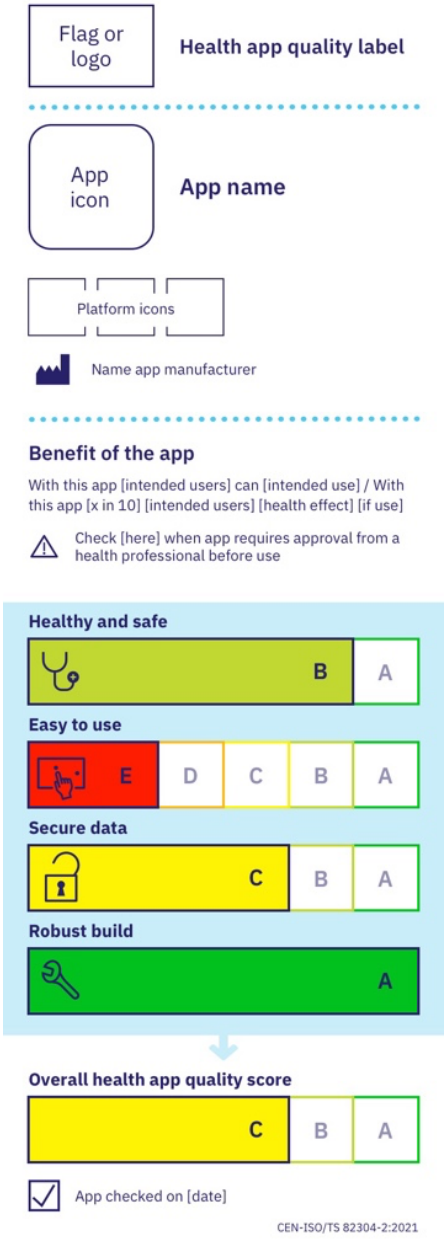
LABEL2ENABLE 3rd workshop report



Preamble

On **November 3, 2023,** the Horizon Europe Label2Enable consortium[1] organized its **third multi-stakeholder workshop** in a series of four workshops over the course of two years with representatives of our key stakeholders. These workshops are supporting a structured multi-stakeholder dialogue and include a backcasting exercise. Backcasting entails defining success of labelling health apps in 5 to 10 years, with a focus on the CEN-ISO/TS 82304-2 label, and how to jointly get there, in a context of the current legislative initiatives.

The presentations during the informative plenary session are available via https://label2enable.eu/third-multi-stakeholder-workshop. Agenda and details captured during the break-outs are found in the Annexes.

Despite 'bomb cyclone' Ciaran's travel issues, autumn influenza and technical issues, we thankfully welcomed 19 participants in person in Brussels, Belgium and another 51 online. The attendees included among others representatives of **patients / citizens / carers** (the European Patients' Forum and user advisory board), **healthcare professionals** (HIMSS, Health Tech Without Borders, Kaunas Clinics, Lund University, National Pirogov Memorial Medical University Vinnytsya, health care professional advisory board), **app assessors / frameworks / libraries** (BSI, Equalis, i~HD, INBIT, ORCHA, Quokka, SQS, Taskforce DMD), **app manufacturers** (COCIR, Digital Europe, EIT Health, Gnomon, Johnson & Johnson, MedTech Europe, Philips), **standard development organizations** (CEN TC 251, GS1, HL7, IEEE, IHE, the Dutch National Standardization Body), **regulatory service providers** (Eppaoa), and **healthcare authorities** (the European Commission, Austria, Catalonia, France, Italy, the Netherlands, Sweden, United States initiative) and global health connector ECHAlliance. and Acumen Public Affairs.

Executive Summary

The question we answered in this workshop has been: *What actions do we need to take in the short, medium and long term collectively and each stakeholder segment separately, to bring about the identified changes working towards achieving the common vision of the preferred future*? We further took a deeper dive into the in-between targets and milestones, drivers and barriers at stakeholder and the collective level, as well as the synergies to be leveraged in accelerating uptake and wide use in Europe and worldwide.

Participants worked in break-out sessions to propose, from each different stakeholder perspective, actions that would need to be commonly supported to realize the vision of the role of the label to reaching the preferred future. These inputs were then used to sketch a common roadmap and its main milestones during the final plenary session. These are summarized in Figure 1.

