

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 2nd Multistakeholder workshop





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

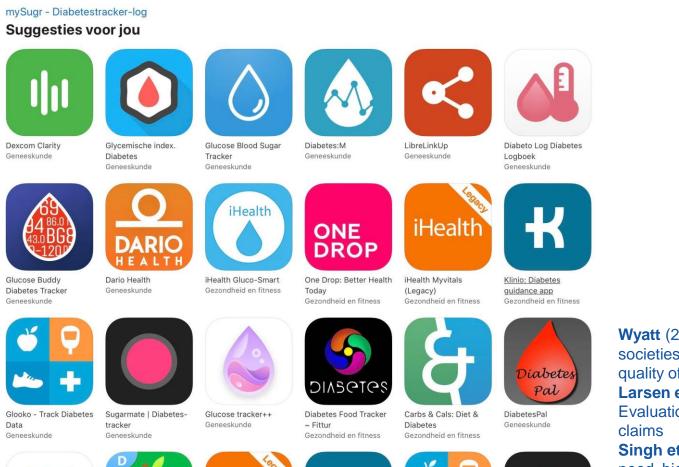
2nd multi-stakeholder workshop – Jun 26, 2023



Jun 26, 2023

## LABEL2 U there are great apps, but how to find them?

App Store Preview



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 highneed, high-cost populations, but gaps remain



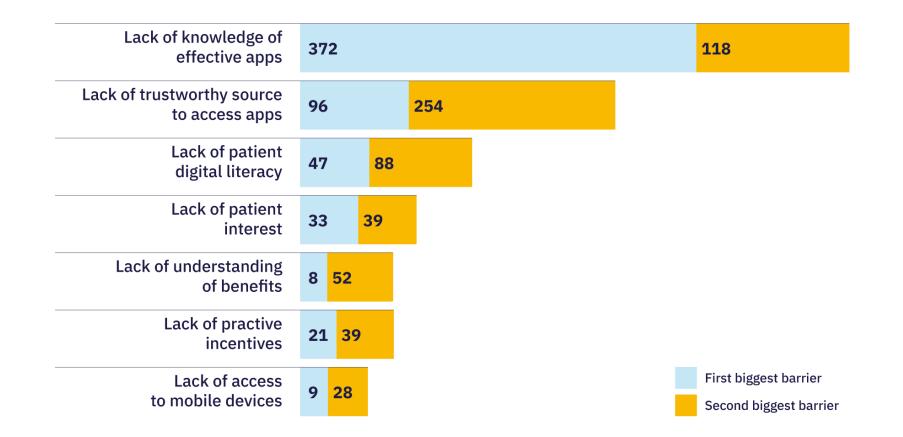
### LABEL2 C choosing a 'good' health app is difficult

37%	The sheer number of health apps makes choosing them confusing
32%	I am not sure health apps will help me
31%	I prefer face-to-face consultations with doctor/nurse
30%	I know of no health apps relevant to me
27%	I am suspicious of health apps, because I don't know who makes them

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



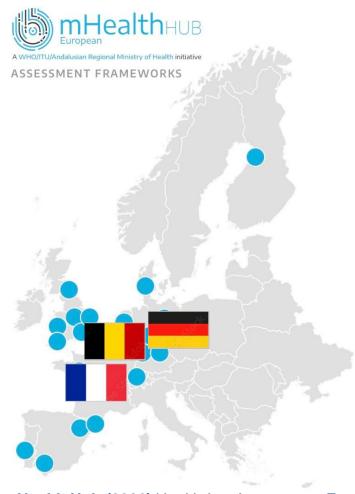
### LABEL2 C choosing a 'good' health app is difficult



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



### LABEL2 U delivering a 'good' health app is difficult



mHealth Hub (2022) Health App Assessment Frameworks

#### Federal Institute for Drugs and Medical Devices

The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V Acide for Mundicitiers, Service Providers and Users





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Early access to reimbursement for digital devices (PECAN)



Jun 26, 2023

## LABEL2 V reviewing a health app is difficult too

- **npj** | digital medicine Health app policy:
- Belgium
- Denmark
- England
- Germany
- Netherlands
- Norway
- Sweden
- Singapore
- United States

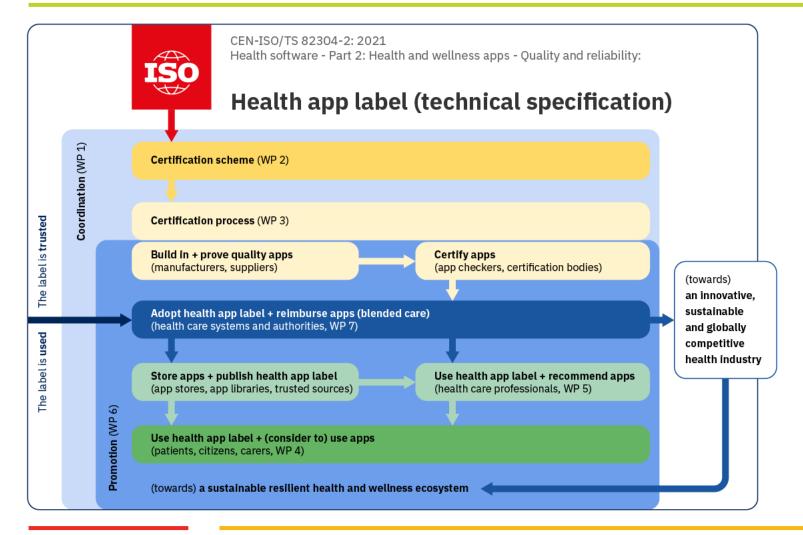
"There is great interest in the use of apps in all the countries evaluated, but even Belgium, Germany and the UK, which are relatively far along in their operationalization of frameworks, are struggling with efficient implementation.

