan abbreviation)
ISO: International Organization for Standardization
L2E: Label2Enable
MDR: Medical Device Regulation
TS: Technical Specification

## Multimedia Appendix 1

Fundamental information and characteristics of CEN ISO/TS 82304-2 and TIC Salut Social Foundation assessment frameworks.

## Multimedia Appendix 2

Governance and maintenance of CEN ISO/TS 82304-2 and TIC Salut Social Foundation assessment frameworks.

## Multimedia Appendix 3

Certification workflows of CEN ISO/TS 82304-2 and TIC Salut Social Foundation assessment frameworks.

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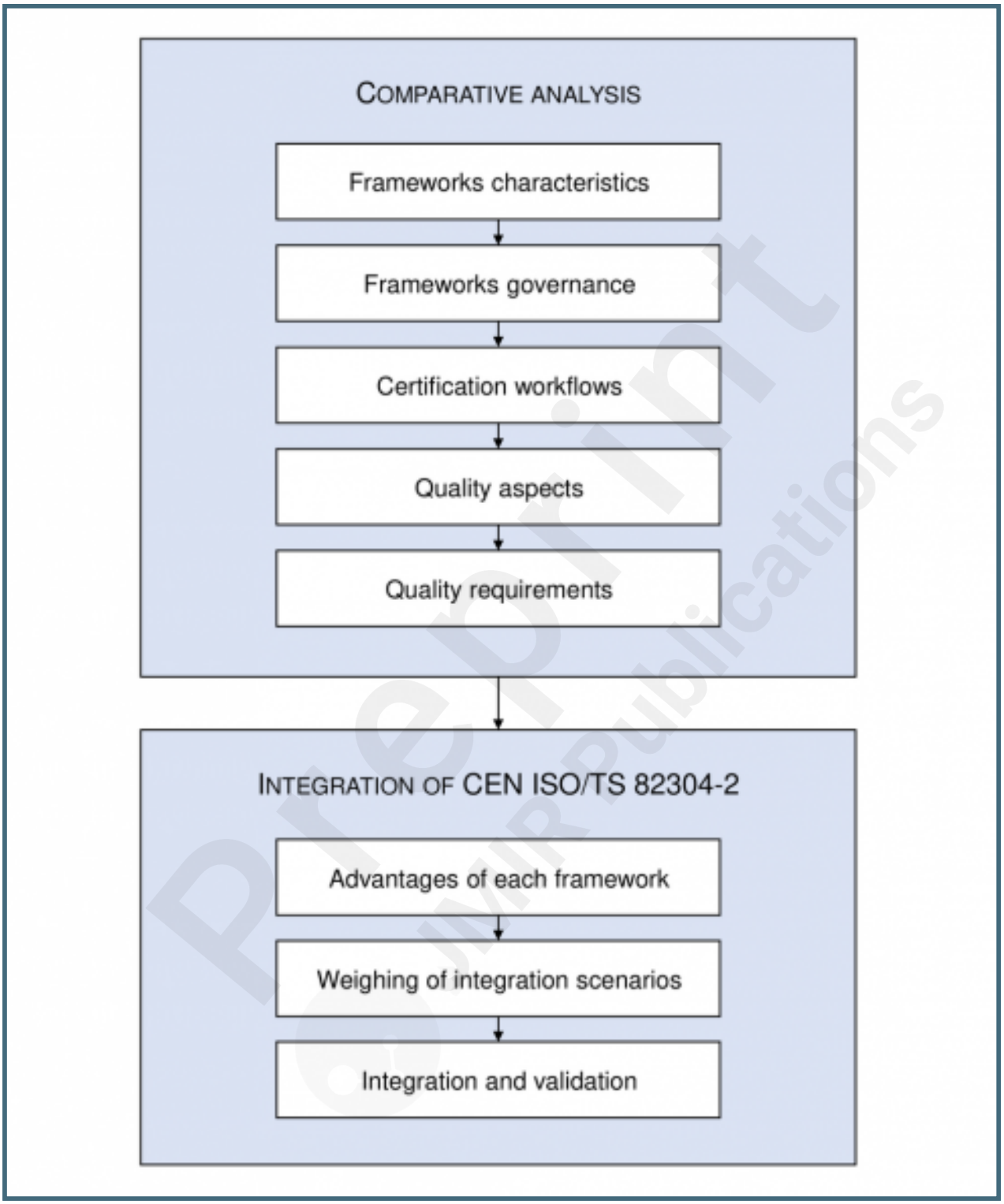
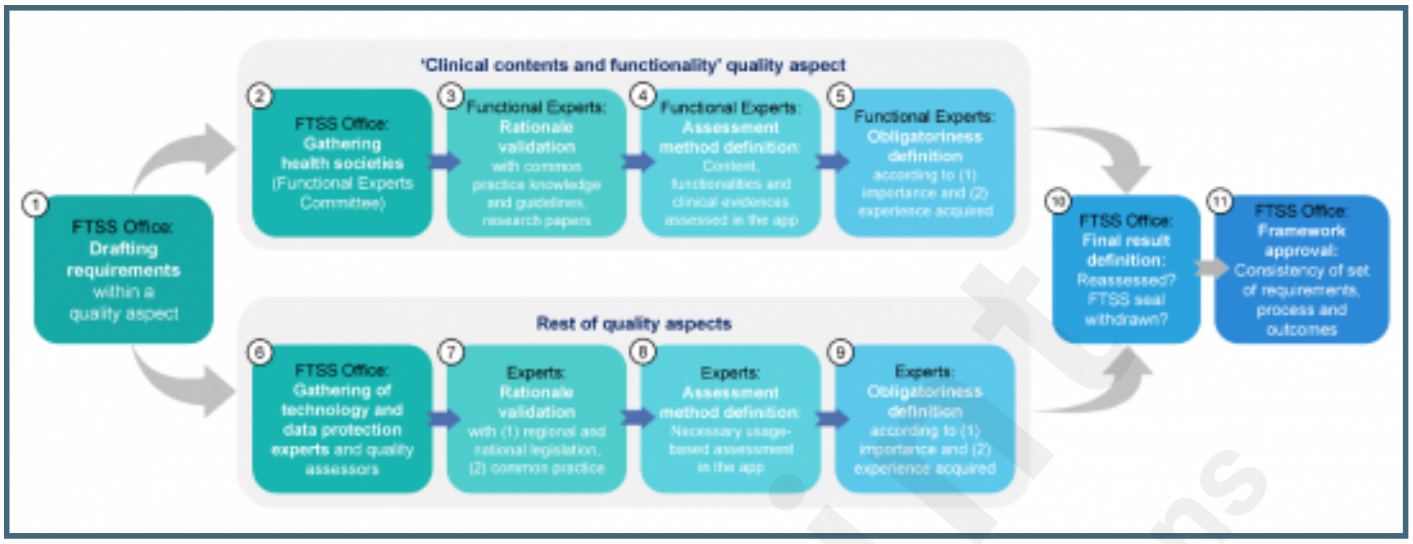
# Supplementary Files

