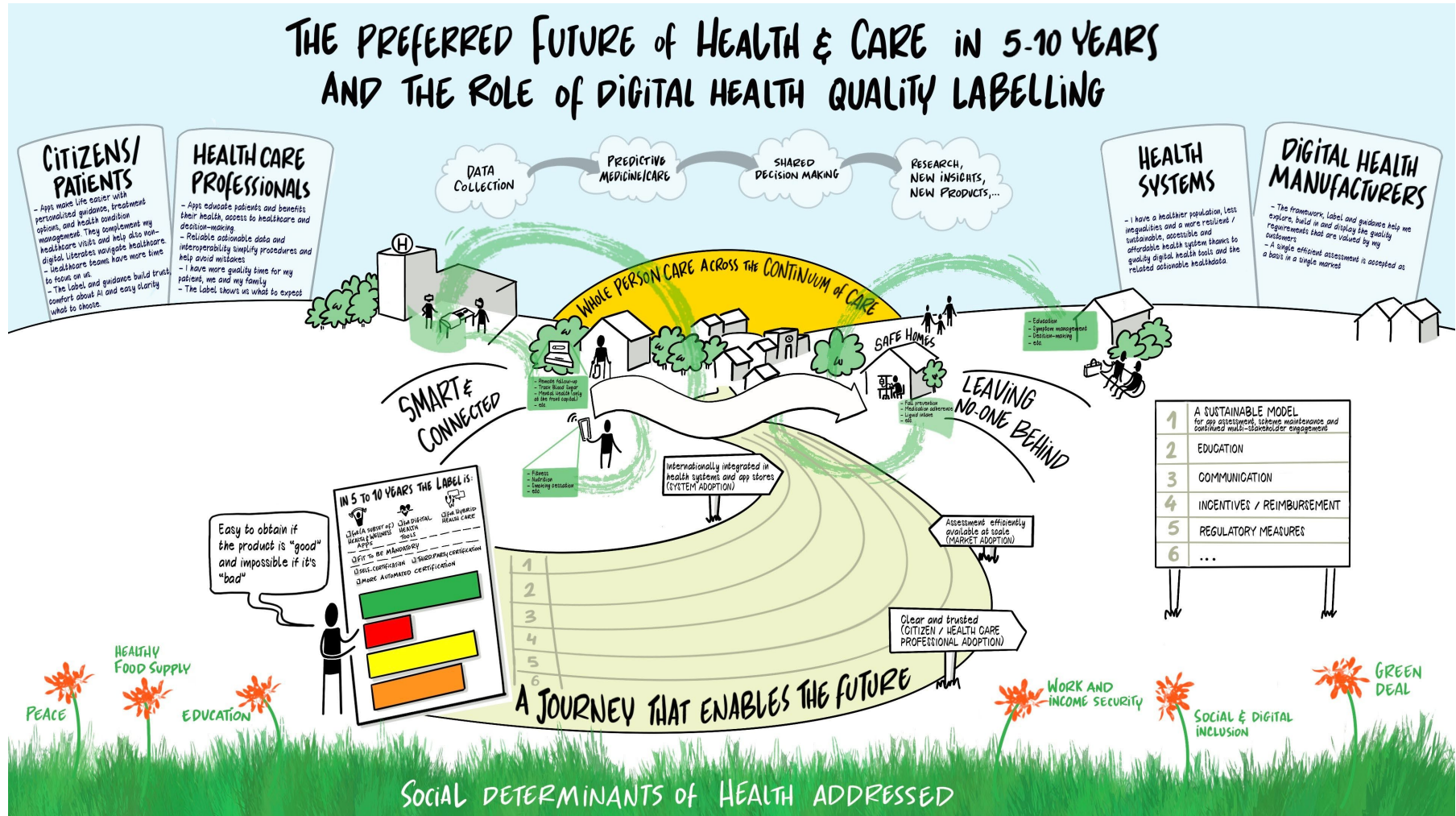


Presenting Label2Enable and CEN-ISO/TS 82304-2

1st Label2Enable Roundtable on reimbursement of health apps

multi-stakeholder potential and need health apps



how to distinguish a 'good' health app?

App Store Preview

mySugr - Diabetestracker-log

Suggesties voor jou



Dexcom Clarity
Geneeskunde



Glycemische index.
Diabetes
Geneeskunde



Glucose Blood Sugar
Tracker
Geneeskunde



Diabetes:M
Geneeskunde



LibreLinkUp
Geneeskunde



Diabeto Log Diabetes
Logboek
Geneeskunde



Glucose Buddy
Diabetes Tracker
Geneeskunde



Dario Health
Geneeskunde



iHealth Gluco-Smart
Gezondheid en fitness



One Drop: Better Health
Today
Gezondheid en fitness



iHealth Myvitals
(Legacy)
Gezondheid en fitness



Klinio: Diabetes
guidance app
Gezondheid en fitness



Glooko - Track Diabetes
Data
Geneeskunde



Sugarmate | Diabetes-
tracker
Geneeskunde



Glucose tracker++
Geneeskunde



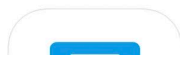
Diabetes Food Tracker
~ Fittur
Gezondheid en fitness



Carbs & Cals: Diet &
Diabetes
Gezondheid en fitness



DiabetesPal
Geneeskunde



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

EU policy context

- The *Green Paper on mobile health* (2014) addresses the potential benefits and risks of health apps, questioning **how to verify or ensure the efficacy of health apps** (e.g. certification schemes) and **how to better inform users** on the quality and safety of these apps
- The *Communication on enabling the digital transformation of health and care in the Digital Single Market* (2018) highlights “digital tools and data for citizen empowerment and person-centred care” as a key priority and proposes **common principles and certification** to facilitate supply of these tools, also by Small and Medium-sized Enterprises
- *CEN-ISO/TS 82304-2:2021 (health and wellness apps – quality and reliability)*, an assignment from the European Commission to the European Committee for Standardization (CEN), International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), delivers a **common health app assessment framework and label**
- The Proposal for a *Regulation on the European Health Data Space* (2022) calls for **voluntary labelling of wellness apps** (Article 31) and a **cascading effect in medical devices** that aim to be interoperable with Electronic Health Record systems
- *Horizon Europe project Label2Enable* creates **ISO 17067 EU certification scheme** for CEN-ISO/TS 82304-2 aligned with EU values and EU legislation, enabling accredited app assessors (third party assessment) to issue **trusted CEN-ISO/TS 82304-2 health app quality labels, scores and reports**

'the EU energy label but then for health apps'

Health app quality label

Flag or logo

App icon

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 A

Easy to use B A

Secure data C B A

Robust build D C B A

Overall health app quality score E D C B A

App checked on [date]

CEN-ISO/TS 82304-2:2021

Egészségügyi alkalmazás minőségi címke

Zászló vagy logó

Alkalmazás ikon

Platform ikonok

Alkalmazás gyártójának neve

Az alkalmazás előnyei
Ezzel az alkalmazással [céltzott felhasználók] [tervezett felhasználás] / Ezzel az alkalmazással [x 10-ből] [céltzott felhasználók] [egészségre gyakorolt hatás] [használat esetén]

Jelölje be [itt], ha az alkalmazás használatához egészségügyi szakember jóváhagyása szükséges.