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







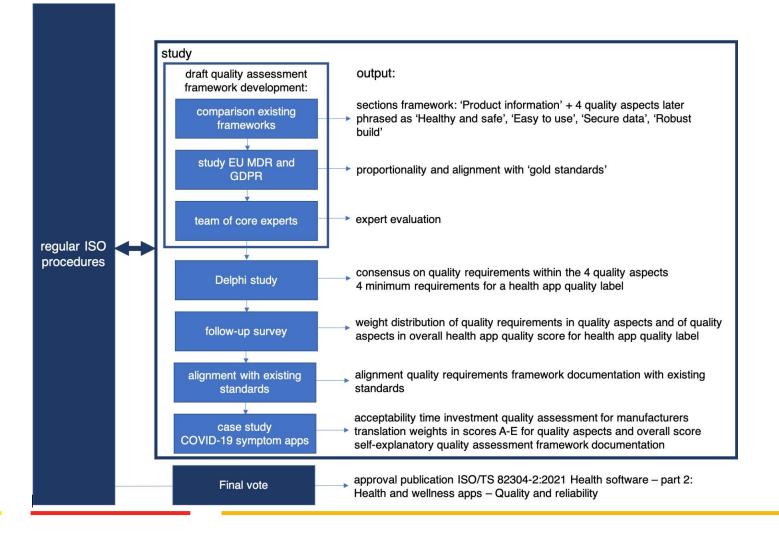


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#### 2<sup>nd</sup> multi-stakeholder workshop

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### LABEL2 Useful, proportional, ...

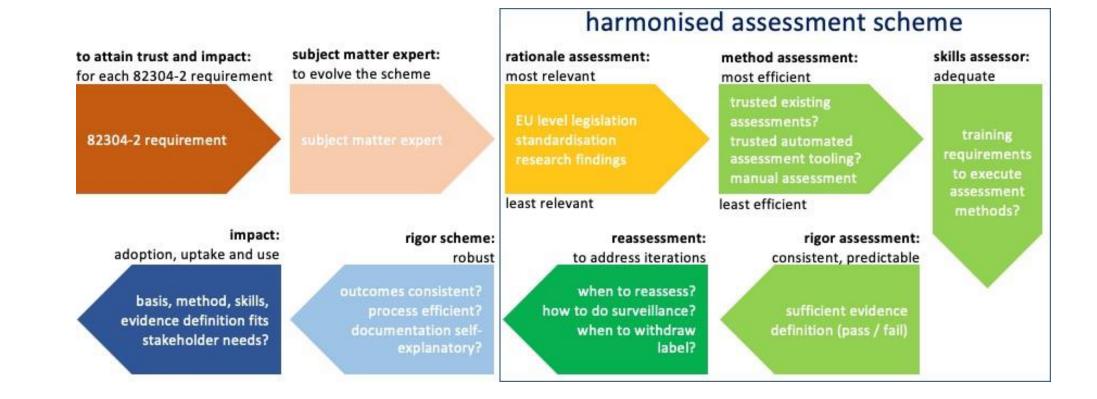


Hoogendoorn et al (2023) What makes a quality health app – Developing a global research-based health app quality assessment framework for CEN-ISO/TS 82304-2: Delphi study



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## LABEL2 U useful, trusted, affordable, scalable, etc.





## LABEL2 CEN-ISO/TS 82304-2:2021 helps choose apps

Flag or logo	Health app quality label
App icon	App name
Platform ic	ns pmanufacturer

#### 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



Inclusive Informative **Proportionate** Testable Relevant Maintained

**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

Label tested with people with low health literacy

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

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

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

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

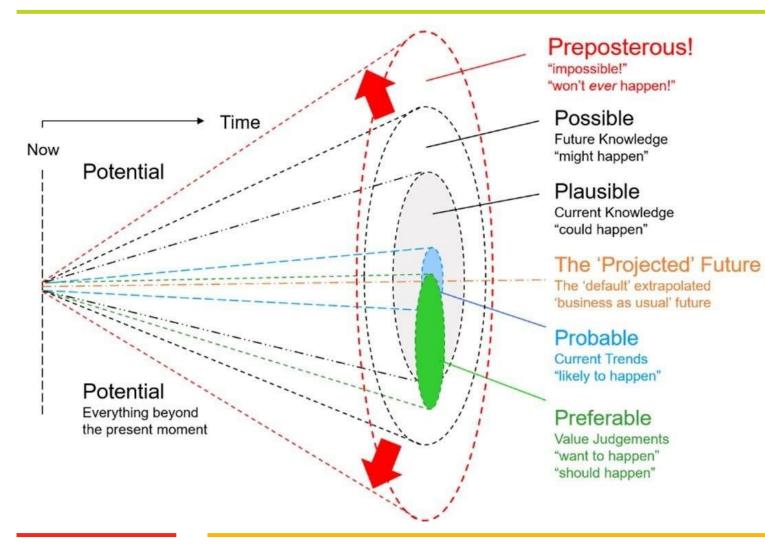


https://ec.europa.eu/commission/presscorner/detail/en/MEMO\_19\_1596



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### LABEL2 2 1st workshop: the preferred vs projected future

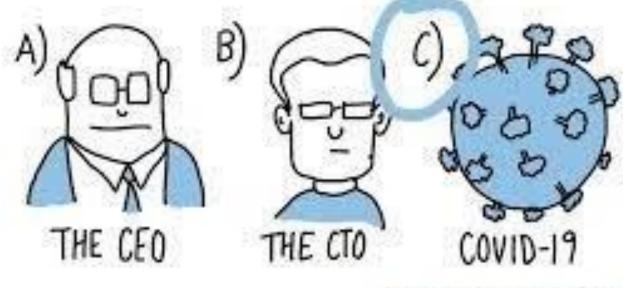


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"The Futures Cone"







BUSINESSILLUSTRATOR COM



### LABEL2 3 1st workshop: the elephant and its habitat





Jun 26, 2023

### LABEL2 2nd workshop: the desire and the path





Jun 26, 2023



#### Desire

**Desires** are states of mind that are expressed by terms like "<u>wanting</u>", "<u>wishing</u>", "longing" or "craving". A great variety of features is commonly associated with desires. They are seen as propositional attitudes towards conceivable states of affairs. They aim to change the world by representing how the world should be, unlike <u>beliefs</u>, which aim to represent how the world actually is. Desires are closely related to <u>agency</u>: they <u>motivate</u> the agent to realize them. For this to be possible, a desire has to be combined with a belief about which action would realize it. Desires present their objects in a favorable light, as something that appears to be good. Their fulfillment is normally experienced as <u>pleasurable</u> in contrast to the negative experience of failing to do so. Conscious desires are usually accompanied by some form of <u>emotional</u> response.







#### Desire path

A desire path (often referred to as a desire line in transportation planning), also known as a game trail, social trail, fishermen trail, herd path, cow path, elephant path, buffalo trace, goat track, pig trail, use trail and bootleg trail, is an unplanned small trail created as a consequence of mechanical <u>erosion</u> caused by human or animal traffic. The path usually represents the shortest or the most easily navigated route between an origin and destination, and the width and severity of its surface erosion are often indicators of the traffic level it receives.



