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.

Label2Enable
defining success of labelling in 5 to 10 years

3rd multi-stakeholder workshop – Nov 3, 2023

Petra Hoogendoorn

there are great apps, but how to find them?

App Store Preview

mySugr - Diabetestracker-log
Suggesties voor jou

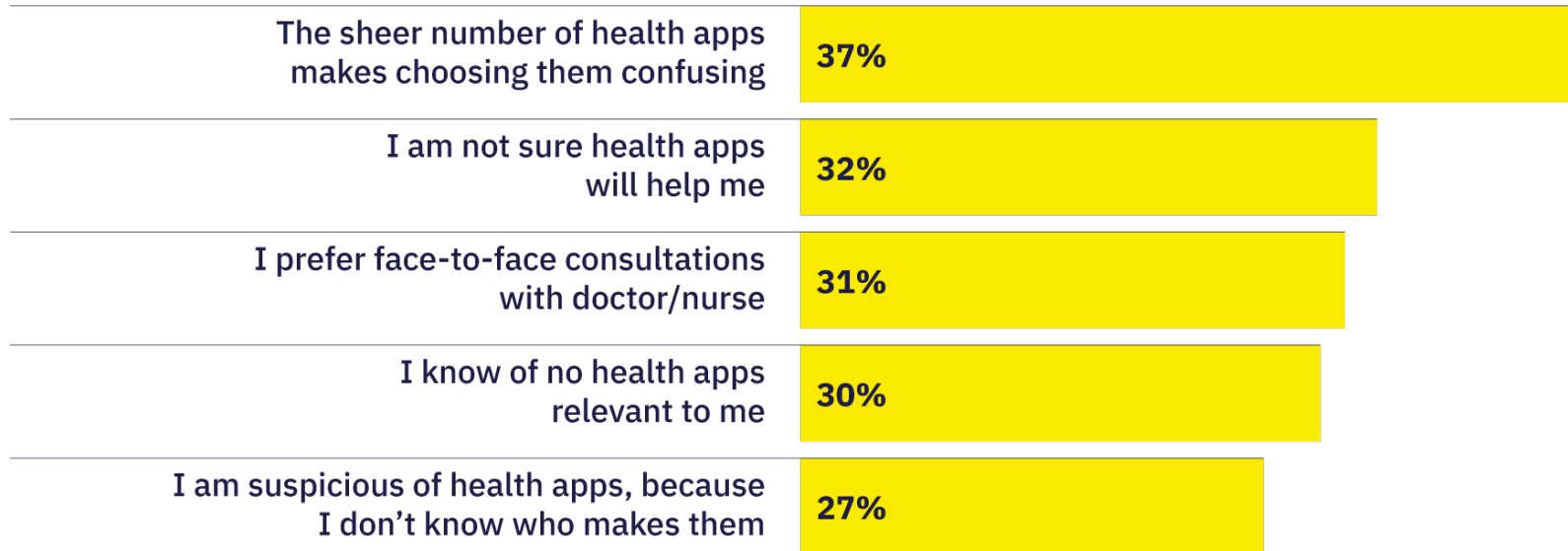|					
Dexcom Clarity Geneeskunde	Glycemische index. Diabetes Geneeskunde	Glucose Blood Sugar Tracker Geneeskunde	Diabetes:M Geneeskunde	LibreLinkUp Geneeskunde	Diabeto Log Diabetes Logboek Geneeskunde
Glucose Buddy Diabetes Tracker Geneeskunde	Dario Health Geneeskunde	iHealth Gluco-Smart Gezondheid 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
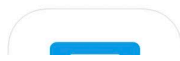
Wyatt (2018) How can clinicians, specialty societies, and others evaluate and improve the quality of apps for patient use?

Larsen et al. (2019) Using science to sell apps: Evaluation of mental health app store quality claims
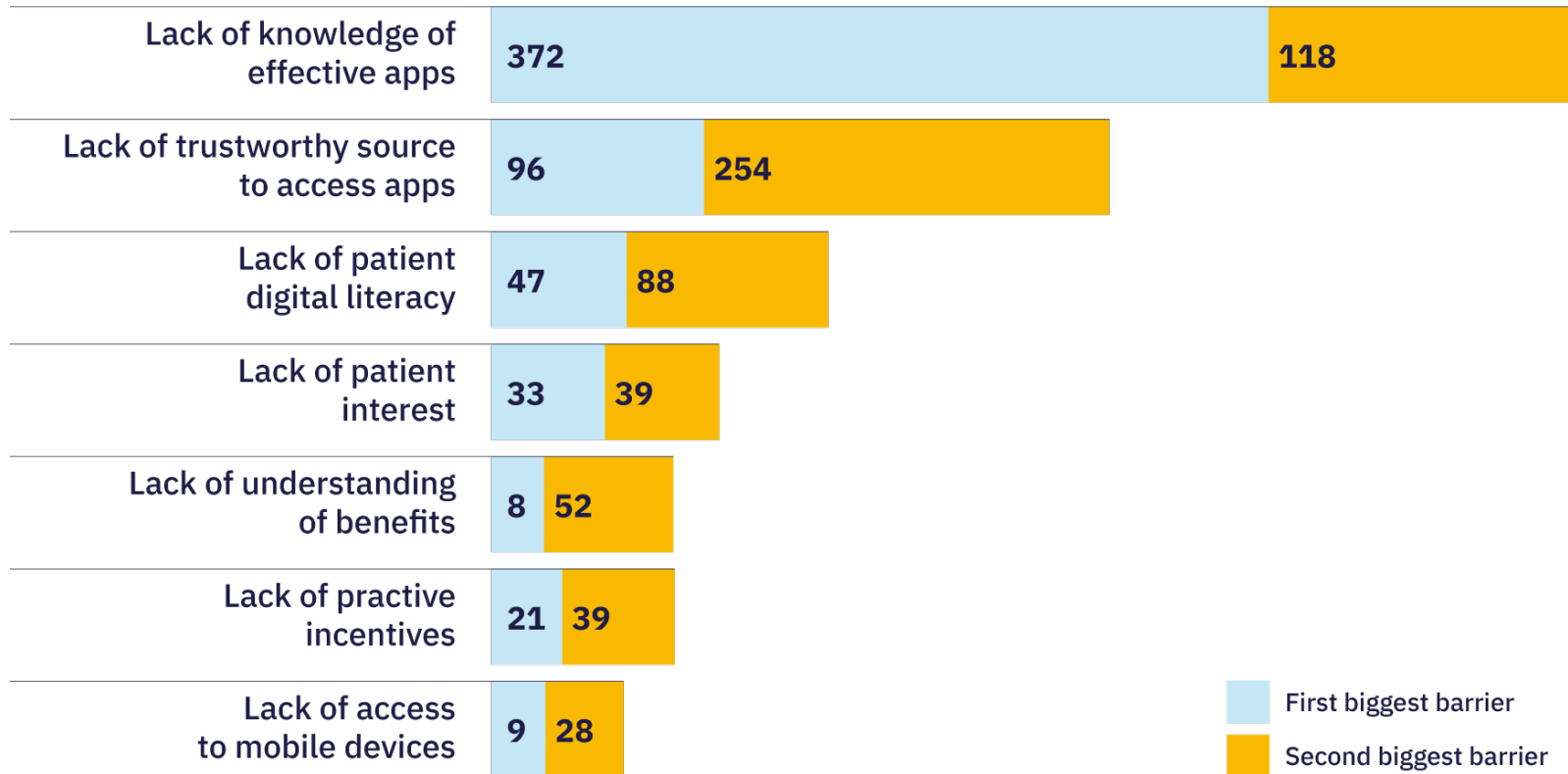
Singh et al. (2016) Many health apps target high-need, high-cost populations, but gaps remain

