Reducing Uncertainty about the Adoption of CEN ISO/TS 82304-2: A Qualitative Interview Study on the Compatibility of a Health App Assessment Framework with Catalan and Italian Health Authorities' Needs

Petra Hoogendoorn, Mariam Shokralla, Romy Wilemsen, Nick Guldemond, Maria Villalobos-Quesada

Submitted to: Journal of Medical Internet Research
on: October 22, 2024

Table of Contents

Original Manuscript **5**
Supplementary Files **26**
Figures **27**
Figure 1 ..... **28**
Figure 2 ..... **29**
Multimedia Appendixes **30**
Multimedia Appendix 1 ..... **31**
Multimedia Appendix 2 ..... **31**

Reducing Uncertainty about the Adoption of CEN ISO/TS 82304-2: A Qualitative Interview Study on the Compatibility of a Health App Assessment Framework with Catalan and Italian Health Authorities' Needs

Petra Hoogendoorn[1] MSc; Mariam Shokralla[1]; Romy Wilemsen[1] MSc; Nick Guldemond[1, 2] MD, PhD Eng; Maria Villalobos-Quesada[1] PhD

[1]National eHealth Living Lab Public Health and Primary Care Department Leiden University Medical Centre Leiden NL
[2]Research Center for Medical Sociology Tsinghua University Beijing CN

Corresponding Author:
Petra Hoogendoorn MSc
National eHealth Living Lab
Public Health and Primary Care Department
Leiden University Medical Centre
Albinusdreef 2
Leiden
NL

Abstract

Background: Health authorities of European Union (EU) Member States (MS) increasingly pursue integration of quality health apps in their healthcare systems. Several of these authorities have developed their own assessment framework (AF) to evaluate the quality of individual health apps, but struggle with its efficient implementation. The European Commission initiated Technical Specification (TS) CEN ISO 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability (hereinafter the "TS" or "innovation") to address the scattered EU landscape of AFs for health apps. Decision-making on adoption of the TS is MS competence and considered an uncertainty-reduction process. "Compatibility" of the TS with MS health authorities' needs and evaluations by peers are effective in reducing this uncertainty and mediate harmonisation.

Objective: To examine the "compatibility" of the TS with the needs of health authorities of two EU MS, to enhance the compatibility of the TS, and potentially reduce the uncertainty of peer health authorities in their considerations on adopting the TS.

Methods: Semi-structured interviews were conducted with a regional (Catalonia, Spain) and a national health authority (Italy). Compatibility was visualised using the Value Proposition Canvas, where we mapped out (a) authorities' needs: "gains", "pains" and "jobs", (b) the TS "products and services" and their distinct characteristics: "gain creators" and "pain relievers", and (c) the compatibility or "fit" between (a) the authorities' needs and (b) the TS.

Results: Despite their diversity, the needs of the two authorities were similar. Both acknowledged the value and need of integrating quality health apps and using an AF. Both experienced that without enabling EU legislation and standardisation, and with the many authorities involved, achieving (consensus on) an AF is challenging. Nine TS-related products and services and 17 distinct characteristics (e.g., its multi-stakeholder evidence base), were found to be compatible with 3/9 gains perceived by authorities (e.g., stimulating prescriptions and use of apps), 7/9 pains (e.g., legislation and harmonisation issues), and 6/11 jobs (e.g., assessing apps). Indirect effects, three anticipated future services and one anticipated gain creator/pain reliever increase this compatibility.

Conclusions: Our results suggest that the TS is compatible with the needs of the two authorities concerned. The similarity in their needs suggests that health authorities share common fundamental needs. Both profiling the needs of the Catalonian and Italian authorities and mapping their compatibility with the TS potentially reduce peer authorities' uncertainties in adopting an AF in general and the TS in particular. More research is recommended to confirm our results in other settings and further finetune compatibility to achieve wide adoption. To our knowledge, this is the first effort to systematically analyse the compatibility of an AF, with the potential to harmonise AFs and accelerate the uptake of health apps.

(JMIR Preprints 22/10/2024:67855)

DOI: https://doi.org/10.2196/preprints.67855

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ **Please make my preprint PDF available to anyone at any time (recommended).**
Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.
No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**
Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain v
Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <a href="http

Original Manuscript

Reducing Uncertainty about the Adoption of CEN ISO/TS 82304-2: A Qualitative Interview Study on the Compatibility of a Health App Assessment Framework with Catalan and Italian Health Authorities' Needs

P. Hoogendoorn[1]*, M. Shokralla[1,2], R. Willemsen[1], N. Guldemond[2], M. Villalobos-Quesada[1]

*Corresponding author

[1] National eHealth Living Lab, Public Health and Primary Care Department, Leiden University Medical Centre.

[2] Research Center for Medical Sociology, Tsinghua University

Abstract

Background: Health authorities of European Union (EU) Member States (MS) increasingly pursue integration of quality health apps in their healthcare systems. Several of these authorities have developed their own assessment framework (AF) to evaluate the quality of individual health apps, but struggle with its efficient implementation. The European Commission initiated Technical Specification (TS) CEN ISO 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability (hereinafter the "TS" or "innovation") to address the scattered EU landscape of AFs for health apps. Decision-making on adoption of the TS is MS competence and considered an uncertainty-reduction process. "Compatibility" of the TS with MS health authorities' needs and evaluations by peers are effective in reducing this uncertainty and mediate harmonisation.

Objective: To examine the "compatibility" of the TS with the needs of health authorities of two EU MS, to enhance the compatibility of the TS, and potentially reduce the uncertainty of peer health authorities in their considerations on adopting the TS.

Methods: Semi-structured interviews were conducted with a regional (Catalonia, Spain) and a national health authority (Italy). Compatibility was visualised using the Value Proposition Canvas, where we mapped out (a) authorities' needs: "gains", "pains" and "jobs", (b) the TS "products and services" and their distinct characteristics: "gain creators" and "pain relievers", and (c) the compatibility or "fit" between (a) the authorities' needs and (b) the TS.

Results: Despite their diversity, the needs of the two authorities were similar. Both acknowledged the value and need of integrating quality health apps and using an AF. Both experienced that without enabling EU legislation and standardisation, and with the many authorities involved, achieving (consensus on) an AF is challenging. Nine TS-related products and services and 17 distinct characteristics (e.g., its multi-stakeholder evidence base), were found to be compatible with 3/9 gains perceived by authorities (e.g., stimulating prescriptions and use of apps), 7/9 pains (e.g., legislation and harmonisation issues), and 6/11 jobs (e.g., assessing apps). Indirect effects, three anticipated future services and one anticipated gain creator/pain reliever increase this compatibility.

Conclusions: Our results suggest that the TS is compatible with the needs of the two authorities concerned. The similarity in their needs suggests that health authorities share common fundamental needs. Both profiling the needs of the Catalonian and Italian authorities and mapping their compatibility with the TS potentially reduce peer authorities' uncertainties in adopting an AF in general and the TS in particular. More research is recommended to confirm our results in other settings and further finetune compatibility to achieve wide adoption. To our knowledge, this is the first effort to systematically analyse the compatibility of an AF, with the potential to harmonise AFs and accelerate the uptake of health apps.

Keywords: *assessment frameworks, mHealth, health apps, wellness apps, digital transformation, Italy, Catalonia, diffusion of innovations, value proposition design.*

Introduction

Health authorities of European Union (EU) Member States (MS) are transforming health and care systems to address current challenges and remove cross-border regulatory barriers for businesses and consumers to progress towards an EU Digital Single Market [1–6]. In this context, health apps (box 1) gain attention and countries are adapting their policies and structures to harvest the potential of these digital solutions to strengthen their healthcare systems [5,7–10].

Box 1. Definitions of health apps, medical apps and wellness apps.

In the context of this article, health apps are defined as apps which are "intended to be used specifically for managing, maintaining or improving health of individual persons or the delivery of care" [11]. Health apps are part of mHealth, which is defined as "medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices" [12]. Health apps include medical apps and wellness apps. Medical apps have been defined as those that fall under an applicable medical device regulation, and wellness apps as those that do not [13].

Not all apps are of good quality, i.e., have a positive and reliable effect on health, and are easy to use, compliant with privacy and data security regulations and standards, robust, and interoperable with Electronic Health Record (EHR) systems [8,9,14]. Determining the quality of individual health apps is challenging for citizens, healthcare professionals (HCPs), and decision-makers [15] for various reasons. First, assessing apps requires specific and diverse expertise. Second, robust evidence (e.g., clinical evidence) and background information are often scarce, inappropriate, or not publicly available [14]. Third, quality assessments and widely-adopted evidence-based evaluation methodologies that consider all these aspects and inform (potential) users about the quality of these apps are not yet common [10].

Several health authorities have developed their own assessment framework (AF) [16]. However, their efficient implementation is challenging [7,15]. The significant overlap in quality criteria across these AFs highlights the potential for harmonisation and related efficiency [17]. Additionally, non-overlapping quality criteria, i.e. a lack of agreement on what constitutes quality, potentially decreases trust [17] and increases inequality. For example, if the challenges to comply with the different AFs result in manufacturers focusing only on the larger markets and widely spoken languages. In the context of multilingualism, an EU founding principle [18], and an abundance of health apps worldwide [19], the availability of native language health apps for the 5 million Finnish-speaking EU residents is, for instance, limited [20]. These aspects highlight the need for harmonisation of AFs at an EU level.

