LABEL2 ENABLE

Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

Testing health app quality labels

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EuroHealthNet Annual seminar 2026

Session 2: Promising health promotion and disease prevention initiatives in the digital era

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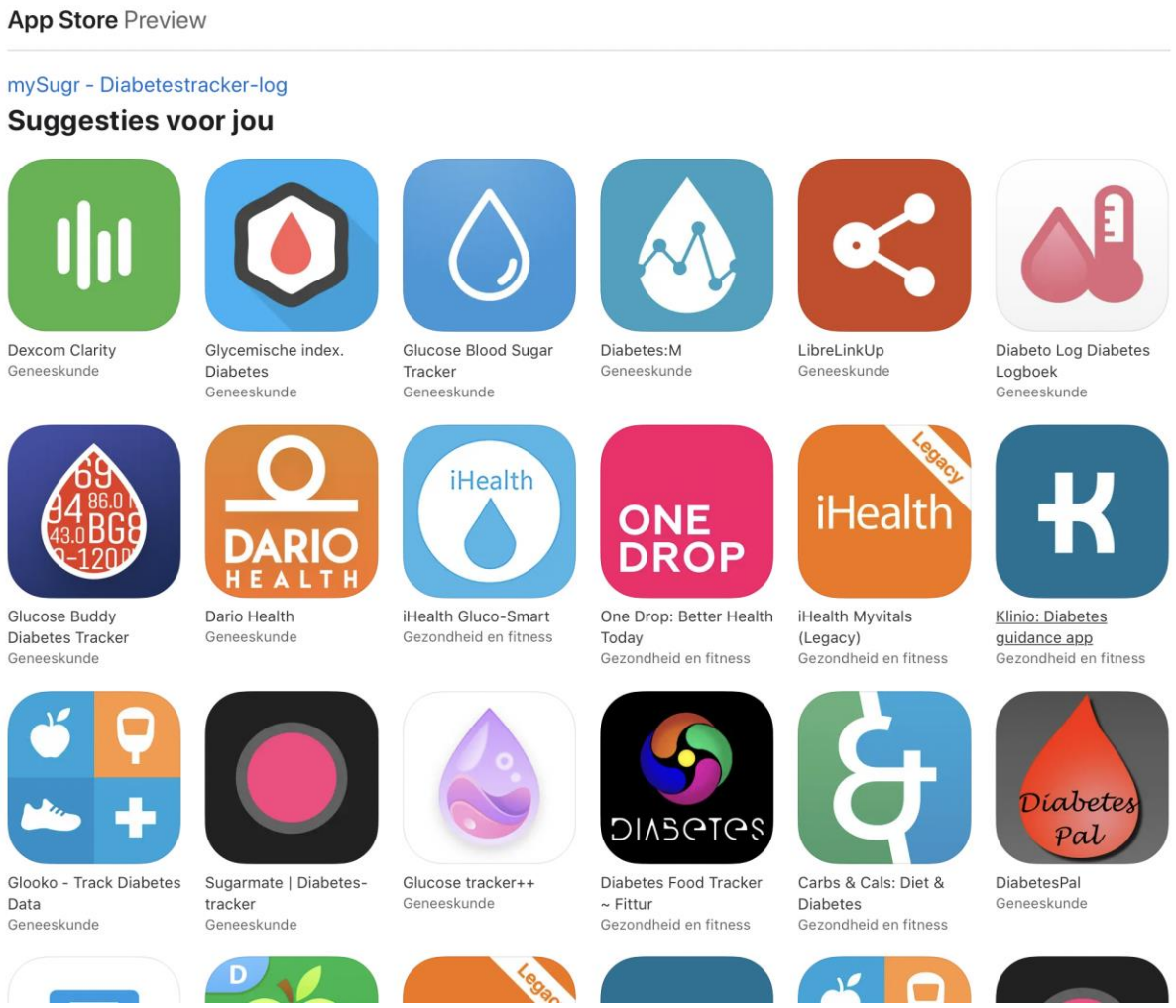
should we steer people to evidence-based apps?