choosing a 'good' health app is difficult

The sheer number of health apps makes choosing them confusing — **37%**

I am not sure health apps will help me — **32%**

I prefer face-to-face consultations with doctor/nurse — **31%**

I know of no health apps relevant to me — **30%**

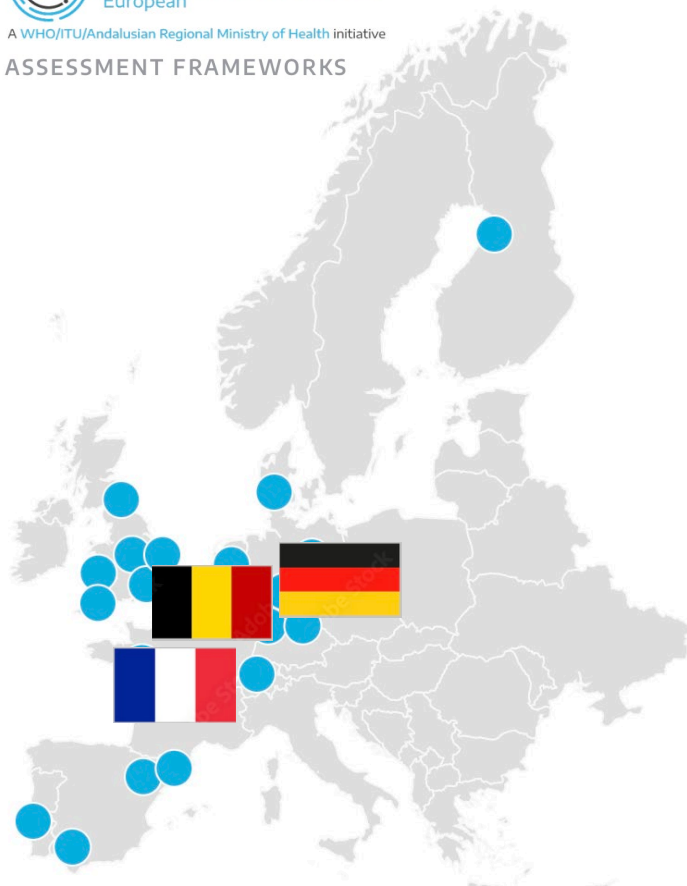I am suspicious of health apps, because I don't know who makes them — **27%**
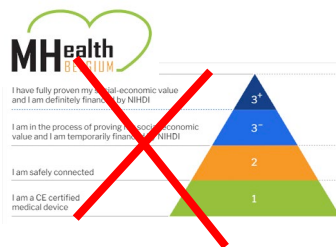
choosing a 'good' health app is difficult

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 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