Both academics and policymakers endorse harmonisation and cross-national regulation of health apps to realise their full potential and benefits [7,10]. The European Commission initiated Technical Specification CEN ISO 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability (hereinafter the "TS" or "innovation") (box 2) to address the scattered EU landscape of health app AFs and progress from 27 national or even more regional markets to a Digital Single Market [6,11]. To achieve EU-wide harmonisation, adoption of the TS among EU MS is needed, which is MS competence and responsibility. Adoption across MS can be described as the diffusion of the TS as an innovation.

Box 2. Brief description of the CEN ISO/TS 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability.

CEN ISO/TS 82304-2:2021 was an assignment from the European Commission to the European Committee for Standardization (CEN) that became a global effort in its collaboration with the International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). The TS has two core products. The first one is a health app assessment framework founded in a Delphi study with 83 experts (Hoogendoorn et al. 2023). The second one is a quality label (multimedia appendix 1) that was inspired by the EU Energy label and Nutri-Score front-of-pack nutrition label designs and the FDA over-the-counter medicine label content. The quality label allows the easy and accessible presentation of the assessment results of a health app and was developed and tested with people with low health literacy [21]. The EU-wide implementation readiness of the TS was supported by the Horizon Europe Label2Enable Project (2022-2024), which developed products and services complementary to the assessment framework and quality label (Label2Enable 2024c).

Innovations and their adoption process can be understood using Rogers' Diffusion of Innovations Theory. Rogers identifies three main attributes of an innovation that predict its future rate of adoption [22]. "Compatibility" is one of these attributes and refers to the degree to which an innovation is perceived as consistent with the existing values, experiences and needs (summarized hereinafter as "needs") of potential adopters. The diffusion of an innovation is considered an uncertainty-reduction process. An innovation that is compatible generates less uncertainty for the potential adopter regarding the success of its deployment. The other main attributes that predict the future rate of adoption, "relative advantage" and "complexity", are beyond the scope of this article and will be analysed in separate studies. Potential adopters tend to rely on peers for information about an innovation's desirable, direct, and anticipated consequences to decrease their uncertainty about adopting it [22]. In this article, we aim to examine the "compatibility" of the TS with the needs of two health authorities in the EU, to potentially enhance the compatibility of the TS, and reduce the uncertainty of peer health authorities in their considerations on adopting the TS.

Methods

Rogers described different ways to research the attributes of innovations, including compatibility. To investigate an innovation's acceptability in its pre-diffusion stage (e.g., test-marketed and piloting), was considered the most suited for this study. This approach allows to identify a "basis for positioning an innovation so that it will be more acceptable, that is, have a more rapid rate of adoption" [22]. "Key informant" interviews are a common method for assessing the acceptability of an intervention [23]. A widely used business tool to visualise and enhance compatibility (also referred to as "fit") of innovations is the value proposition canvas (VPC, figure 1, box 3) [24,25]. The VPC tool has been previously applied to guide the development of, among others, digital health innovations [26–28].

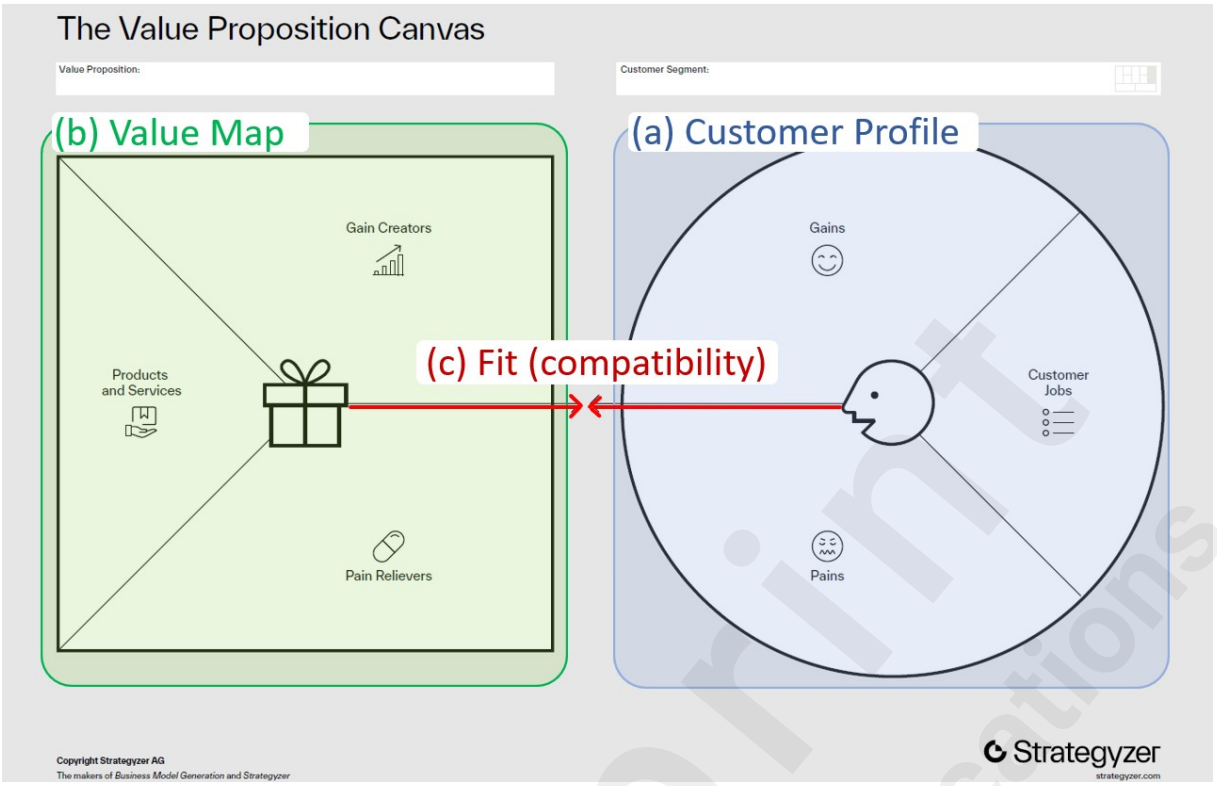


Figure 1. The template of the Value Proposition Canvas (VPC, Osterwalder et al. 2014). Adapted from Strategyzer 2019 to highlight the three main steps to construct the VPC (box 3): (a) Customer Profile, (b) Value Map, and (c) Fit (compatibility).

Box 3. Glossary of value proposition concepts [25].

*The **Customer profile,** at the right-hand side of the Value Proposition Canvas (VPC), describes a potential adopter segment, in this case, health authorities in terms of their:*
***Jobs:** What potential adopters need, want, or desire to get done in their work and their lives.*
***Gains:** Outcomes and benefits potential adopters require, expect, desire, or dream to achieve.*
***Pains:** Negative outcomes, risks, and obstacles that adopters want to avoid, notably because they prevent them from getting a job done (well).*

*The **Value Map,** at the left-hand side of the VPC, makes explicit how the innovation, creates value for the potential adopters' segment:*
***Products and services:** The range of products and services available to potential adopters.*
***Gain creator:** How these products and services create gains and help adopters achieve the outcomes and benefits they require, expect, desire, or dream of by getting a job done (well).*
***Pain reliever:** How these products and services alleviate adopter pains that prevent them from getting a job done (well).*

***Fit or compatibility:** When the elements of the innovation's Value Map contribute to realising the jobs and gains, and address the pains of the potential adopters, as depicted in the Customer Profile.*

In this article, we used the VPC to visualise the compatibility of the TS with the needs of two health authorities (potential adopters of the TS), (i) a regional authority: TIC Salut Social Foundation (Fundació TIC Salut Social, FTSS), the public body organisation that oversees the digital transformation in healthcare in Catalonia, Spain, and (ii) a national authority: the Italian National Institute of Health (Istituto Superiore di Sanità, ISS).

Catalonia established its own AF in 2017 [29–31] and is pursuing adoption of the TS [32]. Italy drafted a Technical Report about wellness, social and health apps which informed the TS [33] and has been using the TS as inspiration in the ongoing process to arrive at quality assessment criteria for inclusion of telehealth solutions in a national catalogue of telehealth, where telehealth includes health apps. Both institutions are partners of the Horizon Europe Label2Enable project (box 2).

Constructing the VPC involves three steps (figure 1, box 3) [25], which we carried out systematically using qualitative research methods. The first step was to develop the “Customer Profile” (figure 1.a). Here, the needs of the potential adopters (health authorities) of an innovation were described in terms of what the two authorities expect to obtain or win from adopting an AF to integrate quality health apps (hereinafter “gains”); the tasks or responsibilities of authorities in that effort (hereinafter “jobs”), and the related challenges that they face (hereinafter “pains”). Semi-structured interviews (multimedia appendix 2) were designed using Strategyzer’s “trigger questions” [34].

Two semi-structured interviews were carried out with three key informants, chosen based on their key position in their respective organisations, and knowledge about the authorities’ policy and plans to assess health apps. One interviewee has been responsible for implementing Catalonia’s mHealth Plan in FTSS for the past 9 years. The second interviewee recently retired from a leadership role at ISS, and the third interviewee had complementary first-hand experience on the topic in dealings with the Italian Ministry of Health. The last two informants played a direct role in drafting the Technical Report, which informed the TS (UNI 2018). The semi-structured interview questions were shared with the key informants in advance. Interviews were performed online, recorded using a secure digital platform and lasted between 1.5 and 2 hours. Recordings were transcribed verbatim and coded using Atlas.ti Web (v7.9) independently by two researchers.