- order of apps
- number of downloads
- app descriptions
- user reviews

are not linked to quality

so currently potential users cannot make an informed decision

Wyatt (2018) How can clinicians, specialty societies, and others evaluate and improve the quality of apps for patient use?

Larsen et al. (2019) Using science to sell apps: Evaluation of mental health app store quality claims

Singh et al. (2016) Many health apps target high-need, high-cost populations, but gaps remain

Hyzy et al. (2024) Don't judge a book or health app by its cover: User ratings and downloads are not linked to quality

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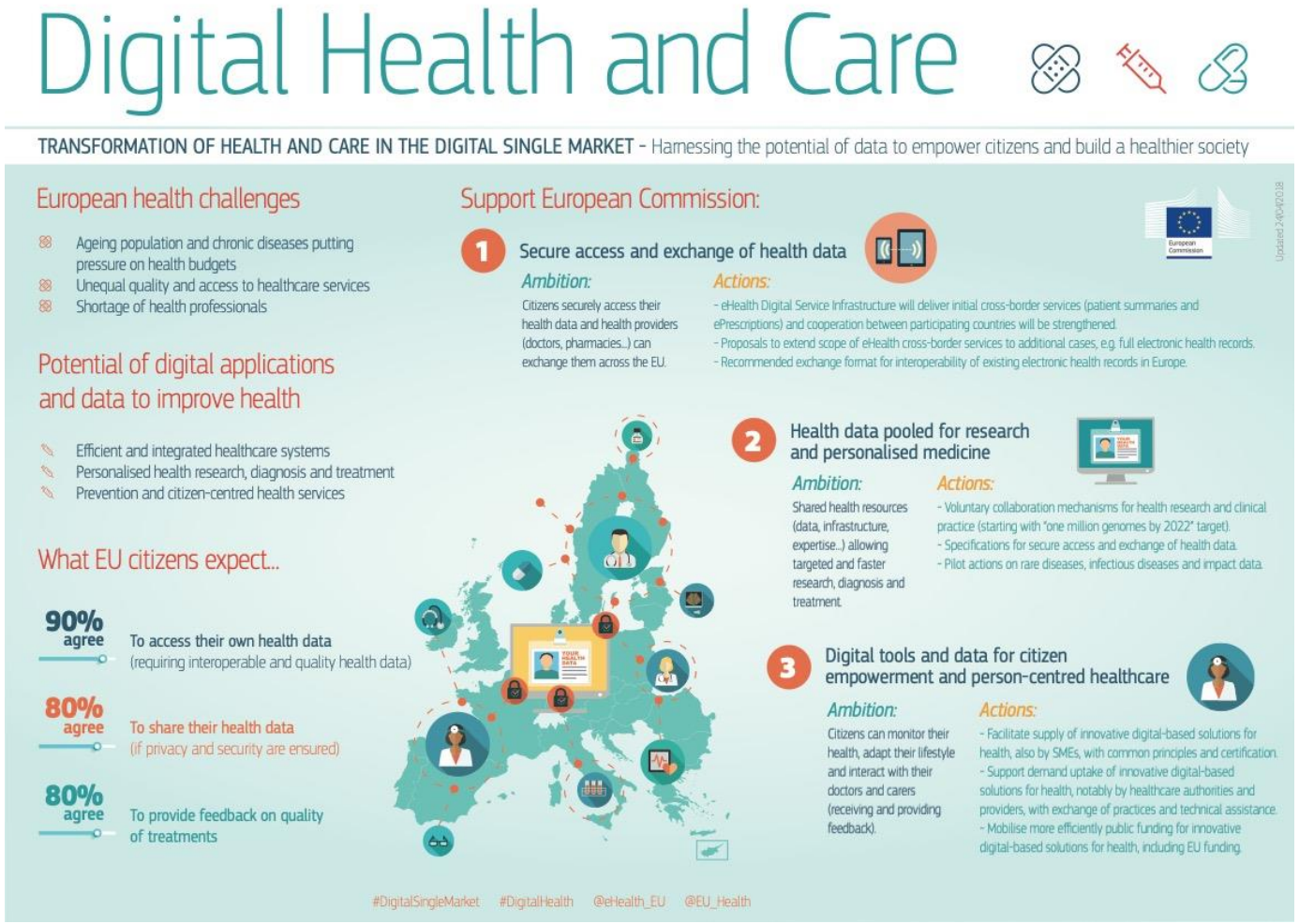
should we steer people? – app benefits and risks