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### LABEL2 2nd workshop: the roped off path



A desire path roped off for revegetation in Brisbane, Australia

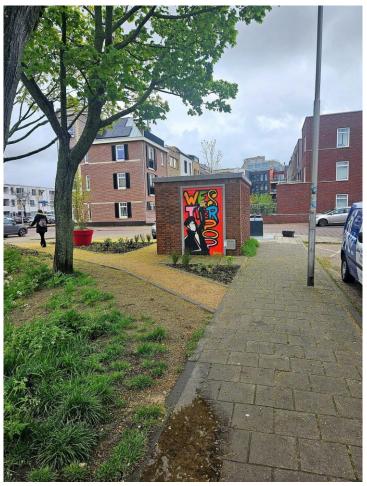
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## LABEL2 2nd workshop: the accommodated path



An accommodated desire path in **Delft**, Netherlands

Desire path

A desire path (often referred to as a desire line in transportation planning), also known as a game trail, social trail, fishermen trail, herd path, cow path, elephant path, buffalo trace, goat track, pig trail, use trail and bootleg trail, is an unplanned small trail created as a consequence of mechanical <u>erosion</u> caused by human or animal traffic. The path usually represents the shortest or the most easily navigated route between an origin and destination, and the width and severity of its surface erosion are often indicators of the traffic level it receives.



Jun 26, 2023



10.00-11.50h - Plenary Session I: Recent developments and inspiration

Inspiration from the journey and results of the EU Energy label - Stamatis Sivitos, DG ENER

Labelling in the EHDS and related developments (AI Act, Pharma Act) - Petra Wilson, HIMSS

Label2Enable patient and health care professional thoughts and feelings -

Gözde Susuzlu, EPF and Antanas Montvila, Kaunas Clinics

#### Label2Enable findings and updates

Healthcare professional survey on recommending health apps - leva Biliunaite, LUMC Testing the label scheme with 24 apps and 5 assessment organisations - Paul Weston, ORCHA Testing the label in 4 corners of Europe: Denmark, France, Hungary, Italy - Vania Putatti, EuroHealthNet

Initiatives of participating stakeholders Levelling the playing field for start-ups - Rita Campos, F6S Back casting with CPME and EJD - Antanas Montvila, EJD





11.50-12.20h - Break-out session I: Stakeholder thoughts and feelings and labelling characteristics
Citizens patients carers and healthcare professionals - Dipak Kalra, Gözde Susuzlu
App assessors, libraries, manufacturers, SDOs, consultants - Petra Hoogendoorn
Health authorities and insurers - Zoi Kolitsi

13.30-14.00h Plenary Session II: Reports from break-out session I

14.00-15.30h 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 in between targets and milestones, drivers and barriers, steady factors and trends? What is your (stakeholder group's) unique role in getting to that future in 5 to 10 years?

**15.45-16.30h Plenary Session III: Reports from break-out session II and wrap up** Input for follow up agenda, dependencies and synergies





# European Health Future Academy



#### Health Trends & Application of Futures Thinking

- HOW TO DEVELOP OR ADAPT YOUR CURRENT STRATEGIES TO FACE THE DIGIT. HEALTH TRANSFORMATION AND PREPARE DIGITAL HEALTH LEADERS?

# Exercises



MAY 2022



European Junior Doctors



#### **Impact-Uncertainty Matrix**

#### MAPPING THE DEGREE OF UNCERTAINTY & IMPACT OF KEY UNCERTAINTIES

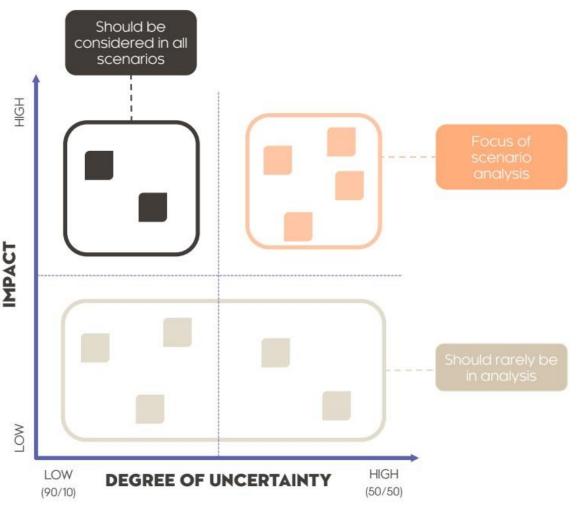
#### IMPACT

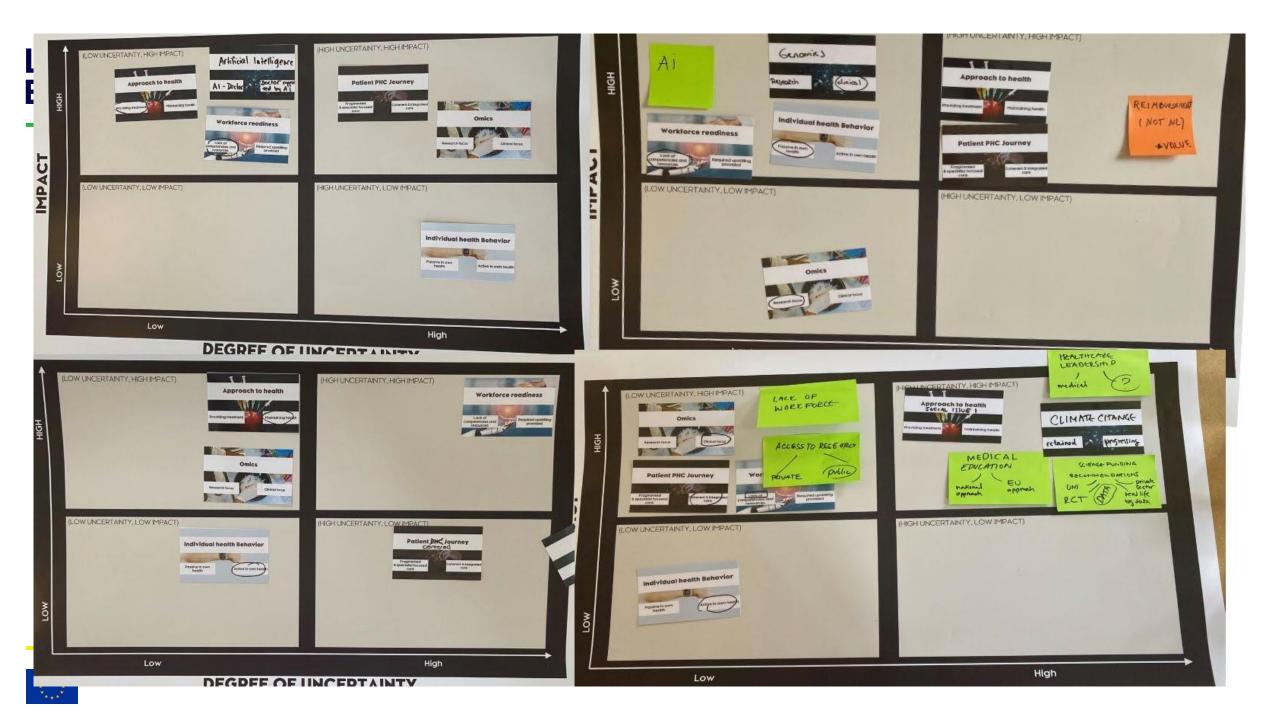
- HIGH expected to have a significant impact that will fundamentally alter the organisation, market, or business environment.
- LOW expected to have an insignificant impact that will
   NOT fundamentally alter the organisation, market, or
   business environment.