Egészséges és biztonságos A

Könnyen használható C B A

Biztonságos adatok D C B A

Robusztus felépítés B A

Általános egészségügyi alkalmazás minőségi pontszám B A

Az alkalmazás ellenőrzése [dátum]

CEN-ISO/TS 82304-2:2021

Label qualité pour appli de santé

Drapeau ou logo

Icône de l'appli

Icônes des plateformes

Nom du fabricant de l'appli

Bienfait de l'appli
Avec cette appli, [utilisateurs prévus] peuvent [utilisation prévue] / Avec cette appli, [x sur 10] [utilisateurs prévus] [effet sur la santé] [si utilisée]

Cochez [ici] si l'appli nécessite l'approbation d'un professionnel de la santé avant d'être utilisée

Saine et sûre B A

Facile à utiliser E D C B A

Données sécurisées C B A

Design robuste A

Score global de qualité de l'appli de santé C B A

Appli vérifiée le [date]

CEN-ISO/TS 82304-2:2021

Marchio di qualità dell'app per la salute

Bandiera o logo

Icona dell'app

Icone della piattaforma

Nome del produttore dell'app

Vantaggio dell'app
Con questa app [utenti previsti] possono [uso previsto] / Con questa app [x in 10] [utenti previsti] [effetto sulla salute] [se utilizzato]

Controlla [qui] quando l'app richiede l'approvazione di un operatore sanitario prima dell'uso

Sano e sicuro D C B A

Facile da usare A

Dati protetti E D C B A

Costruzione solida D C B A

Punteggio di qualità complessivo dell'app per la salute D C B A

App controllata il [data]

CEN-ISO/TS 82304-2:2021

Sundhedsapp kvalitetsmærke

Flag eller logo

App ikon

Platformssikoner

Navn på leverandør af app

Fordel ved appen
Med denne app kan [tilsigtede brugere] [tilsigtet brug] / Med denne app oplever [x ud af 10] [tilsigtede brugere] [sundhedseffekt] [ved brug]

Tjek [her], når appen kræver godkendelse fra en sundhedsperson inden brug

Sund og sikker E D C B A

Let at bruge B A

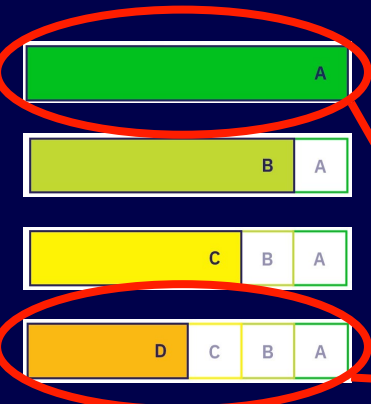
Sikrer data D C B A

Robust konstruktion E D C B A

Samlet kvalitetscore for sundhedsapp E D C B A

App tjekket den [dato]

CEN-ISO/TS 82304-2:2021



the EU energy score



5 jaar garantie

★★★★★ (91)

**Siemens WM14N295NL
iQ300 extraKlasse
wasmachine**

577,- Adviesprijs 759,-

✓ Op voorraad



- Energieklasse C
- Vulgewicht 8 kg
- max. 1400 toeren
- 72 dB centrifugeren

Vergelijk product



Ariel Allin1 PODS cadeau

★★★★★ (1)

**Whirlpool FFD6E 9638
BCEV F wasmachine**

497,- Adviesprijs 629,-

✓ Op voorraad



- Energieklasse D
- Vulgewicht 9 kg
- max. 1600 toeren
- 85 dB centrifugeren

Vergelijk product



Black Friday Deal

★★★★★ (84)

**AEG L8FEN96CAD OKOMix
AutoDose wasmachine**

866,- Adviesprijs 1.329,-

✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1600 toeren
- 76 dB centrifugeren

Vergelijk product



Black Friday Deal

**Miele WED 174 WPS
wasmachine**

1.379,-


✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1400 toeren
- 70 dB centrifugeren

Vergelijk product

the EU energy label



ENERGY LABEL

Siemens WM14N295NL

5 jaar garantie

★★★★★

Siemens iQ300 ext wasmachine

577,- Adviesprijs

✓ Op voorraad

62 kWh / 100

8.0 kg 3:29 43 L

72dB

ABCDEF G

ABCDEF G



Black Friday Deal

★★★★★ (84)

AEG L8FEN96CAD OKOMix AutoDose wasmachine

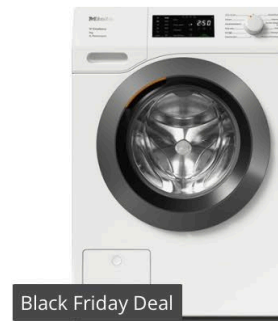
866,- Adviesprijs 1.329,-

✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1600 toeren
- 76 dB centrifugeren

Vergelijk product



Black Friday Deal

Miele WED 174 WPS wasmachine

1.379,-

✓ Op voorraad



- Energieklasse A
- Vulgewicht 9 kg
- max. 1400 toeren
- 70 dB centrifugeren

Vergelijk product

EPREL - European Product Registry for Energy Labelling

Home > Washing machines > 335652



Washing machines

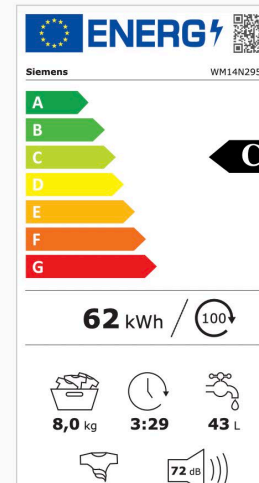
COMMISSION DELEGATED REGULATION (EU) 2019/2014 with regard to energy labelling of household washing machines and household washer-dryers