ISO/TS 82304-2 helps choose, deliver and review apps
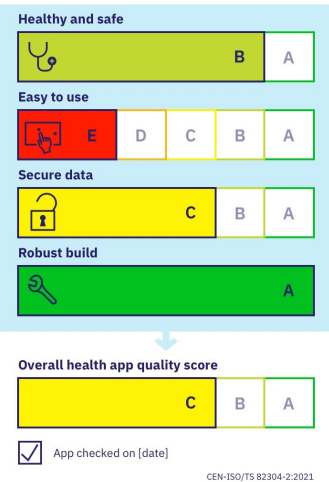
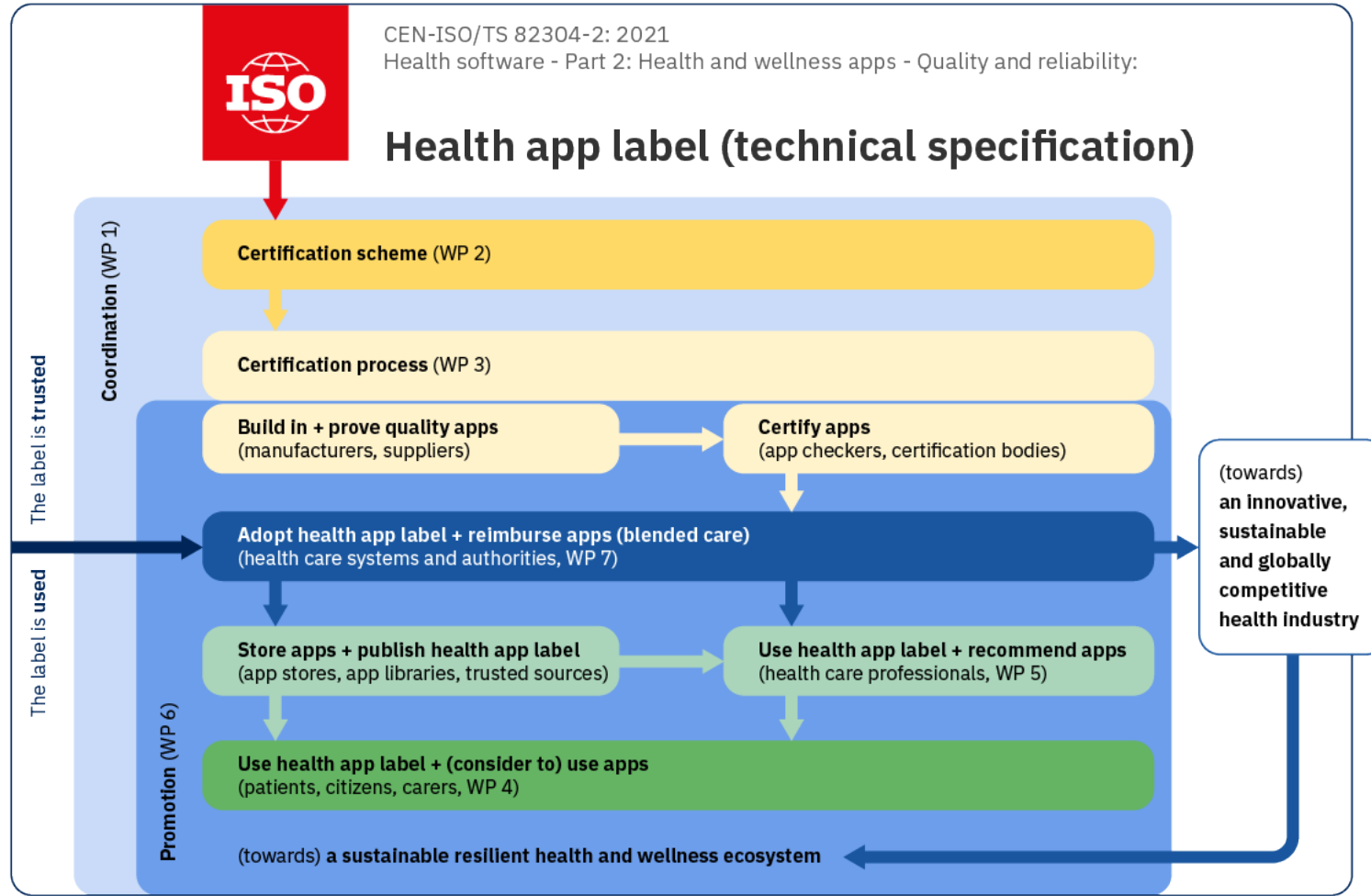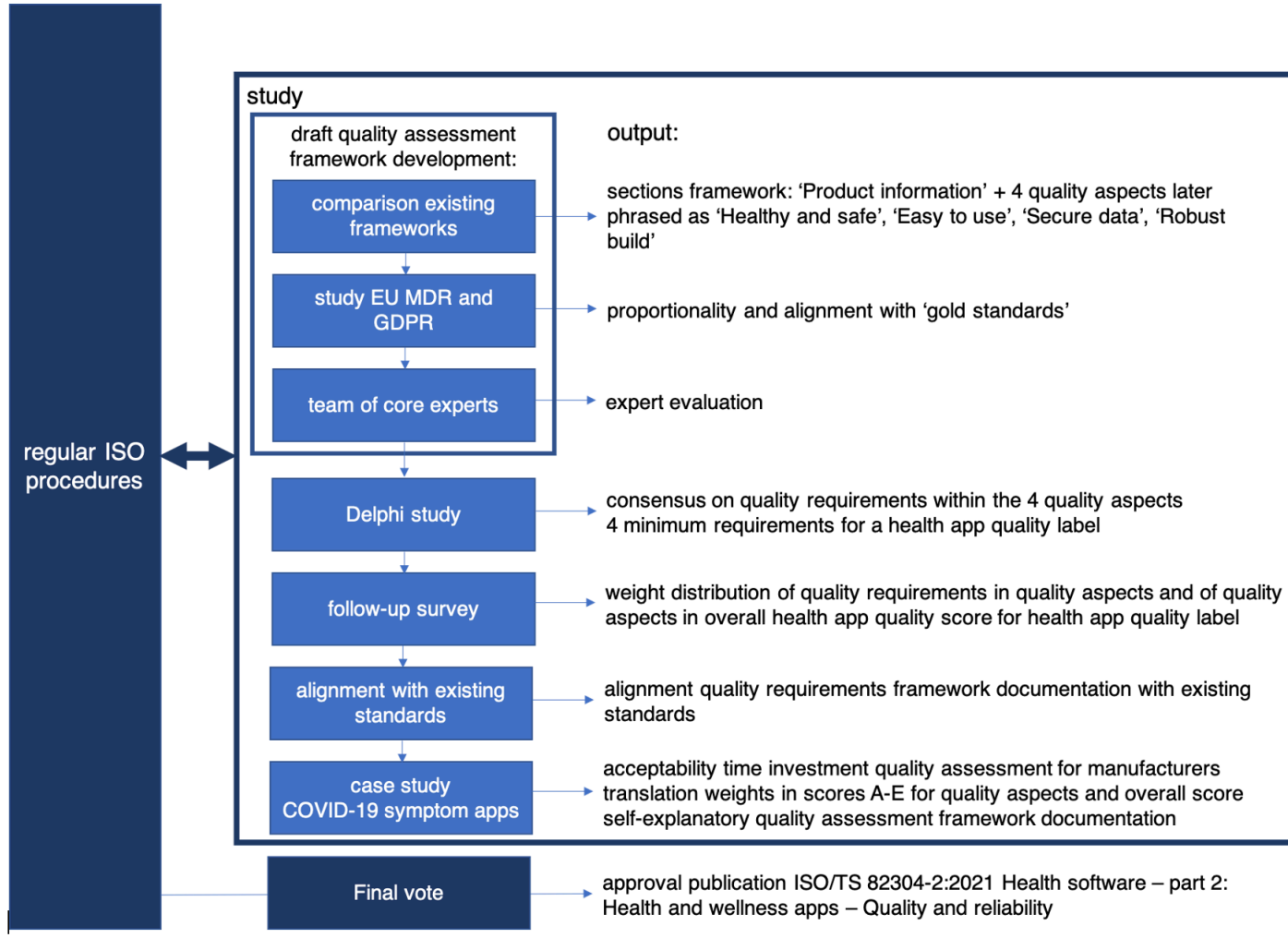|	
Comprehensive	For wellness and medical device apps, not duplicating the work of notified bodies
Evidence-informed	Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries
Inclusive	Label tested with people with low health literacy
Informative	Score, label and report communicate 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	

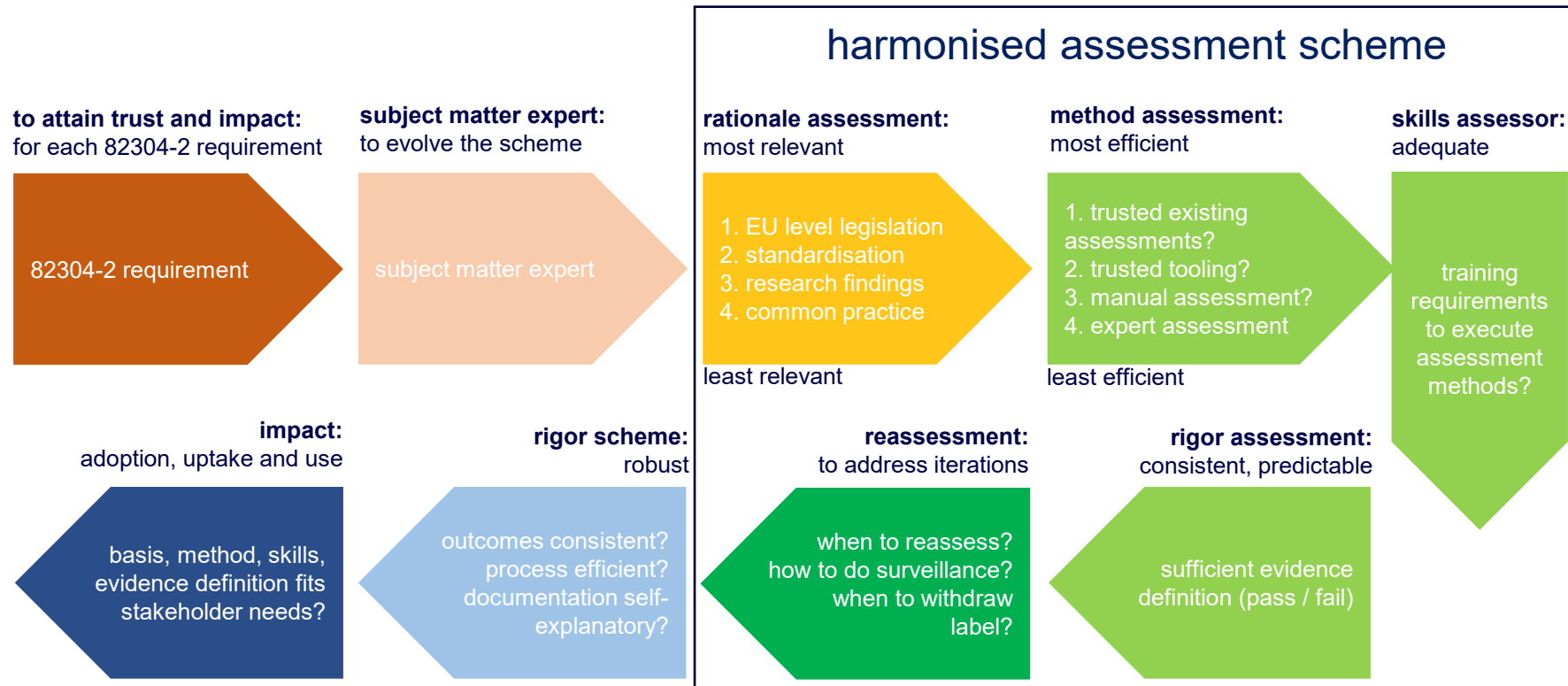https://ec.europa.eu/commission/presscorner/detail/en/MEMO_19_1596

