LABEL2 ENABLE

workshop report

On **February 24, 2023** the Horizon Europe Label2Enable consortium[1] organized its **first multi-stakeholder workshop**. We welcomed 45 participants in person in Brussels, Belgium, and another 31 online. The attendees included representatives of **patients / citizens / carers** (among others the European Patients' Forum, EuroHealthNet, EURORDIS), **healthcare professionals** (European Junior Doctors, European Respiratory Society, European Society of Cardiology, HIMSS), **app assessors / frameworks / libraries** (DEKRA, i~HD, mindapps.dk, NordDEC, Onco Appstore, ORCHA, SQS, Taskforce DMD, Team NB, Therappx), **app manufacturers** (ACT, COCIR, Digital Europe, EIT Health, Johnson & Johnson, MedTech Europe, MoveUP), **standard development organisations** (CEN TC 251, GS1, HL7, IEEE, IHE, the Irish and Danish National Standardisation Body), **healthcare authorities** (the European Commission, Andalusia, Catalonia, France, Germany, Italy, Norway and Poland), insurers / HTA (AIM, Digi-HTA).

In this report you will find links to the **presentations** and a summary of the **discussions**, both plenary and in breakouts on the following three questions:

- what is your **preferred future** with regard to digital health 5 to 10 years from now?
- what do you think is the **projected future**?
- how do you think the **label** can help attain the preferred future?

The CEN-ISO/TS 82304-2 health app quality label

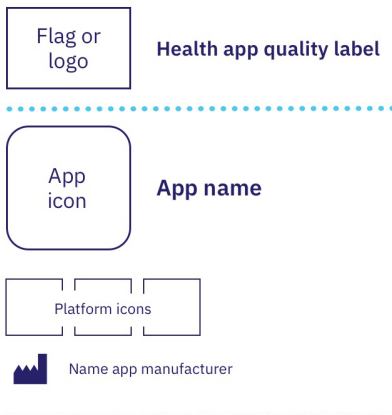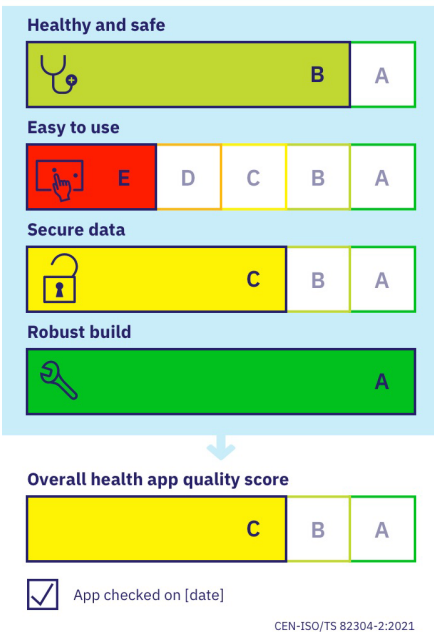|	
Flag or logo	**Health app quality label**
App icon	**App name**
Platform icons	
🏭	Name app manufacturer

Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

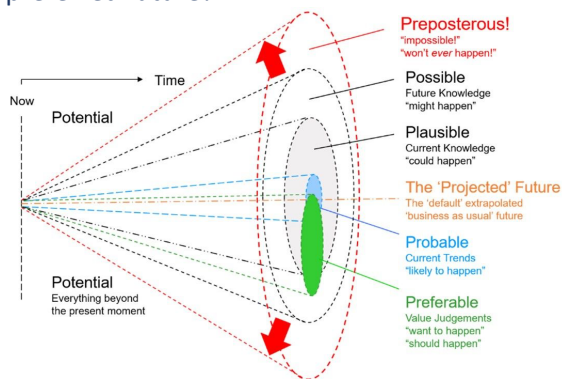⚠ Check [here] when app requires approval from a health professional before use

Healthy and safe

	B	A

Easy to use

E	D	C	B	A

Secure data

C	B	A

Robust build

A

Overall health app quality score

C	B	A

☑ App checked on [date]

CEN-ISO/TS 82304-2:2021

The CEN-ISO/TS 82304-2 health app quality label

The futures cone

This workshop was the first in a series of four workshops over the course of two years with representatives of our key stakeholders. These workshops will support 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 labelling apps as specified in article 31 and annex II of the draft European Health Data Space Regulation. We look forward to welcoming you in the **second multi-stakeholder workshop** which will take place on **June 26, 2023**, again in **Brussels**. On the agenda then will be more results of the project, initiatives of participating stakeholders and how to get towards the preferred future focusing on the role of labelling.