Akbar et al (2020):

74 studies:

- 80 safety concerns identified (67 related to information quality, 13 to app functionality)
- 5/52 reports of actual / potential consequences had potential for patient harm
- 66 reports about gaps in app development, including lack of expert involvement, poor evidence base, and poor validation

European Commission (2018)
Communication on enabling the digital transformation of health and care in the Digital Single Market

Akbar et al. (2020) Safety concerns with consumer-facing mobile applications and their consequences: a scoping review

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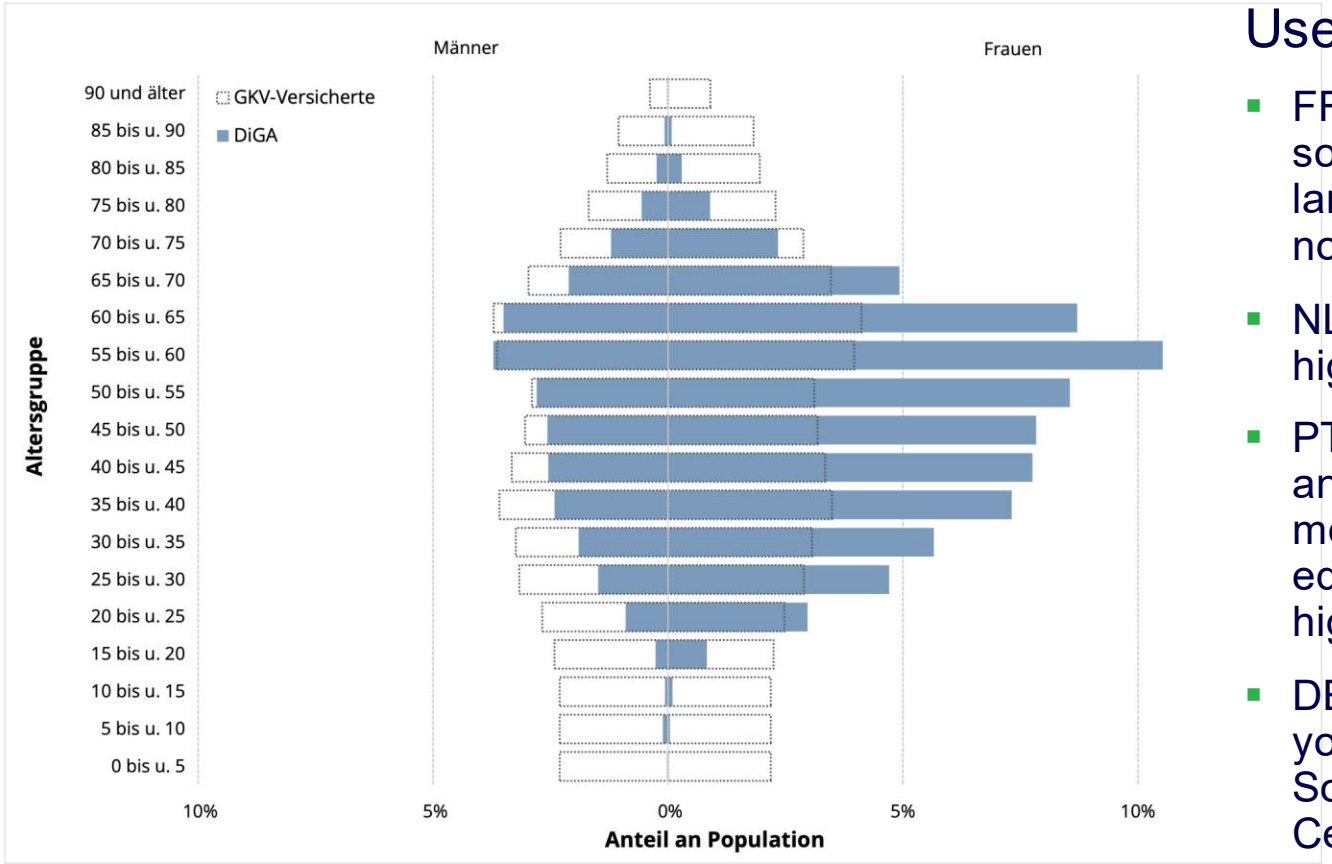
should we steer people? – users vs non-users