#### UNCERTAINTY

- HIGH a 'coin flip' with 50/50 outcomes that are difficult to anticipate, generating high uncertainty
- LOW future trajectory is likely in a particular direction, above 70/30 or below 30/70 outcomes, resulting in low uncertainty

Important: something is **not** uncertain just because we may not want it to happen...

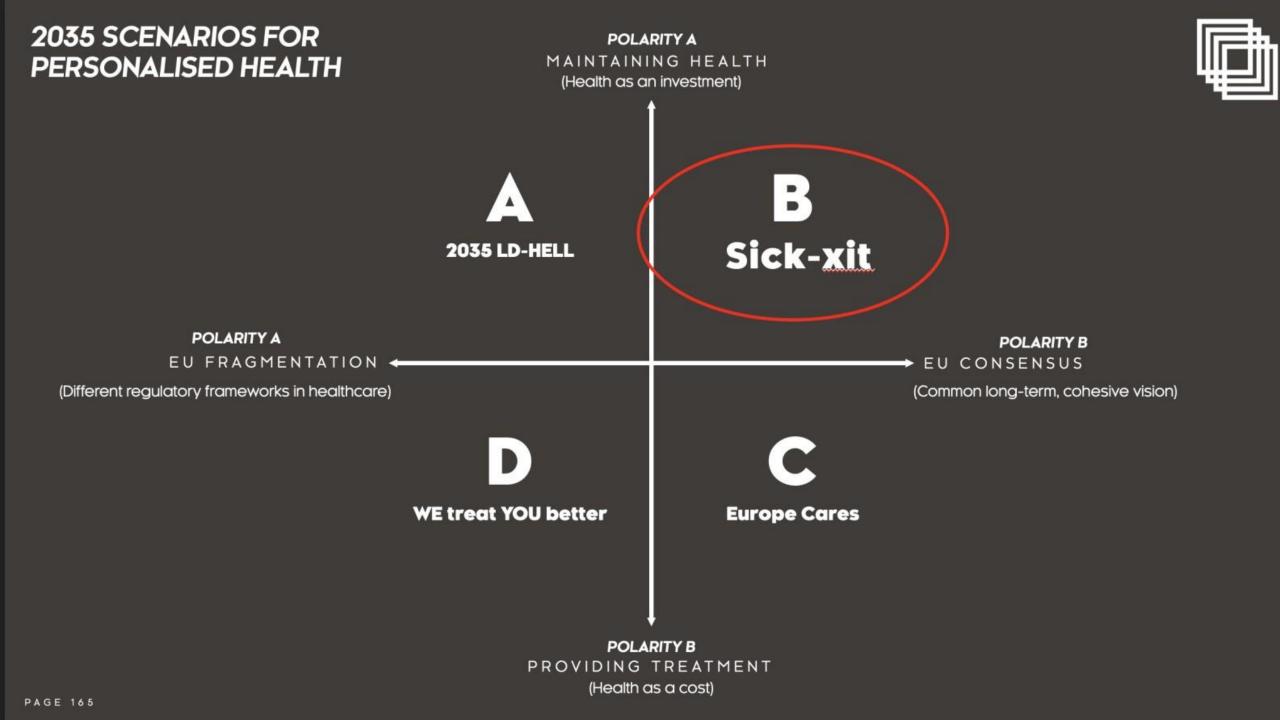








Access & attitudes to data sharing	How protective will society/organisations/governments be about their data? Will data be forfeited or willingly shared or in-between? Is it just health data or other types of data?
Ageing and disease burden	How much focus will be put into NCDs and elderly care? Will there be a focus on palliative care? What will the health landscape look for older people?
Point of care	Where will people go to get healthcare, what will they use? Who will they talk to? How many stages before care starts?
Emerging health technologies	How do you see the influence of AI in the design of future health technologies? What direction will technology go towards?
Role of patients	Will patients have an opinion, or even dictate their healthcare? Consider how patients can be treated as passive recipients of care vs actively engaged in their care, including self-care, self-testing etc.
Workforce	With knowledge expanding, how will education impact the practical aspect of the job? I.e. will the need for constant education take up time? How will professionals stay up-to-date? What roles will grow or become outdated?