A deductive and inductive thematic analysis of the interviews was carried out. Three main themes were predefined based on the VPC: gains, pains, and jobs [25]. We classified a job, as a past, current, or future activity of a healthcare authority, related to adopting an AF to integrate health apps in their healthcare system. Jobs could be the responsibility of the authority interviewed or associated authorities, because from an international perspective authorities’ task divisions may differ and evolve. We applied the same principle to the gains and pains. Subthemes were inductively developed by two researchers and visualised on the VPC. A participant validation step was carried out separately per authority and lasted between 30 and 60 minutes. We did not formally check if data saturation was achieved, however, participant validation confirmed we had captured the most relevant aspects.

The second step of the VPC was to develop the “Value Map” (figure 1. b), which consists of describing the innovation’s “products and services" (the TS and related products and services for health authorities), “pain relievers” (*how* these products/services address the authorities’ “pains”), and “gain creators” (*how* these products/services create “gains” for authorities). Outputs from all Label2Enable work packages were considered [21,35]. Products and services included those currently part of the TS (box 2), co-created in the Label2Enable project, and products and services that will be generated beyond the project during the “Demonstrator phase”. The relevant characteristics of these products and services were subsequently added to the Value Map as gain creators and pain relievers.

The third step of the VPC is to **(c)** Determine the “Fit”, i.e., if the “Value Map” is compatible with the “Customer Profile”. In other words, if the TS, related products and services and their distinct characteristics satisfy the jobs, pains and gains of the authorities. Visualising compatibility (“fit”) was an iterative process of determining and conceptualising the products and services, gain creators

and pain relievers that related to the health authorities' gains, pains and jobs. After this process, a participant validation step was carried out with both authorities simultaneously, which lasted approximately 1 hour. The final manuscript was further discussed with the interviewees at different stages, and all agreed to its publication.

Results

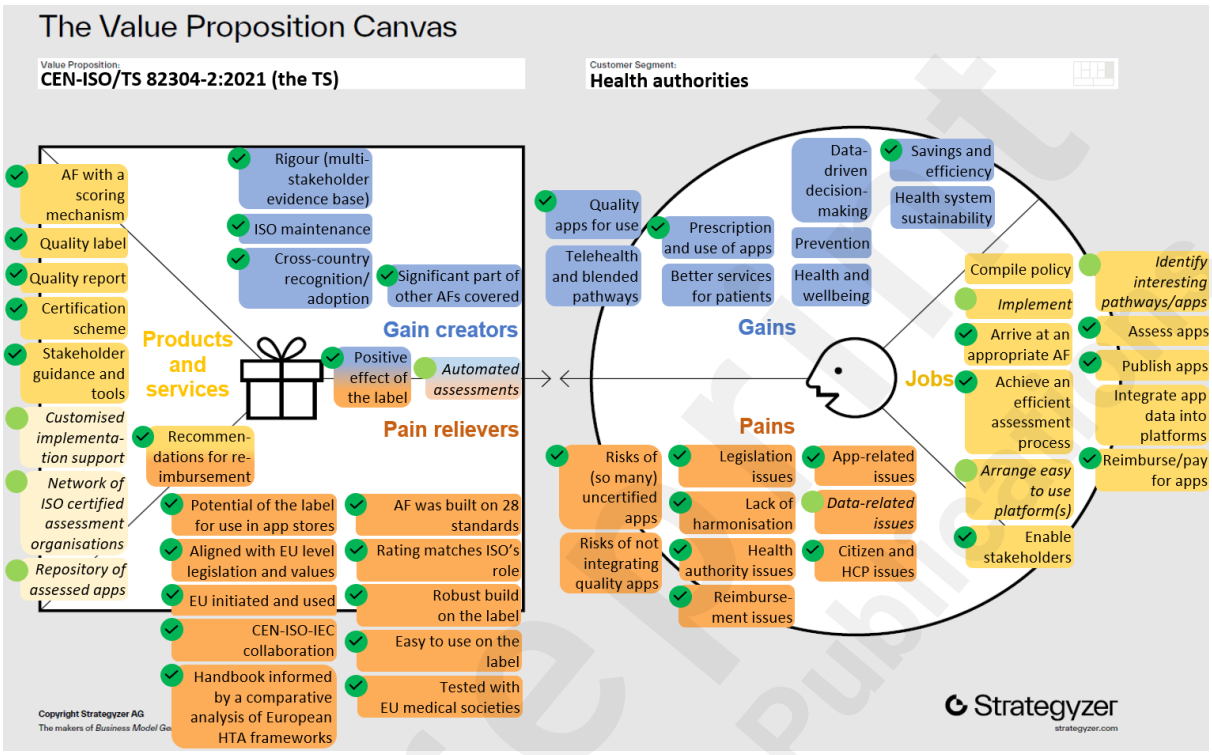


Figure 2. The Value Proposition Canvas (VPC) of the TS for health authorities which pursue an assessment framework to integrate health apps in their healthcare systems, with on the right the "Customer Profile" and on the left the "Value Map". Lighter coloured boxes indicate future services, gain creators and pain relievers. Dark green dots with a check mark indicate the fit (compatibility) with an existing product or service, gain creator or pain reliever. Light green dots without a check mark and italic text indicate future fit (compatibility) derived from the anticipated nature of the related services and gain creator/pain reliever.

a) Customer Profile

In this section we describe the needs of authorities (potential adopters) in terms of gains, pains and jobs.

Gains

Regarding gains, what authorities expect to earn, obtain, or win from adopting an AF and integrating quality health apps, interviewees explained the interest of their region (Catalonia, Spain) or country (Italy), in an AF to identify "Quality apps for use" in "Telehealth and blended care pathways" (Italy and Catalonia respectively, box 4).

Box 4. Key definitions in the Catalonian and Italian context.

Blended care in Catalonia: "The term 'blended' refers to an integration of online and offline components in a treatment process. This means that online and offline components are interconnected in some way and not standalone treatment pathways" [36]. In Catalonia, blended care is framed as "integrated care" within the Catalonian mHealth Plan. This Plan describes that mHealth should always have an impact on the full cycle of provision of care, including services aimed at managing different health conditions. The Plan indicates that there will be a focus on the ten most prevalent diseases; for example, diabetes [37].

Telehealth in Italy: The World Health Organization (WHO) defines telehealth as the "delivery of health care services, where patients and providers are separated by distance [12]. In the Italian context, telehealth or telemedicine, is an innovative approach to healthcare practice by enabling the remote provision of services through the use of digital devices, the Internet, software and telecommunication networks. Telehealth services can be an alternative to traditional services, can support (e.g. to improve accessibility, efficiency, and equity), supplement (e.g. to improve effectiveness and facilitate personalised medicine) or completely replace traditional services [38].

They described how the assessment of apps is instrumental to achieving "Prescription and use of apps", referring to incorporating the prescription or recommendation of apps in the provision of care and the related trusted use of health apps by citizens. Similarly, it can contribute to "Better services for patients" (e.g., improved accessibility, lower waiting times, and better follow-up).

> *"If you want these applications to be recommended by healthcare professionals, we need to provide safe and guaranteed apps to the sick, so we try to establish how we can measure or evaluate these apps and the quality of these apps." (Catalonia)*
>
> *"Certainly, the availability of an agreed, evidence-based assessment framework will give objectivity to the activity of app assessment." (Italy)*
>
> *"They [patients] will have the opportunity to make more virtual visits, sharing the data with their professionals without needing to go to the consult, provide more alerts and provide more predictions, and prevention to avoid disease or avoid being sicker. Also, they will feel more confident and committed to healthier lifestyle habits when using wellness apps. And they can also be more guarded by their professionals. They will feel more followed up." (Catalonia)*
>
> *"Moreover, such apps can also streamline the access of the citizens to the NHS, for example by cutting waiting times for a given service." (Italy)*

For the interviewees, prescription and use of apps would enable "Data-driven decision-making", use of health data derived from an individual's health app use in the delivery of healthcare, seeing both benefits for the prescribing HCP and the provision of effective transversal care. Other benefits mentioned included the possibilities for "Prevention", through promotion of healthier behaviours and end-user's empowerment, and ultimately "Health and wellbeing".

> *"To provide more autonomy to patients and to be more committed to their health, to keep tracking health data more efficiently and having all the information integrated into the public single network, so that all healthcare professionals are able to follow up the patient through the information system." (Catalonia)*
>
> *"The interest of our country is given by the opportunity of providing the best health status of the population, even with limited resources. Health apps can support primary and secondary prevention, by modifying lifestyles." (Italy)*

They described how all the aforementioned gains, translate into "Savings and efficiency" and "Health system sustainability", mentioning aspects such as less in-person visits, more virtual visits, more

equity, earlier diagnosis, and cross-country recognition of app assessments.

> *"I think for healthcare professionals, they [apps] will reduce the number of face-to-face consults for more virtual. They will have a unique platform or a unique space to monitor the data of the patients [...] they receive alerts, for example, so that they focus their attention on critical issues, not revising a lot of data." (Catalonia)*

> *"My personal feeling for sure, savings at the health system level. Access for all the people, or the individuals, as my Constitution says." (Italy)*

> *"Another step that has to be done is updating the current certification framework and consider the possibility to adapt this framework to the Technical Specification of 82304-2, in order to improve the framework for cross-recognition." (Catalonia)*

> *"A sound evaluation framework, recognized by the EU, will be instrumental in optimising the resources spent in assessing health apps in the different EU Countries, by means of the foreseeable cross-country validity of the approval." (Italy)*

Pains

Regarding the pains, the challenges authorities face with respect to assessing and integrating apps, both authorities mentioned context, implementation and app use related items. The "Risks of (so many) uncertified apps", referred to the currently unknown quality of apps and the negative effects for patients, HCPs and the healthcare system. At the same time, interviewees considered the "Risks of not integrating quality apps" and expressed that not integrating apps would be an obstacle to providing better care and other important gains.