Abbildung 20 Inanspruchnahme nach Alter und Geschlecht (2025)



Quelle: Daten des GKV-Spitzenverbandes gem. § 33a Abs. 6 SGB V; Datenjahr 2025; n = 694.769; amtliche KM 6-Statistik
Abbildung der Inanspruchnahme auf anonymisierter Fallebene.

Users:

- FR: < 30 years, women, in higher socio-professional category, live in larger cities – chronic conditions not associated with app use
- NL: younger, higher educated, higher e-health literacy skills
- PT: positive views of digital health and more frequent use are much more common among those more educated, richer, younger and with higher levels of health literacy
- DE, ES, FR, HU, IT, NL, PL , RO: younger age, women, Eastern / Southern Europe (compared to Central Europe), tertiary education

Paradis et al. (2022) Use of Smartphone Health Apps Among Patients Aged 18 to 69 Years in Primary Care: Population-Based Cross-sectional Survey

Bol et al. (2018) Differences in mobile health app use: A source of new digital inequities?

Lima et al. (2025) Acceptance of Digital Health in Portugal: An Example of Digital Divide

Causio et al. (2025) Public perceptions and engagement in mHealth: a European survey on attitudes toward health apps use and data sharing

GKV-Spitzenverband (2026) DiGA-Bericht des GKV- Spitzenverbandes 2025

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should we review + recommend + reimburse apps?

- EU (2018): facilitate supply of innovative digital-based solutions for health, also by SMEs, using **common principles and certification**
- WHO European Region (2022): the **evaluation** of mHealth programmes and **apps should become the norm rather than the exception**
- Uncovska et al. (DE, 2023):
  - 76% willing to use health apps
  - **53% would only use health apps if quality certified by government**,
  - **33% only if prescribed by physicians** (39% average e-literacy vs 27% very high e-literacy)
  - **27% willing to pay out-of-pocket (no amount mentioned)**
- GKV-Spitzenverband (DE, 2026):
  - appr. 58% of all 496.000 DiGA prescriptions in 2025 were by GPs
- Wangler & Jansky (DE, 2024):
  - **24% of 5868 GPs trusted themselves to competently advise patients on DiGA**
  - 14% had prescribed DiGA
  - 13% planned to do so

EU (2018) Transformation of health and care in the digital single market

WHO European Region (2023) The ongoing journey to commitment and transformation – Digital health in the WHO European Region 2023

Uncovska et al. (2023) Patient Acceptance of Prescribed and Fully Reimbursed mHealth Apps in Germany: An UTAUT2-based Online Survey Study

GKV-Spitzenverband (2026) DiGA-Bericht des GKV- Spitzenverbandes 2025

Wangler & Jansky (2024) How can primary care benefit from digital health applications? – a quantitative explorative survey on attitudes and experiences of general practitioners in Germany