Siemens

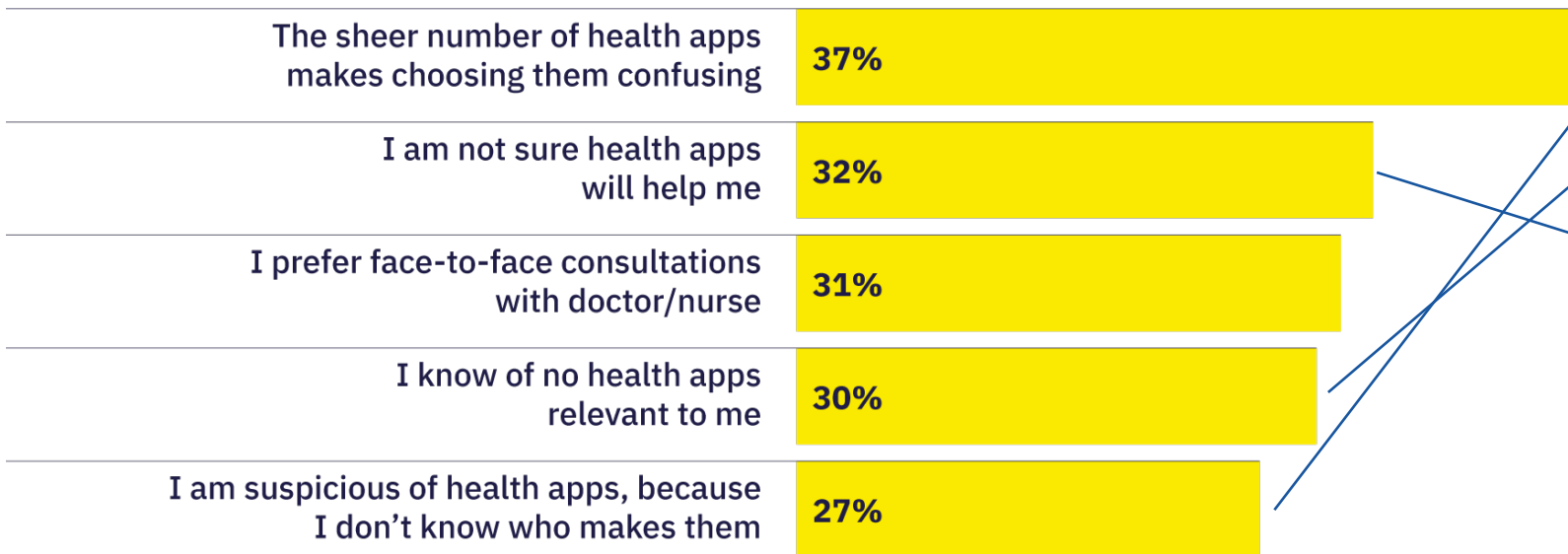
WM14N295NL

General information

	Overall dimensions	85 (Height) x 60 (Width) x 63 (Depth)	cm
	Energy efficiency Index (EEI)	68,6	
	Washing efficiency index	1,04	
	Rinsing effectiveness	4,5	g/kg
8 Kg	Energy consumption [per cycle, eco 40-60 programme]	0,624	kWh
	Weighted energy consumption [per 100 cycles, eco 40-60 programme]	62	kWh
	Water consumption [per cycle, eco 40-60 programme]	43	litres
	Maximum temperature inside the treated textile (Rated capacity)	44	°C
	Maximum temperature inside the treated textile (Half)	37	°C
	Maximum temperature inside the treated textile (Quarter)	23	°C
	Weighted remaining moisture content	52	%
	Spin speed (Rated capacity)	1 400	rpm