# Figures

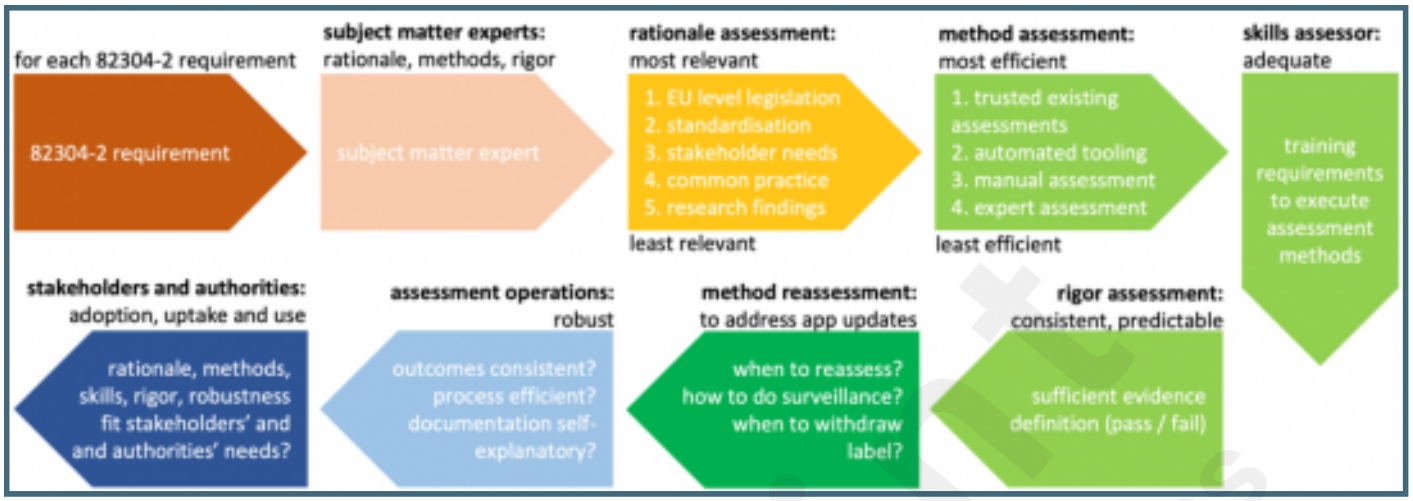
Overview of the methodology used in this study.



