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.

Roundtable on reimbursement and payment of health apps

Tatjana Trupec and Petra Hoogendoorn

Funded by the European Union

Agenda – 3rd Roundtable on reimbursement of health apps

Part 1. Introduction 09:30 –10:20

a. Label2Enable (and) recommendations on the reimbursement of health apps - **Petra Hoogendoorn, Leiden University Medical Center (LUMC)**
b. Strengthening health systems by recommending and prescribing health apps in PHC – **Antoni Dedeu, Senior Advisor in Integrated Primary Health Care, WHO Europe**
c. Towards the European Health Data Space – **Ole Gjerrestad, Policy officer DG SANTE**
d. What is the role of EU level legislation in the pathway to health and wellness apps reimbursement – **Petra Wilson, HIMSS *Break 5min***

Part 2. Decision-makers' perspectives on the reimbursement of health apps 10:25 – 11:15

a. Humber and North Yorkshire (ORCHA) – **Carrie Cranston, Digital Programme Manager, NHS Humber and North Yorkshire Integrated Care System**
b. Croatia – **Siniša Varga, former Minister of Health and former Director of the National Health Insurance Fund in Croatia**
c. Catalonia – **Jordi Piera Jiménez, Director of the Digital Health Strategy Office at the Catalan Health Service**
d. Portugal – **Henrique Martins, Professor, ex. President of the Board of eHealth authority Ministry of Health Portugal**

Part 3. Discussion 11:15 – 12:30

a. Discussion: Recommendations on the reimbursement of citizen / patient-facing health apps – **Tatjana Prenđa Trupec moderating**
b. Conclusion of all 3 roundtables – **Petra Hoogendoorn, Leiden University Medical Center (LUMC)**

Part 1. Introduction

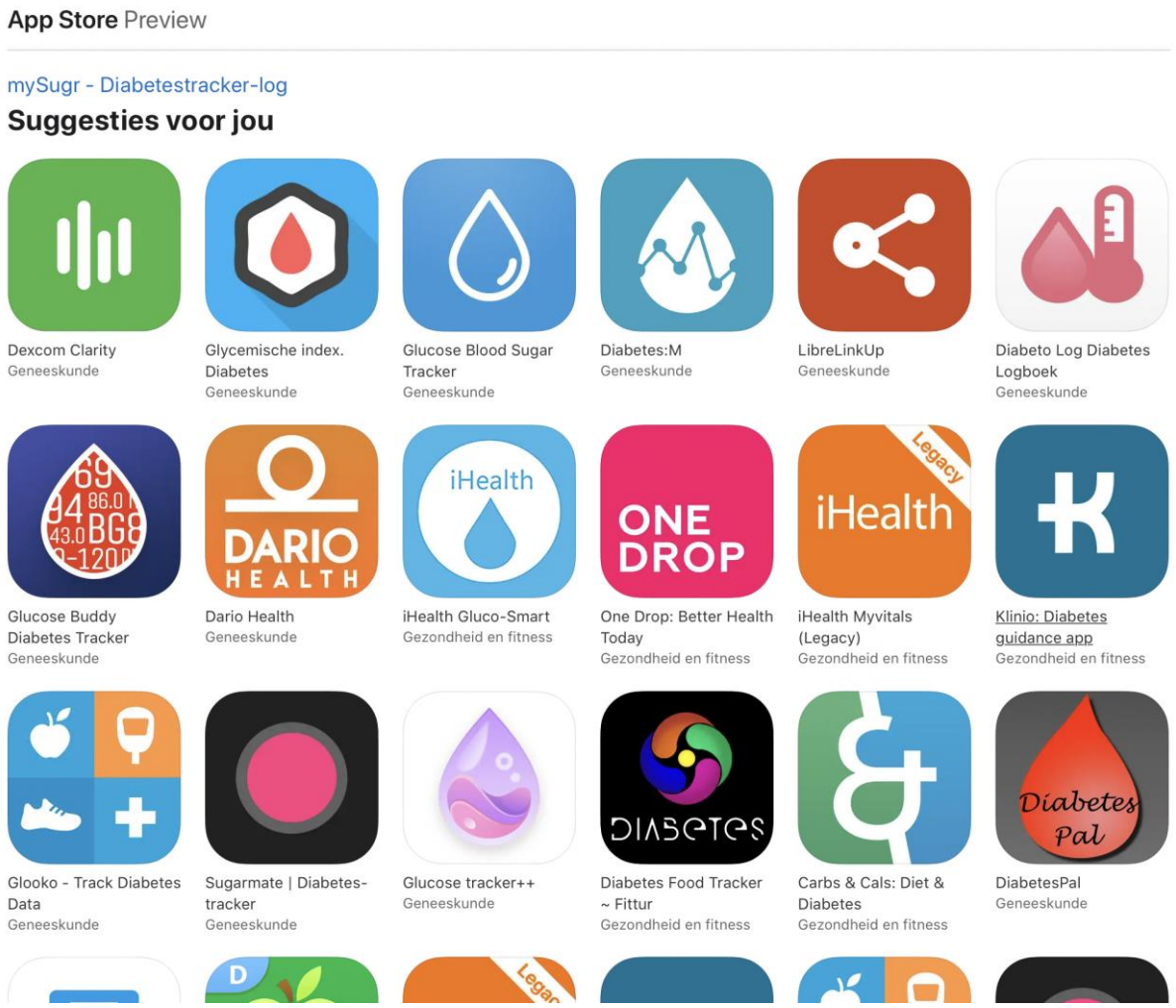
a. Label2Enable (and) recommendations on the reimbursement of health apps
b. Strengthening health systems by recommending and prescribing health apps in PHC
c. Towards the European Health Data Space
d. What is the role of EU level legislation in the pathway to health and wellness apps reimbursement

Funded by the European Union

a. Label2Enable (and) recommendations on the reimbursement of health apps

3rd roundtable on reimbursement and payment of patient / citizen-facing health apps – February 13, 2024

how to distinguish a ‘good’ health app?



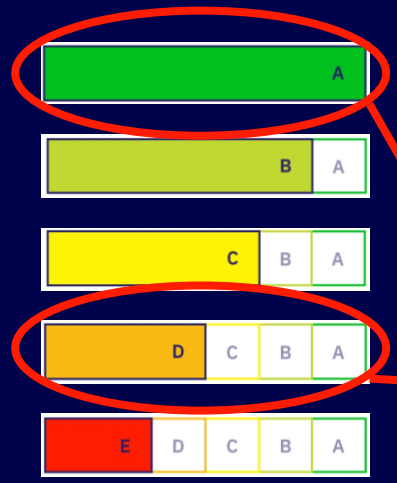
Wyatt (2018) How can clinicians, specialty societies, and others evaluate and improve the quality of apps for patient use?
Larsen et al (2019) Using science to sell apps: Evaluation of mental health app store quality claims
Singh et al (2016) Many health apps target high-need, high-cost populations, but gaps remain

the context: EU policy

- 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**

LABEL2ENABLE

‘the EU Energy label but then for health 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 — A

Easy to use — A

Secure data — A

Robust build — C B A

Overall health app quality score — A

App checked on [date]

CEN-ISO/TS 82304-2:2021

Zászló vagy logó — **Egészségügyi alkalmazás minőségi címke**

Alkalmazás ikon — **Alkalmazás neve**

Platform ikonok

Alkalmazás gyártójának neve

Az alkalmazás előnyei

Ezzel az alkalmazással [célzott felhasználók] [tervezett felhasználás] / Ezzel az alkalmazással [x 10-ből] [célzott 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

Drapeau ou logo — **Label qualité pour appli de santé**

Icône de l’appli — **Nom 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

Bandiera o logo — **Marchio di qualità dell'app per la salute**

Icona dell'app — **Nome 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

Flag eller logo — **Sundhedsapp kvalitetsmærke**

App ikon — **App navn**

Platformsikoner

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

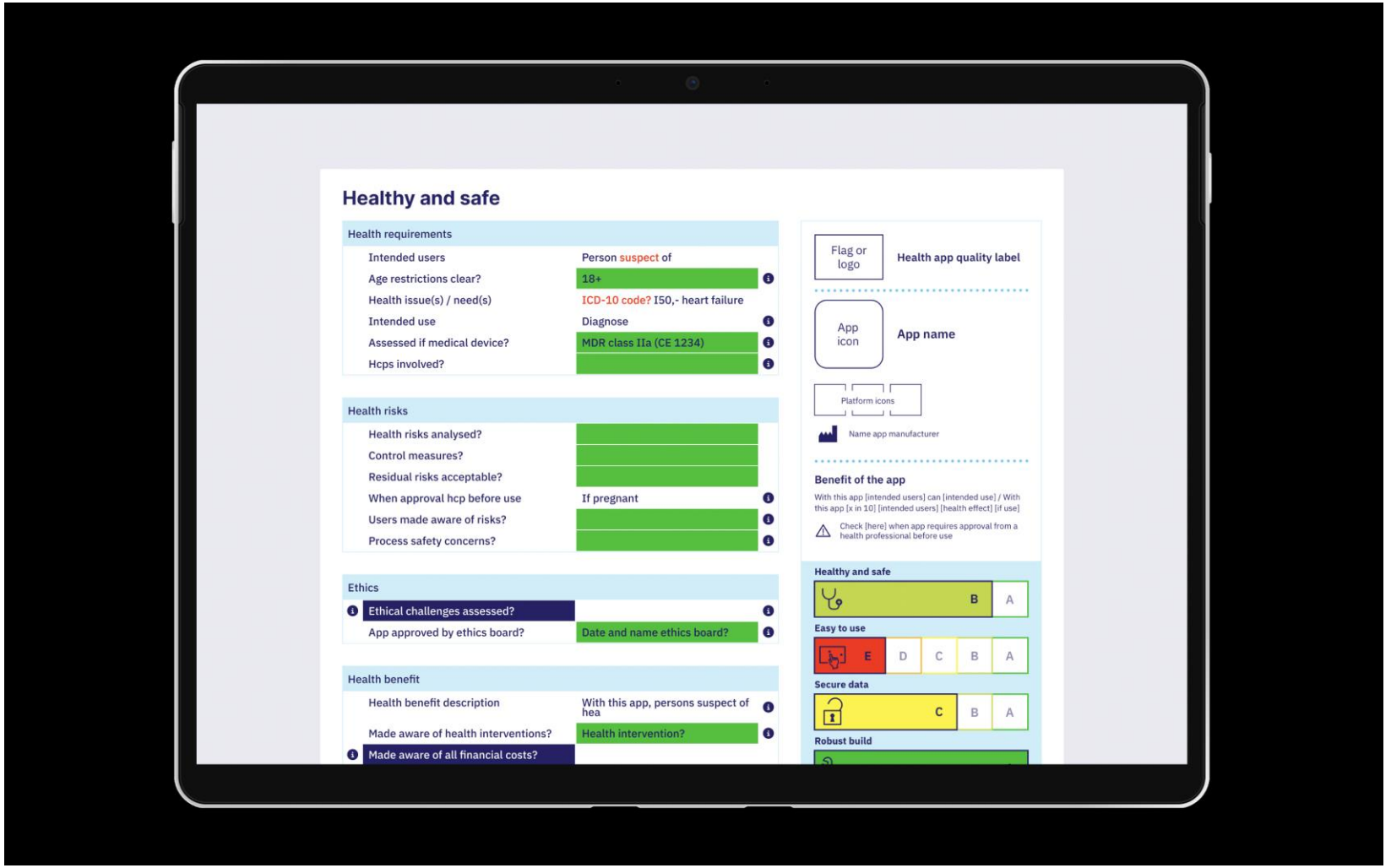
Samlet kvalitetsscore for sundhedsapp — E D C B A

App tjekket den [dato]

CEN-ISO/TS 82304-2:2021

Funded by the European Union

health app quality report – first draft



EU Energy score

5 jaar garantie

(91)

Siemens WM14N295NL iQ300 extraKlasse wasmachine

577,- Adviesprijs ~~759,-~~

✓ Op voorraad

A G C

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

☐ Vergelijk product

Ariel Allin1 PODS cadeau

(1)