presentations

Label2Enable Overview - Petra Hoogendoorn, LUMC and Zoi Kolitsi, i~HD

Plenary Session: The digital single market, uptake and labelling

Addressing current challenges in EU legislation - Birgit Morlion, DG Connect, and Carole Rouaud, DG Santé

Scaling up the adoption of digital therapeutics - Dipak Kalra, i~HD

Label2Enable initial findings
- *Citizen and healthcare professional survey* - Mariam Shokralla, LUMC and Antanas Montvila, Kaunas Clinics
- *Testing the label scheme with 24 apps and 5 assessment organisations* - Paul Weston, ORCHA
- *Learnings from the EU Energy label, front-of-pack nutrition labelling and medication labelling* - Petra Wilson, HIMSS

Why labelling is part of the solution - David Bates, Harvard Medical School / T.H. Chan School of Public Health

Initiatives of participating stakeholders
- *Project safer health apps* - Arve Paulsen, Helsedirektoratet Norway
- *Labelling for interoperability: towards EHRxF best practice* - Catherine Chronaki, HL7
- *Role IHE in the digital health SDO ecosystem* - Derek Ritz, IHE

summary discussions

The preferred future

Healthcare in the preferred future 5-10 years from now will be more personalised and offered wherever and whenever needed. Communication technologies used will be safe and secure and will include online consultations, telemedicine, trustworthy and connected data, apps, analytics, and AI, all wrapped around an individual patient. Today's traditional healthcare delivery environment will have transformed into smart and connected on-site emergency and specialized in-hospital care where the patient will

travel to; however, the greatest volume of services will be travelling to the patient and will be enabled by the patient. Current and emerging technologies and tools will support integrated clinical workflows, streamline clinical procedures, decisions, and information, and support a well governed, protected, productive and rewarding workplace for healthcare professionals.

In our preferred future, digital health will be ethical, the result of co-creation and leave no one behind. There will be a diminishing divide, more health literacy and improved use and understanding of "digital health". Patients will feel enabled to monitor and proactively act on their health. Healthcare professionals will be provided with tools and information to work with patients. They can prescribe digital health services enabled by apps that are fit for purpose. A multi-app connected devices and augmented reality synergistic ecosystem around the patient and signals and analytics feed-back loops will provide continuity from health management to disease management.

Health systems will thrive on mutually trusted relationships across the whole stakeholder landscape and become more resilient, preventing, and reducing disease burden in all possible ways. Populations will enjoy healthier and independent lives. Financial sustainability will come with an equally radical transformation of financing models. Value and outcome will be rewarded and access to services will be ubiquitous for all. Trusted and accessible digital health solutions will be central to enabling this flow of events in our preferred future. We expect the future to be bright with trust in apps from stakeholders and end-users alike. The quality label, extended to all digital solutions, will be a central part of this trust. The enabling of the app label through operationalising its underlying certification scheme is a good example. However, the preferred future is not expected to happen through the app label alone.

The projected future

In the projected – extrapolating current direction – future, technology will be smarter and digital solutions will be more integrated with Electronic Health Records. However, decision makers will still need to go through significant effort to increase adoption rates, reduce the burden for clinicians and stimulate the use of technology, eventually creating demand. They will, for example, need to reward use and promote business models for manufacturers that promote early engagement with clinicians and improve access for patients .The new paradigm is already emerging and we can claim today that adoption and uptake of digital technologies, including apps is receiving good attention in terms of policy and support activities.

The label

In which directions can the label join forces with its stakeholders to influence the evolution of the preferred future?

Mindful of the UTAUT model for technology acceptance[2], behavioural intention of manufacturers to obtain the label, doctors to use the label for supporting the prescription of digital technologies and patients to decide on using digital technologies should take account of:
- **Performance expectancy** (*"the degree to which an individual believes that using the system will help him or her to attain gains in job performance"*): Labelled apps should meet expectations for quality and safety. The label and its certification scheme should be highly trusted, transparent, and

[2] Venkatesh et al (2003) User Acceptance of Information Technology: Toward a Unified View

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synergistic with other assessment schemes. Assessment results should be consistent irrespective of where the assessment takes place. Getting a label should be impossible if an app is "bad".