choosing a 'good' health app is difficult




 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

 **A**

Easy to use

 **A**

Secure data

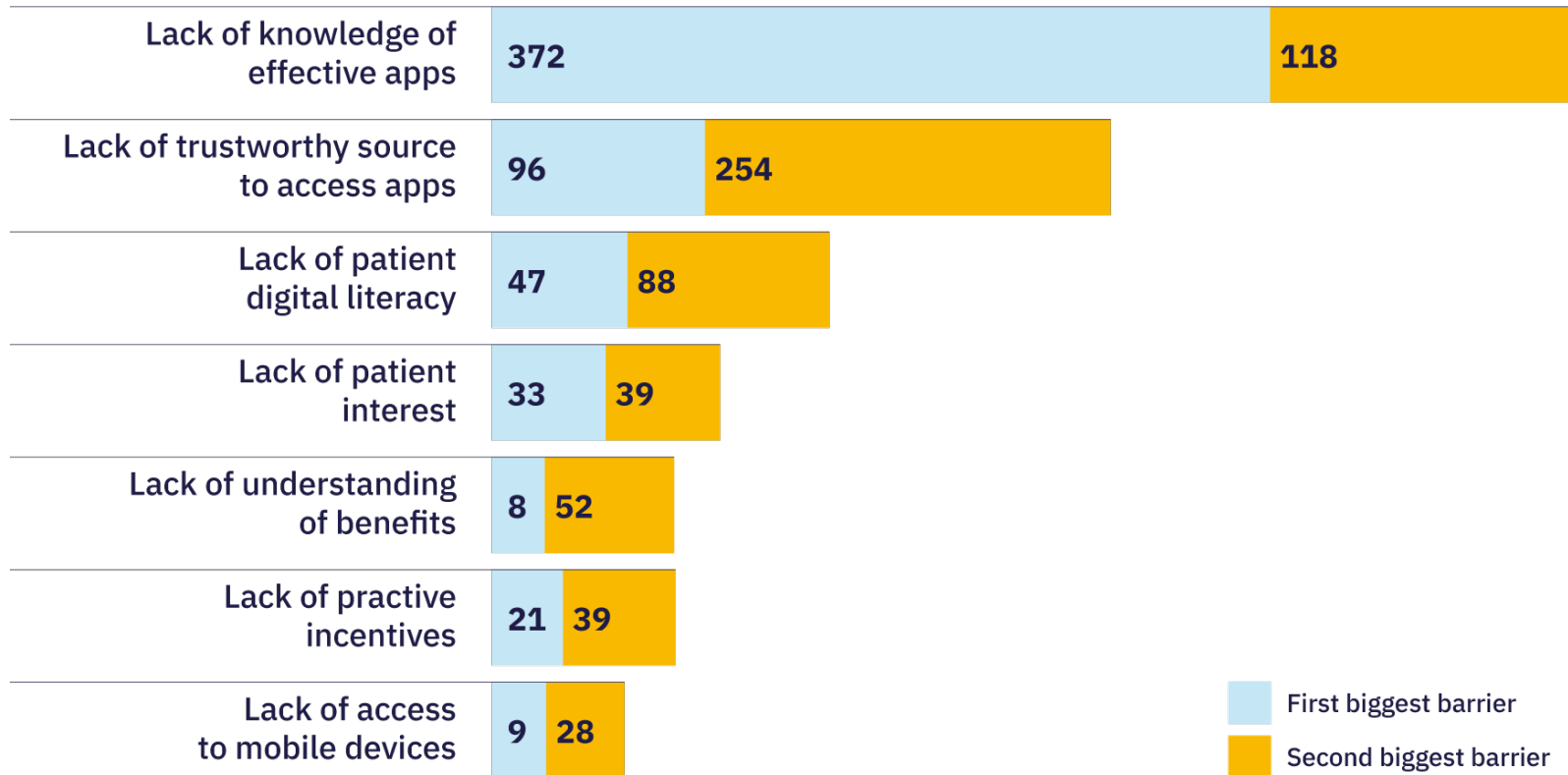
 **A**

Robust build

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

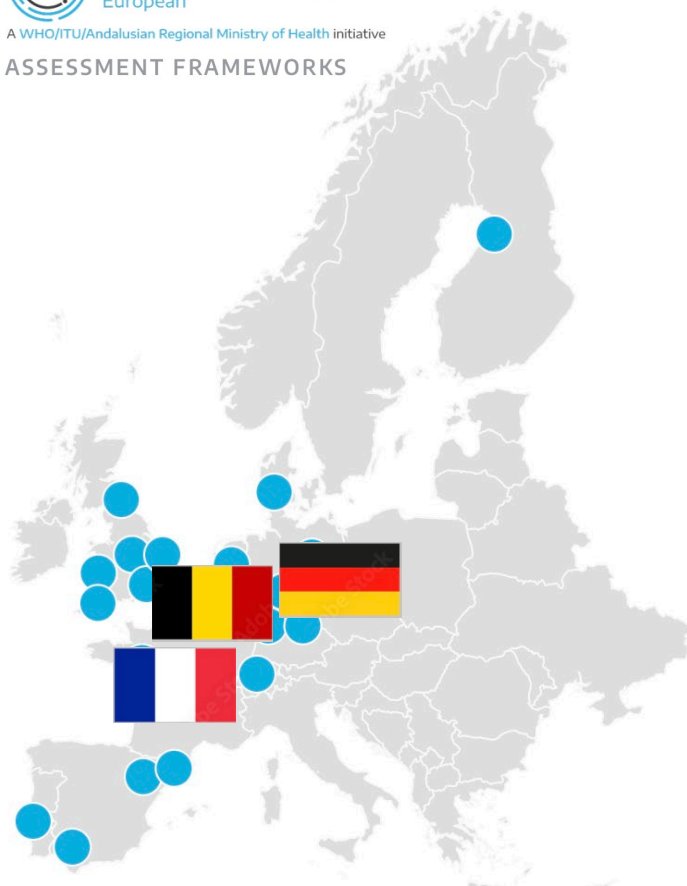
Get-ehealth.eu (2015) What do patients and carers need in health apps – but are not getting? Global survey of 1,120 patients and carers

choosing a ‘good’ health app is difficult

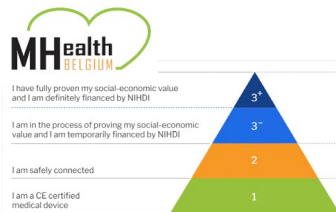
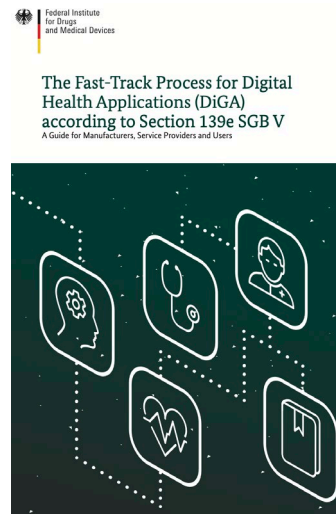


Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study

delivering a 'good' health app is difficult



mHealth Hub (2022) Health App Assessment Frameworks



Early access to reimbursement for digital devices (PECAN)



reviewing a ‘good’ health app is difficult too

npj | digital medicine

Health app policy:

- Belgium
- Denmark
- England
- Germany
- Netherlands
- Norway
- Sweden
- Singapore
- United States

“There is great interest in the use of apps in all the countries evaluated, but even Belgium, Germany and the UK, which are relatively far along in their operationalization of frameworks, are struggling with efficient implementation.

Cross-national efforts are needed around regulation and for countries to realize the benefits of these technologies.”

Essén et al (2022) Health app policy: international comparison of nine countries’ approaches

CEN-ISO/TS 82304-2:2021 helps choose apps

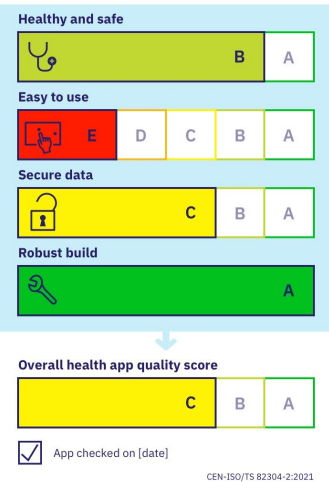
Flag or logo Health app quality label

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

Comprehensive

For wellness and medical device apps, not duplicating the work of notified bodies

Evidence-informed

Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries

Inclusive

Label tested with people with low health literacy

Informative

Score, label and report communicate quality in a glance to the needed detail

Proportionate

At most 81 questions, of which at most 67 score-impacting yes/no questions

Testable

Yes-answers require evidence to be assessed by accredited app assessors

Relevant

Assessment framework founded in a Delphi study with 83 experts from 8 stakeholder groups

Maintained



European Commission (2019) New energy efficiency labels explained

CEN-ISO/TS 82304-2:2021 content

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



Easy to use



Secure data



Robust build



Overall health app quality score



App checked on [date]

CEN-ISO/TS 82304-2:2021

Healthy and safe (50%)

Health requirements, Health risks, Ethics, Health benefit, Societal benefit

Easy to use (15%)

Accessibility, Usability

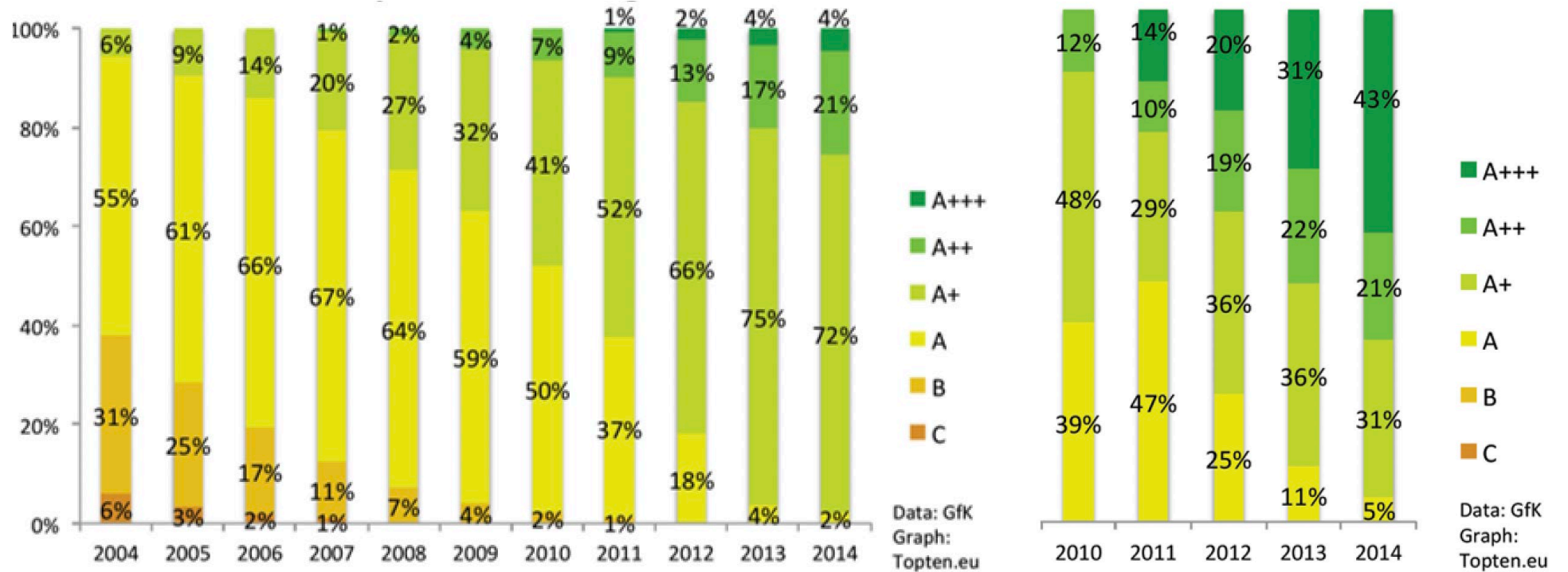
Secure data (25%)