Whirlpool FFDBE 9638 BCEV F wasmachine

497,- Adviesprijs ~~629,-~~

✓ Op voorraad

A G D

- 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

A G A

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

☐ Vergelijk product

Black Friday Deal

Miele WED 174 WPS wasmachine

1.379,-

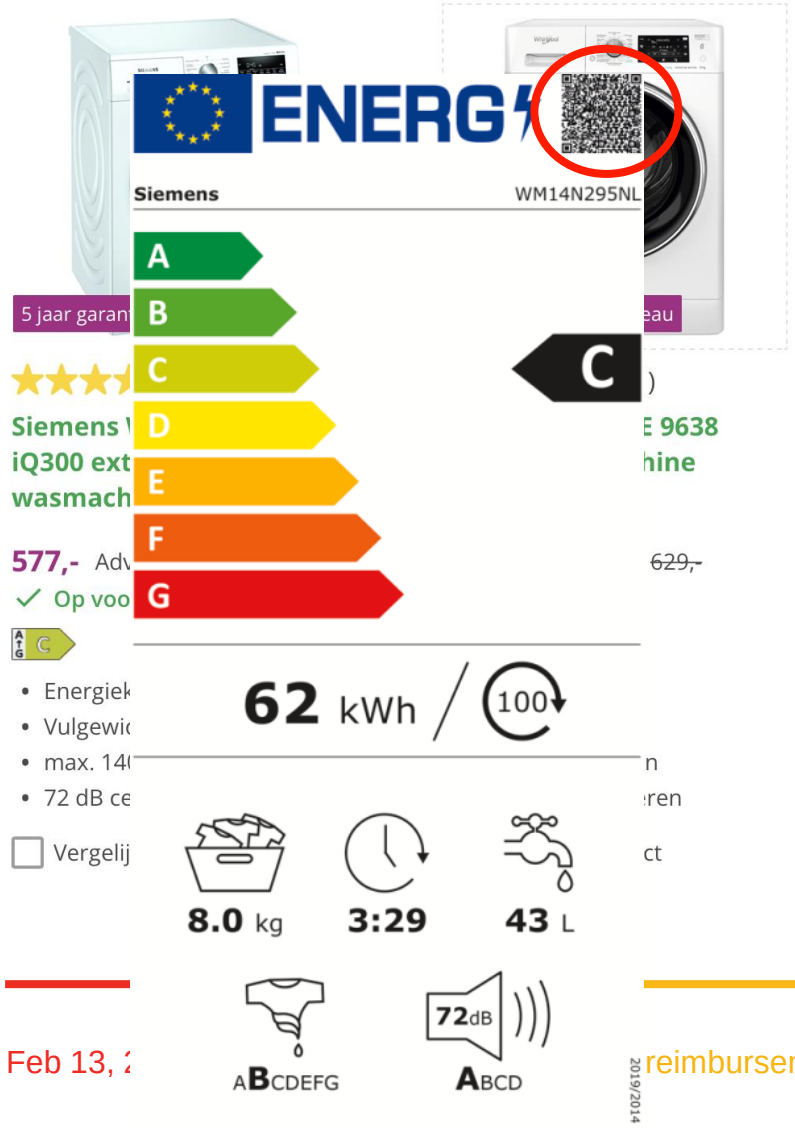
✓ Op voorraad

A G A

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

☐ Vergelijk product

EU Energy label



5 jaar garan

Siemens
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Op voo

- Energiek
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Vergelijk product

Funded by the European Union

EU Energy product information sheet

An official website of the European Union How do you know?

European Commission

English

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

C (A↑G)

8 Kg

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
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

ENERG

Siemens WM14N295NL

A B C D E F G

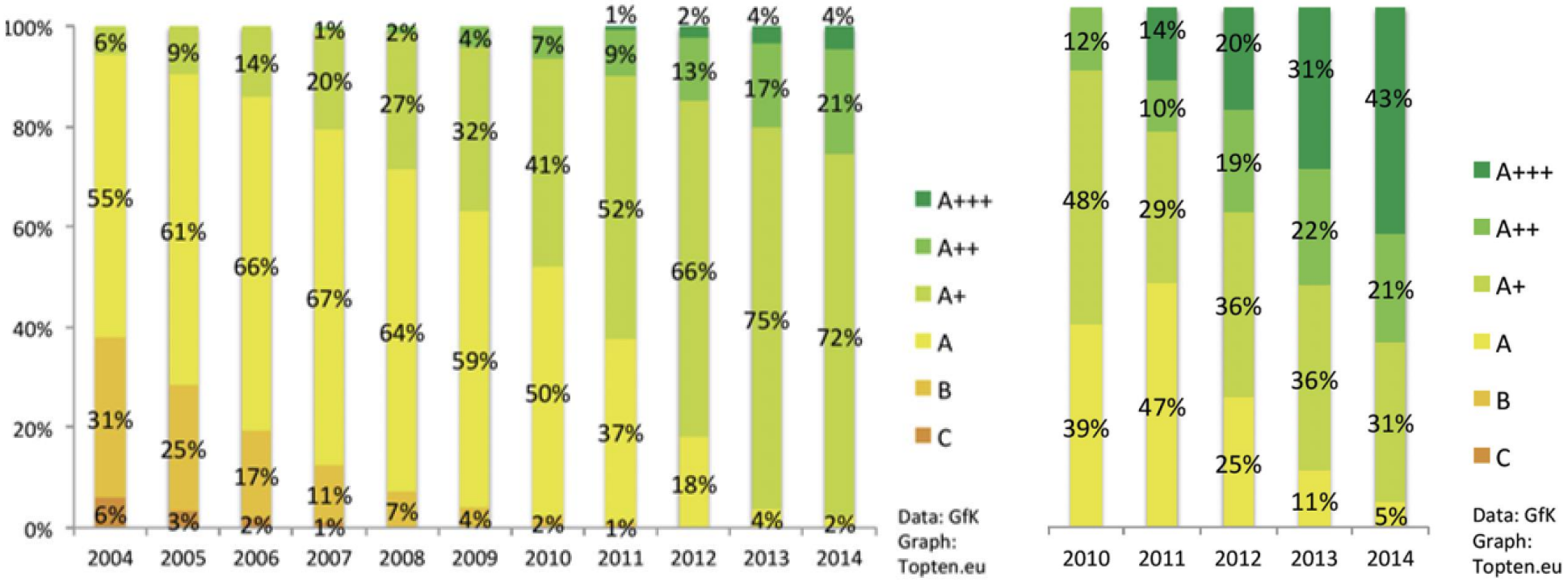
C

62 kWh / 100

8,0 kg 3:29 43 L

72 dB

EU Energy label: drives quality improvement



refrigerator sales

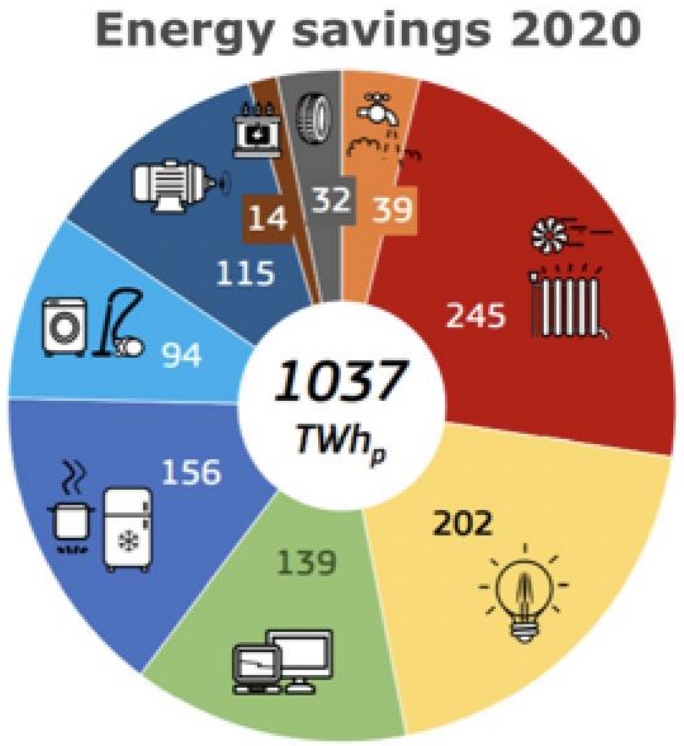
washing machine sales

EU Energy label: creates multi-stakeholder impact

Impacts estimates (2020 vs BaU)

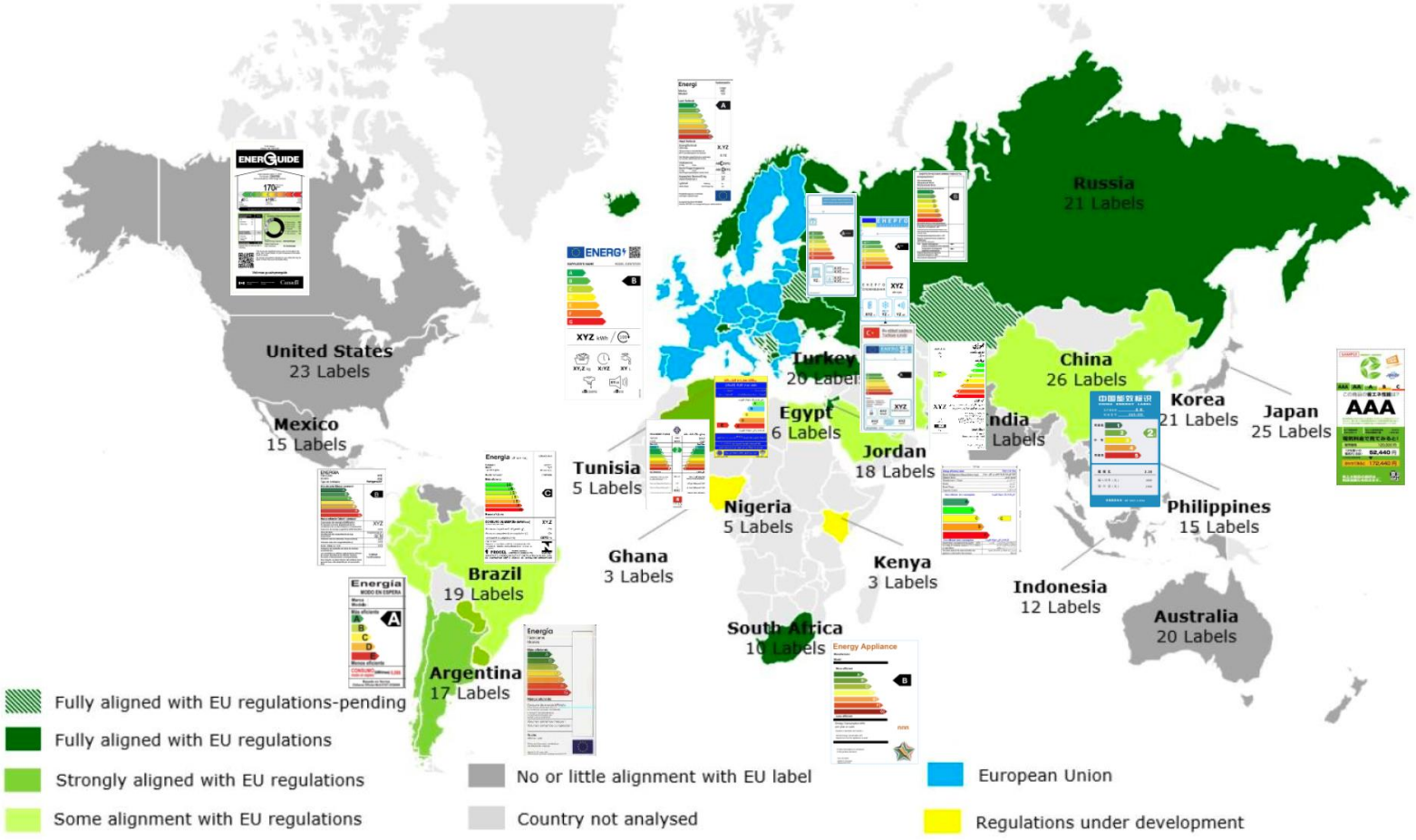
- **1037TWh** primary energy ≅ 7% of total EU 27 primary energy demand
- Electricity: ca. **1000 kWh**/household (27%) ≅ total EU wind production
- **€60 billion/y** in consumer expenditure (€ 210/household) based on pre-2021 energy price estimates
- Additional **business revenue 21 billion** euros and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