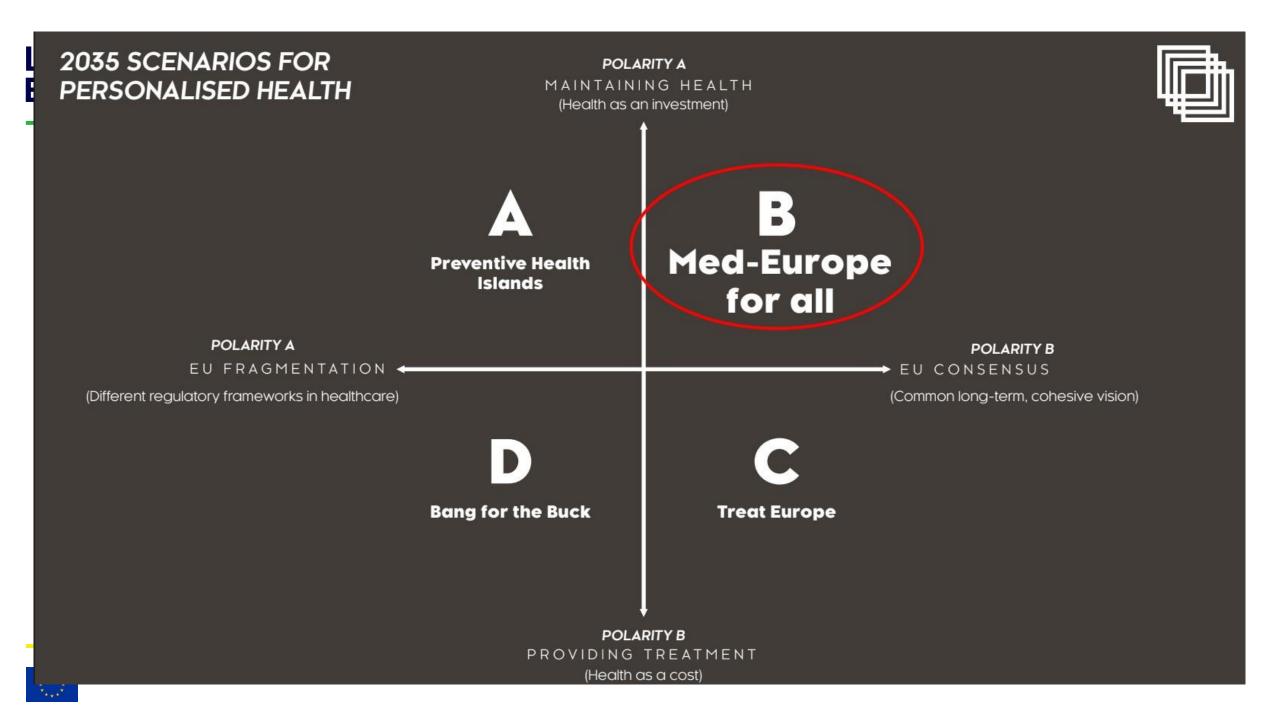




# Sick-xit



Access & attitudes to data sharing	<ul> <li>Not protective</li> <li>Regulation doesn't limit</li> </ul>	Technical data has the same syntax and readability	We need data ab. • Purchases • Movement • Basic life data	
Ageing and disease burden	High focus on prevention of NCDs	Mandatory end of life declaration	Elderly receive most of generated interventions	Palliative care "keep it simple" in collaboration with patients
Point of care	EU insurance covers preventive problems	General screening Stages: 1-3 disease strategy dependent		
Emerging health technologies	Digital health check-ups	Personalised health with prevention orientations	Data analysis for city planning	
Role of patients	Patient opinion likely to be sceptical	Incentive system	Data analysis for city planning	Maintaining health -active Active treatments -passive
Workforce	Higher emphasis on motivational strategies	Less sub-specialities	Even reduced need for constant education	More public educators





# Med-Europe for all



Access & attitudes to data sharing	Data protection	Privacy	Interoperability between states	Regulate how to use data	Transparency, no "big brother"	Optional XX for citizen using XX their data
Ageing and disease burden	Big focus	Big finan proble		Build environment & help elderly	And prevent NCD	Environment that offers and force more physical mobility
Point of care	Specialist	GP	•	Check-up — Centers Europ wide?	0 <b>C</b> -	
Emerging health technologies	Technology will be imple different processes to su avoid mistakes	pport and	Al systems	Intelligent hor hospite		
Role of patients	Patient education	XX				
Workforce	OII <-> Doctor	XX		Robotic surger	Y Radio	ology -> Ol i

## BACKCASTING



#### WHAT

Backcasting is an effective way of connecting a given future to the present and identifying what needs to be done to deliver it. If you have identified alternative futures – or a preferred future – e.g. through a scenario process, backcasting can be used to determine the path of events that will make these scenarios come true.

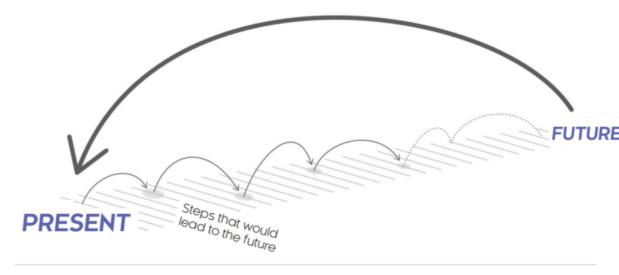
Essentially, a timeline is established in reverse, as you work backwards from the future and identify the key steps, events and decisions that will make it happen. One particular focus of backcasting is to identify what lies within the control of the strategy-makers, and can therefore be managed, and what lies outside their control and therefore needs to be monitored.

Alternatively, backcasting can be used to determine what series of events that could lead to a given undesirable scenario, and what steps could be taken to avoid such a scenario or mitigate its consequences .