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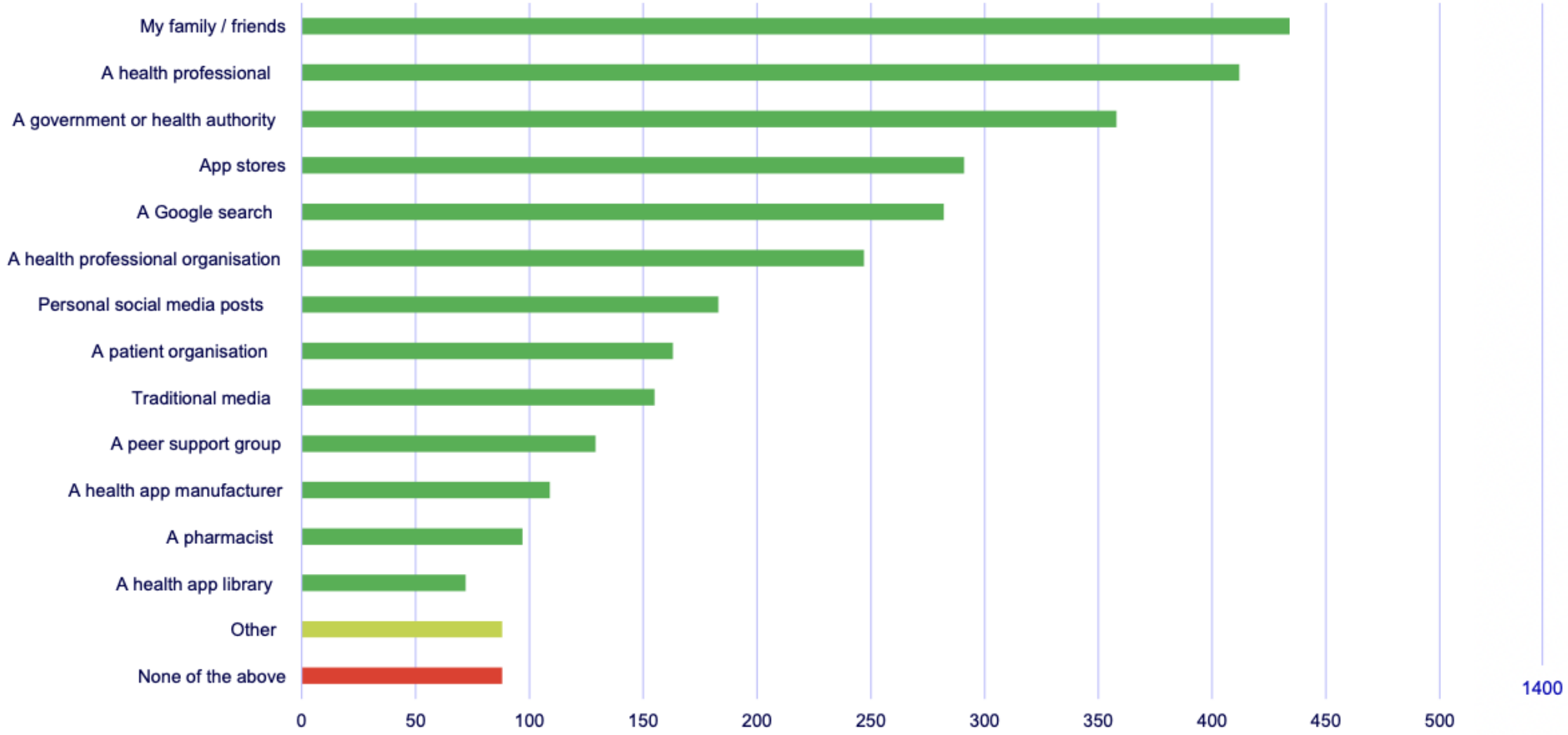
should we review + recommend apps? – citizens

1228

respondents



Shokralla et al. (2026)
Trust and use of recommendations for health apps among European residents: Cross-sectional survey

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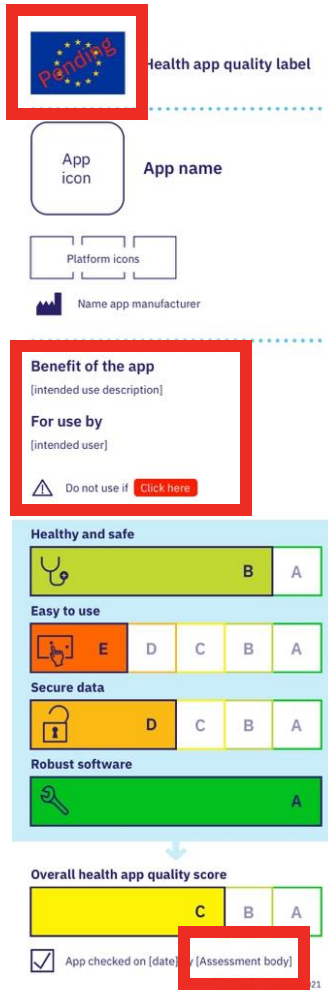
labels – do they work / are they trusted? - citizens