Source: Ecodesign Impact Accounting 2020

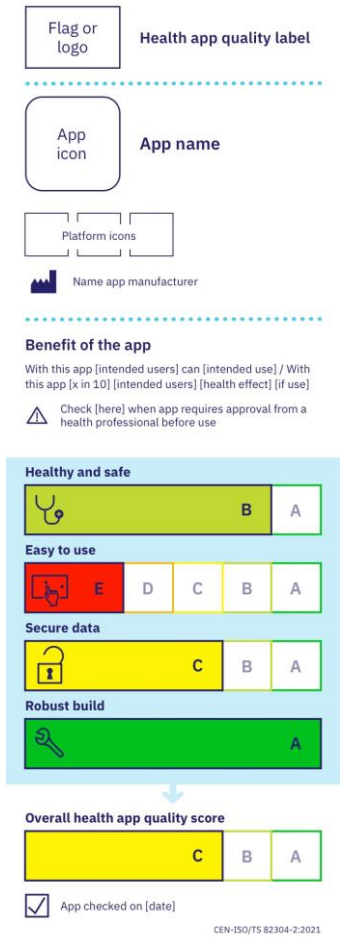


European Commission

EU Energy label: beyond the EU



ISO/TS 82304-2 helps choose, deliver and review apps



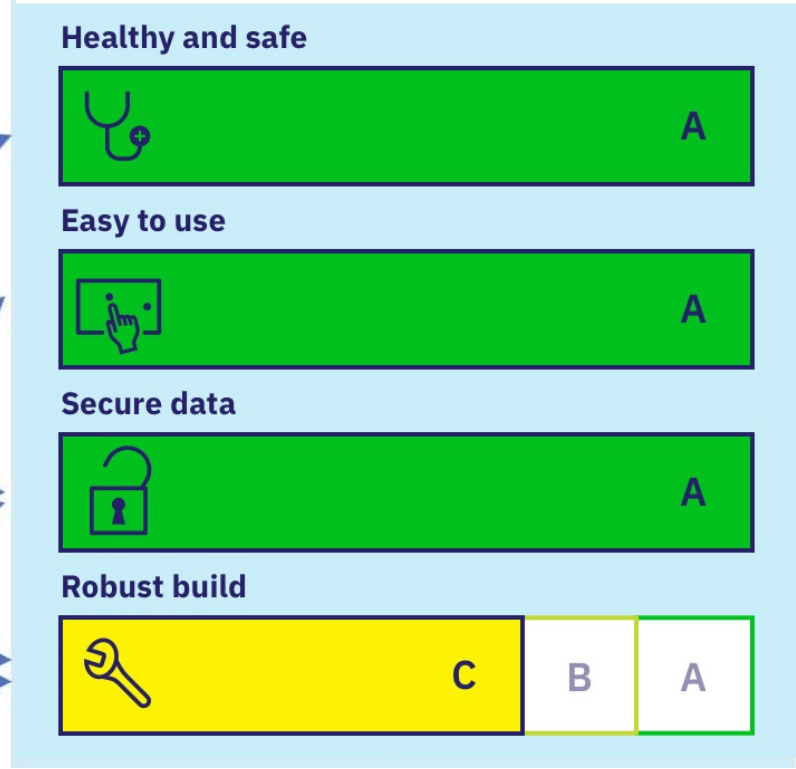
Comprehensive	For wellness and medical device apps, not duplicating the work of notified bodies
Evidence-informed	Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries
Inclusive	Label tested with people with low health literacy
Informative	Score, label and report communicate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

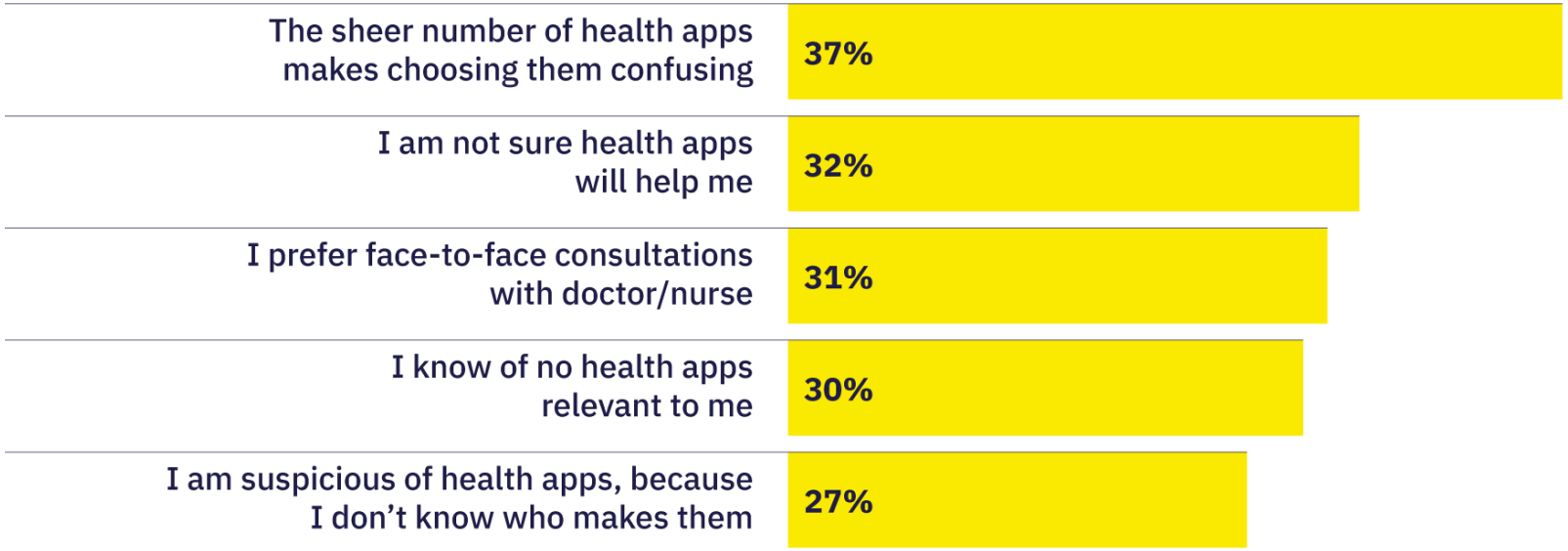
Funded by the European Union

EHDS – alignment Annex II

Annex II
1. General requirements
1.1. achieve the performance intended by its manufacturer and designed and manufactured such that, during normal conditions of use, it is suitable for its intended purpose and its use does not put at risk patient safety.
1.2. designed and developed that it can be supplied and installed, taking into account the instructions and information provided by the manufacturer, without adversely affecting its characteristics and performance during its intended use.
1.3. designed and developed in such a way that its interoperability, safety and security features uphold the rights of natural persons.
1.4. designed and manufactured in such a way that interoperability and compatibility are reliable and secure, and personal electronic health data can be shared with the EHR system.
2. Requirements for interoperability
3. Requirements for security



choosing a 'good' health app is difficult



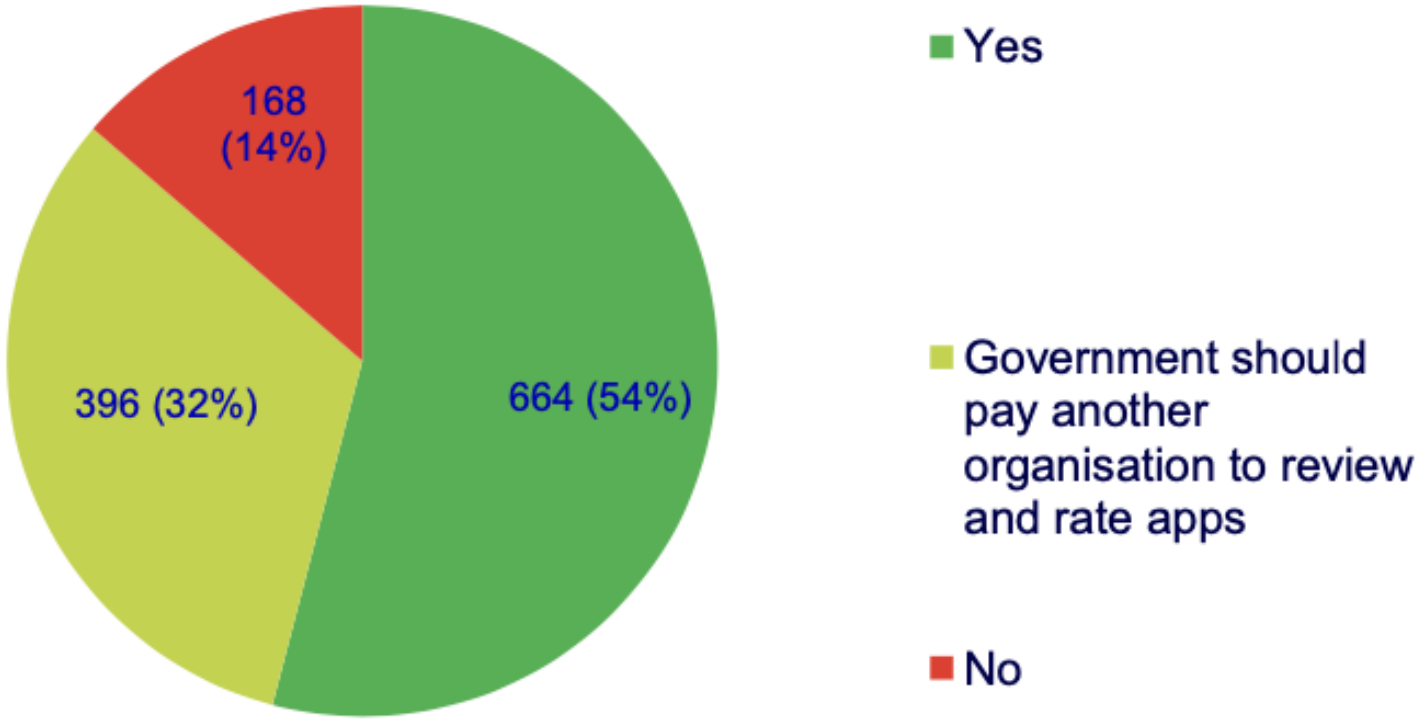
Get-ehealth.eu (2015) What do patients and carers need in health apps – but are not getting? Global survey of 1,120 patients and carers

should the government review and rate health apps?

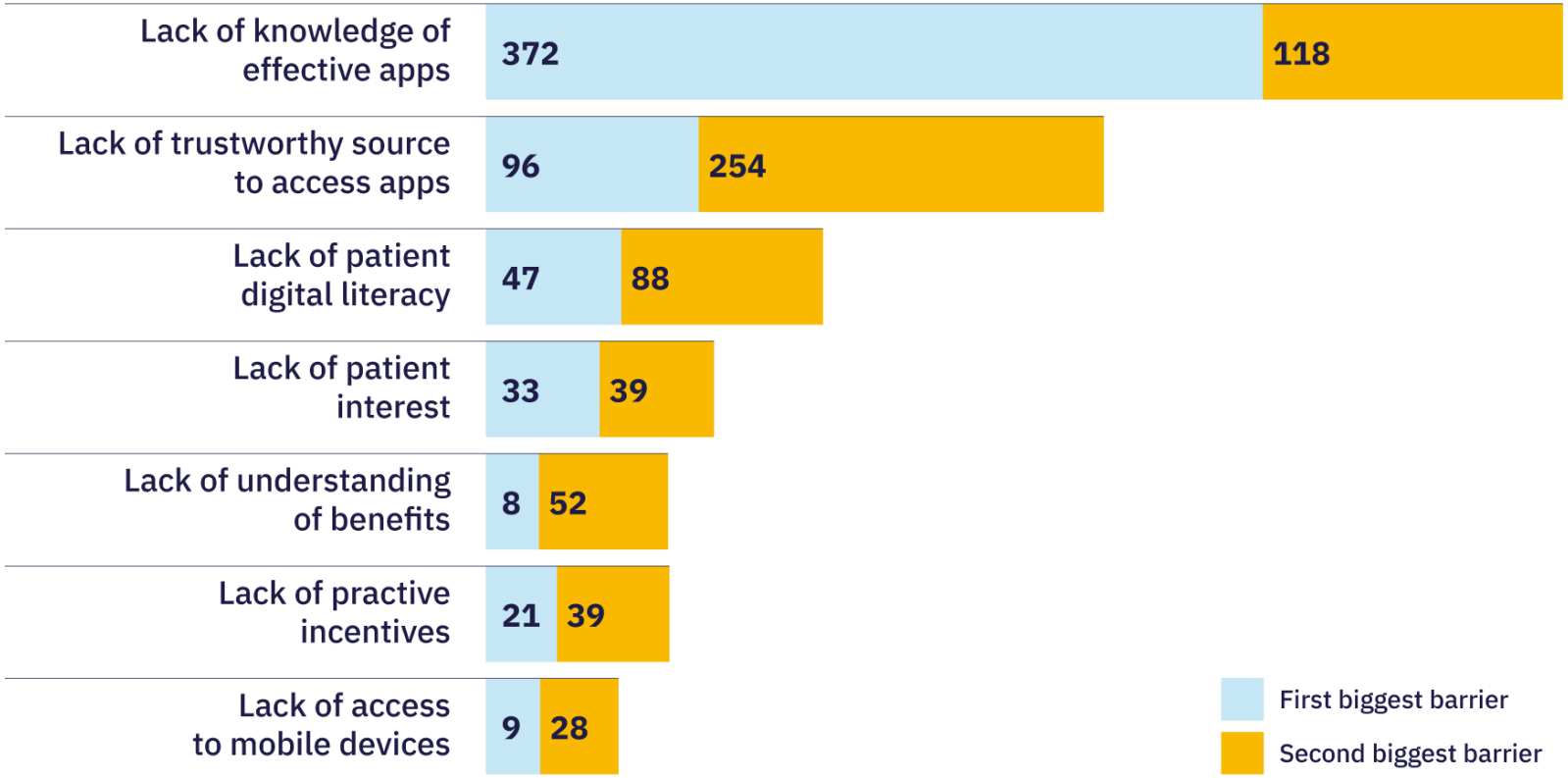
1228

respondents

Do you think the government should review and rate health app quality to help you choose a health app?