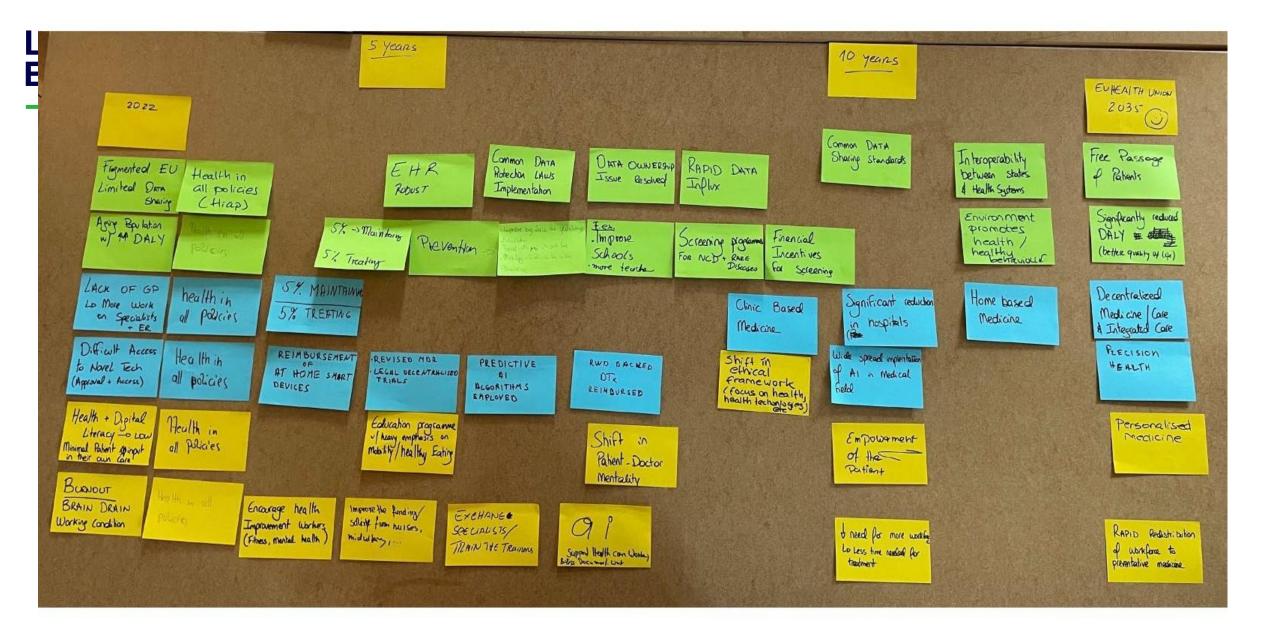
#### WHY

- To connect a given future to the present and identify what needs to be done to deliver it;
- To identify what future events lie within the organisation's control and what events lie outside its control;
- To develop a plan to achieve future success with prioritised steps, creating a realistic picture of the scale of the task ahead and building a shared purpose.













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Plenary Session I: Recent developments and inspiration

Patient /citizen / carer and Healthcare professional advisory board/group thoughts and feelings in the preferred future

Gozde Susuzlu Briggs

Antanas Montvila



# LABEL2 User Advisory Group input and perspective on digital health labelling in the next decade







"During the post pandemic period, patients might feel isolated and disconnected from everything around them. This is why digital health applications should be compared to a compass. When patients are facing challenges in terms of navigating the health care apps, these applications should be a reliable guide, helping them to find the right way to medical information, treatment options and health care providers. As a compass, digital health applications should provide users with accurate information and personalized guidance."

"This picture is about focusing, giving clarity to something that is blurry and unclear. If you are looking through a lens or a magnifying glass, you can see a bigger landscape. Therefore, a digital health label should bring clarity and help patients to clear up misunderstandings."







"An island in the dessert – means that in a world where health care resources are difficult to access, health care applications provide essential information and support at a touch of a bottom.

Just as an oasis that offers relief and sustenance to a traveler, digital health applications offer a vital lifeline to patients seeking medical advice, monitoring and management of their health condition."







"As a signposting and the information found on a highway road sign, the label should help patients to identify the route and show them the right way to go."

"As patients, we should be aware that in general, there are more paths in terms of digital health labelling. Hopefully, this health application gives us information about which way to choose."









"Digital health labelling in the next 5 to 10 years must be about trust. Therefore, a digital health application might help to build trust, credibility and confidence."

"A label can only exist because of digital health. A label should bring simplicity and it must be easy to use. It should give patients a smile. When patients meet doctors or health care professionals who don't know how to encourage them to share information nor give them more understandable information, this can easily lead patients to frustration. Therefore, digital health labelling should give the frustration away. It must be about simplicity, happiness, joy and a general increase of wellbeing. This should be the outcome of the digital label, and this is the reason why we should put patients at first when talking about health care apps."







6/22/2023

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"This picture shows a very active patient. Patients should be embedded in real life, and digital health labelling in the next 10 years should give them more accessibility and visibility."

"Many patients already use health care applications, and they are continuing to use them daily.

For instance, using apps to check blood sugar level makes the process easy and fast to record, monitor blood glucose, and manage diabetes!

This app makes life easier and accessible, and it helps us to understand the meaning of measurement values."









"AI is a hot topic because there are no standards established yet by the regulators. It is a controversial topic and there are lots of biases as regards AI, which can be problematic. However, label makes patients feel more comfortable if they fear AI. Digital health labelling can help health care professionals to focus more on patients instead of spending time on administrative staff. If AI could be replacing the red tape, then health care professionals would have more time to focus on patients. This can also help patients to improve their mental health in the sense that they don't need to look for a therapist in their proximity, but they can choose him from the app."

"We are already surrounded by health apps, but the issue is that some patients are digitally excluded. They don't feel comfortable with using technology. Therefore, we need to educate and make them feel more comfortable about digital health labelling. It means that in the next 10 years, digital health applications should overcome all unmet needs for those who are not digital literates."









"I am skeptical about the fact that digital health labelling can replace our human holistic health care system. This is the reason why we should find a way to promote digital apps but considering the health care professionals as part of the new era.

Despite the digital health labelling, human connection still needs to exist. Therefore, screens should not be replacing doctors and the digital label should contain a disclaimer like this : 'Do not use only digital health application, make sure you stay in touch with your doctor as well!'.

The use of apps and visiting your health care professional should be complementary with each other. "





"Representing choice enabling people to have

digital healthcare that works for their needs"

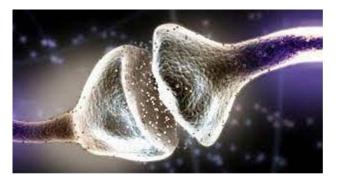


"Representing the label providing a map for

patients to know what to expect from a digital



Healthcare



"Representing connectedness and the ability for healthcare

professionals to gain insights from apps that patients use to help with

	Typical value pe	r 100g 0 30g	serving with 125ml emi skimmed milk
clinical car	ERGY	1606 kJ 379 kcal	733 kJ 173 kcal
	PROTEIN	14 g	9 g
	CARBOHYDRATE of which sugars starch	76 g 17 g 59 g	29 g 11 g 18 g
	FAT of which saturates	1.5 g 0.5 g	2.5 g 1.5 g
	FIBRE	2.5 g	0.8 g
	SODIUM SALT	0.45 g 1.15 g	0.2 g 0.5 g
	VITAMINS: VITAMIN C THIAMIN (B <sub>1</sub> ) RIBOFLAVIN (B <sub>2</sub> ) NIACIN VITAMIN B <sub>6</sub> FOLIC ACID VITAMIN B <sub>12</sub>	(% RDA)           8.3 µg         (167)           134 mg         (167)           1.8 mg         (167)           2.3 mg         (167)           2.4 mg         (167)           2.3 mg         (167)           3.3 µg         (167)           3.4 µg         (167)           3.4 µg         (167)           4.2 µg         (167)	(% RDA) 2.5 µg (50) 42 mg (52) 1 mg (72) 82 mg (51) 0.8 mg (56) 108 µg (54) 1.8 µg (71)
	MINERALS: IRON	11.6 mg (83)	3.5 mg (25)

"Representing labelling being

objective, reliable information which

consumers can expect to be

provided with"





Reducing digital exclusion in rural and remote areas. Better internet access and infrastructure. labels to indicate what can be accessed in low bandwidth areas.