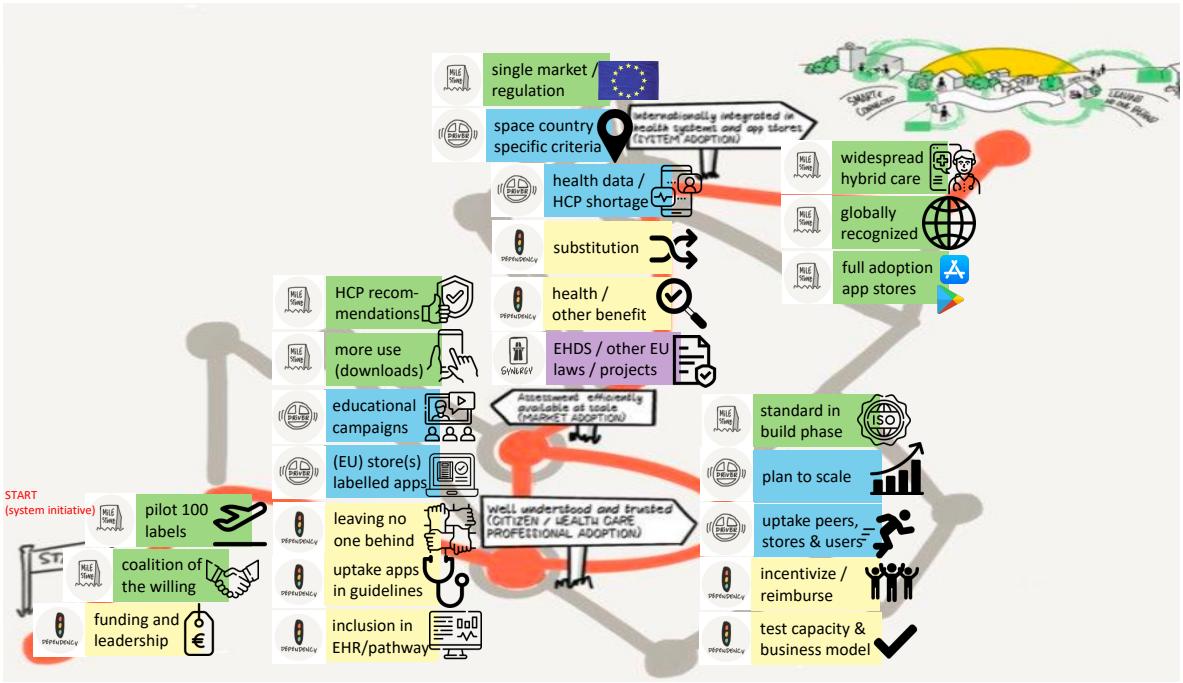


Figure 1. Synthesis of stakeholder perspectives

The **starting point** towards the successful implementation and wide use of TS82304-2 in practice, will therefore be the achievements of Label2Enable, in establishing, testing and validating the concept of the TS 82304-2 Trust framework:

- A TS certification scheme based on ISO 17065, ISO 17067 and ISO 17026
- A handbook for Conformity Assessment Bodies
- A governance model for establishing and maintaining an EU wide network of Certification and Conformity Assessment Bodies
- A new or existing designated sustainable non-profit legal entity, that enables maintenance of the certification scheme and handbook
- A community of practice and associated Stakeholder Forum

For operationalizing the assessment and labeling process we must swiftly transit from project to sustainable operation through the establishment of an EU level entity that will realize the vision of a sustainable trusted labeling activity in the EU and potentially beyond.

A first next step is to create a coalition of organizations that will carry forward **the first phase** starting before the end of the project all the way to rendering the label organization operational and able to attract income streams. This so-called **Coalition of the Willing (CoW**) would elaborate a market strategy including a demonstration phase to build the evidence and aiming to provide a regulatory sandbox, necessary for scaling-up demand for the label from both the manufacturers and the national authorities responsible for adopting quality apps into the health care and reimbursement systems. What was envisaged is that labelling 100 apps during this demonstration phase would provide the volume of evidence needed to enable a spiraling effect:

- From a health system perspective, the more labelled products are in the market, the more meaningful their investments will be e.g. in adopting the label as a trusted mechanism to create efficiencies in their own assessment schemes and eventually adopt quality apps in their clinical care pathways and reimbursement systems.
- From a manufacturer perspective, the more health authorities and HTA-bodies incorporate the label into their health and reimbursement systems for apps, the more attractive and meaningful their investment in affixing the label will be.

Realizing this first phase would require:

(i) Setting up an EU organisation and its appropriate governance, operationalizing the governance and the certification scheme and enrolling several Conformity Assessment Bodies (CABs).

(ii) Attract the interest of manufacturers to participate in this demonstration phase, while at the same time:

(iii) Work with scientific medical societies, to explore how rigor of the certification and for instance profiles of apps can support uptake of apps into related clinical guidelines and prescription practice.