choosing a 'good' health app is difficult

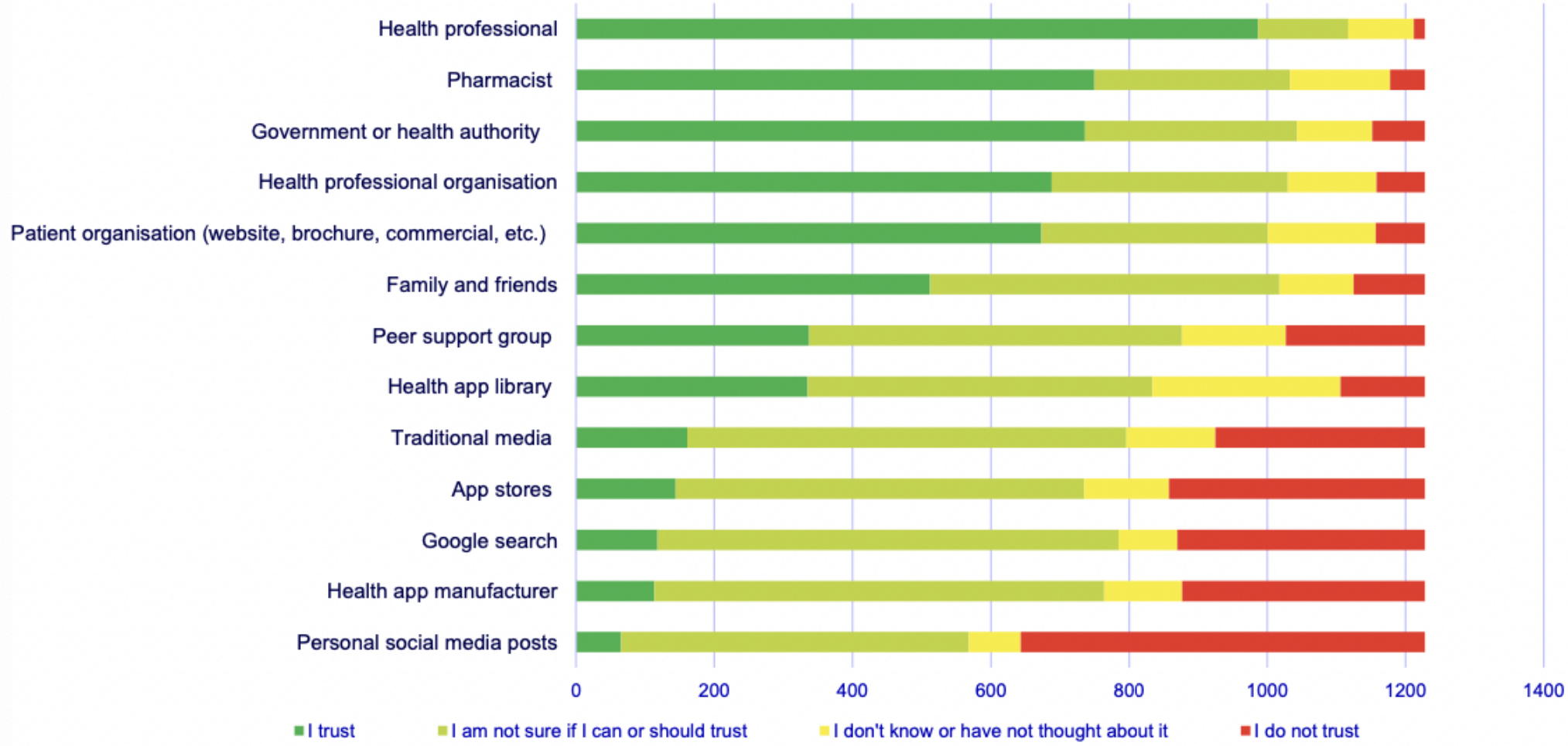


Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study

trusted advice to choose a health app

1228

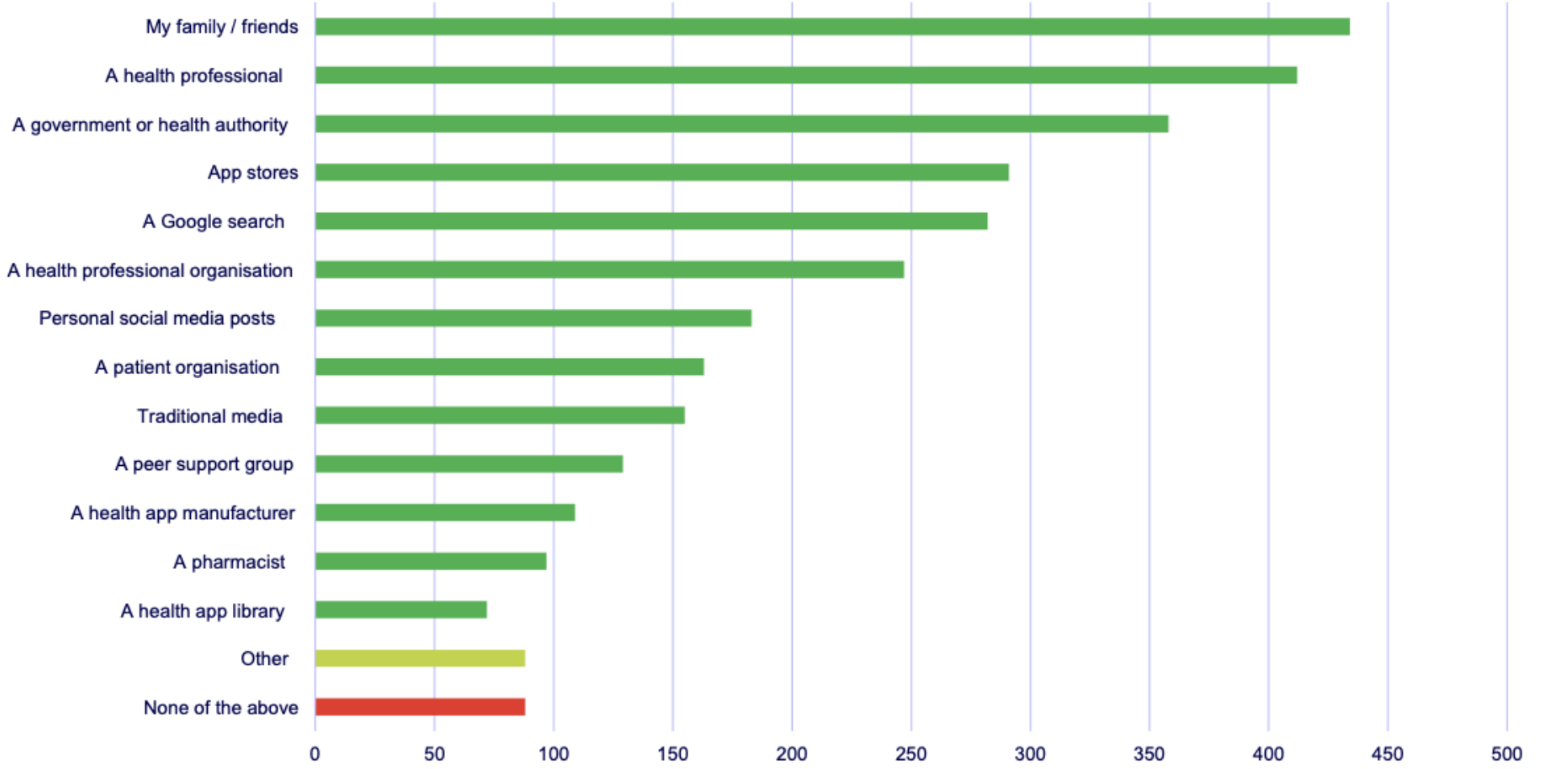
respondents



used advice to choose a health app

1228

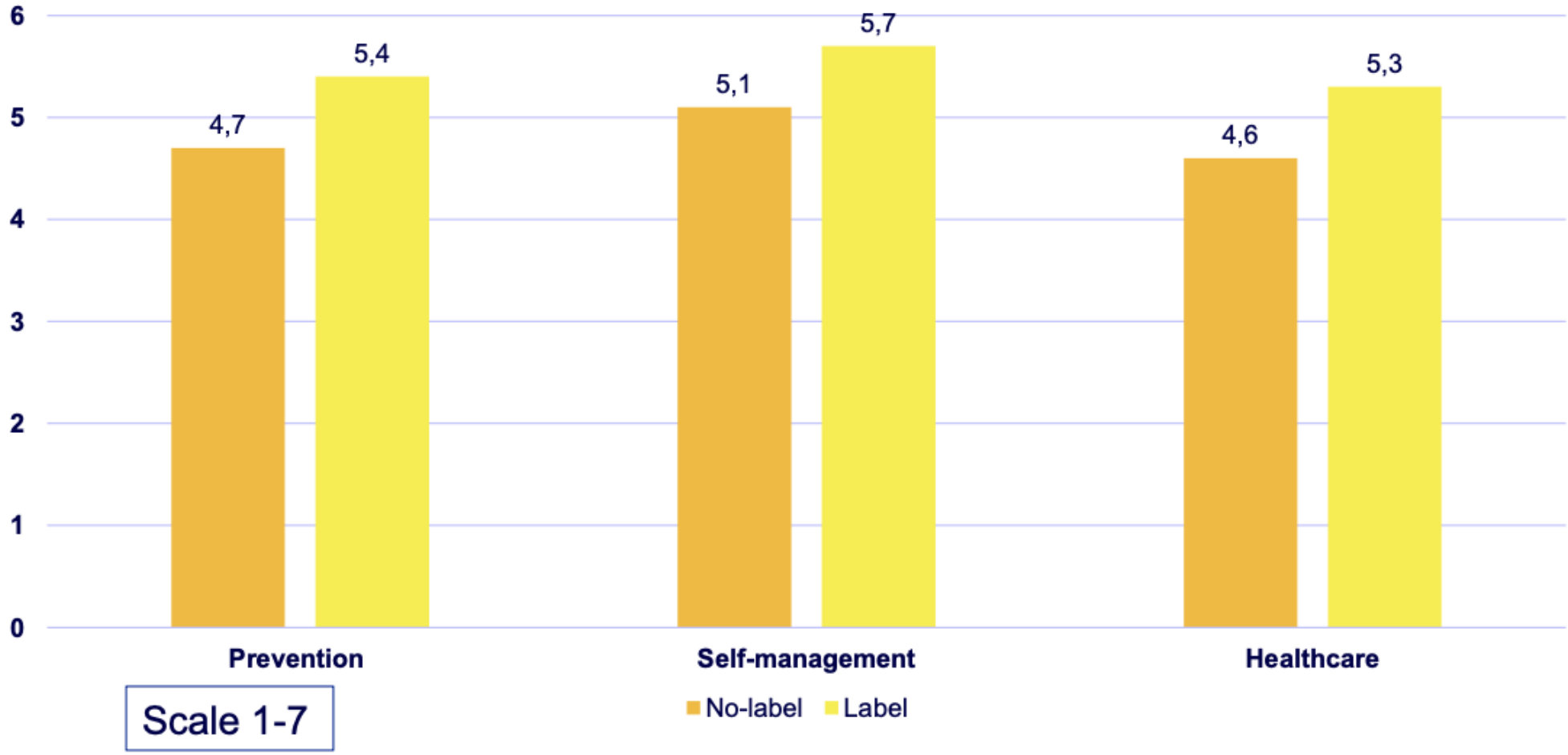
respondents



hcp willingness to recommend health apps

118

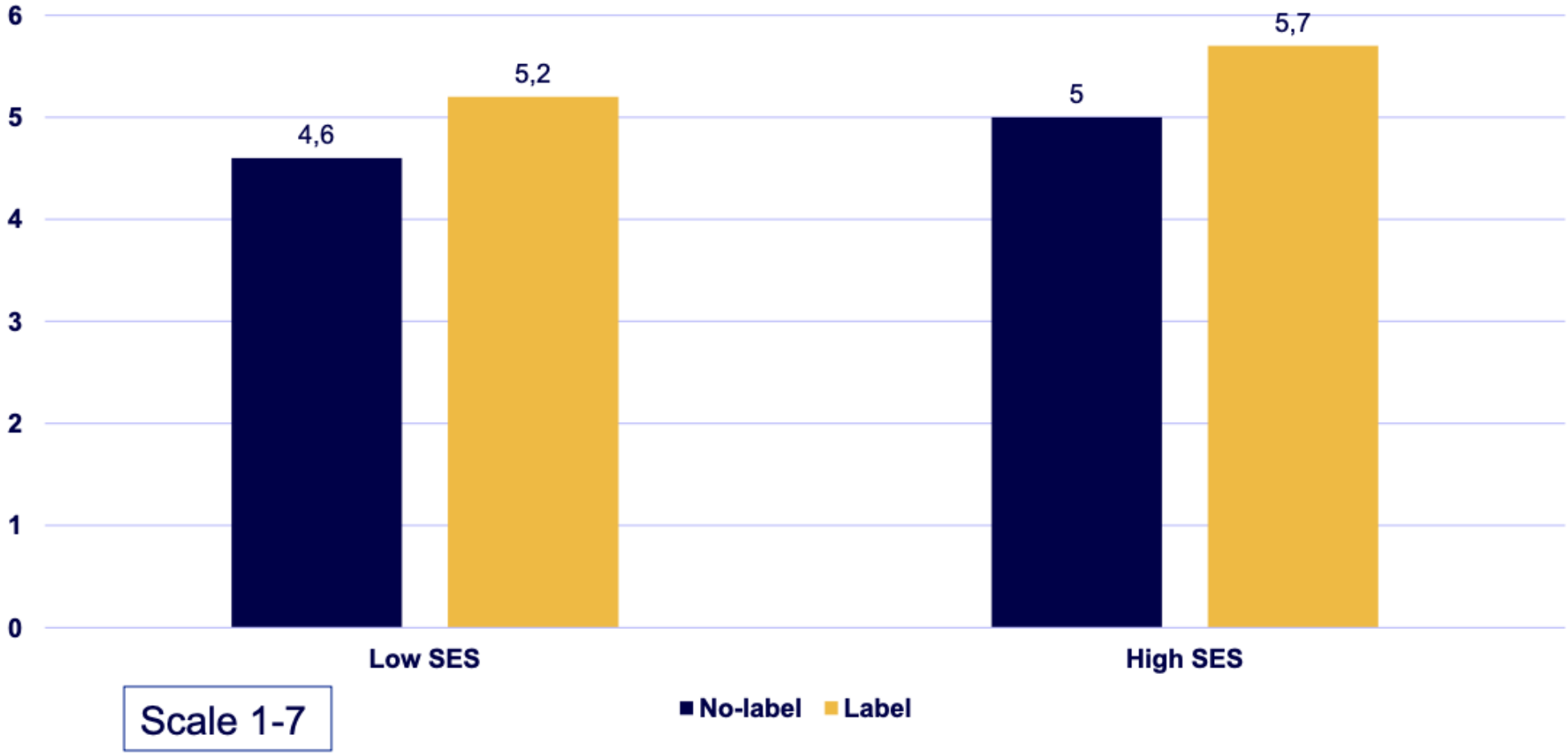
respondents



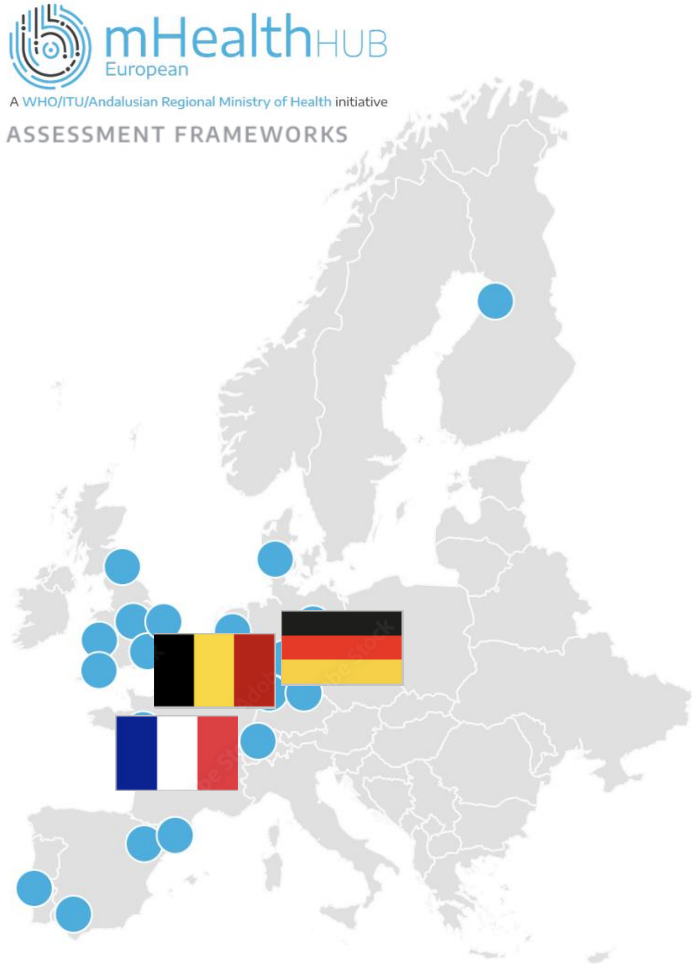
hcp willingness to recommend health apps

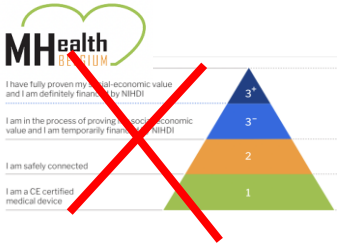
118

respondents

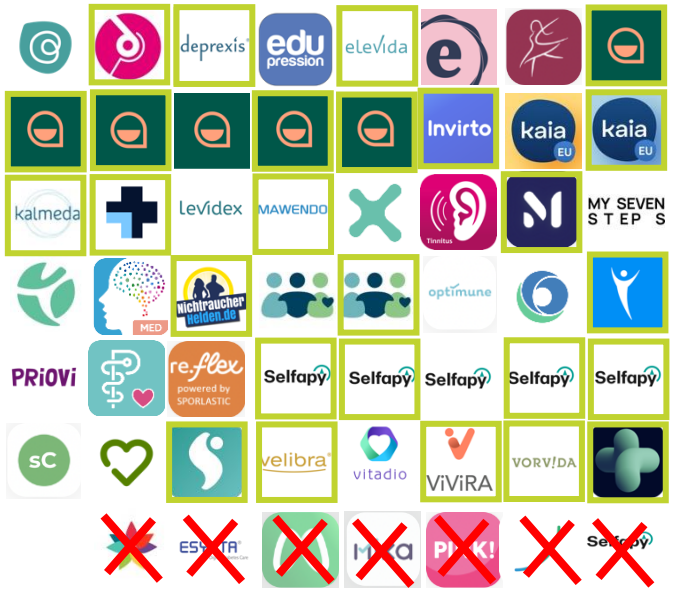


delivering a ‘good’ health app is difficult

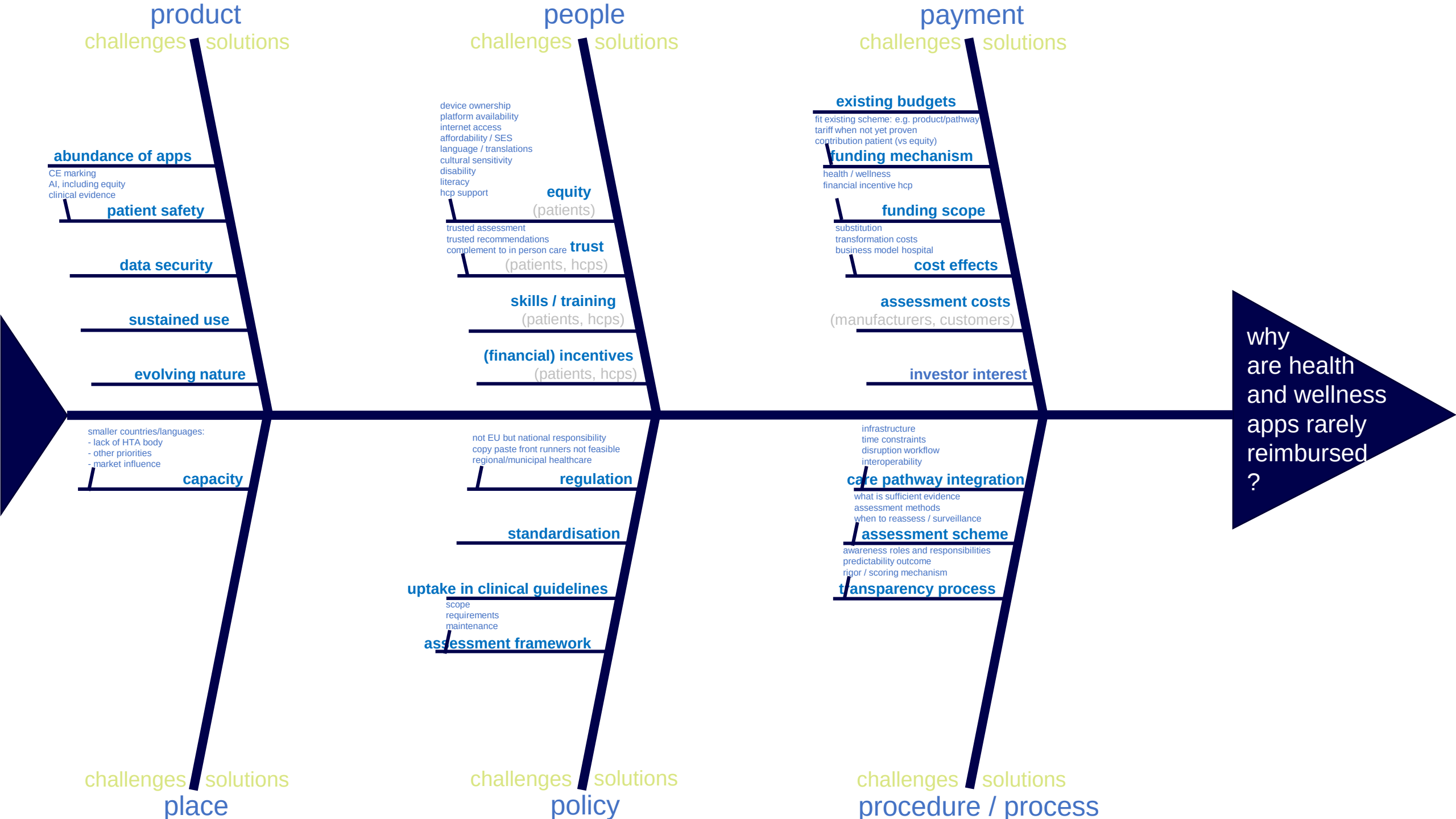




Early access to reimbursement for digital devices (PECAN)



mHealth Hub (2022) Health App Assessment Frameworks


product
challenges solutions
abundance of apps
CE marking
AI, including equity
clinical evidence
patient safety
data security
sustained use
evolving nature
challenges solutions
place
smaller countries/languages:
- lack of HTA body
- other priorities
- market influence
capacity
people
challenges solutions
device ownership
platform availability
internet access
affordability / SES
language / translations
cultural sensitivity
disability
literacy
hcp support
equity
(patients)
trusted assessment
trusted recommendations
complement to in person care
trust
(patients, hcps)
skills / training
(patients, hcps)
(financial) incentives
(patients, hcps)
challenges solutions
policy
not EU but national responsibility
copy paste front runners not feasible
regional/municipal healthcare
regulation
standardisation
uptake in clinical guidelines
scope
requirements
maintenance
assessment framework
payment
challenges solutions
existing budgets
fit existing scheme: e.g. product/pathway
tariff when not yet proven
contribution patient (vs equity)
funding mechanism
health / wellness
financial incentive hcp
funding scope
substitution
transformation costs
business model hospital
cost effects
assessment costs
(manufacturers, customers)
investor interest
challenges solutions
procedure / process
infrastructure
time constraints
disruption workflow
interoperability
care pathway integration
what is sufficient evidence
assessment methods
when to reassess / surveillance
assessment scheme
awareness roles and responsibilities
predictability outcome
rigor / scoring mechanism
transparency process
why
are health
and wellness
apps rarely
reimbursed
?