> *"That is the main risk, not being adopted because professionals don't feel that it helps. Because I think that the patient part is solved. They are using it a lot and they want to be involved." (Catalonia)*

> *"We've in Italy started a long time ago working on apps because we have realised that digital support to healthcare is absolutely mandatory, and it was clear that there was a sort of Wild Wild West with respect to the apps." (Italy)*

> *"The main risk, I think, will be not adopting mobile apps into the healthcare system, not providing sufficiently optimised care to the citizens compared to other territories." (Catalonia)*

> *"At present you lose data, you lose information, you lose the capability to cost, to build a new best practice because you have no sufficient critical mass of data to say something, also to use artificial intelligence appropriately. (Italy)*

Implementation related pains mentioned by the interviewees included "Legislation issues" such as the lack of comprehensive legislation for apps that are not medical devices, and the multiple applicable (emerging) EU legislations, which pose significant challenges to app developers and authorities. "Lack of harmonisation" is a missed opportunity to alleviate the burden of legislation issues and potentially adds to the difficulties.

> *"We are regulating medical devices, the apps that are also medical devices, thanks to the new regulation of medical devices, but we cannot regulate the apps that are not medical devices. That is why we are interested in integrating a sort of certification scheme similar to, or directly, the ISO [82304-2] technical specification." (Italy)*

> "*I am afraid of too much legislation. Too much vertical [legislation] that is not correlated to each other." (Italy)*

> *"We faced the challenge to create the framework from scratch because we did not have*

anything at the time." (Catalonia)

"The risk in the immediate future is that some regional health system starts piloting an evaluation framework without national coordination, in that case [...] it would be more difficult to harmonise the assessment at national level, which could result in enhanced health inequalities." (Italy)

For the interviewees, legislation issues and lack of harmonisation resulted in "Health authority issues". Integration of health apps in healthcare currently involves many authorities. Health apps present an uncharted territory, may be just one of their many topics, and their own interests, roles and responsibilities related to health apps can be unclear, overlapping or conflicting. This makes reaching agreements on issues such as an AF complex. Also, publishing the quality of products, without being able to refer to a recognised (international) standard, could conflict with the authority's role and be perceived as biased from the perspective of the providers of health apps. Finally, they refer to "Reimbursement issues", challenges to structure reimbursement of health apps.

"Something that is really difficult and I think the European region has that problem, is the different actors to be aligned. […] Pff, a lot of actors, that each of them has their needs and it's very difficult to get an agreement to move forward." (Catalonia)

"We have too many agencies, too many institutions that manage all these definitions of digital health and digital health technologies [not aligned taxonomies]. That is why I hope that main documents from Europe could help us to be stricter in the field." (Italy)

"Communicating the quality of a particular product, could actually lead to a "market bias", i.e., putting a product in a favourable position with respect to its competitors (although involuntarily, needless to say). We are instead interested in communicating the relevance of the framework for the app evaluation, as an objective and independent instrument for orienting health choices for personalised digital medicine." (Italy)

"And after that comes defining the reimbursement models, well, I think it will take a lot [of time]." (Catalonia)

The interviewees identified several pains related to the identification, assessment, integration, recommendation and use of apps. These included "App-related issues" (e.g., constant updates, and lack of clinical evidence), "Data-related issues" (e.g., not all data generated by apps is clinically relevant, relevance generally differs per pathology and care pathway, and interoperability issues), and "Citizen and HCP issues" (e.g., limited digital skills).

"Something that is very difficult is how you re-validate based on the framework, how do you reassess the apps. Because the apps change a lot." (Catalonia)

"At present what is lacking is clear sound evidence from clinical trials about the apps. This is a very great problem because also our Ministry of Health is waiting for clinical trial data for authorisation of medical device apps and then to have the data from them." (Italy)

"Then you [HCP] want to monitor a patient based on these health apps, and you want to integrate the data [...] it was very challenging because we had to find specific professionals for each pathology, they tell us or tell the group which are the relevant data." (Catalonia)

"Improve the digital skills of professionals also is very challenging and we try to solve it as well, by providing more training." (Catalonia)

"The target population of some interventions (for example for frailty/chronicity) may find itself hardly capable of exploiting the technology, if the latter is not properly introduced, with a

training appropriate for the digital skills of the subject." (Italy)

Jobs

Regarding the jobs, the tasks or responsibilities of authorities in assessing and integrating apps, the interviewees described activities related to policy, implementation, and operations. In Catalonia, "Compile policy" referred mainly to the "mHealth" Plan [37], which in 2015 triggered the appointment of TIC Salut to "Implement" this plan and create a new AF. In Italy this job was related to the Recovery and Resilience Funding coordinated by the European Commission, which pushed plans for telehealth and an adequate AF [39]. Interviewees discussed their roles as experts and advisors for the government and in the decision-making and implementation of an AF.

"TIC Salut mHealth Office was established after publishing this agreement in 2015, an mHealth plan that was published or was agreed upon in the parliament, where they created TIC Salut in the mHealth area as an instrument to provide or to create these actions, to implement mHealth in the health sector." (Catalonia)

"The National Resilience Program has given us quite a lot of support in that, and a lot of money has actually been poured into healthcare [...] One of the areas which has been impacted very much is telehealth, which includes health apps". (Italy)

Although the jobs overlap, the exact scope targeted in their policies and strategies differs. Catalonia refers to apps embedded in blended care pathways, and Italy to telehealth solutions.

"The electronic health record of the patient was integrated, and we had also the personal portal for citizens. So, the gap that we did have was to integrate the data that came from apps." (Catalonia)

"And so, the focus here in Italy at the moment is on telehealth solutions, which comprise health apps." (Italy)

Important steps in the implementation were, according to the interviewees, to "Arrive at an appropriate AF", "Achieve an efficient assessment process" that is moreover scalable, "Arrange easy to use platform(s)", and "Enable stakeholders" by for example issuing recommendations, tools and accessible information (e.g., [40]).

"So those were the 2 big projects. One is the assessment framework and the other the mHealth platform that goes in parallel. […] The objective of this platform is to include apps that have passed this accreditation and to help healthcare professionals prescribe the apps to their patients." (Catalonia)

"So, the Ministry studied all the proposals from the different experts, and they actually decided to use 82304-2 as the inspirational assessment framework to define the assessment framework for telehealth solutions that are going to be onboarded onto this national catalogue." (Italy)

"The main objective is, now, the number of apps that we want to share. It's our expectation to have at least 30 apps, or 50 depending, but this year at least try to get these 30." (Catalonia)

"And also, we did recommendations, guides, tools. Also, we have the auto-evaluation on our website, that is a questionnaire free and open. […] We made it for the industry, for them being prepared, and to promote creating these quality apps." (Catalonia)

Operations start with what interviewees refer to as a prioritisation of the apps to integrate in the healthcare system ("Identify interesting pathways / apps").

> *"So, we focus on diabetes because it's something that we have different apps that are provided by private companies, and there are a lot of people with this disease, and it is expensive and it's a priority for the healthcare system to provide tools in that way." (Catalonia)*
>
> *"So, there will be a pathway for diabetics, so there would be one for oncology, certain types of oncology and so on." (Italy)*
>
> *"We have these 2000 apps that are identified as interesting apps, that are not certified using our framework obviously, but they are being used by healthcare centres or they are being published in other frameworks like Andalusia or mHealth Belgium, etc." (Catalonia)*

After this prioritisation of apps that are interesting to assess, the assessment can be carried out ("Assess apps") and positively assessed apps and their results in specific quality domains and criteria can be shared ("Publish apps"). Publication of assessed apps enables the series of gains which starts with "Quality apps for use". The next operational step, to "Integrate app data into platform(s)", enables the desired gain "Data-driven decision-making". Catalonia expects the capacity of integrating app data into platforms to become available in 2024-2025 for one care pathway. Italy does not yet carry out assessments and the division of responsibilities among Italian authorities is not yet defined. For both authorities, the final step in the process is to "Reimburse / pay for apps".

> *"Once these apps are validated, we publish the apps on our website, so all citizens know all aspects of the [certification] process." (Catalonia)*
>
> *And in the next stage, we are expecting to integrate the data from these apps of diabetes in the platform that we create." (Catalonia)*
>
> *"We have a group that is working on a specific reimbursement model." (Catalonia)*
>
> *"A policy is at present under discussion thanks to a specific Government Workgroup on digital therapies that involves several stakeholders, scientific and industrials. The latter (Drug and Medical Device industry organisations) are discussing a unitary proposal for a unique reimbursement scheme." (Italy)*

(b) Value Map and (c) Fit

In this section, we present the results of the iterative process of identifying the TS-related products and services and their distinct characteristics in relation to the needs of health authorities. The needs are visualised in the VPC as the challenges (pains), desired outcomes (gains) and tasks (jobs) of the two authorities. When a TS-related product or service or one of its characteristics (gain creator and pain reliever) helps to address or to achieve a gain, pain or job of authorities, we considered it a "fit" (compatibility). The fit was visualised with a green dot (figure 2). We found the TS addressed 3/9 gains, 7/9 pains and 6/11 jobs in part or in full. An anticipated gain creator/pain reliever and three TS-related anticipated future services, would target one extra pain and three extra jobs, enhancing the compatibility to 3/9 gains, 8/9 pains and 9/11 jobs. The six gains, and one pain that remain would be influenced indirectly (e.g., the TS supports the gain "Quality apps for use" which is a prerequisite for all further gains). This would leave only two jobs unaddressed, i.e., "Compile policy" and "Integrate app data into platform(s)".