CEN-ISO/TS 82304-2: 2021
Health software - Part 2: Health and wellness apps - Quality and reliability:

Health app label (technical specification)

The label is **trusted**

Coordination (WP 1)

Certification scheme (WP 2)

Certification process (WP 3)

Build in + prove quality apps
(manufacturers, suppliers)

Certify apps
(app checkers, certification bodies)

The label is **used**

Adopt health app label + reimburse apps (blended care)
(health care systems and authorities, WP 7)

(towards)
an innovative, sustainable and globally competitive health industry

Store apps + publish health app label
(app stores, app libraries, trusted sources)

Use health app label + recommend apps
(health care professionals, WP 5)

Promotion (WP 6)

Use health app label + (consider to) use apps
(patients, citizens, carers, WP 4)

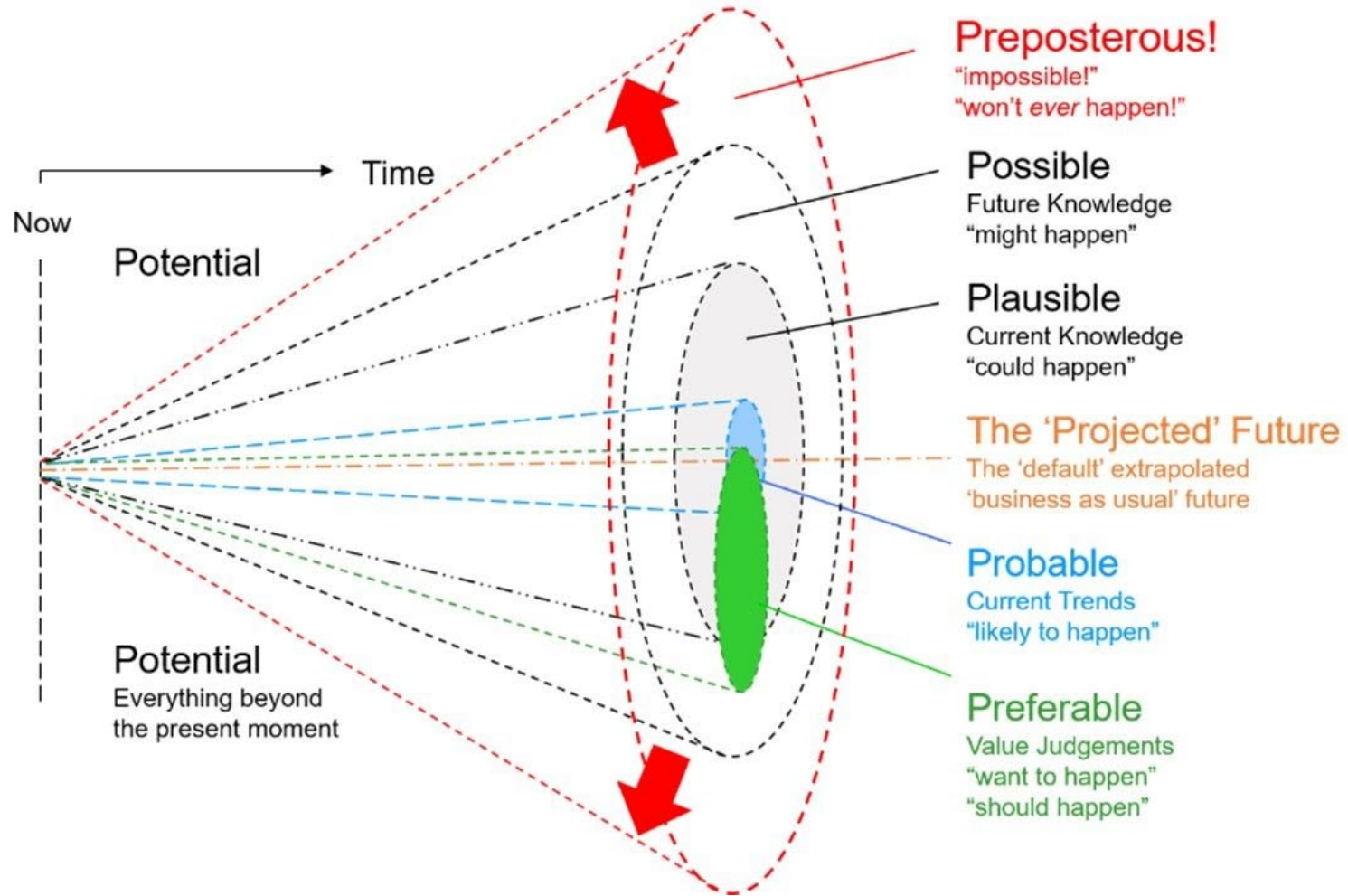(towards) **a sustainable resilient health and wellness ecosystem**

