

## Label2Enable project to LabelDigitalHealth sustainable entity

ISO certification of health apps to scale blended care

May 2024

### Background:

The healthcare industry continues to experience a substantial growth in the number of available health apps, which are estimated to surpass 350,000, reflecting a diverse spectrum of intended uses aimed at improving patient and health system outcomes. However, the abundance of health apps also presents significant challenges for patients, healthcare professionals, and health systems to identify and choose apps that fit particular health needs, and are effective, reliable, and safe. The lack of standardised criteria for evaluating the quality and efficacy of these apps intensifies the problem, leading to potential risks associated with the adoption of applications that are not effective or secure.

Recognizing these challenges, the European Commission has funded the development of the Technical Specification (TS) CEN-ISO 82304-2 (Health and wellness apps - quality and reliability) and subsequently the Label2Enable project (2022-2024), a collaboration of 14 multi-stakeholder and expert partners from 7 European countries.

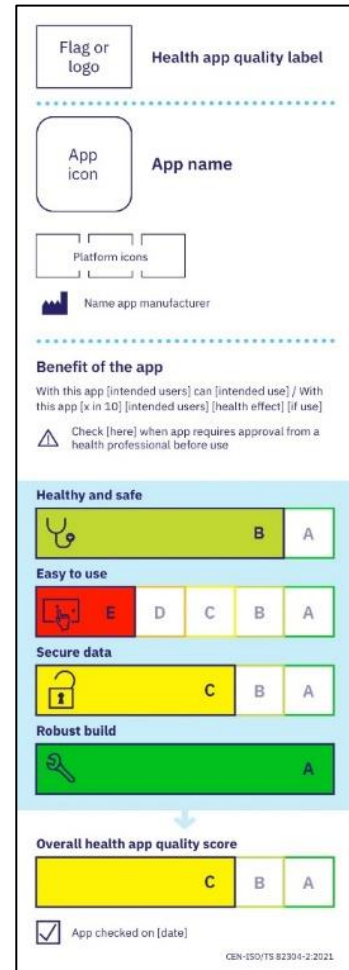
### Approach:

Label2Enable has been championing the adoption of the CEN-ISO/TS 82304-2 assessment framework, its quality label and related report for health and wellness apps. Inspired by the EU Energy label, the CEN-ISO/TS 82304-2 label shows the health app assessment results at a glance and is accessible in 26 languages. The health app quality report intends to provide a basis for medical societies and health care professionals to recommend a health app and for insurers to decide on reimbursement.

Label2Enable envisions a digital single market where high-quality and safe health apps are used at scale for prevention, health care and self-care. Through the development of a standards-based certification scheme and handbook for app assessors, Label2Enable has created conditions for issuing the TS 82304-2 label, delivering enhanced transparency, and fostering trust.

We believe that trust in label can be built and maintained by:

- **Testing activities:** Label2Enable tested the CEN-ISO/TS 82304-2 label with people with low health literacy in 4 corners of Europe (France, Hungary, Italy, Sweden). Iterative versions of the app assessor handbook were tested with 24 health app manufacturers and 5 assessment organisations from 5 countries. Eight medical societies were consulted to provide feedback on the CEN-ISO/TS 82304-2



CEN-ISO/TS 82304-2 label

health app quality report, which was developed by the Label2Enable healthcare professional advisory board in collaboration with the patient citizen carer advisory board.

- **Policy and legislation activities:** Label2Enable examined existing EU legislation frameworks for energy labelling, front-of-pack nutrition labelling, and medication labelling to provide a baseline of understanding on similarities and lessons learnt that the project could benefit from. We aligned the CEN-ISO/TS 82304-2 app assessor handbook with EU level legislation, in particular the European Medical Device Regulation (MDR) and General Data Protection Regulation (GDPR) as well as collaborate with Joint Action Xt-EHR regarding the European Health Data Space (EHDS) Regulation Article 31 (labelling wellness applications).
- **Stakeholder engagement:**
  - **Surveys:** The Label2Enable project conducted several surveys to achieve an adequate understanding of stakeholder needs and behaviours. Over 1200 citizens from 33 countries responded to our survey on whose recommendations for health apps they used and trusted. It revealed that 86.3% of respondents thought that the government should review and rate health apps or pay another organisation to do so, to help choose the right health app. An experimental vignette study and follow-up survey with 116 and 290 healthcare professionals (HCPs), respectively, demonstrated that the quality label increased HCP willingness to recommend apps to both patients with high and low social economic status and detailed which further interventions are needed to promote prescription behaviour. A Discrete Choice Experiment with 41 health app manufacturers and 46 health system representatives from 21 countries explored willingness to pay for types of health app quality assessments. Two final studies with 750 and 1056 persons of varying health literacy are still being analysed at the time of writing. The first explores the effect of the label and an explanatory short video on the label on choosing health apps, the second investigates how to effectively display the label in app stores and the interplay of the objective label information and the subjective star ratings.
  - **Stakeholder workshops, roundtables and articles:** The Label2Enable series of 3 roundtables on reimbursement of health apps explored related challenges and multi-stakeholder solutions with 135 participants from 34 countries and resulted in an infographic visualising 9 recommendations. Over 150 participants in four multi-stakeholder back casting workshops on success of digital health labelling in 5 to 10 years resulted in a roadmap. Four scientific articles will add further guidance for health authorities and medical societies. An article with the European Society of Cardiology is currently in press. Two others focusing on health authorities with or without a health app assessment framework will be submitted in June. A final article will detail how a comparative analysis of CEN-ISO/TS 82304-2, the EUnetHTA core model and the Dutch, English, French, German, Finnish and Australian assessment frameworks informed the CEN-ISO/TS 82304-2 handbook. These collaborative and scientific efforts ensure the health app quality label is robust, relevant, and effective in fostering digital health advancements, optimising health and societal outcomes.

## On the way to sustainability: LabelDigitalHealth

In recent months, a "Coalition of the Willing" has focused on preparing the ground towards sustainability. To this end, LabelDigitalHealth has been created as a sustainable trusted, multi-stakeholder EU initiative that will be hosted by the European Institute for Innovation through Health Data (I<sup>2</sup>HD).

LabelDigitalHealth aims to scale up multi-stakeholder value by efficiently enabling stakeholders to deliver, demonstrate, promote, and choose quality health apps. Towards this objective, it will support an EU-wide assessment network and explore more automated assessments to create the needed affordable scalable capacity that meets the demands of app manufacturers, (national) assessment bodies and app stores. As a first step, LabelDigitalHealth will develop a market strategy that includes a demonstration phase involving the labelling of 100 apps, to serve as a regulatory sandbox. This phase is vital for boosting demand for the label among app manufacturers and national health authorities, facilitating the integration of quality health apps into European healthcare and reimbursement systems. LabelDigitalHealth will establish a network of assessors across the EU that will operate under the ISO 17000 series compliant Label2Enable Certification Scheme owned and maintained by this new organisation.

Operations during the initial demonstration phase will therefore focus on generating the evidence of value with health authorities, health providers, medical societies, insurers, and HTA-bodies who seek to progress towards quality blended care pathways, with a critical mass of labelled health apps.

Are you interested how you can support and benefit from this initiative? Please contact:

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### About Label2Enable:

**Label2Enable** is an EU-funded project championing the sustainable adoption of CEN-ISO/TS 82304-2 quality labelling of health and wellness apps.

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