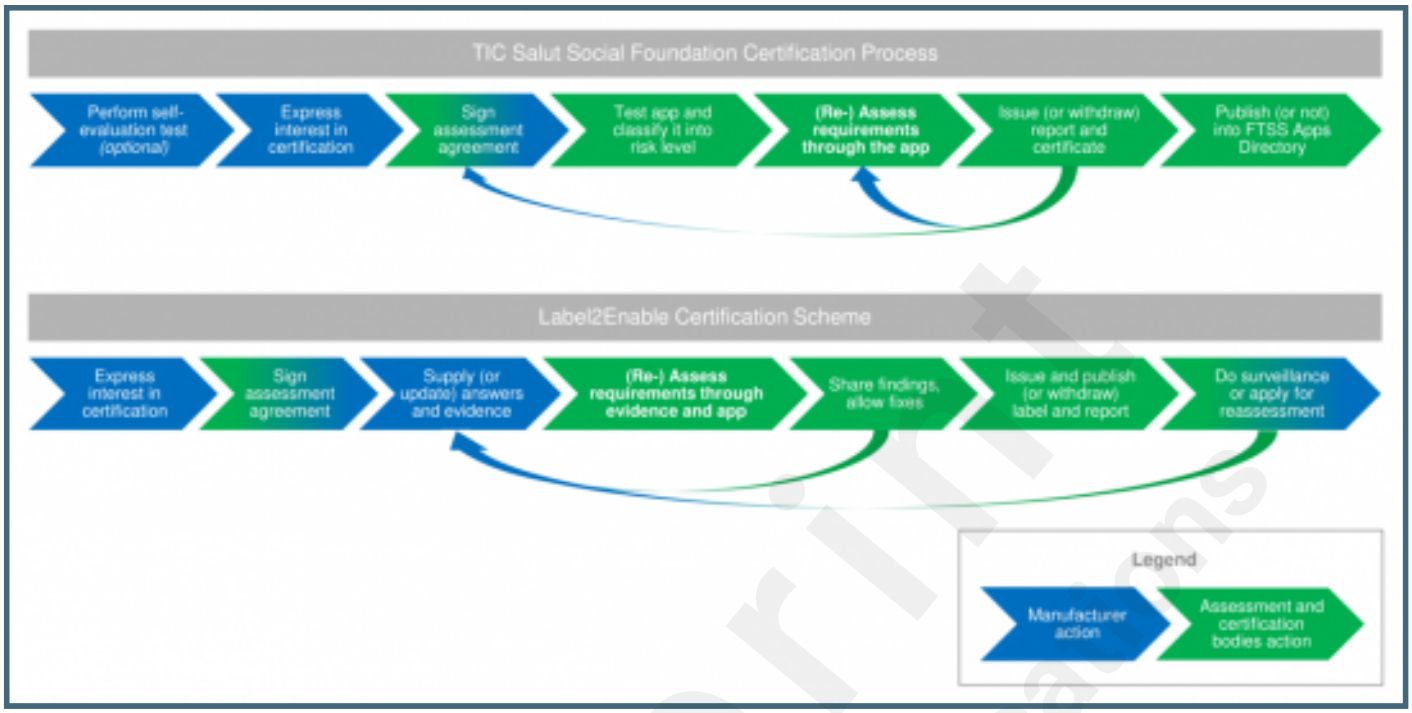
Methodology of definition and maintenance of each quality aspect within the TIC Salut Social Foundation (FTSS) assessment framework.