Hoogendoorn et al (2023)
What makes a quality health app – Developing a global research-based health app quality assessment framework for CEN-ISO/TS 82304-2: Delphi study
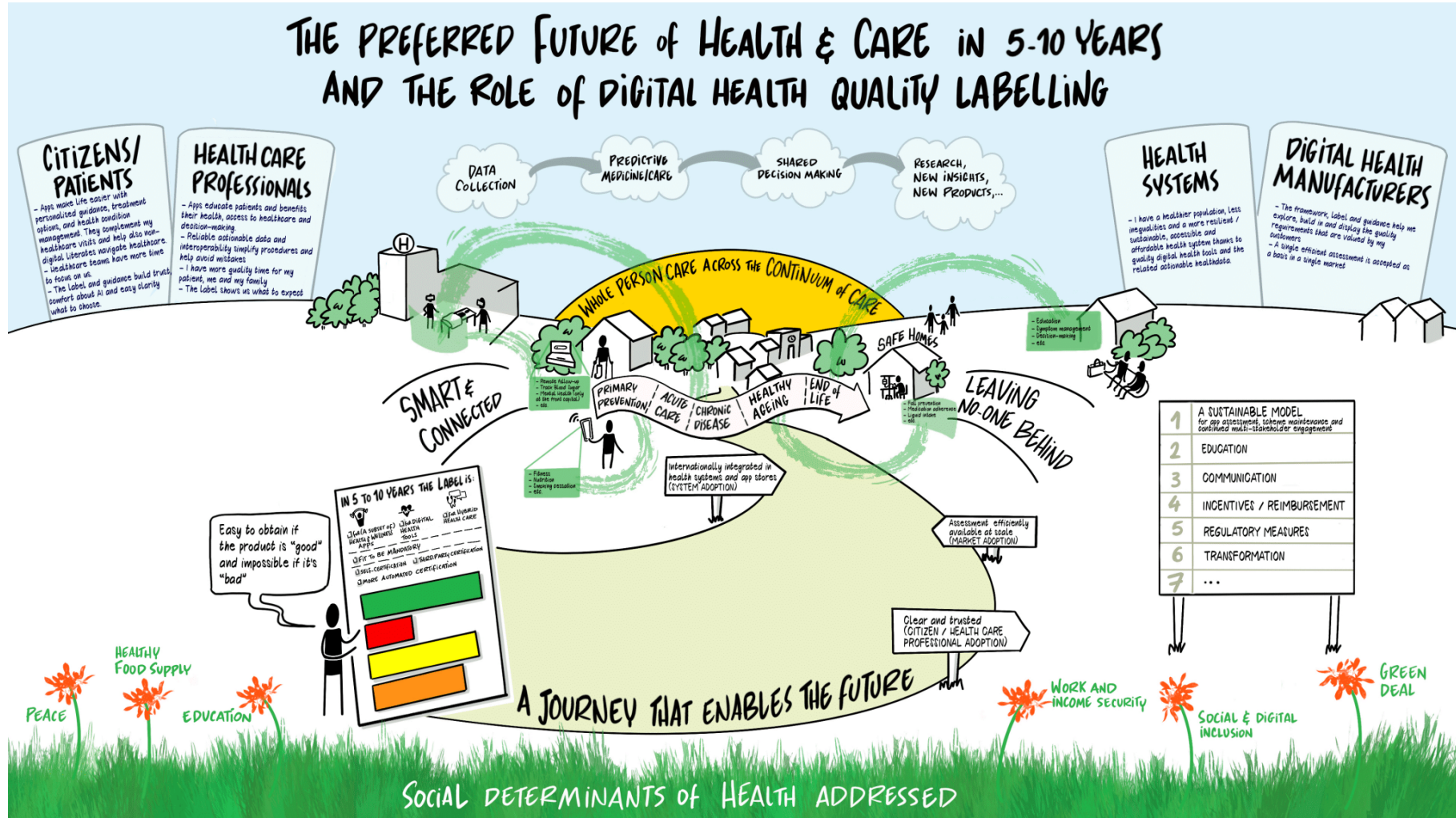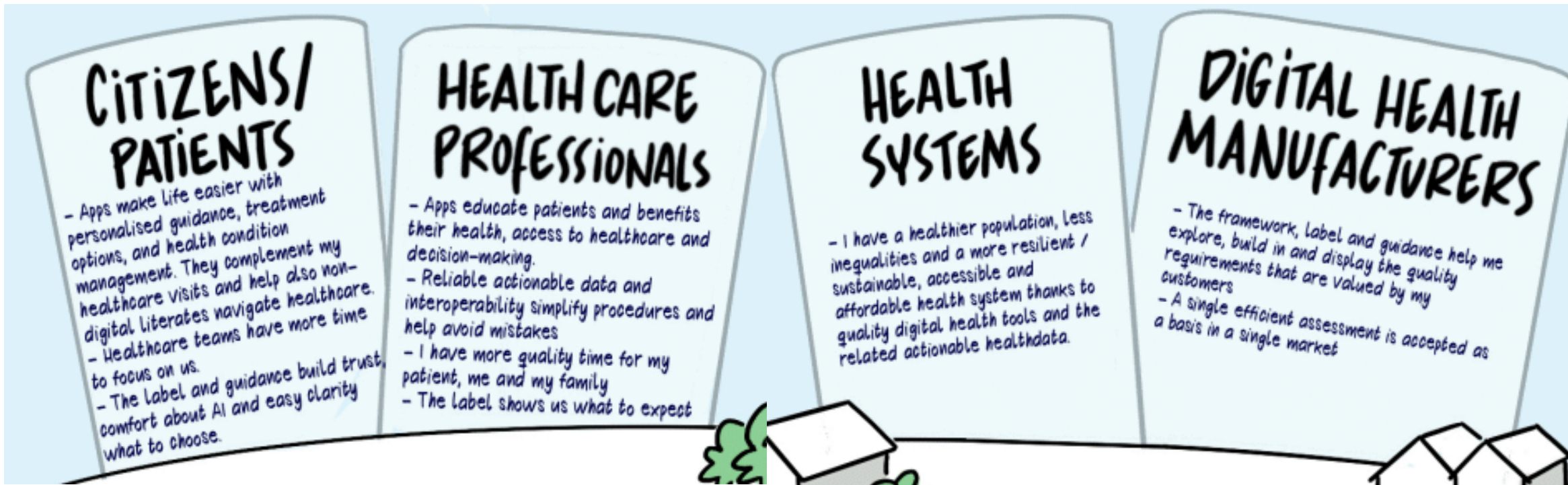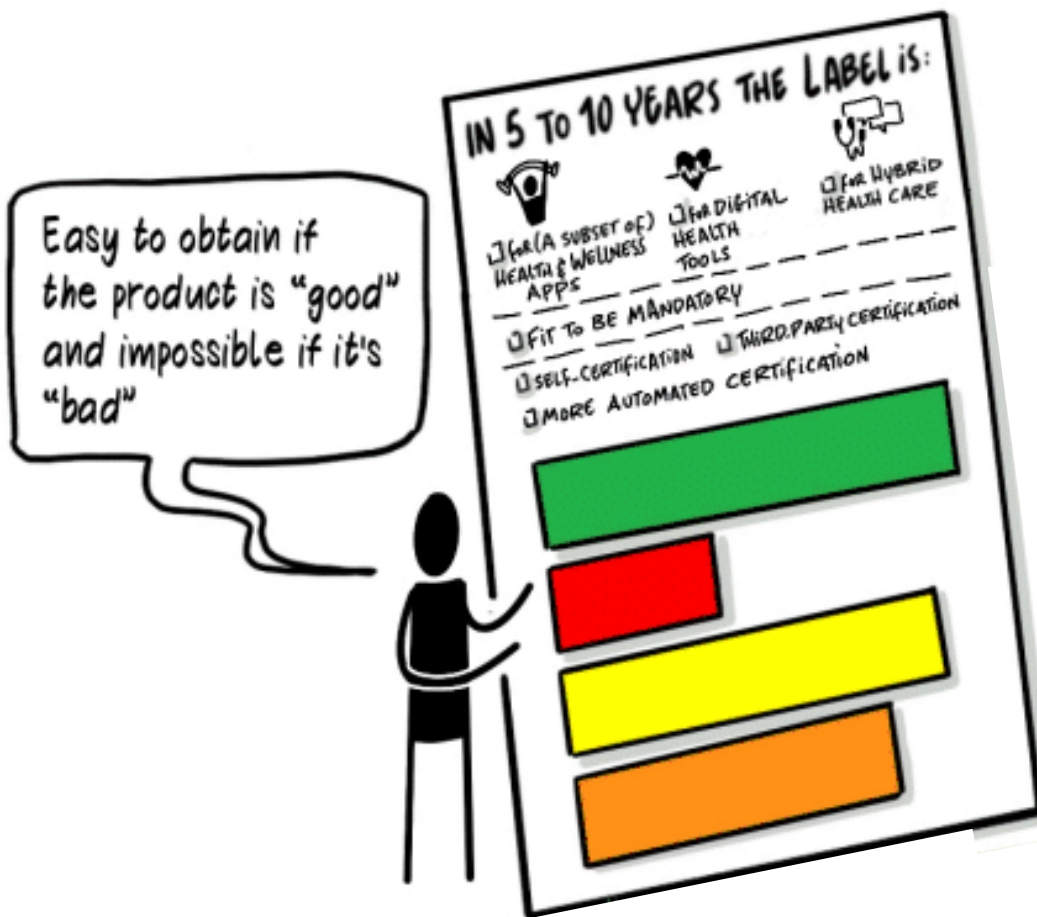
trusted, scalable, self-explanatory, etc.

