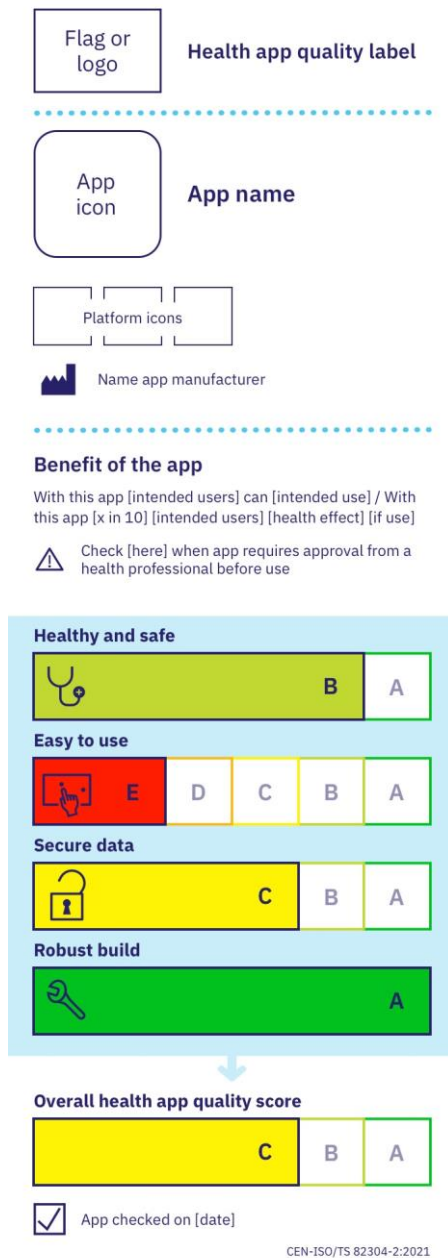




Second multi-stakeholder workshop 26 June 2023



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

Second multi-stakeholder workshop on June 26, 2023 at CEN-CENELEC, Rue de la Science 23, Brussels, Belgium. As part of our workplan, we will run a series of four workshops over the course of two years with representatives of our key stakeholders: app assessors, app manufacturers, app libraries and app stores, citizens / patients / carers, healthcare professionals, health authorities, insurers and Standard Development Organizations (SDOs). These workshops will support a structured multi-stakeholder backcasting exercise.

Backcasting entails defining success of labelling of 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 of the draft European Health Data Space Regulation. In the first workshop we jointly characterized the preferred future of digital health and the role of labelling. Please find in the agenda an initial sketch of the preferred future based on these discussions and via this link the presentation slides: <https://label2enable.eu/first-multi-stakeholder-workshop>.

We will start this second workshop with a short discussion on the sketch and subsequently detail the journey with the label to get there: What changes are needed for bringing about this future? Who are needed to realize the changes and activities required? What are in between targets and milestones, drivers and barriers, and factors and trends that are assumed to be steady or cannot be influenced? What is each stakeholders' unique role in getting there?

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 Label2Enable consortium partners¹ mirror the main mHealth stakeholders. Leiden University Medical Center coordinates the Label2Enable project.



agenda

Given the topic we hope to again welcome many stakeholders in Brussels. Thank you for indicating your attendance to the workshop, the (optional) dinner and any dietary restrictions soonest, so we can adequately inform our suppliers. For those who cannot join in person, click [here](#) to join us online.

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June 26th

TIME	TOPIC
9h00-9h30	Arrival CEN-CENELEC, Rue de la Science 23, Brussels
9h30-10h00 (30 min)	Welcome remarks and introduction Petra Hoogendoorn, LUMC and Zoi Kolitsi, I~HD Looking back and ahead: workshop objectives
10h00-10h40 (40 min)	Plenary Session I: Recent developments and inspiration Moderated by Petra Hoogendoorn, LUMC Inspiration from the journey and results of the EU Energy label DG ENER, tbc Labelling in the EHDS and related developments (AI Act, Pharma Act) Petra Wilson, HIMSS Patient /citizen / carer and Healthcare professional advisory board thoughts and feelings in the preferred future Gözde Suzuslu, EPF and Antanas Montvila, Kaunas Clinics
10h40-11h00	COFFEE BREAK
11h00-11h50 (50 min)	Plenary Session I: Recent developments and inspiration Moderated by Petra Hoogendoorn, LUMC Label2Enable findings and updates

	<ul style="list-style-type: none"> - Healthcare professional survey on recommending health apps Ieva Biliunaite, LUMC - Testing the label scheme with 24 apps and 5 assessment organisations Paul Weston, ORCHA and Menno Kok, EIT Health - Testing the label in four corners of Europe: Denmark, France, Hungary, Italy Vania Putatti, EuroHealthNet <p>Initiatives of participating stakeholders Organisations tbc</p>
11h50-12h20 (30 min)	Break-out session I: Stakeholder thoughts and feelings in the preferred future And, how do those thoughts and feelings affect labelling characteristics? Should the label cover digital health / (health and wellness) apps, be voluntary / mandatory, self-certification / third party certification? Why?
	Citizens / patients / carers and healthcare professionals Moderator: Dipak Kalra
	App assessors, app libraries and app stores, app manufacturers and SDOs Moderator: Petra Hoogendoorn
	Health authorities and insurers Moderator: Zoi Kolitsi
12h20-13h30	LUNCH BREAK
13.30 -14.00 (30 min)	Plenary Session II: Reports from break-out session I
14h00-15h30 (90 min)	Break-out session II: What changes are needed for bringing about this preferred future? Who are needed to realize the changes and activities required? What are <ul style="list-style-type: none"> - in between targets and milestones, - drivers and barriers, - factors and trends that are assumed to be steady or cannot be influenced? What is your (stakeholder group's) unique role in getting to that future? 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 Identifying dependancies and potential synergies Wrap up