Products and services

Six current and three future products and services were identified, which are compatible with ("fit") nine authorities' jobs (figure 2, table 1). The two core products of the TS are an "AF with a scoring mechanism" and a health app "Quality label" (multimedia appendix 2) [11]. The quality label is a key aspect that differentiates the TS from other AFs. In the Label2Enable project four TS-related products were co-created with the relevant stakeholders. First, the health app "Quality report", is a more

detailed version of the label [21]. Second, the ISO 17000 series compliant “Certification scheme” for the TS, which includes the app assessor handbook for use by certified conformity assessment bodies [21]. Third, “Stakeholder guidance and tools”, refers e.g. to educational videos on the label for citizens and assessment guidance for manufacturers [41]. Fourth, a series of “Recommendations for reimbursement” of health apps [42]. The upcoming demonstrator phase aims to assess the first 100 apps, test and optimise the multi-stakeholder value of the health app quality report and explore how to exploit the potential of “Automated assessments” for a subset of quality requirements. This phase is planned to deliver three extra services, “Customised implementation support”, a “Network of ISO certified assessment organisations", and a “Repository of assessed apps”.

Table 1. Compatibility (fit) of the TS and related products and services with the authorities’ jobs.

Job	Product / service
*Implement**	*Customised implementation support**
Arrive at an appropriate AF	AF with a scoring mechanism
Achieve an efficient assessment process	Certification scheme *Network of ISO certified assessment organisations**
*Arrange easy to use platform(s)**	*Repository of assessed apps**
Enable stakeholders	Stakeholder guidance and tools *Network of ISO certified assessment organisations**
*Identify interesting pathways/apps**	*Repository of assessed apps**
Assess apps	AF with a scoring mechanism Certification scheme Stakeholder guidance and tools *Network of ISO certified assessment organisations**
Publish apps	Quality label Quality report *Repository of assessed apps**
Reimburse/pay for apps	Quality report Recommendations for reimbursement

* Anticipated services planned to be established during the demonstrator phase, and jobs to be relieved by these TS future services.

Gain creators

Five current and one anticipated gain creators were identified (figure 2), which are compatible with (“fit”) three gains pursued by authorities (table 2). First, the “Rigour (multi-stakeholder and evidence-based)” of the AF, the assessment process (promising inter-rater reliability) and the handbook for assessment organisations, which are in part already reported in scientific publications [21,43,44]. Second, “ISO maintenance”, refers to the regular ISO review procedures, which ensure that the TS remains up-to-date and potentially evolves to an International Standard (IS). Third, the TS can facilitate “Cross-country recognition/adoption”, which in turn can increase the number of assessed apps available, optimise resource allocation (the label is effectively a screening) and minimise the duplication of efforts. Fourth, the “Positive effect of the label” on manufacturers’ intent to improve the quality of their app, HCP’s willingness to prescribe apps, and citizens’ intent to download and ability to choose quality apps [21,44,45]. These effects could be amplified by citizens’ trust in the recommendations of health apps by HCPs (80%) and expressed need for health authorities to review and rate apps (86%) [46]. Fifth, preliminary findings of a comparative analysis of CEN ISO/TS 82304-2 with European HTA frameworks and subsequent alignment [21] show that the handbook has

a “Significant part of other AFs covered”. For authorities, this could mean a reduction of the conformity assessment workload, since already labelled apps would only need to be assessed against a limited set of context-specific requirements. Sixth, “Automated assessments” refers to the potential of partially automatising app assessments, which would benefit quality (rigour), efficiency, affordability, and scalability of assessments and reassessments.

Table 2. Compatibility (fit) of gains authorities perceive in adopting an AF for health apps and the TS gain creators.

Gain	Gain creator
Quality apps for use	Rigour (multi-stakeholder and evidence-base) ISO maintenance Cross-country recognition / adoption
Prescriptions and use apps	Positive effect of the label
Savings & efficiency	Cross-country recognition / adoption Significant part of other AFs covered *Automated assessments**

*Future gain creator planned to be established during the demonstrator phase.

Pain relievers

Thirteen current and one anticipated pain reliever were identified (figure 2), which are compatible with (“fit”) eight pains (table 3). First, the “Potential of the label for use in app stores”, the common marketplace for health apps. The TS has global applicability (ISO), a label, a scoring mechanism and scalability potential with the “Automated assessments” and “The network of ISO certified assessment organisations”. These distinct characteristics are considered attractive for app stores (personal communications) to rank apps and inform potential users about the quality of (labelled) apps. Second, the “Positive effect of the label” on manufacturers’ quality improvement plans and HCPs’ willingness to prescribe apps. Third, the handbook for app assessment organisations was “Aligned with EU level legislation and values” [21], and the AF was built on the EU Medical Device Regulation (MDR) and General Data Protection Regulation (GDPR) principles [43]. Fourth, the TS and Label2Enable are “EU initiated and used”. A draft version of the TS was made available to support the creation of COVID-19 apps and referenced in the EU toolbox for COVID-19 tracing apps [47], and the TS is foundational for drafting implementing legislation for labelling wellness applications (that claim interoperability with an EHR system) in the European Health Data Space (EHDS) Regulation. Fifth, the TS is a “CEN-ISO-IEC collaboration”, three renowned international standardisation organisations. Sixth, the handbook was “Informed by a comparative analysis of European HTA frameworks”, i.e., EUnetHTA core model, and the Dutch, English, Finnish, French and German HTA frameworks for health apps [21]. Seventh, distinctive from other AFs, the “AF was built on 28 standards” [43,48]. This includes the recognised NICE Evidence Standards Framework [49,50], which was used as a foundation for the CEN ISO/TS 82304-2 AF. Eighth, “Rating matches ISO’s role” to “agree on the best way of doing things, make lives easier, safer and better, enabling trade the world over” [48]; enabling authorities to refer to unbiased and standardised assessment results. Ninth, the “Recommendations for reimbursement”, which are the result of a series of workshops for health authorities, HTA bodies and insurers, with 135 participants from 34 countries [42]. Tenth, “Automated assessments” could help address the need to frequently reassess apps. Eleventh, the visibility of “Robust build on the label”, which includes 4 interoperability requirements, is expected to promote manufacturer investments in interoperability. Twelfth, the incorporation of the aspect “Easy to use on the label” could contribute to addressing inequity in prescription and use of health apps and promote continued use of apps [51]. Thirteenth, given the importance of medical societies for HCPs in promoting prescription and use of apps [52,53], the quality report was “Tested with EU

medical societies" to evaluate and enhance its usefulness for medical societies in providing guidance for HCPs in recommending quality health apps [21]. Additionally, the results of mapping the TS with the information needs of cardiologists regarding digital health applications, carried out with the European Society of Cardiology, indicated compatibility [54].

Table 3. Compatibility (fit) of pains authorities perceive in adopting an AF for health apps and the TS pain relievers.

Pain	Pain reliever
Risks of (so many) uncertified apps	Potential of the label for use in app stores Positive effect of the label
Legislation issues	Aligned with EU level legislation and values EU initiated and used
Lack of harmonisation	CEN-ISO-IEC collaboration Informed by a comparative analysis of European HTA frameworks AF was built on 28 standards EU initiated and used
Health authority issues	Rating matches ISO's role
Reimbursement issues	Recommendations for reimbursement
*App issues**	*Automated assessments**
Data issues	Robust build on the label
Citizen and HCP issues	Positive effect of the label Easy to use on the label Tested with EU medical societies

*Future pain relievers planned to be established during the demonstrator phase.

Discussion

In this article, we systematically examined the compatibility of the TS with the needs of two health authorities, aiming to further enhance the compatibility of the TS with their needs, and ultimately, to reduce the uncertainty of peer authorities in considering adoption of the TS. The two studied authorities were diverse. FTSS is located in Catalonia, a region in Spain with 8 million citizens with an already established AF for health apps and wearables and has an assessment process in place. ISS is based in Italy, a country with 59 million citizens and is working on an AF for telehealth, which includes health apps. We found that despite their diversity, their needs (gains, pains and jobs), largely overlapped. This suggests that health authorities share common fundamental needs. Differences in needs could be attributed to being a national advisory body in a country currently without an established AF (a focus on legislation issues – Italy) and a regional implementing organisation with an AF (a focus on execution of policy – Catalonia). Both authorities see a need for and benefits of the uptake of health apps and using a common AF. This confirms WHO's recommendations to make mHealth evaluation with a common methodology the norm rather than the exception [10]. At the same time, it is apparent that without enabling (EU) legislation and standardisation, and with the many authorities involved, it is a challenge to establish an AF. For countries or regions with a small population, arriving at an appropriate (sufficiently rigorous) AF might not even be feasible, given costs, capabilities, and limited attractiveness for manufacturers.