harmonised assessment scheme

to attain trust and impact:
for each 82304-2 requirement

82304-2 requirement

subject matter expert:
to evolve the scheme

subject matter expert

rationale assessment:
most relevant

1. EU level legislation
2. standardisation
3. research findings
4. common practice

least relevant

method assessment:
most efficient

1. trusted existing assessments?
2. trusted tooling?
3. manual assessment?
4. expert assessment

least efficient

skills assessor:
adequate

training requirements to execute assessment methods?

impact:
adoption, uptake and use

basis, method, skills, evidence definition fits stakeholder needs?

rigor scheme:
robust

outcomes consistent? process efficient? documentation self-explanatory?

reassessment:
to address iterations

when to reassess? how to do surveillance? when to withdraw label?

rigor assessment:
consistent, predictable

sufficient evidence definition (pass / fail)

1ˢᵗ workshop: the preferred future

"The Futures Cone"

CITIZENS/PATIENTS
– Apps make life easier with personalised guidance, treatment options, and health condition management. They complement my healthcare visits and help also non-digital literates navigate healthcare.
– Healthcare teams have more time to focus on us.
– The label and guidance build trust, comfort about AI and easy clarity what to choose.

HEALTH CARE PROFESSIONALS
– Apps educate patients and benefits their health, access to healthcare and decision-making.
– Reliable actionable data and interoperability simplify procedures and help avoid mistakes
– I have more quality time for my patient, me and my family
– The label shows us what to expect

HEALTH SYSTEMS
– I have a healthier population, less inequalities and a more resilient / sustainable, accessible and affordable health system thanks to quality digital health tools and the related actionable healthdata.

DIGITAL HEALTH MANUFACTURERS
– The framework, label and guidance help me explore, build in and display the quality requirements that are valued by my customers
– A single efficient assessment is accepted as a basis in a single market

report 2nd workshop: the path (1/3)

a sustainable model for app assessment and certification scheme maintenance and continued multi-stakeholder engagement

an entity should be established to maintain the label certification scheme, collect, and publish the evidence, including a label verification service; if and when mandatory and regulated, the latter will likely become a normative EU database

education

- reach out to the entire population to bridge the gap between early and late adopters of the label
- consider, in particular, digitally deprived citizens and otherwise disadvantaged populations
- embed in digital health literacy programs and in financing and quality incentivization policies
- facilitate access to technology and facilities
- train students early in their career
- prepare and support the workforce

report 2nd workshop: the path (2/3)

communication

- pursue an adoption roadmap for market and consumer uptake
- an adequate understanding and trust will promote uptake by consumers and health care professions, which in turn will contribute to a path to reimbursement and other revenue-based business models
- market demand for certification and labeling will drive establishment of a or more Certification Bodies, competition is likely to create a need for certification, which in turn will create certification capacity with Conformity Assessment Bodies
- create demand for and supply of skilled assessors
- create a market for supporting Certification Bodies and Conformity Assessment Bodies and training of assessors
- eventually prepare the ground and conditions for EU level legislation

incentives / reimbursement

- affordable quality
- address unmet needs and equity
- fewer apps broader scope?
- evidence based health app selection and acquisition choices
- beyond reimbursement of apps also recognize health care professionals' support role and time allocated

Funded by the
European Union

regulatory measures
- EU harmonization implies legal intervention at EU level
- Based on EU labeling framework in place
- labelling may be voluntary or obligatory; likely to impose third party assessment for certain categories of apps/digital health technologies
- Member States establish oversight mechanisms
- EU level co-ordination, monitoring, and updates
- EU database of labels and labelled products
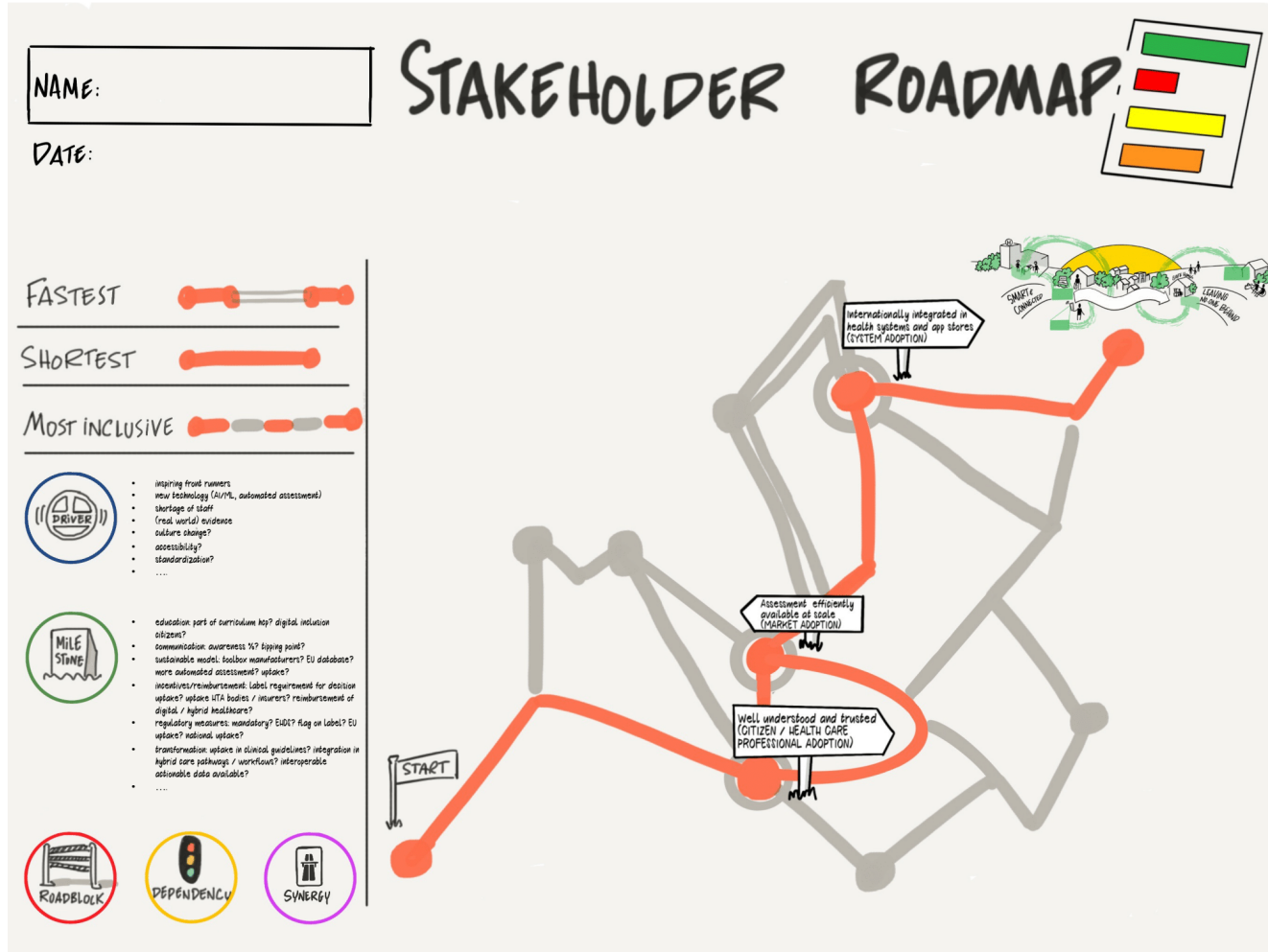- meet prerequisites: sufficient Member State interest and demand for legislation

