

LABEL2 **ENABLE**

Press release

Label2Enable: Horizon Europe enables EU quality label for health and wellness apps

On June 1, 2022, Horizon Europe project 'Label2Enable' will start. Fourteen organizations from seven countries (Belgium, Croatia, Germany, Italy, Lithuania, the Netherlands, and Spain) will join forces for two years to promote the ISO/TS 82304-2 health app assessment framework and label in Europe.

An ageing population and chronic diseases are putting more and more pressure on health budgets in Europe. The quality and accessibility of healthcare services are unequal, and the shortage of healthcare professionals increases. There is a growing recognition that health apps can strengthen healthcare, self-management, and prevention. Research shows, for example, that apps embedded in care can promote a healthier lifestyle, provide more disease insight, less symptom burden, less hospital admissions, more efficiency and even a longer lifetime. However, referrers and users currently lack information they need to determine the quality and reliability of health apps. This is a barrier to the use of apps. App manufacturers experience the varying national approval processes as confusing and unclear as to what is expected and the depth of evidence that is required by each approval body.

In 2021, 'ISO/TS 82304-2 - health and wellness apps - quality and reliability' was published. The Label2Enable project uses the golden opportunity of ISO/TS 82304-2 and its health app quality label to break through the impasse and promote broad use and ditto supply of quality health apps. The objective of Label2Enable is threefold: achieve trust, use and adoption.

Trust

Consortium partners i-HD, ORCHA, HIMSS, EIT Health and COCIR cooperate in the pillar Trust. They will create and test the ISO/TS 82304-2 handbook for accredited health app assessment organizations, in ISO terminology an ISO/IEC 17065 certification scheme. They will ensure that the handbook contains appropriate assessment methodologies, aligns with EU legislation and values, produces the same consistent results regardless of the assessment organization involved, and works as well for app manufacturers. They will secure maintenance of the handbook after the project and enable accreditation of assessment organizations. They will also investigate if legislation for the label is sensible and who is to pay for the assessment.

Use

Consortium partners European Patient Forum, Kaunas Clinics, LUMC, EuroHealthNet and the University of Amsterdam cooperate in the pillar Use. They will investigate who consumers trust most to give them recommendations on health apps and what will also help people with low health literacy to use the quality label. They will find out what healthcare professionals need in the detailed app report to be able to recommend health apps and how to display the label effectively in app stores, app libraries and trusted sources.

Adopt

Consortium partners empirica, i-HD, LUMC, ISS, Fundacio TIC Salut and Tatjana Prenda Trupec cooperate in the pillar Adopt to promote ISO/TS 82304-2. They will involve stakeholders through various channels. With 'use stories' of pilots with ISO/TS 82304-2 in Italy, Catalonia, and the Netherlands, they will provide insights how to implement the ISO assessment framework effectively. Finally, they will explore with health insurers and health technology assessment bodies how the ISO assessment framework can help in decision-making on reimbursement of health apps.

Petra Hoogendoorn will coordinate Label2Enable from the National eHealth Living Lab, Leiden University Medical Center the Netherlands, Department of Public Health and Primary Care.

More information

Romy Willemsen: R.F.Willemsen@lumc.nl


As of September 2022: www.Label2Enable.eu

[NeLL - Homepage](#)

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

 **D** **C** **B** **A**

Secure data

 **E** **D** **C** **B** **A**

Robust build

 **A**

Overall health app quality score

C **B** **A**

App checked on [date]