- **Effort Expectancy** (*"the degree of ease associated with the use of the system"*): The label and its certification scheme should be easy to understand. The certification process should be streamlined, proportionate, and accessible to manufacturers everywhere in Europe. Getting a label should be easy if an app is "good". [*In the next workshop we will be able to present our findings on testing the label with people with low health literacy in 4 member states and further results in testing the certification scheme with 24 health app manufacturers and 5 app assessment organisations from 5 different countries.*]
- **Social influence** (*"the degree to which an individual perceives that important others believe he or she should use the new system"*): Looking for and using the label should become a new normal, for a healthcare professional a guideline in prescribing apps and a consumer habit in choosing what to download from app stores. Getting the label and using its requirements to build quality health apps should become an industry standard, that is rewarded by consumer, healthcare professional and insurer behaviour. [*Obviously we welcome multi-stakeholder support for labelling apps and its value also for secondary use of data in feedback to the EHDS.*]
- **Facilitating conditions** (*"the degree to which an individual believes that an organisation and technical infrastructure exists to support the use of the system"*): The label helps in facilitating conditions, especially if easily available in app stores and supported by targeted promotion and education. Health literacy and payment around the label must be in focus. [*We expect to show more on (co-creating) education around the label in the third workshop.*]
- **Moderation effects:** Gender, age, experience, and voluntariness of use may influence intentions to use the label and apps. According to literature, the intention to use health apps was determined by performance expectancy - which the label helps indicate - moderated by age and smartphone experience. Younger men had more intention to use apps if facilitating conditions were better, older men if less effort was needed[3] - which the easy to use score in the label and the age appropriateness score in the health app quality report may help indicate.

breakout sessions

The preferred future

Citizens / patients / carers and healthcare professionals	In the preferred future empowered patients will be central in co-designing their own pathways with their clinicians. Emphasis will be on prevention and disease monitoring enabling them to be more proactive in their health. They will choose tools for capturing patient generated data, to be combined with clinician generated data and making it available for the development of further knowledge. Healthcare professionals will have access to easy-to-use, seamless tools and will be provided with and be supported to acquire the needed digital health skills. It will be possible to prescribe apps or tools in the same way as an Xray or a drug.

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[3] Nunes et al (2019) Acceptance of Mobile Health Applications: Examining Key Determinants and Moderators

Technology will become simpler and more user friendly and intuitive. The new normal will be co-operating multi-app and wearables, multi-vendor ecosystems around a patient with continuity from health management to disease management.

Health economics models will help identify the most cost-effective way to manage healthcare. Digital health will be bullet proof against cybersecurity threats and technology failure should never lead to major damage. This is a pre-requisite to allowing ourselves the same level of dependency on technology as we are prepared to do with other sectors.

App assessors, app libraries and app stores, app manufacturers and SDOs	In the preferred future, apps will be very interoperable, also thanks to a common interoperability framework. Data or actually insights used will be at most one day old, integrated and used extensively to benefit health, personalised, preventive, more sustainable, allowing more meaningful interactions between health care providers and patients. There won't be a market for digital health solutions that don't have a good label. Instead, the label will be used in decision making on reimbursement and the now hundreds of thousands of mostly not very good apps will become less yet significantly better quality apps with a label that everybody understands and label limitations everyone is aware of. Manufacturers have tooling that helps them easily build in and pre-assess quality. Certification has become very efficient, available in all countries, cost effective, affordable, and agile given changes in apps. Funding mechanisms have evolved. Stakeholders, the population, and end-users alike have much more trust in digital health in general, thanks to the quality label. Digital Health has become Health, the new normal that eventually may enable people to be treated close to home, at home and in their own lives. The haves and have nots have become a thing of the past, as the divide in who has and who has not a smartphone, who knows how to use a smartphone and who does not, has disappeared. If we do it right the impact, also for the 150 low and middle income countries, will be huge. In the high resources environment these changes will reduce costs, in the low resource environments they will increase access.
Health Authorities, Payers	Healthcare in the preferred future 5-10 years from now will be more personalised and offered wherever and whenever it is needed. Communication technologies used will be safe and secure and will include online consultations, telemedicine, trustworthy and connected data, apps, analytics, and AI, all wrapped around an individual patient. Today's traditional healthcare delivery environment will have transformed into smart and connected on-site emergency and specialized in-hospital care where the patient will travel to; however, the greatest volume of services will be travelling to the patient and will be enabled by the patient. Current and emerging trustworthy technology for communication, online consultations, remote consultation technologies and tools will support integrated clinical workflows, streamline clinical procedures, decisions, and information, and support a well governed, protected, productive and rewarding workplace for health professionals. This will contribute to making

health systems more sustainable, inclusive, and resilient. Eventually the line between healthcare and digital health will disappear.