transformation
- uptake in clinical guidelines
- integration into clinical care pathways / workflows
- interoperability with electronic health records

1	A SUSTAINABLE MODEL for app assessment, scheme maintenance and continued multi-stakeholder engagement
2	EDUCATION
3	COMMUNICATION
4	INCENTIVES / REIMBURSEMENT
5	REGULATORY MEASURES
6	TRANSFORMATION
7	...

Internationally integrated in health systems and app stores (SYSTEM ADOPTION)

Assessment efficiently available at scale (MARKET ADOPTION)

Clear and trusted (CITIZEN / HEALTH CARE PROFESSIONAL ADOPTION)

1	**A SUSTAINABLE MODEL** for app assessment, scheme maintenance and continued multi-stakeholder engagement
2	EDUCATION
3	COMMUNICATION
4	INCENTIVES / REIMBURSEMENT
5	REGULATORY MEASURES
6	TRANSFORMATION
7	...

MILE STONE

- education: part of curriculum hcp? digital inclusion citizens?
- communication: awareness %? tipping point?
- sustainable model: toolbox manufacturers? EU database? more automated assessment? uptake?
- incentives/reimbursement: label requirement for decision uptake? uptake HTA bodies / insurers? reimbursement of digital / hybrid healthcare?
- regulatory measures: mandatory? EHDS? flag on label? EU uptake? national uptake?
- transformation: uptake in clinical guidelines? integration in hybrid care pathways / workflows? interoperable actionable data available?

building on the 2nd workshop

- inspiring front runners
- new technology (AI/ML, automated assessment)
- shortage of staff
- (real world) evidence
- culture change?
- accessibility?
- standardization?
- ....

ROADBLOCK

DEPENDENCY

SYNERGY

LABEL2 ENABLE
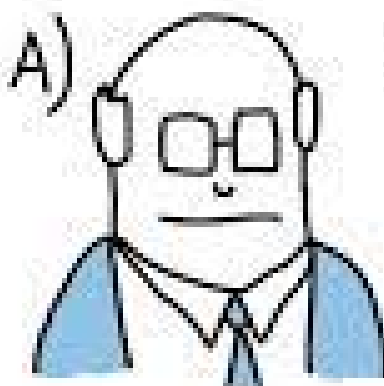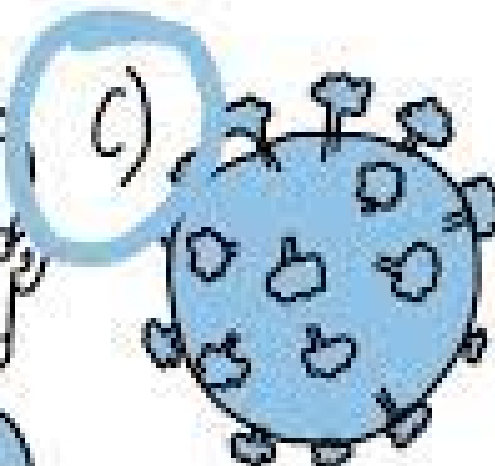
NewScientist

Sign in | Enter search keywords

When will Storm Ciaran hit and what makes it a bomb cyclone?

The strongest winds from Storm Ciaran are expected to hit south England on the morning of 2 November, and the storm may set a record for the lowest air pressure recorded in 200 years

By Michael Le Page

1 November 2023

Europe Bomb Cyclone (Storm Ciaran): November 1-4, 2023

MILES PER HOUR

WXCHARTS.COM

yet innovative solutions will likely emerge then

The European Commission and WHO launch landmark digital health initiative to strengthen global health security

- "By using European best practices we contribute to digital health standards and interoperability globally—to the benefit of those most in need." said Stella Kyriakides, Commissioner for Health and Food Safety.

- "With **80 countries** and territories connected to the **EU Digital COVID-19 Certificate**, the EU has set a global standard. I am pleased that the WHO will build on the privacy-preserving principles and cutting-edge technology of the EU certificate to create a global tool against future pandemics," added Thierry Breton, Commissioner for Internal Market.

problem   solved

agenda

09.50-10.55h - Plenary Session I: Recent developments and inspiration

Inspiration from front-of-pack nutrition labelling – later in November

The changing EU landscape for health and wellness apps - Petra Wilson, HIMSS

Label2Enable findings and updates

TS 82304-2 certification scheme and sustainability considerations – Christophe Maes, Charlie McCay, I~HD

Testing the label scheme with 24 apps and 5 assessment organisations – Liz Ashall-Payne, ORCHA, Menno Kok – EIT Health

Discrete choice experiment on the value proposition of health app assessment – Anna Frey, ORCHA

Exploring the value of 82304-2 in decision-making on reimbursement – Tatjana Prenda-Trupec, OptimIT

Co-creating and testing educational communication around the label – Corine Meppelink, University of Amsterdam

Initiatives of participating stakeholders

agenda

11.15-12.30h - Break-out session I: What is a realistic roadmap to success of the label?