Privacy, Security

Robust build (10%)

Technical robustness, Interoperability

EU Energy label: refrigerator & washing machine sales



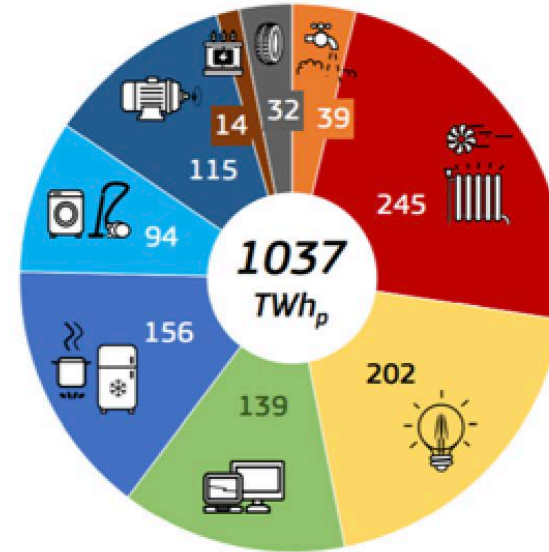
EU Energy label: impacts estimates

Impacts estimates (2020 vs BaU)

- **1037TWh** primary energy \cong 7% of total EU 27 primary energy demand
- Electricity: ca. **1000 kWh**/household (27%) \cong total EU wind production
- **€60 billion/y** in consumer expenditure (€ 210/household) based on pre-2021 energy price estimates
- Additional **business revenue 21 billion** euros and related **jobs increase by 324 thousand**