When is compatibility of the TS *sufficient* for authorities? Osterwalder argues that an innovation does not have to address all potential adopter' needs, yet it should satisfy the most essential (unrealized) gains, most extreme (unresolved) pains and most important (unsatisfied) jobs and preferably be "difficult to copy" [25]. We found that the TS has a range of products and services with distinct characteristics that address in part or in full all but two needs of the two health authorities studied i.e., the jobs "Compile policy" and "Integrate app data into platform(s)". To what extent these two jobs would classify as *important (unsatisfied) jobs*, and

as such should be addressed in the future by the TS, needs to be determined in future research. Many of the distinct characteristics (gain creators and pain relievers) are difficult to copy; for example, its multi-stakeholder evidence base, international standardisation nature, comprehensiveness of the label, and its development as an EU initiative that has already been applied at the EU level.

Whether the TS, related products, services and their distinct characteristics (are perceived to) *sufficiently satisfy* potential adopters' needs, could not be measured conclusively given the pre-diffusion stage of the TS at the time of this study. Such measurements and potential further finetuning of the compatibility of the TS, which could further reduce uncertainty, are part of the upcoming plans for the demonstrator phase. The aims for this phase include assessing the first 100 apps, developing the aforementioned additional three services and one gain creator/pain reliever, and testing the health app quality report. We also aim to explore if a further reduction in duplication of efforts, would increase compatibility and reduce uncertainty. Could, for instance, the need to "Arrange easy to use platform(s)" for assessed apps be addressed with an EU-level "Repository of assessed apps" and/or EU efforts to materialise the "Potential of the label for use in app stores"? Could such strategies increase the rate of adoption of the TS, prevent EU MS (and potentially medical societies) from having to invest individually in such platforms, and thus pave the way for EU-wide adoption of the TS and uptake of health apps in the region?

The authorities´ jobs can be put in context with the five stages of the innovation-decision process in organisations described by Rogers [22]. The first stage is "agenda setting", when one or more individuals in an organisation identify a problem and seek a compatible innovation to solve it. During this stage, the authorities' job "Compile policy" needs to be carried out. WHO figures show that 83% (44/53) of its European region member states (MS) reported having a national digital health policy or strategy. This includes 23/27 (85%) of EU MS. Yet only 28% (13/47) reported having an entity for mHealth quality oversight, which relates to the second job, "Implement" [55].

After agenda setting, Rogers' next stages of the innovation process in organisations are, "matching" (testing the feasibility of the innovation in solving the organisation's problem), and "redefining/restructuring" (reinventing the innovation to accommodate the organisation's needs and structure). These are related to the identified jobs "Arrive at an appropriate AF" and "Achieve an efficient assessment process". Catalonia has already carried out these jobs and published the methodology used to compare the TS to their previous AF and implement the TS [32]. They reported a small percentage of additional context-specific requirements, similar to reports in the Australian context [56], and as previously suggested [17]. This knowledge could further reduce peer authorities' uncertainty and inspire their own "matching" and "redefining/restructuring" efforts. The rest of the reported jobs, including "Assess apps" would follow once the first four have been achieved. Going back to the status of the European region reveals that while 83% (44/53) of WHO European region MS reported having a national digital health policy or strategy, only 15% (6/39) reported evaluation of government-sponsored mHealth ("Assess apps") [10].

The low percentages of MS having entities for mHealth quality oversight and government-sponsored mHealth evaluation raise questions. Do other MS encounter the same significant challenges (pains) as Catalonia and Italy in satisfactorily arriving at an appropriate AF and assessing health apps? Could that be the reason for not assessing apps? Or could it be that these MS have different needs, perhaps not even perceive, contrary to Catalonia and Italy, that

an AF is a much-needed solution? Or do they perhaps perceive other most essential (unrealised) gains, most extreme (unresolved) pains and most important (unsatisfied) jobs, making an AF less of a priority or other distinct AF characteristics a necessity? Analysis of the national policies [55] could validate the generalisability of the Catalan and Italian needs; or produce alternative Customer Profiles, perhaps related to Rogers' adopter types; innovators, early adopters, early majority, late majority and laggards [22]. Such an analysis would support future alignment of the TS with the EU region at large, contribute to the development of new services, such as "Customised implementation support", and inform peer authorities' decision-making on the TS adoption. In other words, an analysis of MS policies through the lens of the current VPC could potentially support the EU region in scaling the evaluation of mHealth using a common methodology and promote equitable uptake of quality apps.

Strengths and limitations

This study is to our knowledge, the first report to systematically analyse the compatibility of an existing AF with health authorities' needs, which has the potential to address the scattered EU landscape, progressing towards a Digital Single Market and improving the uptake of health apps. The timing of the study (pre-diffusion) exploited the potential to contribute to pre-adoption compatibility, the effectiveness of the future demonstrator phase, and the rate of adoption of the TS. Our study was based on the perceptions of three key informants associated with two authorities in two EU countries, each part of a larger landscape of health authorities, each with a focus on health apps as part of a larger scope of digital health technologies (Catalonia: health apps and wearables, Italy: telehealth). The limited number of key informants can be attributed to the pre-diffusion phase of the TS, i.e. the TS was published in 2021 and from 2022 to 2024 the Label2Enable project has co-created the TS supportive products and services with stakeholders. The two authorities involved, partners from the Label2Enable project, are the first pre-release test users in the EU. The key informants are among the first individuals to evaluate the TS. Such a limited scope requires future validation, and we specifically pledge to extend this analysis to the national policies of the EU MS. The diversity of the two authorities in terms of geographical scope, roles and responsibilities, population size, triggers, scope of digital health technologies, target pathways and health apps, and status of the AF, increases the chance of generalisability of our results.

Conclusions

Our results suggest compatibility of the TS with the overlapping authorities' needs to arrive at an appropriate TS, that would allow the uptake of health apps in their healthcare systems. The perceptions and experiences of health authorities captured in this study provide an evidence-based ground for peer authorities to reduce their uncertainties related to the adoption of an AF and the TS in particular. It also established the basis to carry out a wider analysis to understand the compatibility of the TS with other EU MS needs, which would confirm or finetune the TS and its distinct characteristics. This is, to our knowledge, the first report to systematically analyse the compatibility of an existing AF with authorities' needs, with the potential to address the scattered EU landscape, progressing towards a Digital Single Market and improving the uptake of health apps.

Acknowledgments

We would like to express our deepest gratitude to the key informants, Carme Pratdepadua Bufill, Mauro Grigioni, and Pier Angelo Sottile, and Giuseppe d'Avenio, who generously shared their time, insights, and expertise. Their invaluable contributions and perspectives have been instrumental in shaping the findings of this study. The views and opinions expressed in this article are those of the

individuals who participated and do not necessarily reflect the official policy or position of the institutions they are affiliated with.

This study was funded by the European Union (Project: 101057522 — Label2Enable — HORIZON-HLTH-2021-IND-07). Views and opinions expressed are, however, those of the authors only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them.

Authors' Contributions
Funding acquisition: PH, MSh, Supervision: PH, Conceptualization / Methodology: MSh, RW, PH designed the semi-structured interviews, Investigation: MV-Q led the interviews with support from MSh. Data Curation: MV-Q transcribed the recordings verbatim, which PH proofread, Formal analysis/Validation: PH and MV-Q coded using deductive and inductive approaches, Visualization: PH visualised in the VPC with feedback from MV-Q. Writing – original draft: PH, MV-Q, Writing – review and editing: MSh, RW and NG.

Conflicts of interest
None to declare.

Ethics approval and consent to participate
The requirement for approval by an ethics or scientific research committee was deemed unnecessary according to Dutch national regulations, since the study was not subject to the Medical Research Involving Human Subjects Act (WMO for the Dutch abbreviation), and according to the guidelines of the Central Committee on Research Involving Human Subjects (CCMO). Verbal consent to carry out and record the interviews was obtained from all participants before starting the interview and before publication.

Abbreviations
AF: assessment framework
EU: European Union
GDPR: EU General Data Protection Regulation
EHDS: European Health Data Space
FTSS: TIC Salut Social Foundation
HCP: healthcare professional
ISO: International Organization for Standardization
ISS: Italian Superior Institute of Health
NICE: UK National Institute for Health and Care Excellence
MDR: EU Medical Device Regulation
MS: Member State
OECD: Organisation for Economic Co-operation and Development
TS: CEN ISO/TS 82304-2:2021 Health software - Part 2: Health and wellness apps - Quality and reliability
VPC: value proposition canvas
WHO: World Health Organisation
WMO: Medical Research Involving Human Subjects Act
UNI: Italian Standards Body