draft recommendations for reimbursement of apps

1. **Govern** – Establish governance: who within the health authority is responsible for exploring and decision-making on assessment and reimbursement of health apps?
2. **Value** - Acknowledge ap**ps can do things that pills can't and vice versa**. Both in their own way potentially contribute to health, wellbeing and can impact citizen, patient, carer and overall burden of the health system. Assess both the positive value and potential adverse effects or risks of apps, whether integrated in hybrid care pathways or not, for your public health and health system, now and in the future. Examples may include advances in prevention, early diagnosis, patient self-management, treatment adherence, health literacy, health professional efficiency, cost-effectiveness, primary and secondary data. Adverse effects, for which assessment can be a mitigation, may span privacy and security, regulatory compliance, user engagement, disparities, and technology lifetimes.
3. **Focus** - Identify types of apps that can deliver this value for specific health issues in which care pathways and if applicable for which types of patients. Evaluate these apps for potential payment or reimbursement in these care pathways.
4. **Assess** – Establish a framework for assessing health apps through internal processes or outsourcing. Consider incorporating a trusted EU framework within your own additional national requirements, creating an accelerated more efficient assessment. Ensure the assessment results are easily accessible, also to patients and citizens (e.g. label in frequently used trusted sources).
5. **Create** - Create the environment in which apps can deliver value. Integrate properly evaluated high-quality health apps in care pathways to maximize their value and facilitate potential substitution or cost reduction. If the value requires a role of a health professional, fund that role. Facilitate and provide incentives for industry to deliver quality products, addressing present and future needs. Ensure that reimbursement rates consider added value, quality, societal benefits, investments needed to acquire the indicated evidence, sustained equitable use, seamless integration of app data in EHRs, etc. and enable further investments to meet future demands. Set up the needed infrastructure. Enable interoperability and safe data exchange between EHR systems and patient-facing health apps. Use standards.
6. **Fund** – Foster reimbursement of quality apps, making them part of a new normal and accessible to all. Allocate related funds, consider innovative payment models, and explore need for further policies.
7. **Specify** - Recognizing that if you judge an app by its ability to be a pill or vice versa we will believe either one is stupid, explore and communicate appropriate outcome measures and potentially also comparators (standard of care, if possible with an EU perspective, waiting list, other digital / hybrid care) and scope to consider (e.g. wider value of behaviour change and literacy) to capture the true value and thus make adequate decisions on initial and final reimbursement. Consider that beyond individual benefit, apps can progress societal benefit with the data they produce for secondary use.
8. **Enable** – Promote the education of health care professionals (medical school, post-graduate, Massive Open Online Courses, also by professional societies and manufacturers). This education should include how to analyse app data to safely capture the value of data in primary use and ultimately secondary use. Educate citizens and patients on benefits and risks associated with health apps and how to recognise trusted sources.
9. **Support** – Co-create a support role for patients and consumers similar to pharmacists for drugs and consumer organisations for consumer products, alongside efforts from manufacturers to create easy to use apps and of insurers and hcps to require and reward such ease of use. Involve professional societies to provide guidance for health professionals on how to identify apps to recommend and their recommended use, also in relation to other health interventions. Integrate this guidance in regular clinical guidelines.
10. **Measure** –Measure value transparently. Publish reports and explore what else needs to be arranged to capture the attainable value of health apps. Enable and incentivise such results. Realise that without quality apps, integrated in care pathways, users trained and resulting data being used, adequate outcome measures and ditto scope, etc. the measurements do not reflect attainable value.

reviewing a health app is difficult too

npj | digital medicine

Health app policy:

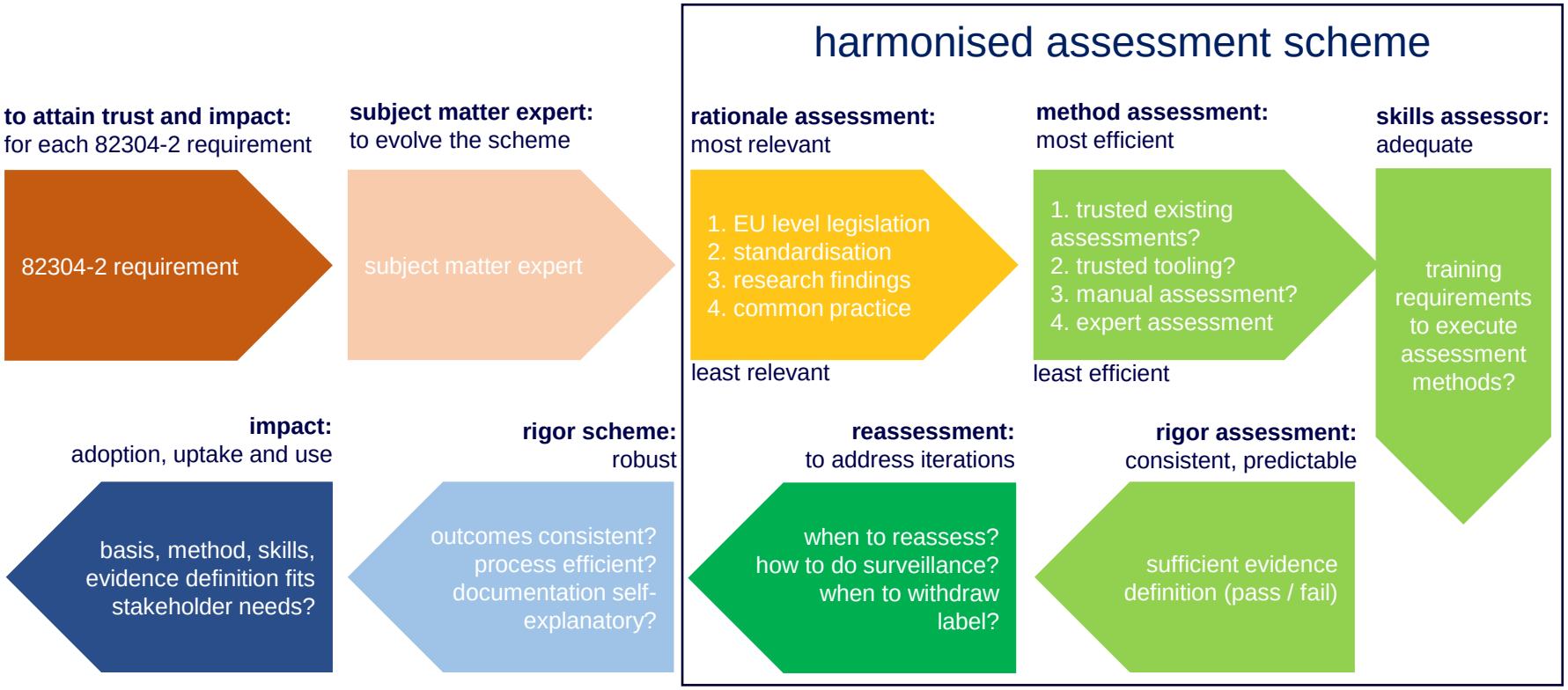
- Belgium
- Denmark
- England
- Germany
- Netherlands
- Norway
- Sweden
- Singapore
- United States

"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

common practice – comparison



comparison – (key) requirements

- CEN-ISO/TS 82304-2
- EUnetHTA core model
- DiGA (DE)
- DAQ/DTAC (EN)
- DigiHTA (FI)
- PECAN (FR)
- Leidraad (NL)

- 5.2.2.1 health risks
- 5.2.3.1 ethical challenges
- 5.2.4.5 health benefit
- 5.2.5.1 societal benefit

aim 80-90-95% generic vs context-specific quality

Table 1: Mapping of assessment domains to ISO 82304-2 Health software — Part 2: Health and wellness apps — Quality and reliability standard

PROPOSED ASSESSMENT DOMAIN	ISO 82304-2:2021	NOTES
Acceptability User, cultural and health professional acceptance that the app is suitable for its intended purpose.	Not included	This domain has been added to ensure alignment to the needs of the Australian health and wellbeing ecosystem including health care needs, intended users, models of care and our diverse multicultural population.
Safety and trust The app is free from unacceptable risk, the information included can be trusted and implications of using the app are transparent to the intended user.	Healthy and Safe	There is a strong alignment in these areas. Some of the risk measures are recommended for implementation in a later version of the Assessment Framework as medium to high risk assessment is covered by TGA. This will allow time for the assessing organisation to mature.
Ease of use The app is designed and delivered in such a way that it is accessible and usable by its intended users.	Ease of Use	
Privacy and security The app is designed and delivered to secure it from threats, complies with Australian Privacy legislation and processes personal data only with consent.	Secure Data	Privacy and Security has been modified to reflect Australian legislation and standards with the addition of Consent Management and User Control as requested by stakeholders.
Technical quality assurance The app is developed using best practices and is technically robust and, where relevant, can successfully exchange data using Australian recognised standards.	Robust Build	This has been modified to reflect Australian standards and the maturity of the app developers and assessing organisation.

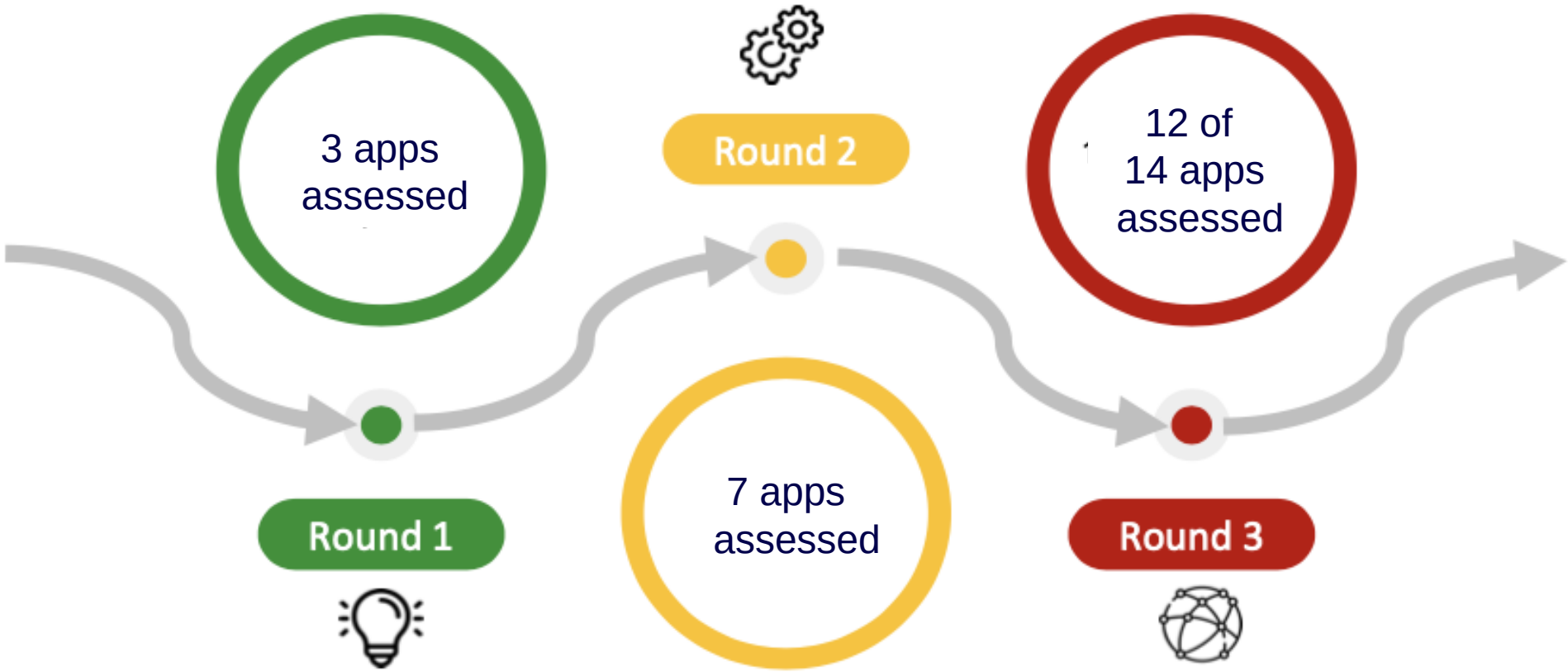
- reduced assessment if already an 82304-2 label

Phase 1: Triage
Basic information on the app and app developer is collected. This is used to determine:

- whether the app is eligible for assessment
- whether the app qualifies for a streamlined (that is, reduced) assessment because it complies with other regulations or standards such as:
  - TGA regulation
  - ISO 82304-2 Health software — Part 2: Health and wellness apps — Quality and reliability
- the complexity of the app, which will inform the type of assessment criteria and measures it will be assessed against.