Future funding models will be driven by outcomes and the patient will have a role in shaping such outcomes. However, social determinants for health must be accounted for and democracy of innovation needs to secure that digital health is ethical and secures equal access to its benefits.

Synergies with other sectors such as agriculture and the food industry can support prevention and better health.

Healthcare professional advisory board (separate meeting end of March)	In the preferred future, a data driven approach will prevail where technologies such as dashboards, patient-doctor communication and interprofessional collaboration tools, and AI based clinical decision will shape a new care delivery landscape across levels of care. Digital health will be part of university curricula for health professionals and continuing professional development. Health professionals will have access to sufficient information on quality of the apps they will be recommending, including the underlying evidence and the strength of such evidence, as well as reimbursement and financing policies. To this end, the role of professional associations will be invaluable in creating and delivering the needed guidance on the proper use of quality apps in diverse care situations. At the same time, combined with language sensitive approaches, care delivery will become increasingly more accessible from anywhere, within and across borders.

The projected future

Citizens / patients / carers and healthcare professionals	If business as usual, the projected future may entail enlargement of population segments with increased needs and a greater digital divide. Health will lag behind in its digital transformation compared to other sectors such as commerce. Major threat is the shortage of healthcare workforce with physicians that are too overburdened to engage in innovations.
App assessors, app libraries and app stores, app manufacturers and SDOs	The speed of integration of digital technology and its availability for all, evolving a very hospital centric system to a more patient driven system where tools are available, adopted and prescribed where needed, not lowering the bar but making it easy for manufacturers to make patient safe privacy preserving high quality applications that actually solve current problems, will depend on changes in reimbursement and tooling. Learning from the front-of-pack nutrition label we also have to acknowledge that having the lowest score on the cheese or bacon you like may not affect purchasing behaviour. And how are we going to adequately address multimorbidity. Are we going to have them use five or six apps? How does that affect the label?
Health Authorities, Payers	Not much will happen with the labelling alone. We need to combine a set of activities and barriers for uptake. We need to reduce the clinical burden. We need to have stimuli for people to use technology. They need to know what the barriers are. We need to create demand through building trust, targeted promotion, targeted education, health literacy, payment, around the label.

Healthcare professional advisory board	Telemedicine is already providing solutions for strengthening the resilience of health systems as seen in the pandemic and now experience in war stricken areas of Ukraine. However, a proliferation of technologies without proper prioritisation around healthcare challenges and health professionals' and patients' needs is at risk of increasing burden of health professionals and create concerns as to its proper use, especially in maintaining and strengthening the important doctor-patient relationship.

The label

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Citizens / patients / carers and healthcare professionals	**Support** upskilling and health and digital health literacy initiatives, educate users. **Promote** a quality culture amongst manufacturers including transparency on ethics, privacy, and security; promoting synergies across app manufacturers and multi-app cooperation; champion user-centred design, for enhanced user experience. **Usability:** An easy navigable way to view the label and recognize the potential of digital health solutions.
App assessors, app libraries and app stores, app manufacturers and SDOs	**Compliance:** No matter which colour the rating, it should be clear that the app is safe and fulfils legal requirements. On the other hand, a usability score is informative, may depend on the context and should not be decisive in reimbursement. **Communicate:** Manufacturers if you want to stand out get a label. Health professionals use the label to recommend apps. The general public if you want a high quality app, look for this label.
Health Authorities, Payers	**Communication:** Be targeted in communicating the value of trusted digital health interventions and solutions broadly to citizens, health professionals and health authorities. **Stimulation** of the digital health market ensuring industry acceptance and buy-in and identifying incentives for all actors involved; reducing silos in tech assessment and payment; bring on board app stores and google stores to display the label eventually preferred to self-review; maintain affordable cost of certification. **Recognition** amongst all key actors and particularly national assessment schemes as a trusted, reliable international assessment framework; secure government buy-in and regulator support to allow the label to become a funding/reimbursement requirement.
Healthcare professional advisory board	**Guidelines:** Work with professional societies to create guidelines for health professionals on how to introduce apps in their daily practice and on how to leverage on the label for prescribing. **Requirements:** App providers should take measures to ensure upfront that the apps they are developing meet requirements for usability and add value to the clinical practice should they be adopted by the health professional communities.