References

[1] Kivimäki M, Batty GD, Pentti J, Shipley MJ, Sipilä PN, Nyberg ST, et al. Association between

socioeconomic status and the development of mental and physical health conditions in adulthood: a multi-cohort study. The Lancet Public Health 2020;5:e140–9. https://doi.org/10.1016/S2468-2667(19)30248-8.
[2] OECD. Health for Everyone?: Social Inequalities in Health and Health Systems. OECD; 2019.
[3] Hou X, Sharma J, Zhao F, editors. Silver Opportunity: Building Integrated Services for Older Adults around Primary Health Care. The World Bank; 2023.
[4] WHO. Health and care workforce in Europe: time to act. Copenhagen: World Health Organization, Regional Office for Europe; 2022.
[5] European Commission. Green Paper on Mobile Health ("mHealth"). 2014.
[6] European Commission. COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society.
[7] Essén A, Stern AD, Haase CB, Car J, Greaves F, Paparova D, et al. Health app policy: international comparison of nine countries' approaches. Npj Digit Med 2022;5:31. https://doi.org/10.1038/s41746-022-00573-1.
[8] Milne-Ives M, Van Velthoven MH, Meinert E. Mobile apps for real-world evidence in health care. Journal of the American Medical Informatics Association 2020;27:976–80. https://doi.org/10.1093/jamia/ocaa036.
[9] Stecher C, Pfisterer B, Harden SM, Epstein D, Hirschmann JM, Wunsch K, et al. Assessing the Pragmatic Nature of Mobile Health Interventions Promoting Physical Activity: Systematic Review and Meta-analysis. JMIR Mhealth Uhealth 2023;11:e43162. https://doi.org/10.2196/43162.
[10] WHO. The ongoing journey to commitment and transformation: digital health in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2023.
[11] ISO. Health software — Part 2: Health and wellness apps—Quality and reliability. ISO/TS 82304-2:2021(E) 2021.
[12] WHO. mHealth: new horizons for health through mobile technologies: second global survey on eHealth. WHO Global Observatory for eHealth 2011.
[13] Maaß L, Freye M, Pan C-C, Dassow H-H, Niess J, Jahnel T. The Definitions of Health Apps and Medical Apps From the Perspective of Public Health and Law: Qualitative Analysis of an Interdisciplinary Literature Overview. JMIR Mhealth Uhealth 2022;10:e37980. https://doi.org/10.2196/37980.
[14] Grundy Q. A Review of the Quality and Impact of Mobile Health Apps. Annu Rev Public Health 2022;43:117–34. https://doi.org/10.1146/annurev-publhealth-052020-103738.
[15] van Velthoven M, Powell J. Do health apps need endorsement? Challenges for giving advice about which health apps are safe and effective to use. DIGITAL HEALTH 2017;3:205520761770134. https://doi.org/10.1177/2055207617701342.
[16] European mHealthHUB. D2.1 Knowledge Tool 1. Health apps assessment frameworks. 2021.
[17] Frey A-L, Phillips B, Baines R, McCabe A, Elmes E, Yeardsley-Pierce E, et al. Domain coverage and criteria overlap across digital health technology quality assessments: a systematic review (preprint) 2024. https://doi.org/10.31219/osf.io/qg9vd.
[18] European Union. CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION 2012/C 326/02. Official Journal of the European Union C 326/391. 2012.
[19] IQVIA Institute. Digital Health Trends 2021. Innovation, evidence, regulation and adoption. 2021.
[20] Voutilainen M. Report on Finnish-language mobile applications related to welfare and health in Google Play -store and in the EUDAMED -database. Finnish Coordinating Center for Health Technology Assessment; 2022.

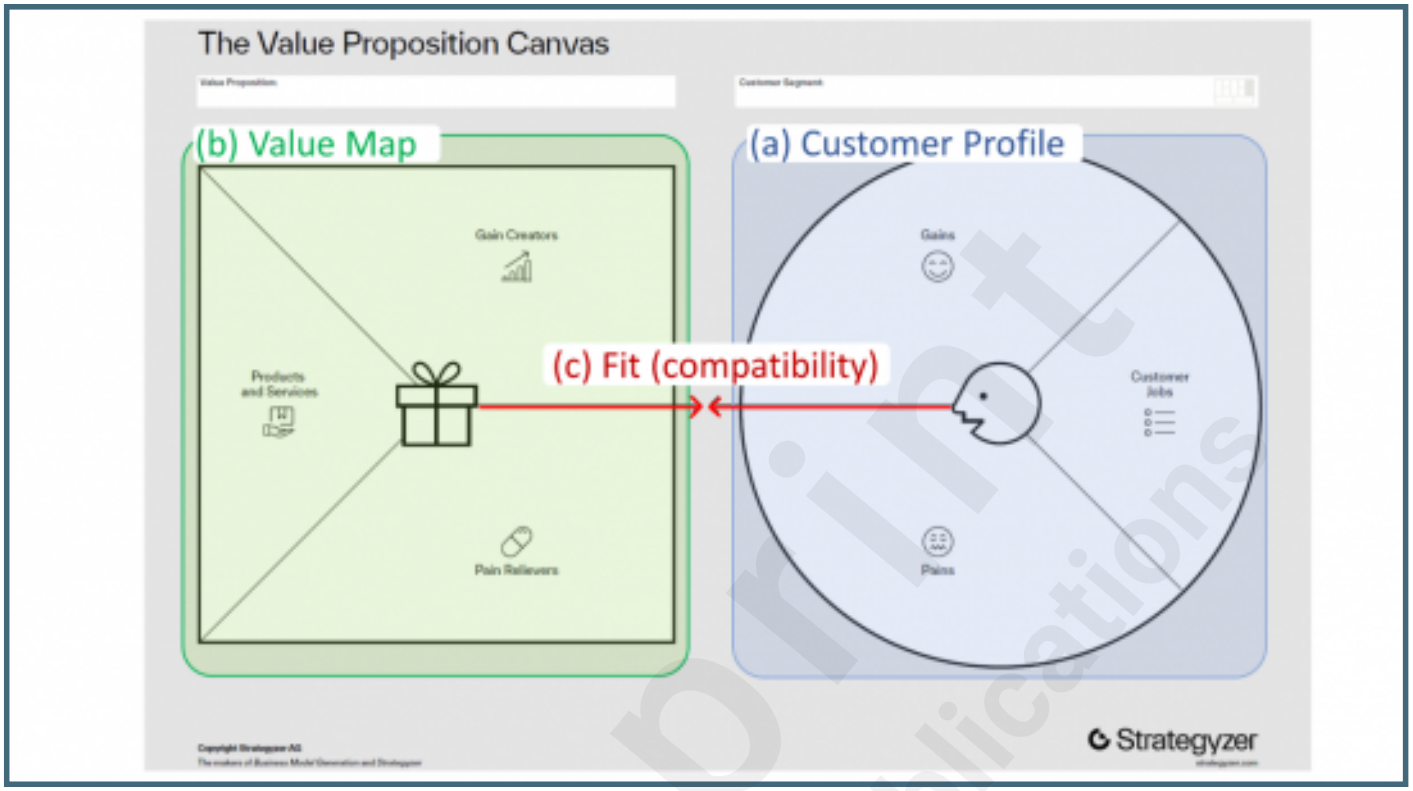
[21] Label2Enable. EU Research Results. Adopting ISO 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps. CORDIS 2024.
[22] Rogers EM. Diffusion of innovations. 4th ed. New York: Free Press; 1995.
[23] Ayala GX, Elder JP. Qualitative methods to ensure acceptability of behavioral and social interventions to the target population. J Public Health Dent 2011;71. https://doi.org/10.1111/j.1752-7325.2011.00241.x.
[24] Kyhnau J, Nielsen C. Value Proposition Design: How to create products and services customers want. Journal of Business Models 2015:Vol-3 No 1 (2015): Journal of Business Models. https://doi.org/10.5278/OJS.JBM.V3I1.1105.
[25] Osterwalder A, Pigneur Y, Bernarda G, Smith A, Papadakos P. Value proposition design: how to create products and services customers want. Get started with. Hoboken, NJ: Wiley. A limited but free version is available at: https://www.strategyzer.com/library/the-value-proposition-canvas; 2014.
[26] Lentferink A, Polstra L, D'Souza A, Oldenhuis H, Velthuijsen H, Van Gemert-Pijnen L. Creating value with eHealth: identification of the value proposition with key stakeholders for the resilience navigator app. BMC Med Inform Decis Mak 2020;20:76. https://doi.org/10.1186/s12911-020-1088-1.
[27] Chakraborty I, Edirippulige S, Vigneswara Ilavarasan P. The role of telehealth startups in healthcare service delivery: A systematic review. International Journal of Medical Informatics 2023;174:105048. https://doi.org/10.1016/j.ijmedinf.2023.105048.
[28] Wrede C, Braakman-Jansen A, Van Gemert-Pijnen L. How to create value with unobtrusive monitoring technology in home-based dementia care: a multimethod study among key stakeholders. BMC Geriatr 2022;22:921. https://doi.org/10.1186/s12877-022-03550-1.
[29] López Seguí F, Pratdepàdua Bufill C, Rius Soler A, De San Pedro M, López Truño B, Aguiló Laine A, et al. Prescription and Integration of Accredited Mobile Apps in Catalan Health and Social Care: Protocol for the AppSalut Site Design. JMIR Res Protoc 2018;7:e11414. https://doi.org/10.2196/11414.
[30] López Seguí F, Pratdepadua Bufill C, Abdon Gimenez N, Martinez Roldan J, Garcia Cuyas F. The Prescription of Mobile Apps by Primary Care Teams: A Pilot Project in Catalonia. JMIR Mhealth Uhealth 2018;6:e10701. https://doi.org/10.2196/10701.
[31] c. Reference Documents (Documents de referència, in Catalan). 2024. https://ticsalutsocial.cat/que-fem/actiusdigitals/documents-de-referencia/, https://ticsalutsocial.cat/wp-content/uploads/2021/07/guia-proces-acreditacio-fts.pdf, https://ticsalutsocial.cat/wp-content/uploads/2021/09/2021_Criteris-certificacio_CAT_v3.0.pdf (accessed March 5, 2024).
[32] Llebot Casajuana B, Hoogendoorn P, Villalobos-Quesada M, Gómez Freixa M, Pratdepadua Bufill C. Integration of CEN-ISO/TS 82304-2 for Existing Health Authorities' App Assessment Frameworks: A Comparative Case Study in Catalonia (submitted to JMIR for back to back publication) n.d.
[33] UNI. UNI/TR 11708:2018 Informatica Medica - Caratterizzazione delle APP nel contesto della salute, benessere e stili di vita (Health Informatics – Criteria to identify apps in the wellness, social and health context). In Italian. 2018.
[34] Strategyzer. Customer Gains. Customer Jobs. Customer Pains. Trigger questions. 2019.
[35] Label2Enable. Results 2024.
[36] Wentzel J, Van Der Vaart R, Bohlmeijer ET, Van Gemert-Pijnen JEWC. Mixing Online and Face-to-Face Therapy: How to Benefit From Blended Care in Mental Health Care. JMIR Mental Health 2016;3:e9. https://doi.org/10.2196/mental.4534.
[37] Government of Catalonia. Governmental agreement by which the Master plan mHealth is approved (Acord del Govern pel qual s'aprova el Pla Mestre de Mobilitat (mHealth.Cat)). (In