Australian Government
Australian Digital Health Agency

testing the scheme: 5 CABs, 3 rounds, 24 apps



willingness to pay for health app assessment

46 health systems

41 manufacturers

21 European countries

For health systems

	Assessment A	Assessment B
Cost per app assessment *(paid by your organisation)*	1,000 Euros per assessment	2,000 Euros per assessment
Time it takes until assessment results become available *(once all app-related evidence has been submitted to the assessment organisation by the developer)*	Results available in **6 months**	Results available in **1 month**
Re-assessment frequency *(assume that your organisation does not pay for re-assessments)*	Re-assessment **every two years**	Re-assessment **every year**
Percent of your peers who recommend the assessment *(as per a survey conducted across organisations similar to yours)*	**50%** of your peers recommend the assessment	**90%** of your peers recommend the assessment
Increase in the willingness to recommend/use health apps among healthcare professionals and the public *(as a result of trust in the assessment)*	Results in a **moderate** increase in willingness to use health apps	Results in a **large** increase in willingness to use health apps

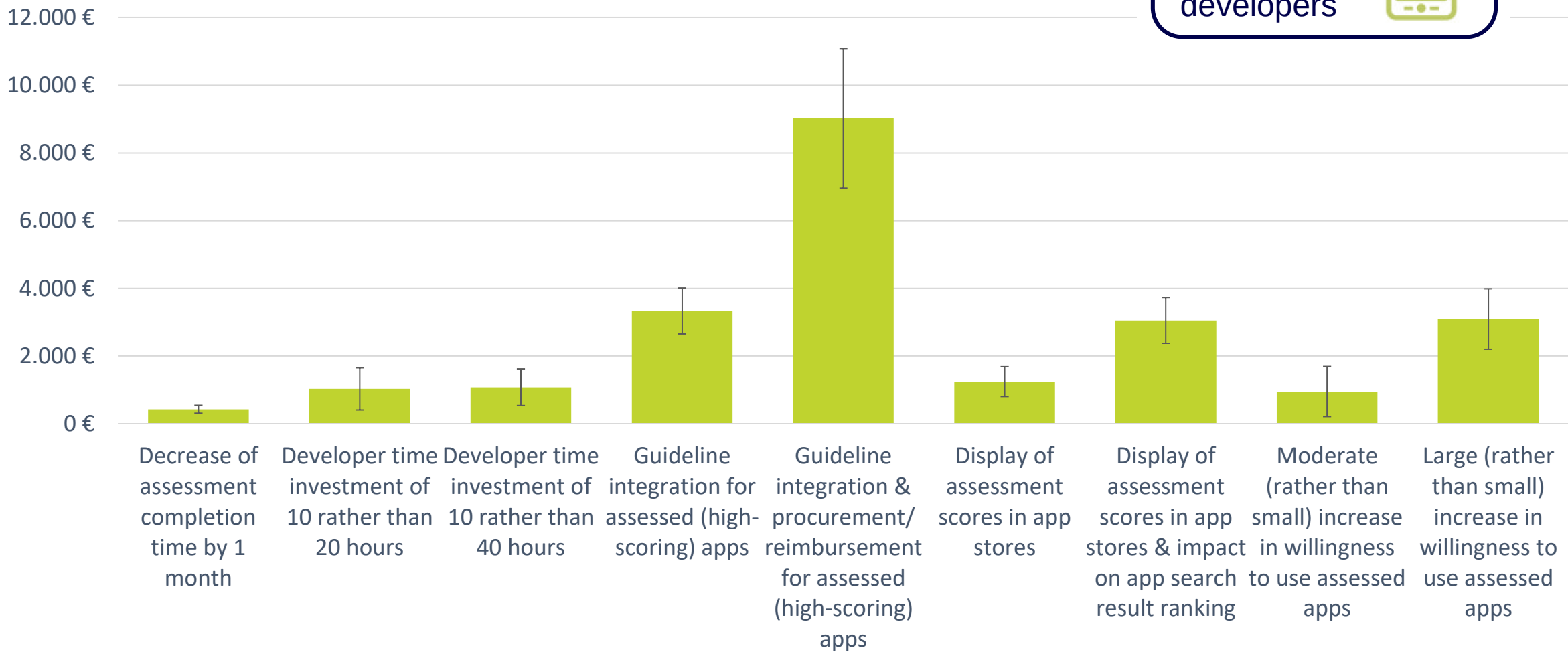
For health app developers

	Assessment A	Assessment B
Cost per app assessment *(paid by your organisation)*	**2,000 Euros** per assessment	**1,000 Euros** per assessment
Time investment made by your organisation *(to collate app-related evidence for the assessment)*	**40 hours** invested by your organisation	**10 hours** invested by your organisation
Time it takes until assessment results become available *(once your organisation has submitted all app-related evidence to the assessor)*	Results available in **3 months**	Results available in **6 months**
Impact of the assessment on clinical care uptake of your app *(if the results meet stakeholder requirements)*	Results in app integration into care **pathway guidelines and** app reimbursement/ **procurement**	Results in app integration into care **pathway guidelines** but **not** in app reimbursement/ **procurement**
Integration of assessment results into Google Play and Apple App stores	Option to prominently **display** assessment **results** in app stores **and prioritisation** in search result **rankings**	**No** option to prominently **display** assessment **results** in app stores and **no impact on** search result **rankings**
Increase in willingness to use your health app(s) among potential customers *(as a result of trust in the assessment)*	Results in a **moderate** increase in willingness to use your health app(s)	Results in a **large** increase in willingness to use your health app(s)

Funded by the European Union

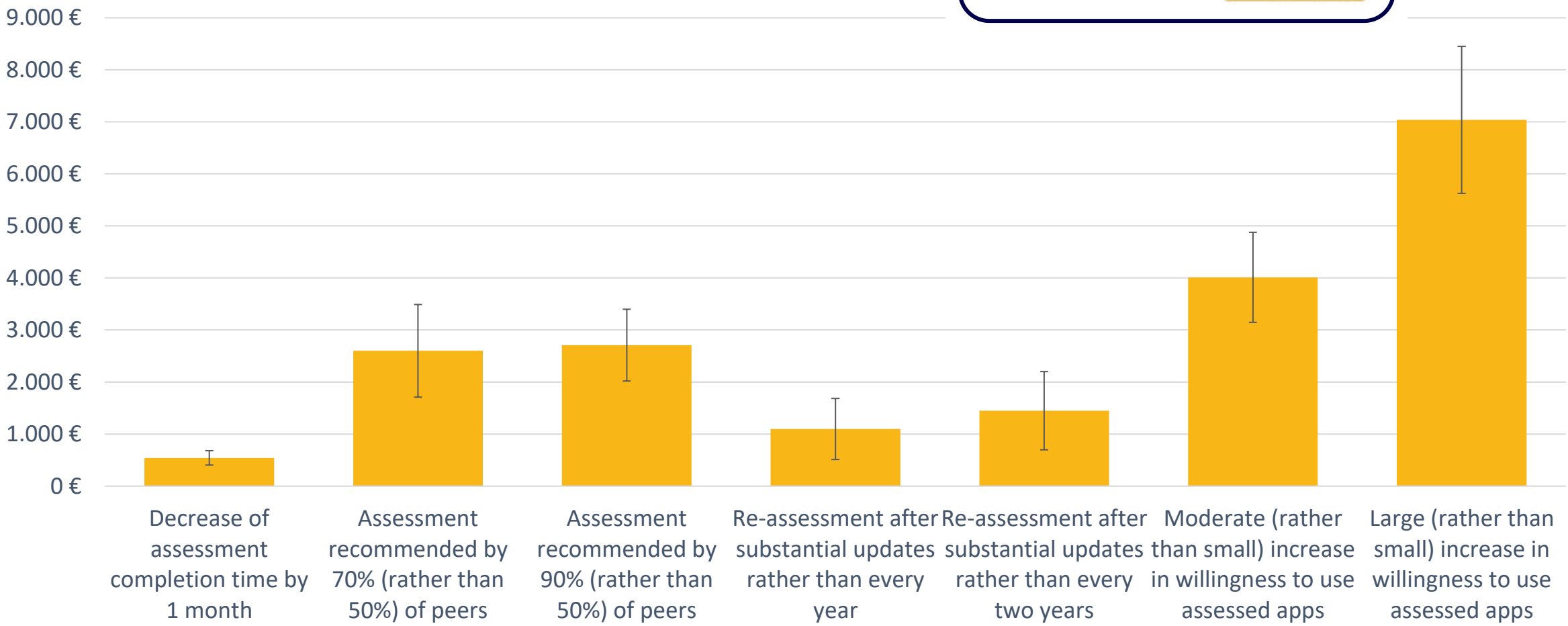
willingness to pay

health app developers

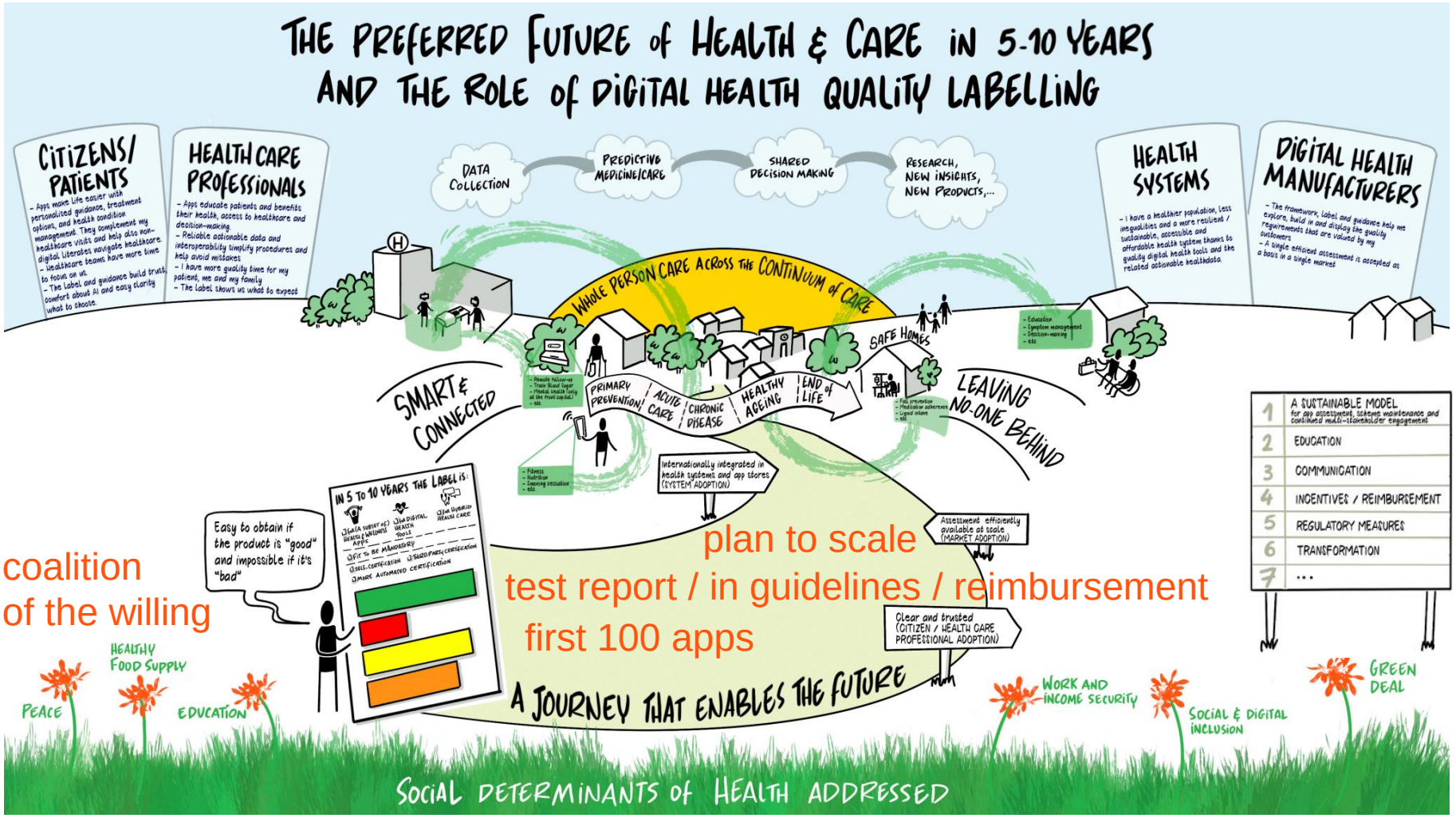


willingness to pay

health system representatives



multi-stakeholder success in 5 to 10 years



coalition
of the willing

plan to scale
test report / in guidelines / reimbursement
first 100 apps

b. Strengthening health systems by recommending and prescribing health apps in PHC