Improvements in digital health literacy. Innovations in place to help people use digital health technologies. Labels to indicate user friendliness and accessibility.



Interoperability within health systems. Better integration and flow of data. Labels to indicate how it connects to other elements of wider systems.



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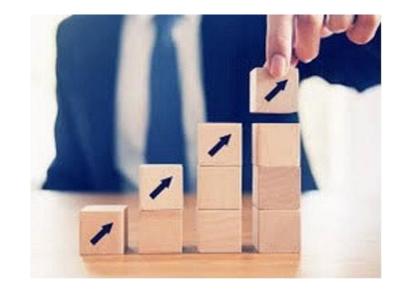
"The future in 5 to 10y will need a significant paradigm change. To get different attitudes and skills – digital thinking and digital skills – from the future health workforce, a radical and emergency change has to happen in medical and healthcare professionals education NOW, these take 5-10y to mature, including those who just graduated. So my feeling is that there IS NO sense of emergency in high level health and educational policy makers, without a FEELING OR URGENCY, no significant change will be visible

in 5 to 10y really, as digital health will only have impactful results if processes and services transformation happens."









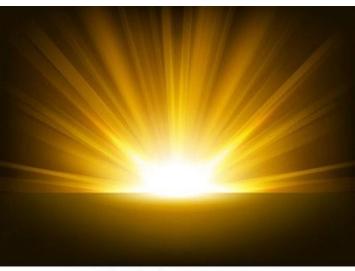


"The outlook about the digital health future is positive. I think it adds to the overall development and bettering of the services, but

on the other hand it is still very much a labyrinth when it comes to understanding the full scope of it."







shutterstock.com · 514502512





"My thoughts and feelings regarding the digital health future: the yellow light at the end of darkness symbolises a new improved era, however there is a slight worry that the "new" might be failed by the current rusted ways with gaps yet unfilled. Digital health future to me is very much like a child yet with many options in their cubicle to chose from and the most important aspect if for it to be protected - hence the firm steal in the last picture"







"Completely digital health future now still appears to sometimes be as fictional as Narnia – other world - where we are still searching for our ways out to return to the deep, truthful contact with our patients. Then on the other hand every day with more and more digital solutions and requirements being introduced seems to be like chasing an acorn – trying to not undermine your actual medical services. And then one sometimes feels like the horse in animal farm – tired, overworked, but working for what seems to be a common bigger

purpose , trying no to fail the society"



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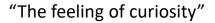


"Fear of over-reliance on technology"

"Dreadfulness of less human interaction"

"Doubt and uncertainty"







"Daily convenience and easier

planning"









"This describes a feeling of serenity and tranquility that this future will bring to my daily work routine as a doctor, by simplifying procedures and offering more quality time for my patients but also for me personally and my family. It also symbolizes the equilibrium between work commitments and personal commitments, which is always an intended goal for all healthcare professionals". "This is supposed to be an all-inclusive resort hotel, which is a metaphor for UHC in this future world of digital transformation. Every patient and citizen will be included in accessing healthcare services but also decision-making".





### **Positive**

- Trust
- Education and Literacy
- .Guidance
- Inclusion
- Better care and work-life balance
- Better access
- Better interoperability

### Negative

- Fear of over-dependency and less human interaction
- Scepticism towards positive impact in explored time frame





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# Thank you for your attention

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antanas.montvila@kaunoklinikos.lt





#### Disclaimer

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them.

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#### Summary for Multistakeholder meeting – June 2023

Healthcare professional survey on recommending health apps *Preliminary findings* Presenter: ieva Biliunaite

The goal of the presentation was to present preliminary findings of the study evaluating healthcare professionals' willingness to recommend apps with and without the CEN-ISO/TS 82304-2 label.

The study was aimed at all healthcare professionals (physicians, nurses, but also mental health professionals, pharmacists, etc.) who were licensed to practice in the EU, Iceland, Liechtenstein, Norway, and Ukraine. All participating healthcare professionals were randomly divided into two groups: one group was informed about the quality label while the other wasn't. Then, healthcare professionals were provided with six short stories describing scenarios in which they could choose to recommend different apps (prevention, self-management, or healthcare) to patients with differing backgrounds (either with low or high socioeconomic backgrounds). After reading each of the stories, healthcare professionals were asked to answer nine questions about their attitude toward recommending apps. At the end of the study, participants were also asked about their demographic characteristics as well their previous experience of recommending apps as well as whether they received patient requests for recommending apps.

We have received a total of 116 responses from healthcare professionals across Europe. Currently, a scientific article is submitted for publication. The article and the full findings will be shared after the article's acceptance for publication.





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Testing the label in four corners of Europe: Denmark, France, Hungary, Italy

### Vania Putatti, Policy Coordinator, EuroHealthNet







**EuroHealthNet** 

The Partnership for Health, Equity and Wellbeing

Help build a sustainable, fair and inclusive Europe

Tackle health inequalities between and within European states









Funded by the European Union



### nd equity



# LABEL2 Digital transformation and equity

Ability to **reach vulnerable groups** and peripherical areas

Enhanced **prevention** models through better population health monitoring

Person-centered approaches

Actively **manage personal health** and care

Better (self-)observance of healthier behaviours

More **efficiency** and sustainability of health systems and improved **affordability** 





# LABEL2 Digital transformation and equity



**Digital divide** exacerbates inequalities, where populations that have poorer health outcomes continue to have poorer health outcomes despite technological improvements

**Unsafe** use of digital technologies, especially in the treatment of sensitive data, can expose people (namely the those more vulnerables) to negative outcomes

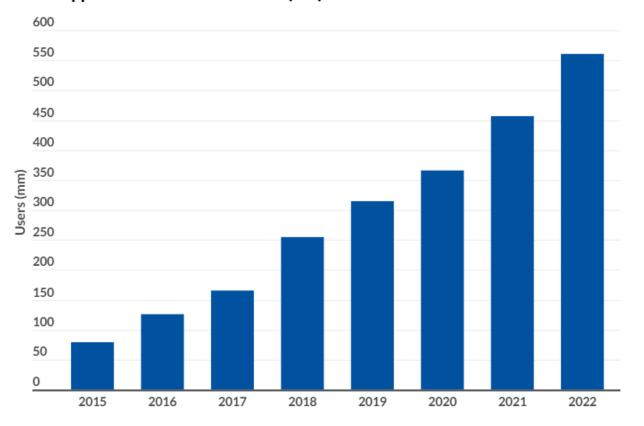
Bias in the development of AI algorithms can result discriminatory outcomes toward underrepresented groups