Catalan). 3 February 2015.
[38] Italian Presidency of the Council of Ministers. Permanent Conference for the Relations Between the State, the Regions and the Autonomous Provinces of Trento and Bolzano (Conferenza Permanente Per i Rapporti tra lo Stato, le Regioni e le Provincie Autonome di Trento e di Bolzano). 2020.
[39] NextGenerationItalia. Italian National Plan for Recovery and Resilience (Piano Nazionale di Ripresa e Resilienza) (In Italian). 2021.
[40] Foundation TIC Salut Social. Digital assets, Self-assessment test. TIC Salut Social Foundation. 2024.
[41] Label2Enable Showcase. https://vimeo.com/showcase/11257693. Oscar Smeulders; 2024.
[42] Label2Enable. Recommendations for the reimbursement of health apps.
[43] Hoogendoorn P, Versluis A, Van Kampen S, McCay C, Leahy M, Bijlsma M, et al. What Makes a Quality Health App—Developing a Global Research-Based Health App Quality Assessment Framework for CEN-ISO/TS 82304-2: Delphi Study. JMIR Form Res 2023;7:e43905. https://doi.org/10.2196/43905.
[44] Frey A-L, Leigh S, Toro C, Bufill CP, McCay C, Trupec TP, et al. Preferences and willingness to pay for health app assessments among healthcare stakeholders: a discrete choice experiment (preprint).
[45] Biliunaite I, Van Gestel L, Hoogendoorn P, Adriaanse M. Value of a quality label and European healthcare professionals' willingness to recommend health apps: An experimental vignette study. J Health Psychol 2024:13591053241258205. https://doi.org/10.1177/13591053241258205.
[46] Shokralla M, et al. How European residents trust and use recommendations for health apps: Pan-European survey (forthcoming). JMIR mHealth and uHealth 2024. http://dx.doi.org/10.2196/64468.
[47] eHealth Network. Mobile applications to support contact tracing in the EU's fight against COVID-19 Common EU Toolbox for Member States. Version 1.0. 2020.
[48] ISO. About ISO. 2024.
[49] NICE. Evidence Standards Framework for Digital Health Technologies. 2019.
[50] Dittrich F, Mielitz A, Pustozerov E, Lawin D, Von Jan U, Albrecht U-V. Digital health applications from a government-regulated directory of reimbursable health apps in Germany—a systematic review for evidence and bias. mHealth 2023;9:35–35. https://doi.org/10.21037/mhealth-23-17.
[51] Vaghefi I, Tulu B. The Continued Use of Mobile Health Apps: Insights From a Longitudinal Study. JMIR Mhealth Uhealth 2019;7:e12983. https://doi.org/10.2196/12983.
[52] Dahlhausen F, Zinner M, Bieske L, Ehlers JP, Boehme P, Fehring L. Physicians' Attitudes Toward Prescribable mHealth Apps and Implications for Adoption in Germany: Mixed Methods Study. JMIR Mhealth Uhealth 2021;9:e33012. https://doi.org/10.2196/33012.
[53] Richter JG, Chehab G, Stachwitz P, Hagen J, Larsen D, Knitza J, et al. One year of digital health applications (DiGA) in Germany – Rheumatologists' perspectives. Front Med 2022;9:1000668. https://doi.org/10.3389/fmed.2022.1000668.
[54] Caiani E, Kemps H, Hoogendoorn P, et al. The need for a priori standardized assessment of evidence to facilitate adoption of mobile health in clinical practice.
[55] WHO. Exploring the digital health landscape in the WHO European Region: digital health country profiles. World Health Organization. Regional Office for Europe. ISBN: 978-92-890-6099-8. 2024.
[56] Australian Digital Health Agency. Assessment framework for mHealth apps 2024.

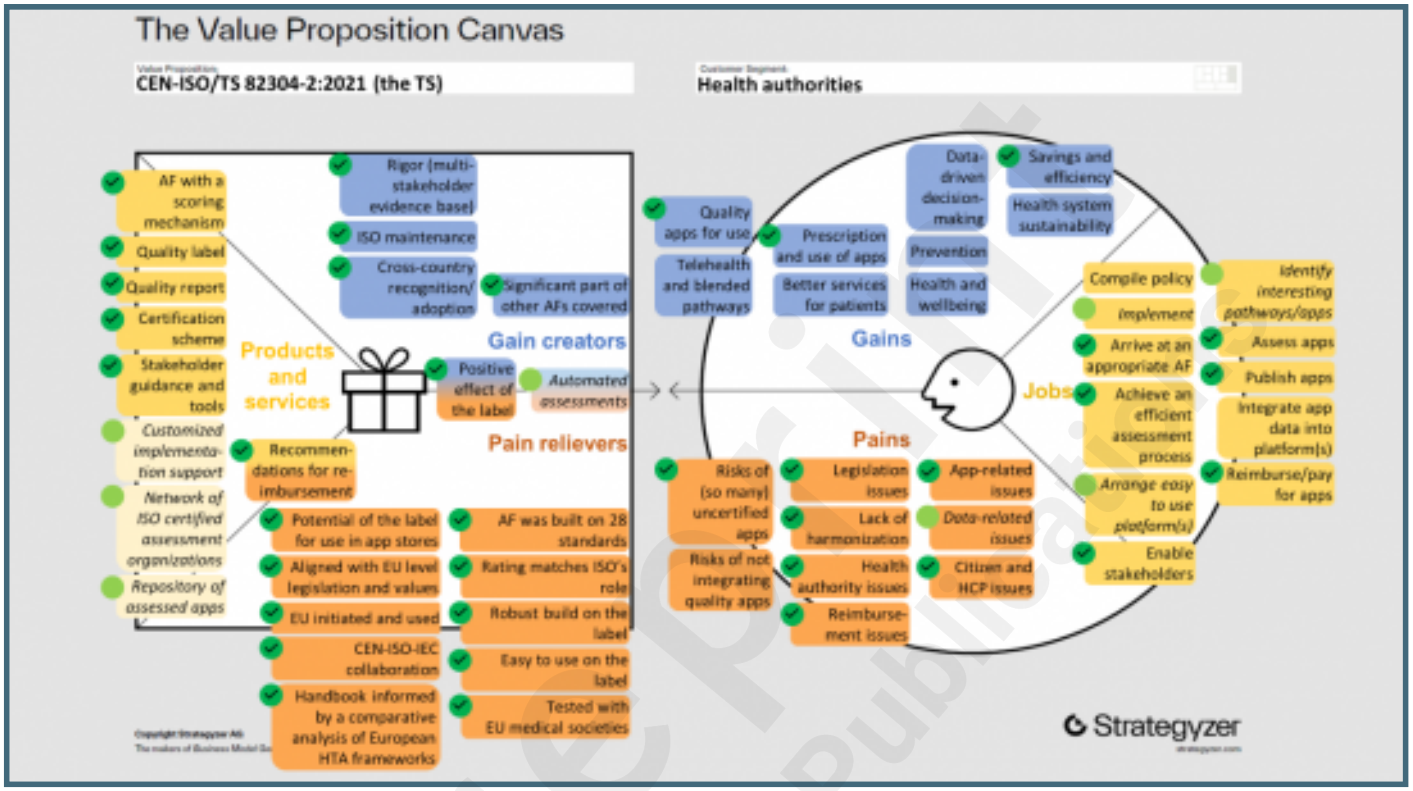
Supplementary Files

Figures

The template of the Value Proposition Canvas (VPC, Osterwalder et al. 2014). Adapted from Strategyzer 2019 to highlight the three main steps to construct the VPC (box 3): (a) Customer Profile, (b) Value Map, and (c) Fit (compatibility).



The Value Proposition Canvas (VPC) of the TS for health authorities which pursue an assessment framework to integrate health apps in their healthcare systems, with on the right the “Customer Profile” and on the left the “Value Map”. Lighter coloured boxes indicate future services, gain creators and pain relievers. Dark green dots with a check mark indicate the fit (compatibility) with an existing product or service, gain creator or pain reliever. Light green dots without a check mark and italic text indicate future fit (compatibility) derived from the anticipated nature of the related services and gain creator/pain reliever.



Multimedia Appendixes

The CEN ISO/TS 82304-2 Label.
URL: http://asset.jmir.pub/assets/e4c46a622aa744496a373fbcbff49e29.docx

Interview Topic Guide.
URL: http://asset.jmir.pub/assets/d255c7868c307e45c62e4688fe994796.docx