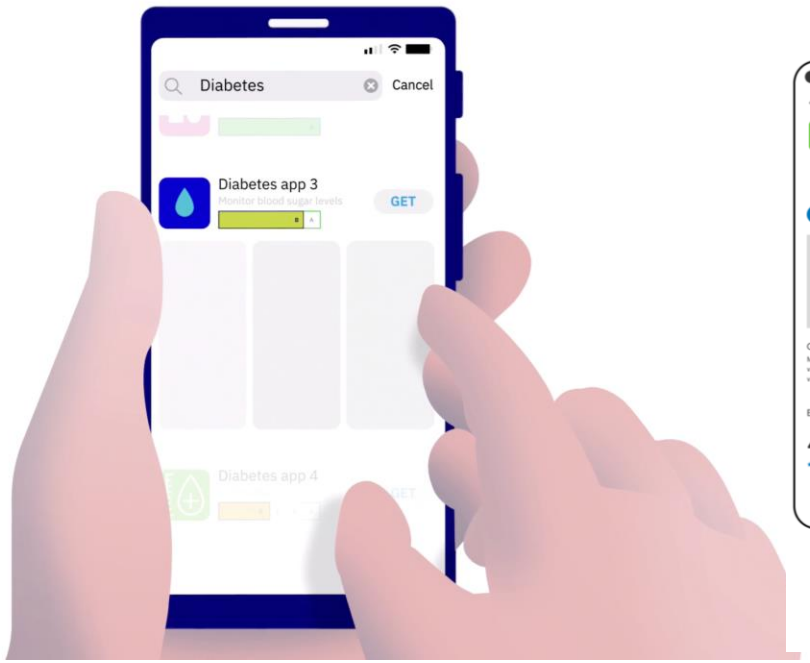
Hoogendoorn et al. (upcoming) Usability testing the CEN-ISO/TS 82304-2 health app quality label in all 4 corners of Europe

Pajor et al. (upcoming) Testing the effectiveness of an explanatory video about a health app quality label: An experimental study

https://vimeo.com/showcase/11257693

Adriaanse et al. (upcoming) Beyond the Stars: How Objective Quality Labels vs. Subjective Star Ratings Shape the Decision to Download Health Apps





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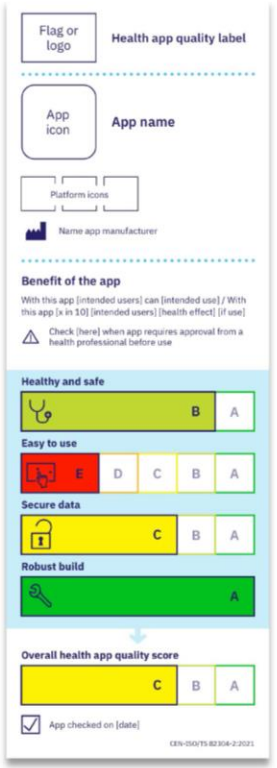
labels – do they work / are they trusted? - doctors

Biliunaite et al. (2024) Value of a quality label and European healthcare professionals' willingness to recommend health apps: An experimental vignette study

Caiani, Kemps, Hoogendoorn et al. (2024) Standardized assessment of evidence supporting the adoption of mobile health solutions: A Clinical Consensus Statement of the ESC Regulatory Affairs Committee

The need for ESC guidance and standardized assessment of evidence (label and report) to facilitate adoption of mobile health in clinical practice