(iv) Demonstrate in an operational setting proof of the concept, that labelled apps accompanied by a fit-for-purpose quality report can support scientific decisions to include the prescription and use of high-quality apps into clinical practice.

(v) Explore within the health systems and authorities context (country) specific requirements and decision-making on the TS and reimbursement for these apps and (HCP) support needed.

(vi) Establish a Regulatory Sandbox for EU and national regulators, providing the needed evidence of impact, costs and benefits and promoting cross-country recognition.

(vii) Plan to scale.

The **next phase** leading to sustainability is envisaged as a process of continuous rise of volumes of users of labeled apps and of scaling up certification capacity in response to growing demand, e.g. with more automated assessment.

A generalised use of the label by health authorities, whether mandatory or not, will result in market defragmentation and promote wide use of labelled apps by citizens, patients and health professionals. A (regulatory) database of labelled apps will also create transparency as to the quality of the apps that are placed in the market. Wide adoption by App stores will further make quality apps accessible to consumers and health professionals.

Wide EU adoption of the TS and the label will inspire its global use and conversely, the EU adoption roadmap will be informed and learn from successful strategies and implementations world-wide.

Digitally enabled health systems through quality digital solutions will support effectively our common preferred future.

The 4th and final workshop of these series will take place in Brussels on April 4, 2024, and will focus on optimising the sustainability strategy and plan of action. These will be described in an extended form of this document, through enriching this with inputs from 2-3 intermittent on-line stakeholder consultations.

Annex I: Workshop agenda

November 3rd

TIME	TOPIC — CEN-CENELEC, Rue de la Science 23, Brussels
9h00-9h30	**Arrival**
9h30-9h50 (20 min)	**Welcome remarks and introduction** Petra Hoogendoorn, LUMC and Zoi Kolitsi, I~HD **Looking back and ahead: workshop objectives**
9h50-10h55 (65 min)	**Plenary Session I: Recent developments and inspiration** Moderated by Petra Hoogendoorn, LUMC **The changing EU landscape for health and wellness apps** Petra Wilson, HIMSS **Label2Enable findings and updates** - ***TS 82304-2 certification scheme and sustainability considerations*** Christophe Maes, Charlie McCay, I~HD - ***Testing the label scheme with 24 apps and 5 assessment organizations*** Liz Ashall-Payne, ORCHA and Menno Kok, EIT Health - ***Discrete choice experiment on the value proposition of health app assessment*** Anna Frey, ORCHA - ***Exploring the value of 82304-2 in decision-making on reimbursement*** Tatjana Prenda-Trupec, OptimIT - ***Co-creating and testing educational communication around the label*** Corine Meppelink, University of Amsterdam
10h55-11h15	**COFFEE BREAK**
11h15-12h30 (75 min)	**Break-out session I: What is a realistic roadmap to success of the label?**
	Citizens / patients / carers and healthcare professionals Moderator: Gözde Susuzlu, Rapporteur: Christophe Maes
	App assessors, app libraries and app stores, app manufacturers, SDOs and regulatory service providers Moderator: Petra Hoogendoorn, Rapporteur: Menno Kok
	Health authorities and insurers Moderator: Zoi Kolitsi, Rapporteur: Charlie McCay
12h30-13h30	**LUNCH BREAK**
13.30 -14.15 (45 min)	**Plenary Session II: Reports from break-out session I**
14h15-15h30 (75 min)	**Break-out session II: Multi-stakeholder dependencies and synergies** 3 breakouts of mixed stakeholder groups
15h30-15h45	**COFFEE BREAK**
15h45-16h30 (45 min)	**Plenary Session III: Reports from break-out session II** **Discussion: Input for follow-up agenda** **Wrap-up**

Annex II: Reports from break-out and plenary sessions

REPORTS FROM BREAK OUTS - Introductory questions and discussions (all, plenary room): Rapporteur: Menno Kok

- What is the interplay between ISO-82304-2 and EHDS regulation / CE mark / MDR and GDPR?
  These are operationalised in the adherent countries according to national legislation.
- Small countries argue that they do not have their own HTA bodies (should they rely on "the neighbours"?)
- How do we deal with the overwhelming number of apps available at App stores?
- What is the outlook for a start-up company?
  a. Day one they start with a dream and a lot of technical expertise (but often lack business ideas).
  b. Will they develop themselves into a market player or seek collaboration with a wired partner?