Source: Ecodesign Impact Accounting 2020

Energy savings 2020

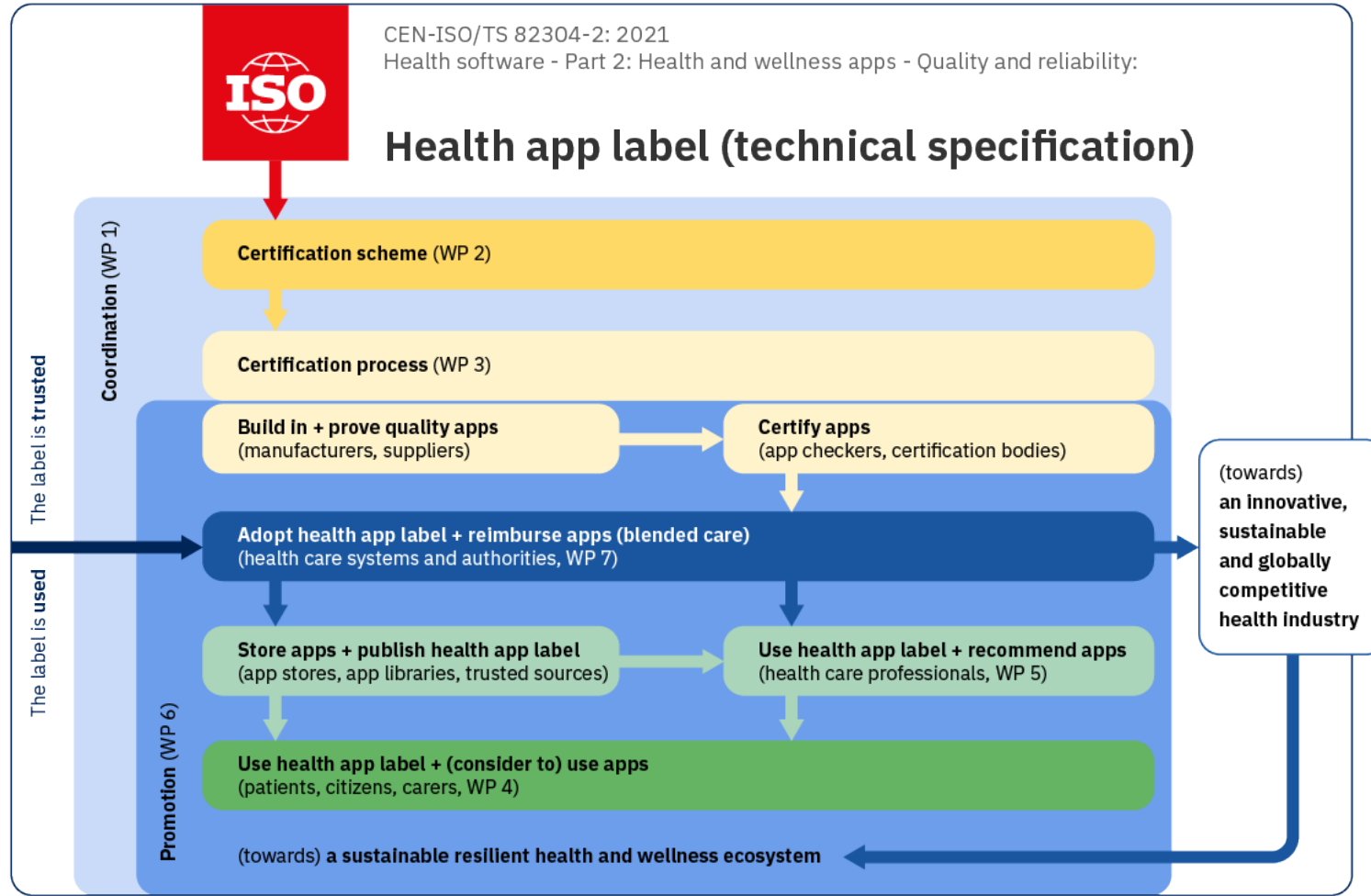


the consortium: intentionally multi-stakeholder

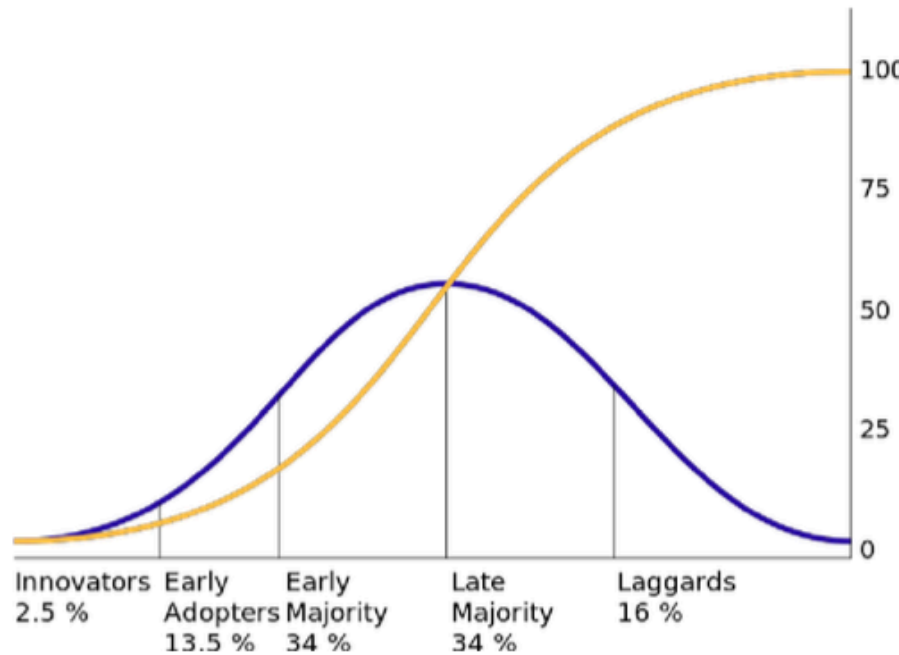
- **Title** Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.
- **Duration** June 2022 – May 2024
- **Instrument** Horizon Europe
- **Type** Coordination and Support Action
- **Grant Agreement number** 101057522
- **Partners**



our aim: multi-stakeholder trust, use and adoption



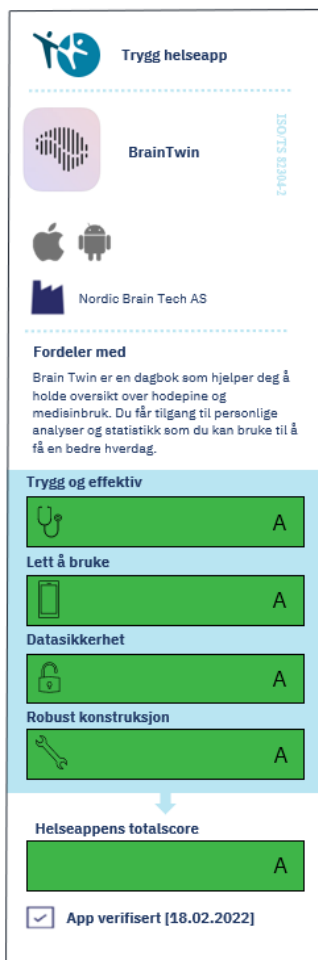
Rogers' diffusion of innovation theory



how people, over time, adopt a new idea, behavior, or product

5 main factors that influence adoption:

- **relative advantage**
the degree to which an innovation is seen as better than the current idea or solution
- **compatibility**
the consistency of the innovation with the values, experiences and needs of potential adopters
- **complexity**
how difficult the innovation is to understand and/or use
- **trialability**
the extent to which the innovation can be tested or experimented with before a commitment to adopt is made
- **observability**
the extent to which the innovation provides tangible results



Trygg helseapp

BrainTwin ISO/TS 82304-2

Nordic Brain Tech AS

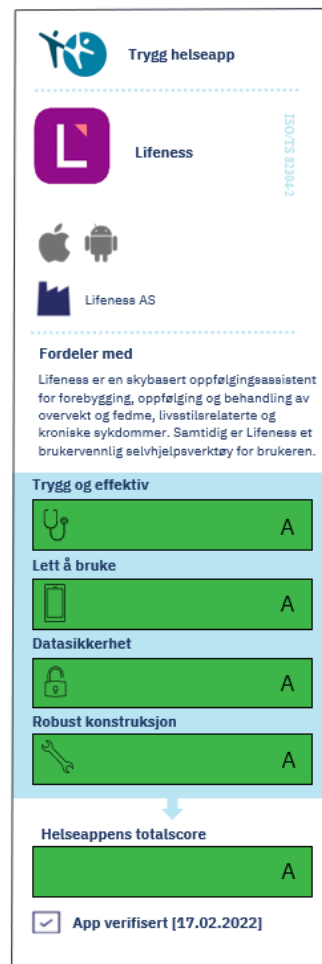
Fordeler med
Brain Twin er en dagbok som hjelper deg å holde oversikt over hodepine og medisinbruk. Du får tilgang til personlige analyser og statistikk som du kan bruke til å få en bedre hverdag.

Trygg og effektiv

- Trygg og effektiv **A**
- Lett å bruke **A**
- Datasikkerhet **A**
- Robust konstruksjon **A**

Helseappens totalscore **A**

App verifisert [18.02.2022]



Trygg helseapp

Lifeness ISO/TS 82304-2

Lifeness AS

Fordeler med
Lifeness er en skybasert oppfølgingsassistent for forebygging, oppfølging og behandling av overvekt og fedme, livstilrelaterte og kroniske sykdommer. Samtidig er Lifeness et brukervennlig selvhjelpsverktøy for brukeren.

Trygg og effektiv

- Trygg og effektiv **A**
- Lett å bruke **A**
- Datasikkerhet **A**
- Robust konstruksjon **A**

Helseappens totalscore **A**

App verifisert [17.02.2022]

11. Digital applications

Health data generated by wellness applications and other digital health applications do not have the same data quality requirements and characteristics of those generated by medical devices.¹¹ Only certified digital applications which comply with ISO standards (e.g., ISO/TS 82304-2 on Health and wellness apps – Quality and reliability) and are CE approved can be integrated into the EHR systems. That data from certified digital apps should only be added to the EHR with agreement of the treating physician.

For secondary use, the integration of health data from wellness apps in EHR systems should only be included if medically provided.

The use of health data for secondary purposes generated by these applications must only be done with prior consent within the meaning of the GDPR regarding natural persons.¹² Wellness applications must not be able to access data in the EHR.

Helsedirektoratet (2022) Tryggere helseapper
The Standing Committee of European Doctors (2022) Position on the European Health Data Space
Van der Storm et al (2023) Apps in healthcare and medical research European legislation and practical tips every healthcare provider should know

beyond the EU: globally competitive

Figure. Example of a Possible Health App Grading Label

Health App Grading		
Weight Loss Coach		
Information app designed to provide guidance on diet and exercise to lose weight		
Time commitment: 3 minutes, 4 times a day		
Known health benefits: 3-lb weight loss in 4 weeks		
Warning: do not use with weight loss medication		
	Score (out of 5)	Grade
Honesty ^a	3.2	C
Health information	2.1	D
Technical information ^b	2.2	D
Security and privacy	5.0	A
Ease of use	4.4	B
Popular rating	4.8	A
Best for: people who want to lose weight		
Special features: weight tracking with digital scale, send weight data to medical record, game-based encouragement, English- and Spanish-language options		

^aAccuracy of claims including cost, consent, and the accuracy of the app store definition.

^bSoftware performance, stability, interoperability, bandwidth, and application size.



David W. Bates, M.D., M.Sc.