- Patient-population, intended use, operating ranges
- Clinical validation with appropriate standards
- Reported against nominal performance
- Sufficient power and follow-up, meaningful difference
- Level of evidence
- Co-development with relevant stakeholders
- Maintenance of health information



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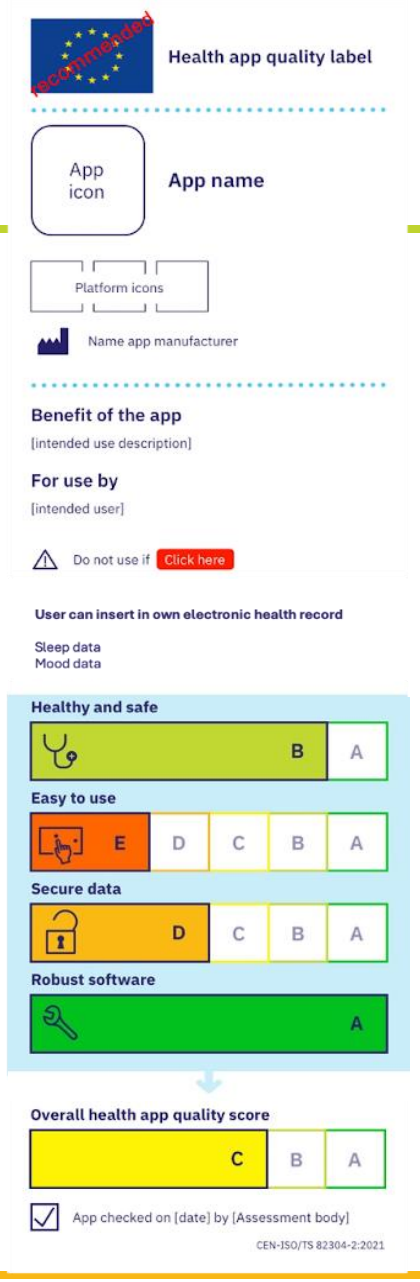
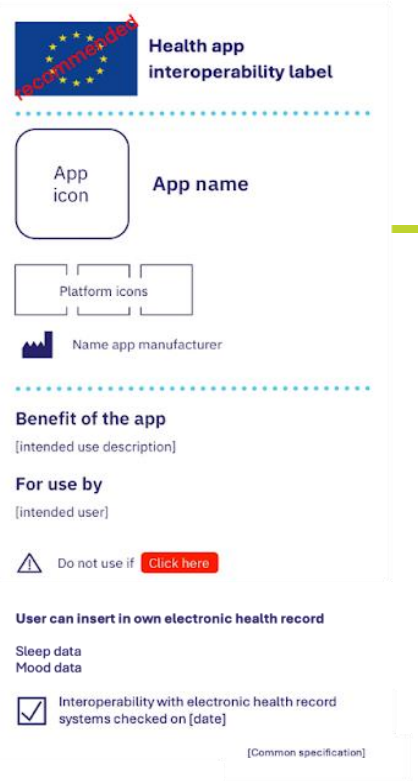
appetite EU regulation?

Proposal to benefit from existing evidence without eroding trust:

- **abbreviated label on EU level** (EHDS Article 47(1), self-declaration, at the right: N.B. only wellness apps for which interoperability with an EHR system is claimed, focus on interoperability and security)
- **full label on member state level** (EHDS Recital 50, third-party assessment, at the left: harmonization with ISO 82304-2)





Hoogendoorn, Molnar & Wilson (2025)
Input for Xt-EHR joint action deliverable D8.3

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next steps

Adoption decision-making support

Label2Scale proposal (HORIZON-HLTH-2026-01-IND-03) builds on Label2Enable multi-stakeholder roadmap to the preferred future and includes WP for citizens which explores equitable:

- app recommendations
- label positioning in app store context
- repositories
- national marketing strategies (DE: manufacturers, NL: insurer / GP workflow, NO: authority)