Quality and affordability represent a substantial barrier in accessing digital technologies



### LABEL2 S Exponential increase in health apps

Health App Annual Users 2015 to 2022 (mm)



Sources: Company data, EU-Startups, BBC, Market Watch, Think with Google



 Over 350,000 health apps in 2022

- 250 new apps released every day
- Health apps 47% of all apps in 2021 (+ 28% from 2015)



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**Title presentation** 





### "People who are most in need of support (in particular, older people and those experiencing social deprivation) are often least likely to engage with digital platforms"

2021, Digital Inverse Care Law in the Time of COVID-19: Potential for Digital Technology to Exacerbate or Mitigate Health Inequalities





Help everyone understanding and assessing the digital health app...

...while addressing equity challenges

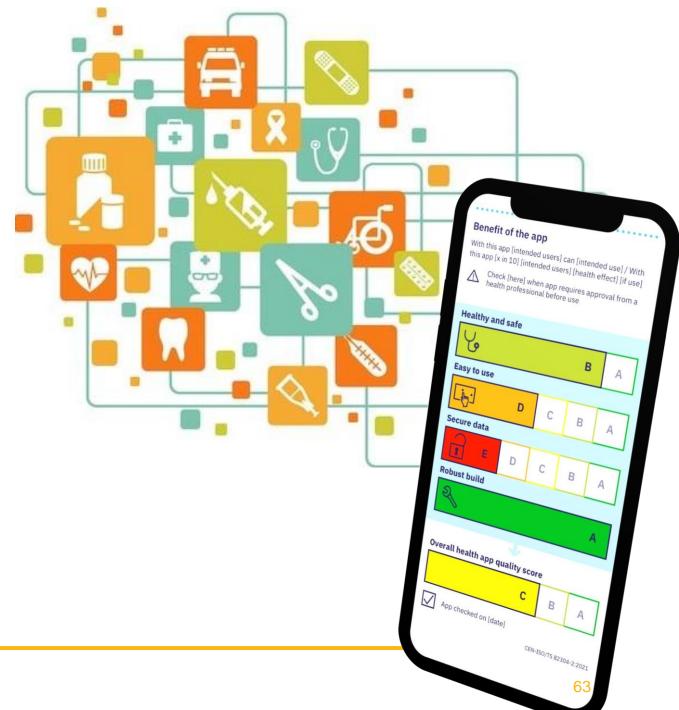




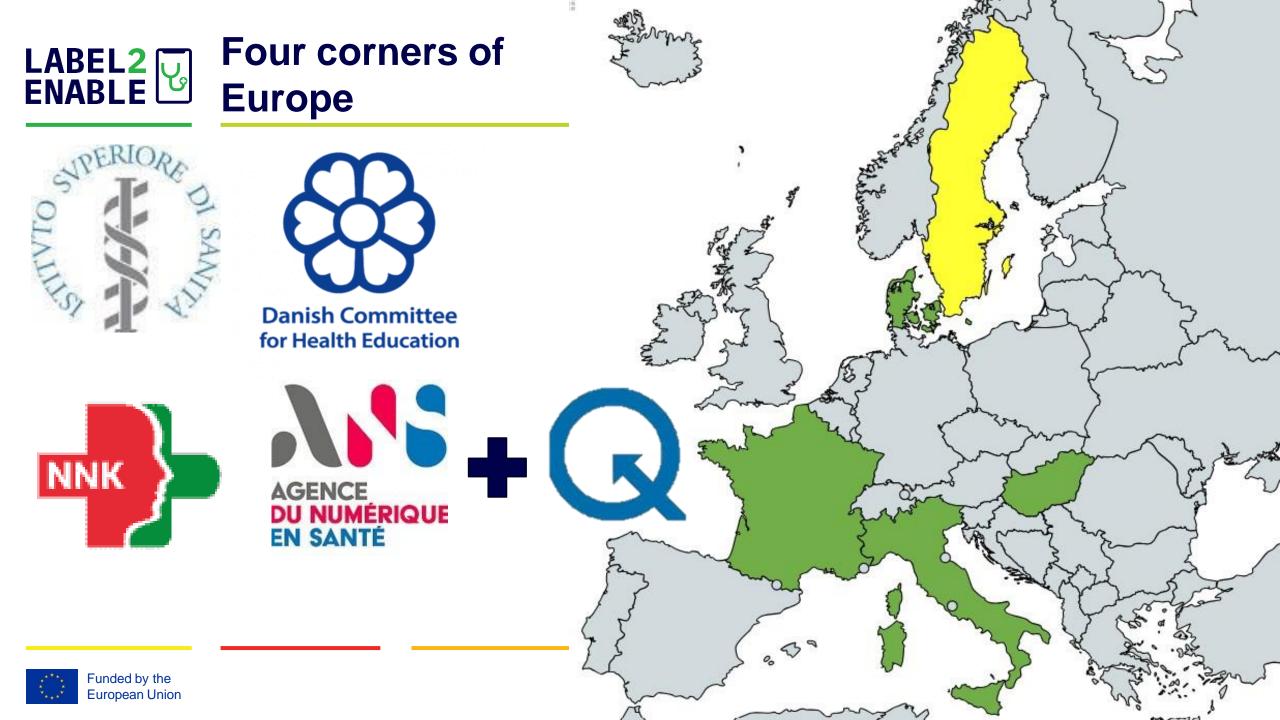


Test with people with low digital health literacy...

...if it works for the most vulnerable, it works for everyone









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label

Funded by



- 5 people with low digital health literacy
- 1.5h per session
- National language
- Fixed methodology







Understandability of the the various elements of the label:

- Text
- Icons
- Colors
- Rating system
- Etc.







- **1.Confusion**: The interviewees expressed confusion, particularly in associating colors with letters
- **2.Need for clarity**: The questions posed in the interviews were perceived as unclear, contributing to the participants' confusion
- **3.Importance of a legend**: The suggestion is made for a legend that explains the colors and their corresponding letter associations
- **4.Lack of awareness about healthcare apps**: The interviewees demonstrated a lack of clarity regarding the usefulness of healthcare apps and the significance of labels









### ...to be continued





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.

## Thank you

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