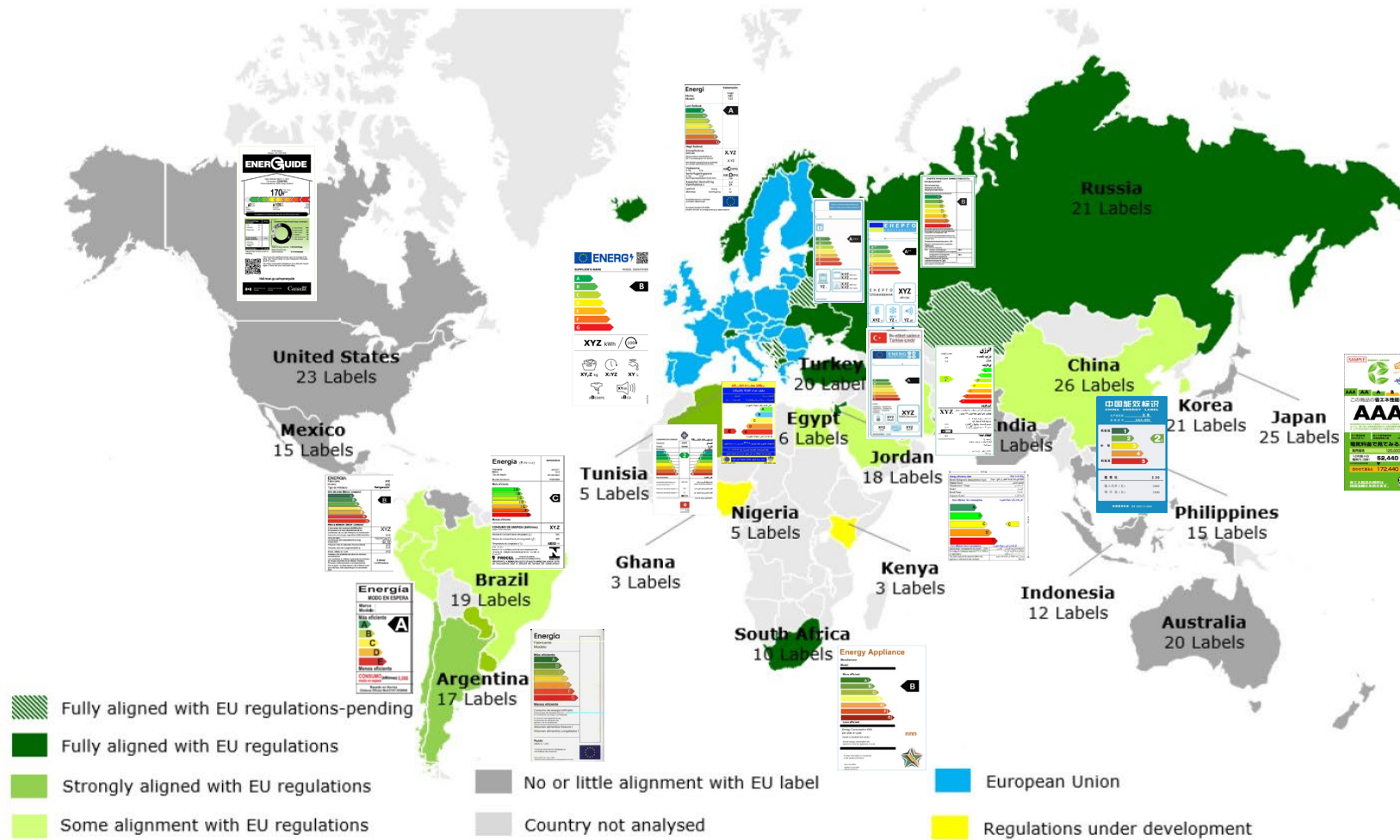
Chief, Division of General Internal Medicine, Brigham and Women's Hospital
 Medical Director, Clinical and Quality Analysis, Mass General Brigham
 Professor of Medicine, Harvard Medical School
 Professor of Health Policy and Management, Harvard T.H. Chan School of Public Health

Dr. Bates served as the chair of the Food and Drug Administration Safety and Innovation Act (FDASIA) workgroup which advised the FCC, FDA, and Office of the National Coordinator about issues around regulation of health information technology.

new US initiative: “please feel free to mention that we are eager to collaborate and minimize reinvention of great work across the globe”

Bates et al (2018) Health Apps and Health Policy – What Is Needed?

beyond the EU: the EU energy label



Societal benefits and implementation stages

1st Label2Enable roundtable on reimbursement of health apps

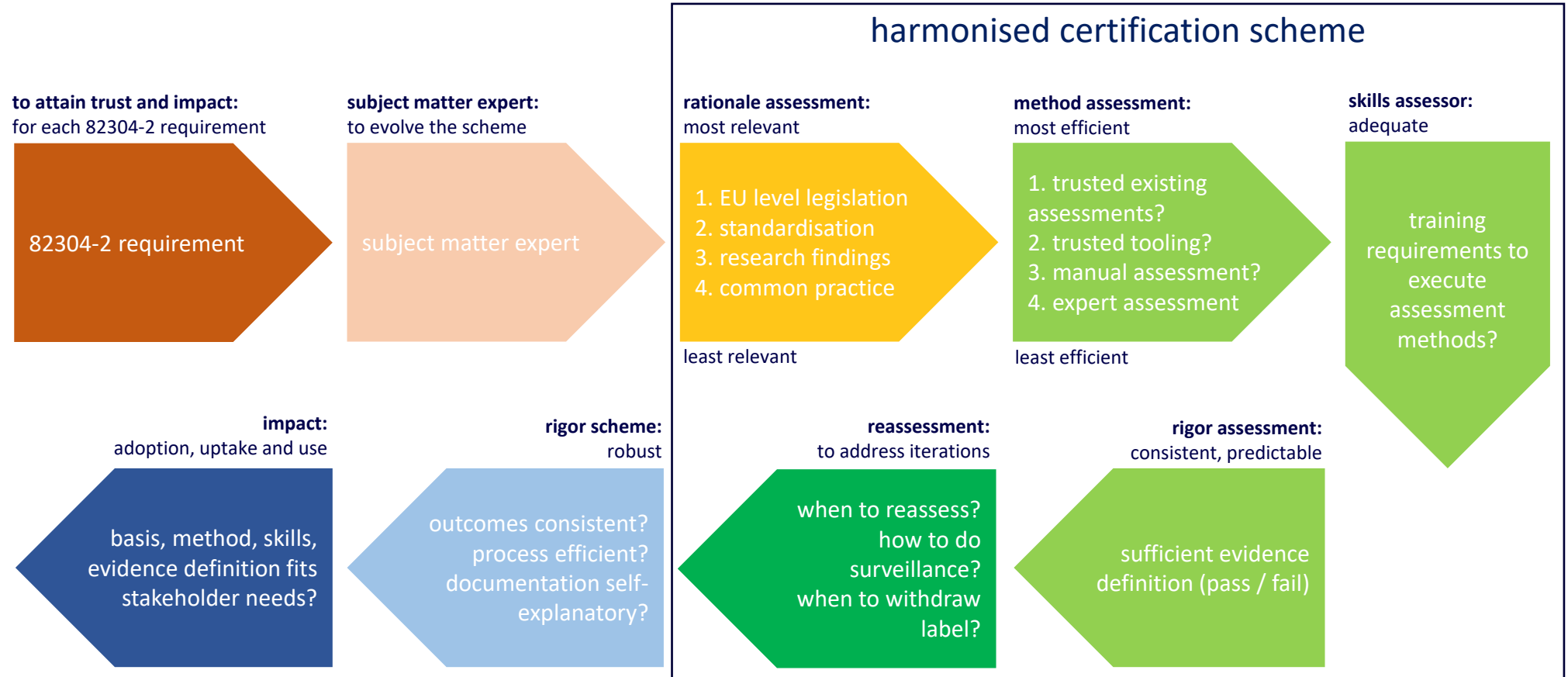
survey – implementation stages

as far as I know in my country (region):