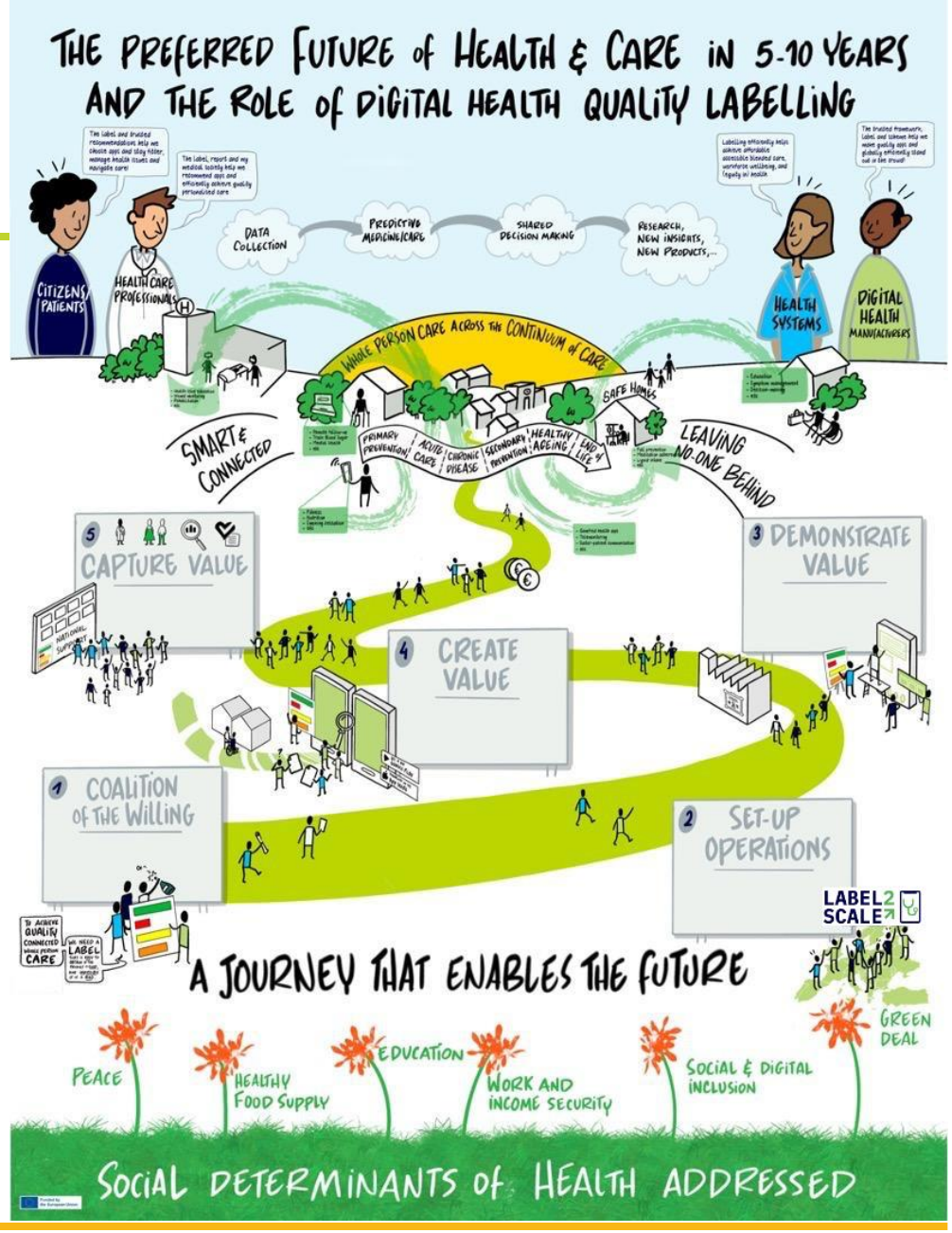
https://label2enable.eu/assets/downloads/label2enable_preferred-future-health-and-care-visual-1716569529.pdf

https://diga.bfarm.de/de/verzeichnis

https://digizo.nu/proceszoeker/

https://tjenester.helsenorge.no/verktoy

https://www.youtube.com/watch?v=MhQxDz7-2J0



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