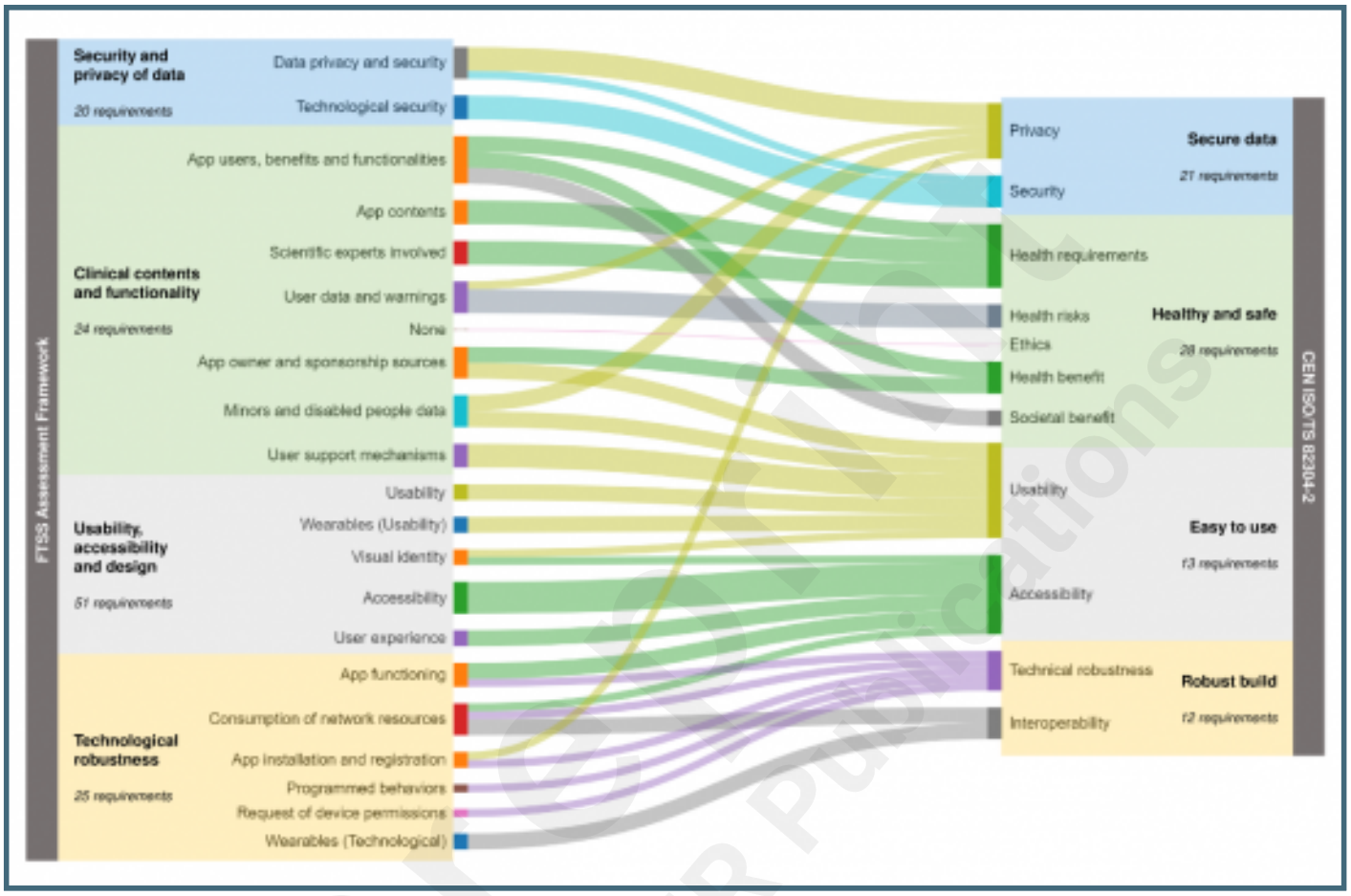
Methodology to co-create the handbook app assessment for CEN ISO/TS 82304-2 (abbreviated as 82304-2).