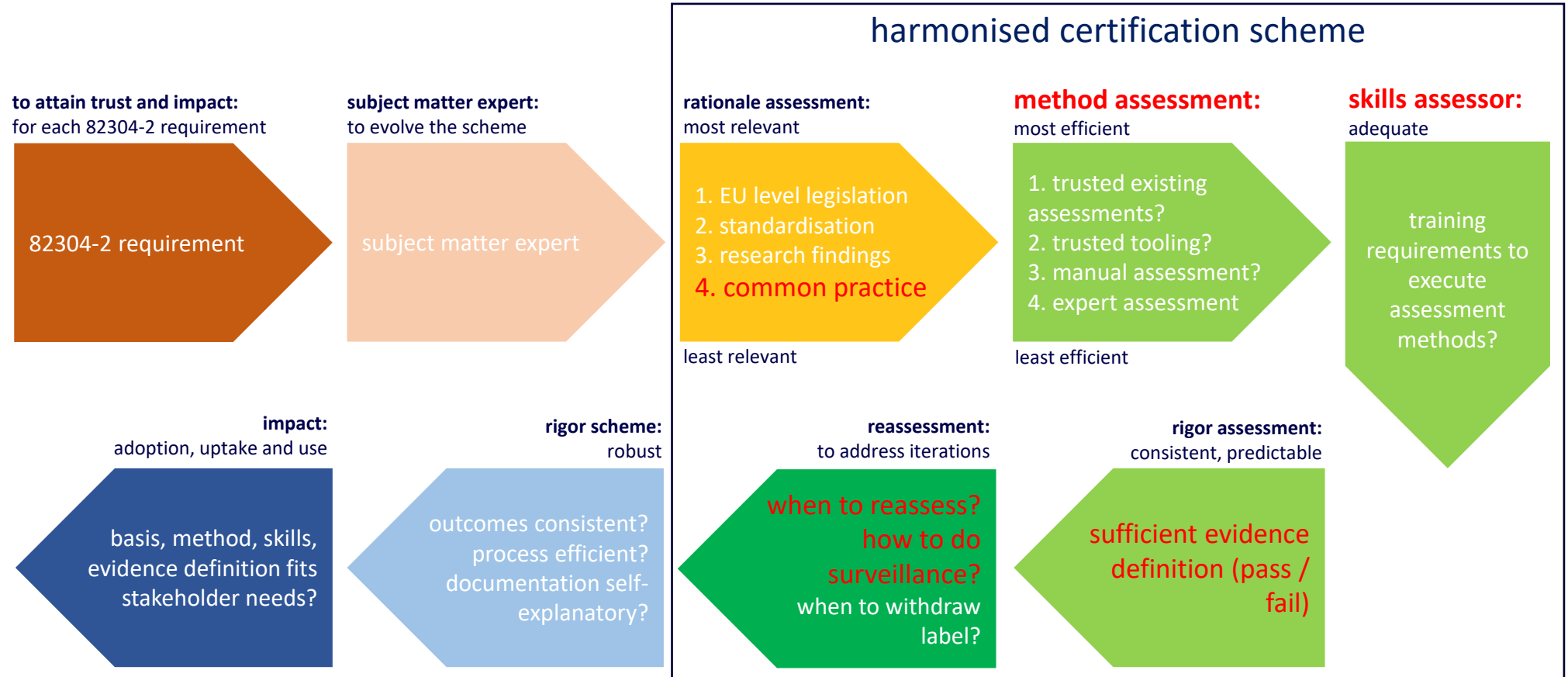
multiple options possible:

- health app policy is considered
 - health app policy is available
 - health apps are quality assessed / certified
 - health apps are reimbursed / paid for
 - health care professionals prescribe health apps
 - health apps are in clinical guidelines
 - health apps are in care pathways
 - health care professionals use patient data from health apps
 - health care professionals get health app education / support
 - citizens get health app education / support
 - none of the above
-

trusted certification scheme



trusted certification scheme: common practice



5.2.5.1 Is evidence available of a **societal benefit** of using the app?

EVIDENCE: Societal benefit evidence. Where many resources are available, provide the most important 5 to 10.

Evidence can include evidence relating to non-digital versions of the health intervention and evidence of demonstrably equivalent health apps.

Societal benefit can refer to Reference [55]:

- **Information**, which includes a positive effect on lack of population denominator, delayed reporting of events, lack of reliable data, communication roadblocks, lack of access to information or data, insufficient utilization of data and information and lack of unique identifiers;
- **Availability**, which includes a positive effect on insufficient supply of commodities, services, equipment and/or qualified health professionals;
- **Quality**, which includes a positive effect on poor experiences for persons with health needs, health issues, at risk for health issues or informal carers, insufficient health professional competence, low quality health commodities, low health professional motivation, insufficient continuity of care, inadequate supportive supervision and poor adherence to guidelines;
- **Acceptability**, which includes a positive effect on lack of alignment with local norms and programs which do not address individual beliefs and practices;
- **Utilization**, which includes a positive effect on low demand for services, geographic inaccessibility, low adherence to treatments and loss to follow up;
- **Efficiency**, which includes a positive effect on inadequate workflow management, lack of or inappropriate referrals, poor planning and coordination, delayed provision of care and inadequate access to transportation;
- **Cost**, which includes a positive effect on high cost of manual processes, lack of effective resource allocation, expenses of persons with health needs, health issues, at risk for health issues or informal carers and lack of a coordinated payer mechanism;
- **Accountability**, which includes a positive effect on insufficient engagement of persons with health needs, health issues, at risk for health issues or informal carers, unawareness of service entitlement, absence of community feedback mechanisms, lack of transparency in commodity transactions, poor accountability between the levels of the health sector, and inadequate understanding of the beneficiary populations.

[55] WHO 2018. *Classification of digital health interventions v1.0 (WHO/RHR/19.06)*.

<https://www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/>

for the 2° round table: your perspectives

- what types of societal evidence do you distinguish for a health app?
 - examples: list WHO and DiGA
- what do/would you consider sufficient evidence for (these types of) societal evidence?
- what are your thoughts, if any, on:
 - the assessment method for societal evidence?
 - the skills assessors need to assess societal evidence?
 - when to reassess societal evidence?
 - surveillance of societal evidence?



Open your smartphone browser and go to

live.voxvote.com

enter the following numbers

PIN: 25785

Voting is **anonymous**.

Screen name or **(nick)name** is optional.