Report Group 1: Stakeholder Roadmap - App assessors, app libraries, app manufacturers:

Start (Brussels Midi):

Published evidence & Clear guidance for compliance
Unawareness about the label [Roadblock]
First label issued to app
Reimbursement and investors [Dependencies]
Trust [Dependency]
Mapping against existing HTA criteria to provide assurance

Midway (Brussels Central):

Label mandatory for obtaining reimbursement (?) [Drivers]: consequences need to be carefully considered
Prescription and recommendation [Driver]
Social Networks
App stores to provide ranking (based on ISO 82304-2)
Not based on questionnaire; rather continuous assessment to enable manufacturers to take continuous measures to ensure compliance increasing adoption
Other mandated framework launch

Finish (Brussels North):

US 50 million dollar Peterson Health Technology Institute
EU Buy-in to match
Regional development agenda [Synergy]
HTA agencies: a careful cost benefit analysis is required for each app

Report Group 2: Stakeholder roadmap - Health care providers and health systems, health care providers:

- Health care providers are a key stakeholder group: what would be a suitable mechanism to collect their feedback?
- Payers will be interested in cutting costs: does the app provide the cheaper and qualitatively equivalent (or better) solution? What are long term consequences of reimbursement of an app?

- National authorities need to take into account that apps will spread across national borders
- Patient organisations are potential drivers of adoption.
- Train-the-trainer approaches to reduce or prevent disparities.
- Use the power of use cases (success stories), particularly with wellness apps.
- Confident citizens and patients may be the early adopters. Making smart use of this group may help much broader adoption.

Report Group 3: Stakeholder roadmap - Health authorities and insurance companies:

- Health systems need to employ apps to collect and share health data with citizens. There is therefore added value that apps may bring to users by providing access to personal health data.
- Evidence (and *intellectual access* to the evidence) that an app delivers value is an important driver of adoption.
- Whether or not the label should become a prerequisite for reimbursement remains an undecided issue.
- What do we do with the overwhelming amount of apps available through app stores (also with respect to the previous point)?

Plenary Discussion - Sustainable future for the label beyond the current project:

For technical reasons, the two groups discussed together in round II.
In June 2024 all deliverables are expected to be there, but "nothing works" (i.e. the label has not been implemented). How can the label be put to work to stimulate national adoptions of apps ("marketing aspect" from the manufacturers perspective), and will adoption remain to be a national affair only or can Brussels "push"?
Factors that will enhance the chances for (national and transnational) adoption:

- 360 degrees stakeholder support demonstrated
- A business plan for a sustainable label organisation
- A proper HTA process to establish scientific over economic proof
- Preparation of the market (users, payers) including training and education
- A home base (house of health apps) for the above organisation
- Letters of intent to lead the project into scalability
- (can L2E deliver 80(+) % of a national assessment?)

What do we need to do?

- Look for another source of programme funding, or
- Rather seek implementation funding?

(or) Should we go for test implementation first, with clear proof-points (a regulatory sandbox with letters of intent from the stakeholders stating that "if it works, we're in"!)?

The L2E strategy should be carefully aligned with the interests of the key stakeholders:

(No 1) Manufacturers:

Mostly small (young) companies, often aiming at a single product (and themselves in a critical growth phase with many dependencies), and
Some established companies (MedTech and Pharma) providing brand recognition, sustainability and marketing capacities.

(No 2,3,4..) Regulators, payers, users (citizens/patients, HCPs), governments, app stores (and other) stakeholders:

Draw in additional organisations that are prominently active in the field, such as: The European Consumer organisation and the AGE platform.
For health care professionals the journey (of adoption) needs to be planned ahead as well.
The demand for app solutions also comes from the health care systems: what does that imply for business models for the label?

Annex III: Post-its

Drivers:

- collect data from patient
- drive adoption of mon espace health
- data sharing
- social networks – app stores
- prescription or recommendation
- mapping against existing HTA criteria to provide assurance
- mandatory (whether reimbursed or not)
- pressure for self-care and self-management by disease burden (“baby boomer avalanche”)
- connect to national organisations for communication in national languages
- communication about label only useful if there are labelled apps (use cases / examples)
- patient access to data
- trusted apps: security, ethics, interoperability
- once the ISO/TS has become a standard, the reimbursement model finalised and the coverage is adequate / in line with national requirements, we’ll see the label uptake increase
- cost and reimbursement structure will always create roadblocks but according to Anna Frey’s results, if a European/national consensus exists, reasonable costed evaluations and reduction in overlapping requirements will help
- trusted apps, security, ethics, interoperability
- collecting data for EHDS
- continuous improvement
- improve healthcare
- data sharing
- collecting data from patients
- catalogue needs to focus on B2C apps
- transparency
- patient access to data
- low compliance
- social prescriptions
- prescription or recommendation

Roadblocks:

- cultural contextual sensitivity
- unawareness about the label
- other mandated framework launch
- lengthy evaluation process – cf MDR certification currently
- alignment between national and EHDS frameworks
- defining recommendation or prescription practices, what does this look like?
- poor knowledge of the label
- figuring out the data architecture to enable data flow from apps to the patient records (at provider side) and drive care plans
- low compliance

- social media campaign
- patients organizations are active on promoting the label
- pressure for more selfcare in chronic conditions
- HCPs and pharmacy recommend labelled apps to patients
- use cases of labelled apps
- connect the national organisations

Milestones:

- context – culture
- hcp: make my life easier! safe time
- users learning about label
- value proposition: (communication – data transferability between patient <-> clinician) added value?
- first label issued
- requirements to become an app checker
- benefit for my health literacy – better health care consultations for me
- healthcare payers need criteria for what to offer and to fund
- need for more health apps with added value besides – Google – Apple – apps bundled with trackers
- choice of apps
- hcps recommending label to patients
- health and care professionals prepare guidelines that involve apps in the process
- first apps certified
- patient: do I get the app for free? (more likely when approved for quality)
- first label
- network of approved assessors
- understanding: awareness about the apps, experience with using the apps in the past / present
- securing implementation phase
- committee of all stakeholders
- getting program funding beyond the timelines of the project to continue (Label2Enable) leadership and enable implementation – public private partnership also from other projects / in relation to EHDS and EHRxF
- commitment critical mass of stakeholders to implement: coalition of the willing
- go to market strategy label
- involve (more) BEUC / ANEC / digital group / AGE platform / Eurocarers
- first label issued
- campaign self-care / % awareness benefits apps patients + hcps
- evidence and EMA/FDA type approvement drives uptake hcps and other stakeholders
- incentivize hcps: value proposition health apps for hcps / integration of apps by health systems / professional associations / uptake funding for their time spent
- trusted (known) central database that perhaps links with EHRs and personal support: the home of health apps (mindful of different generations now and then)
- hcps start recommending / prescribing apps
- people start using apps
- hcps start using / use app data

- clarity assessment process (cost and benefits) to sell to manufacturers – pilot after the 24 apps we're testing with / technology demonstrator / proof of value -> scalability market
- 1st label / assessed app and promoted as such also by manufacturers
- regulatory sandbox with letter of intent with clear proof points
- (growing) network of certified assessors
- label requirement for reimbursement / health system adoption
- HTA involvement / substitution of current treatment with apps
- manufacturers' buy-in results from other and own stakeholder uptake: label enables stick out from the crowd / create trust (large companies already stand out and need proof of scalability / multi-country uptake minimum level)
- primary role European Union
- lobby manufacturers to app stores etc. / EU
- uptake by app stores etc.
- see how label fits in (what other context specific requirements)
- some sort of European adoption (similar to directive energy label 1992)
- evaluation: 1. evidence based criteria (clinical trials, feedback from users, data etc.), 2. data security, 3. privacy, 4. user experience
- define criteria for reimbursement, which type of apps are eligible for reimbursement
- confident citizens
- patients embrace the logic of the label and see it as a personal benefit and begin to choose applications according to the same tag logic and share relevant feedback with patients (how to read the tag and what is the most important criterion for the patient)
- at least 30-50% patients in each EU country are presented with the label
- rate of patients using health apps is growing (for example 30% growth)
- patients know how to read the label (survey)
- patients organisations attend the meetings of further development and updates of apps
- hcps are asked by patients about health apps recommendations (survey)
- patients (customers) give feedback with Net promoter score (aim 30-70)
- awareness and experience with using apps
- choice of apps
- awareness about health app label
- value proposition
- apps as personal healthcare
- healthcare payers need criteria for what to offer and to fund
- ISO/TS becoming a standard

Dependencies:

- investors
- reimbursement
- trust
- published evidence & clear guidance for compliance
- does require funding (from those that benefit)
- since the ISO TS framework is quite demanding for app developers, it may turn out to be a barrier for SMEs, who have no large regulatory resources in-house
- cost-benefit analysis, cost-effectiveness of reimbursement
- properly trained app assessors
- citizen engagement

- HCP engagement
- for authorities it is important to assess the benefit/cost ratio of a new intervention, in this perspective it is useful to highlight the elements of a quality assessment framework that can be part of a HTA analysis

Synergies:

- USD 50 mln Peterson Institute – EU buy-in to match
- regional development agencies
- collaboration with experts from different stakeholder groups: hcps, patients, tech experts
- health professionals and independent organisation agreeing on label usability
- clinical validation