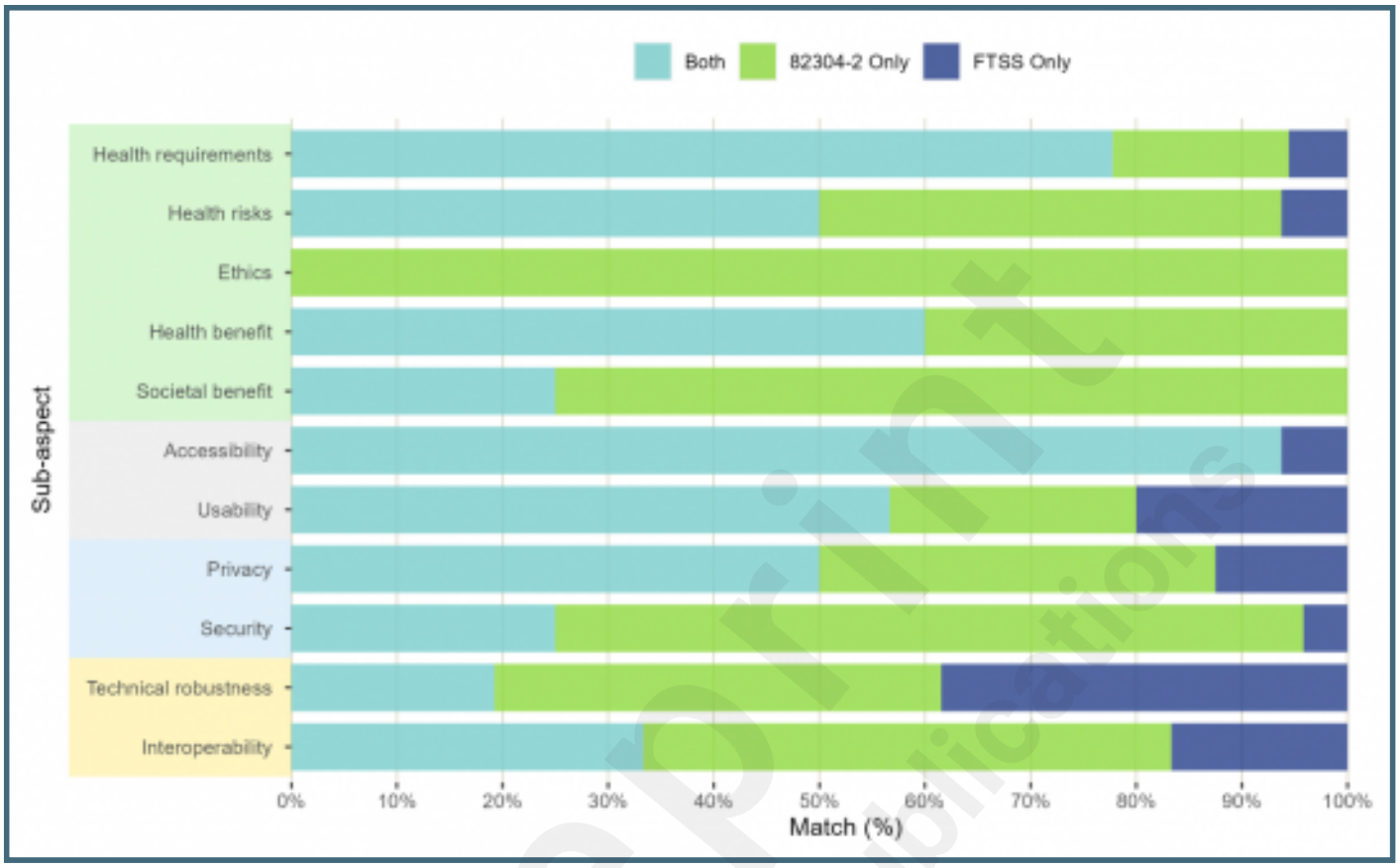
Overview of certification workflows of TIC Salut Social Foundation (above) and Label2Enable Certification Scheme (below).



Matches found between the four quality aspects of TIC Salut Social Foundation (FTSS) assessment framework and CEN ISO/TS 82304-2, represented with the same background color (blue, green, grey and yellow); and main connections between the different sub-aspects of both frameworks. Connections were found when the concepts assessed in the requirements were similar. Note that this is a qualitative analysis; thus, the thickness of the connection lines is not numerically representative.



Percentage match of concepts between CEN ISO/TS 82304-2 (abbreviated as 82304-2) and TIC Salut Social Foundation (FTSS) assessment framework across each assessment sub-aspect.



# Multimedia Appendixes

Fundamental Information and Characteristics of CEN ISO/TS 82304-2 and TIC Salut Social Foundation Assessment Frameworks.
URL: http://asset.jmir.pub/assets/3a3885f3bb3211f53848aeef255294e4.docx

Governance and maintenance of CEN ISO/TS 82304-2 and TIC Salut Social Foundation assessment frameworks.
URL: http://asset.jmir.pub/assets/3694ca25517b215d4dfa14a0ae0d3694.docx

Certification Workflows of CEN ISO/TS 82304-2 and TIC Salut Social Foundation Assessment Frameworks.
URL: http://asset.jmir.pub/assets/d90412cadc944e22477f542ffb48b566.docx