Citizens patients carers and healthcare professionals - Gözde Susuzlu, Christophe Maes

App assessors, libraries, manufacturers, SDOs, consultants - Petra Hoogendoorn, Menno Kok

Health authorities and insurers - Zoi Kolitsi, Charlie McCay

**13.30-14.15h Plenary Session II: Reports from break-out session I**

14.15-15.30h Break-out session II: Multi-stakeholder dependencies and synergies

15.45-16.30h Plenary Session III: Reports from break-out session II and wrap up
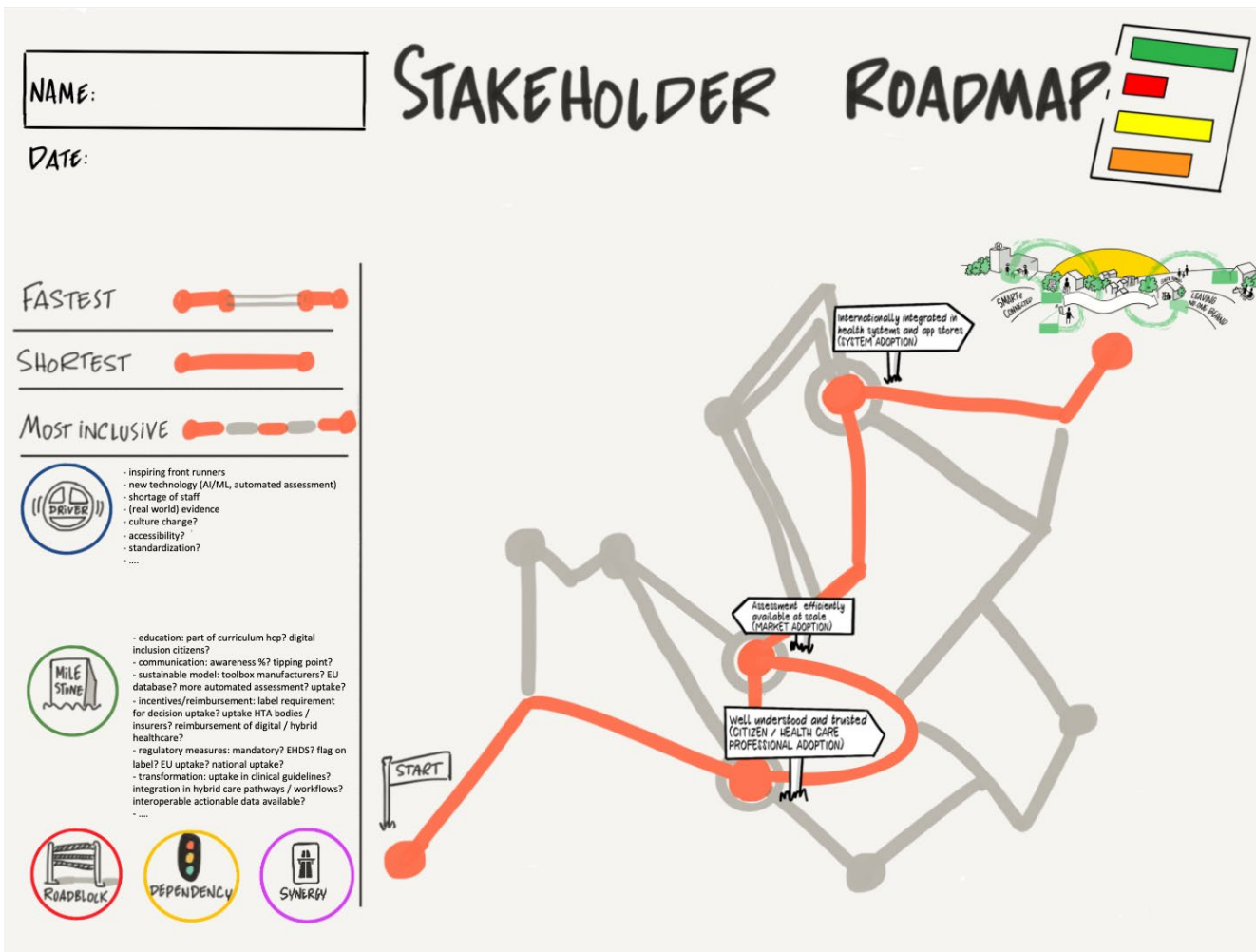
- **information session**
- **break-out I: stakeholder roadmaps**
  - name: stakeholder group
  - focus on your own stakeholder group: what needs to happen to arrive at each major milestone? what intermediate milestones need to be reached by your stakeholder group?

- **break-out II: ecosystem**
  - merge stakeholder milestones
  - what needs to happen for intermediate milestones to be reached collectively by the ecosystem?
  - identify synergies and optimise efficiency
  - LESS IS MORE!

for online participants: actively participate :-)
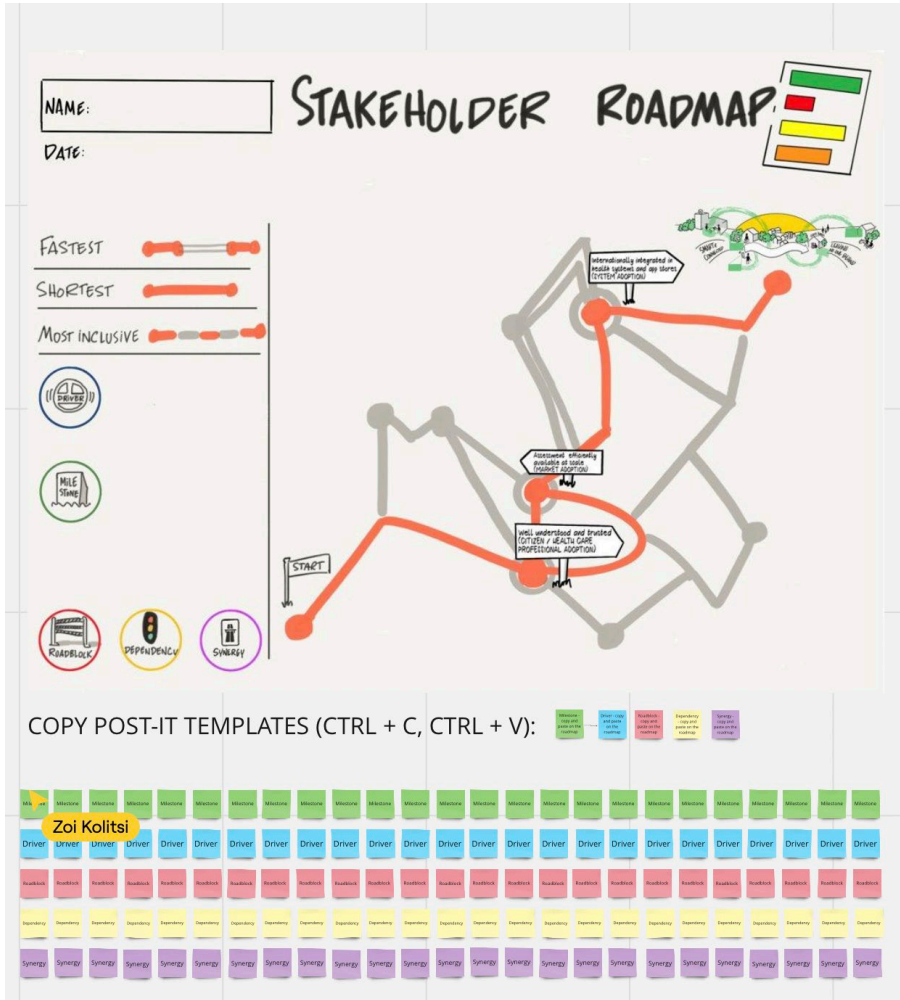
- Miro: https://miro.com/app/board/uXjVNT8Book=/
  - use adequate color post-it

- alternatively indicate in chat Teams
  - D: driver - …
  - B: barrier - …
  - M: milestone - …
  - De: dependancy - …
  - S: synergy - …

- discussion:
  - raise your hand to intervene (shout out if we miss it)
  - place your comments in the chat