plenary

Shaping a common future vision

We used the Indian parable of the elephant and the blind men to shape a common future vision. In this story a group of blind men come across an elephant and attempt to find out what it is, each touching a different part and thus describing a different characteristic of the elephant. Their collective wisdom leads to seeing the whole elephant.[4] We invited attendees in Brussels and online to help us label (using sticky notes) "the elephant in the room": What are the needed characteristics of the quality label ("the elephant") and what needs to happen around the label ("the habitat") to attain the preferred future in 5 to 10 years. The content of these labels was:
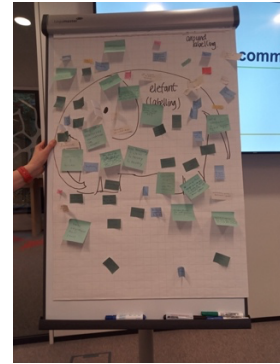
Health app labelling ("the elephant")

- Getting my label should be easy **IF** my product is "good" and impossible if it's "bad"
- Full transparency: ethics, privacy, security
- Clear evidentiary requirements
- Confidence and trust
- Trust: user and public
- Option for health professionals to test health apps
- Reliability
- Configuration management: what happens when things are combined
- Multi-app cooperation
- Truly drive healthcare innovation for patients
- There should be a clear way to use different pathways for different apps as wellness apps and digital tx (therapeutics) need different depth of evaluation
- Market acceptance and industry buy-in
- Community building
- Harmonisation / mutual recognition
- Mutual recognition of app assessments
- Selective and recognised
- Market stimulation
- Meets framework of standards and regulations
- Simplicity
- Inclusiveness
- Inclusivity
- Consider the digital divide gap
- Equity of access
- Encouraging user-centred design
- User experience

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[4] [Baldwin (2019)](#) The Blind Men and the Elephant

- Subsidiarity -> selfcare
- Think globally, act within the elephant
- Lower the threshold
- Alignment with reimbursement
- Cost intensiveness
- Cost of certification and market dominance and visibility (*split in 3?*)
- Plan a business model: who should pay?
- Easy to understand
- Would app stores and google stores be open to display the label instead of their self-review system?

Around health app labelling ("habitat elephant")

- Healthcare professional awareness and general public awareness
- Lack of awareness
- Enhance the visibility / advertise digital health in general
- Recognition and promotion to be known by citizens
- Communication
- Where is the elephant going?
- Industry and government buy-in
- Government regulator support
- Regulation should be connected to labelling
- Reducing silos in tech assessment and payment
- HTA harmonisation in EU
- Label is a funding / reimbursement requirement
- Trust building
- User acceptance
- Privacy and security concerns
- Mouse: What is new can be scary need a lot of explanation
- Protection of individuals performing evaluation to not get sued
- Lack of interoperability
- Quantification of savings enabled by the apps (required to fund the latter)
- Recognize the potential of digital health solutions
- Incentives for all actors involved
- Reimbursement should be connected to labelling
- Upskilling
- Education how to use a digital product
- Health literacy and digital health literacy
- Educate users
- Education
- Pointer to toolkit
- Code to download all details
- An easy navigable way to view the labels
- Regulatory issues

We will soonest send a link to the presentations, the draft agenda for the next multi-stakeholder workshop on **June 26** in **Brussels**, and visuals of the preferred future and the role of the label, knowing a picture may say more than a thousand words. We look forward to welcoming you then, to your feedback on the visuals (what are missing elements, what do you consider positive and what negative aspects) to help further paint the picture of the preferred future and mostly how to get there. Thank you for joining us and for adding your perspectives.

The Label2Enable Coordination and Support Action (Jun22-May24) is a Horizon Europe project that aims to promote the Europe-wide adoption of CEN-ISO/TS 82304-2 and its quality label for health and wellness apps. The project has 3 pillars: Trust, Use and Adoption of a quality certification scheme. The main deliverable of the **Trust** pillar is a robustly tested, efficient, self-explanatory certification scheme for the CEN-ISO 82304-2 health app assessment framework, that (a) complies with the ISO 17000 certification series and all applicable EU level legislation and core values, (b) is easy to use for (accredited) app assessors and app manufacturers, (c) is trusted by end users, health care professionals (HCPs) and insurers, and (d) delivers consistent results. The main deliverable of the **Use** pillar is information and communication materials to support citizens in downloading and using an app and HCPs in recommending an app. The main aim of the **Adoption** pillar is a single market (cross-country recognition of 82304-2's certification scheme). The Label2Enable consortium partners mirror the main mHealth stakeholders. Leiden University Medical Center coordinates the Label2Enable project.