Funded by the European Union

World Health Organization
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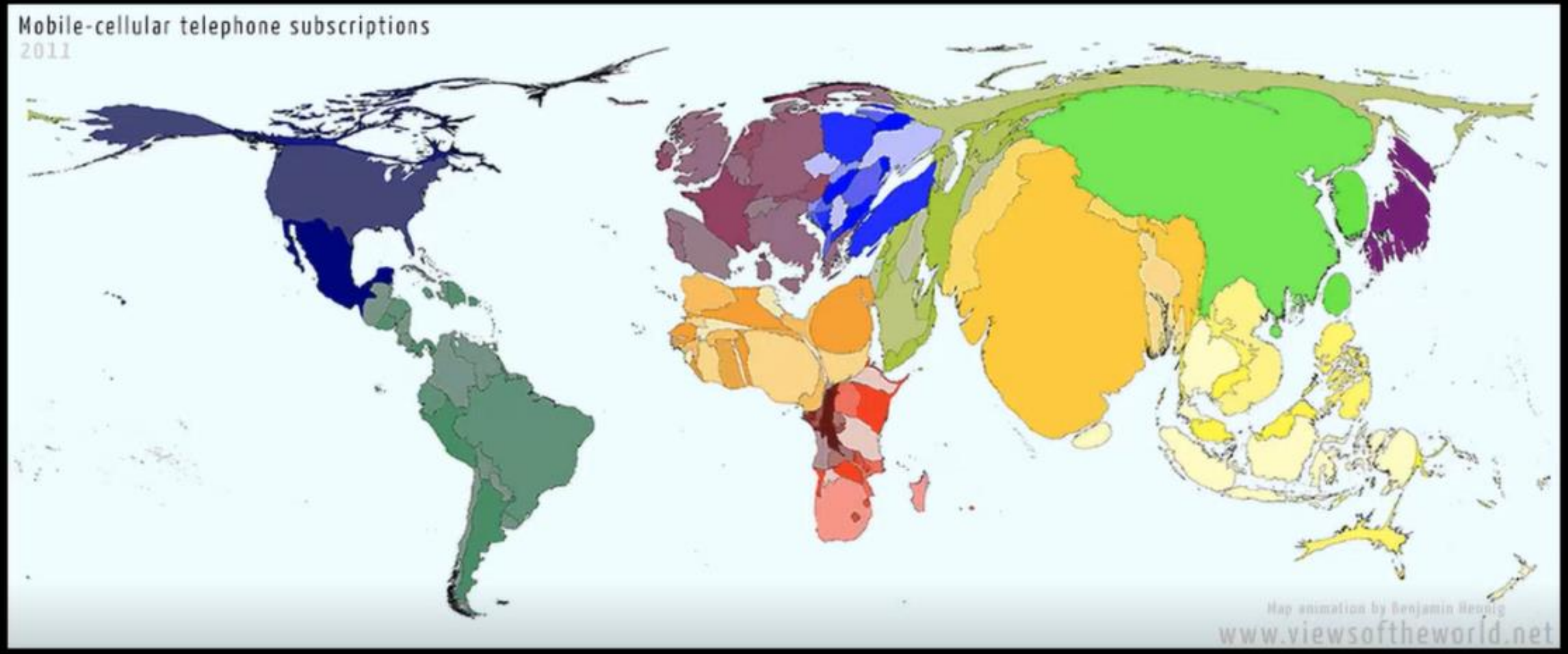
Strengthening health systems by recommending and prescribing health apps in PHC

Toni Dedeu
Senior Advisor on Integrated Primary Health Care
WHO European Centre for PHC
WHO EURO

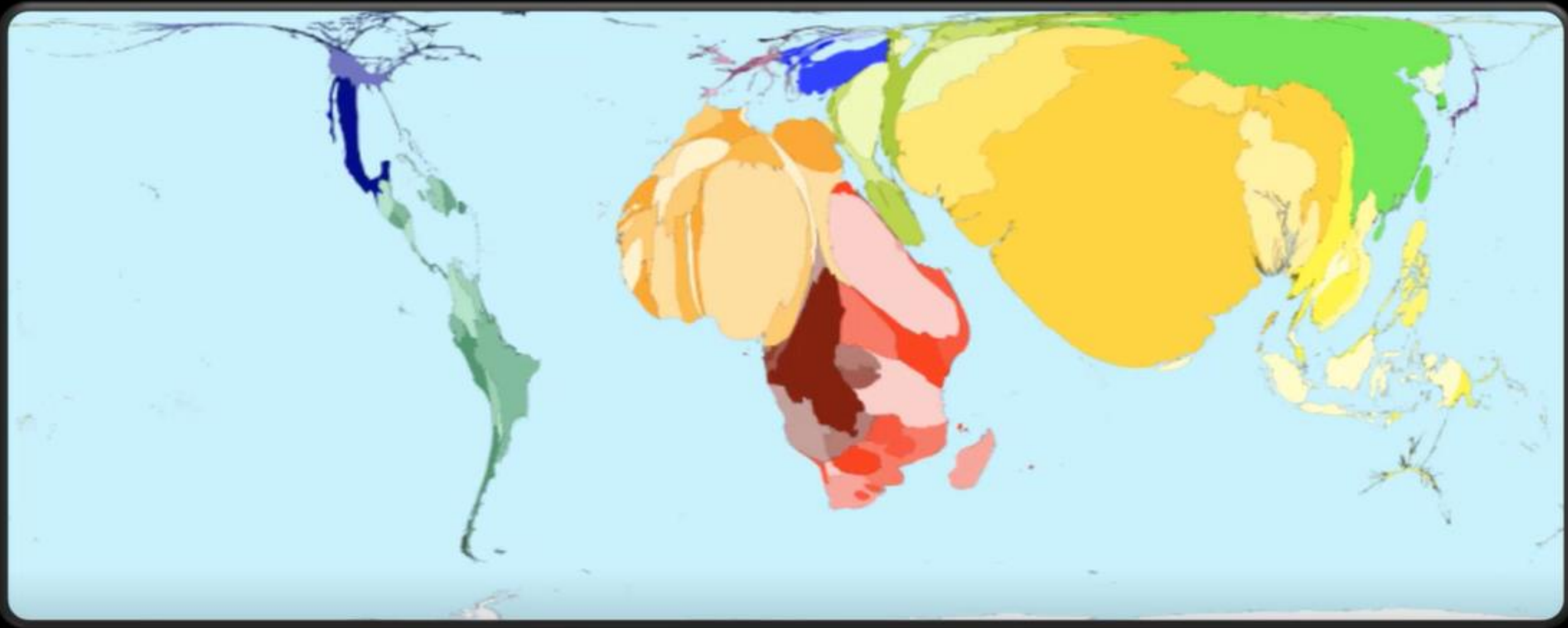
LABEL2ENABLE
3rd Roundtable on reimbursement and payment of health apps

13th February 2024

The Mobile Phone “Revolution” - 2000-2016



Overlap of Problem and Possible Opportunity



Maternal & Neonatal Mortality World Map

©2022 Worldmapper.org

10+yrs of stewardship of Digital Health “experimentation” to "transformation"

2012

ITU & WHO National eHealth Strategy Toolkit

2018

World Health Assembly (WHA) Resolution on Digital Health

Formation of Global Digital Health Partnership (GDHP)

WHO Classifications of Digital Health Interventions

2019

WHO Guidelines: Recommendations on digital interventions for health system strengthening

Digital Health Atlas

2020

Global Strategy on Digital Health 2020 - 2025

Digital Health Investment Implementation Guide (DIIG)

2023

Global Initiative on Digital Health

Global Digital Health Certification Network

Global Initiative on AI for Health

DH Classifications v2.0

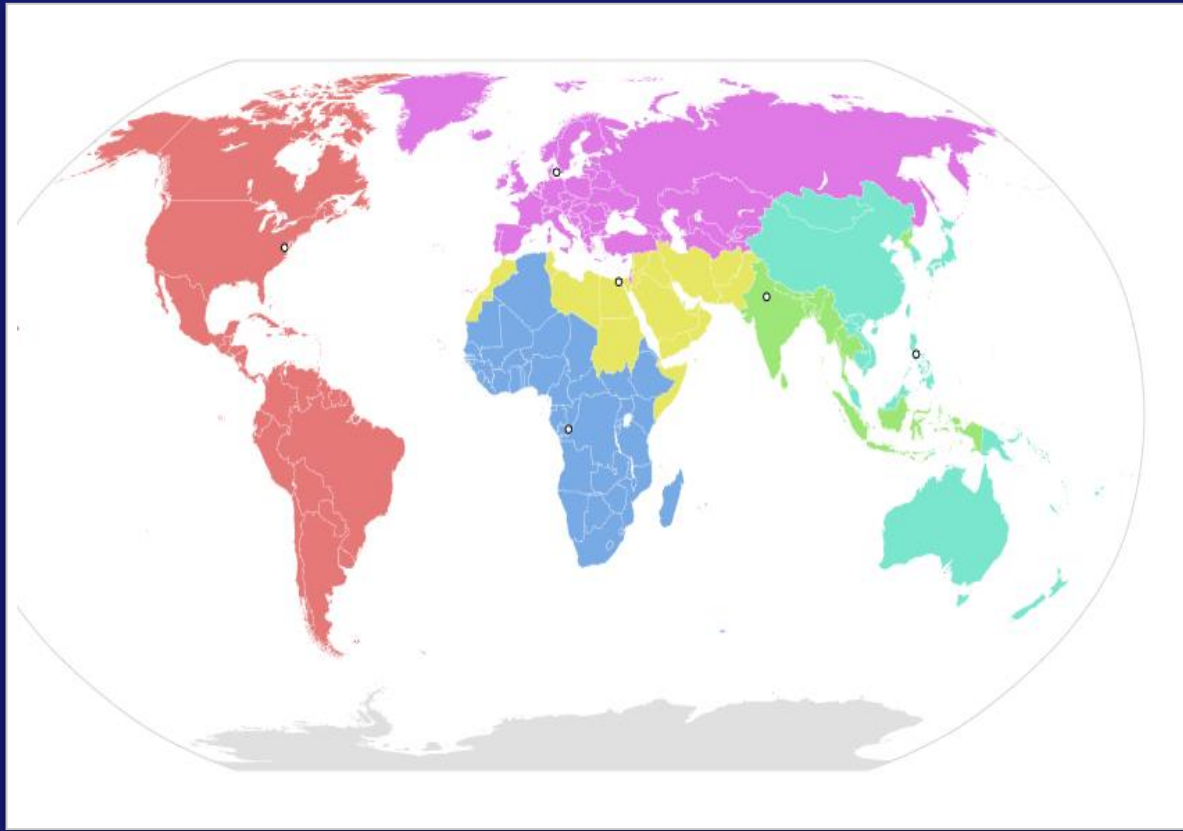
Global DH Monitor (Maturity Tracker)

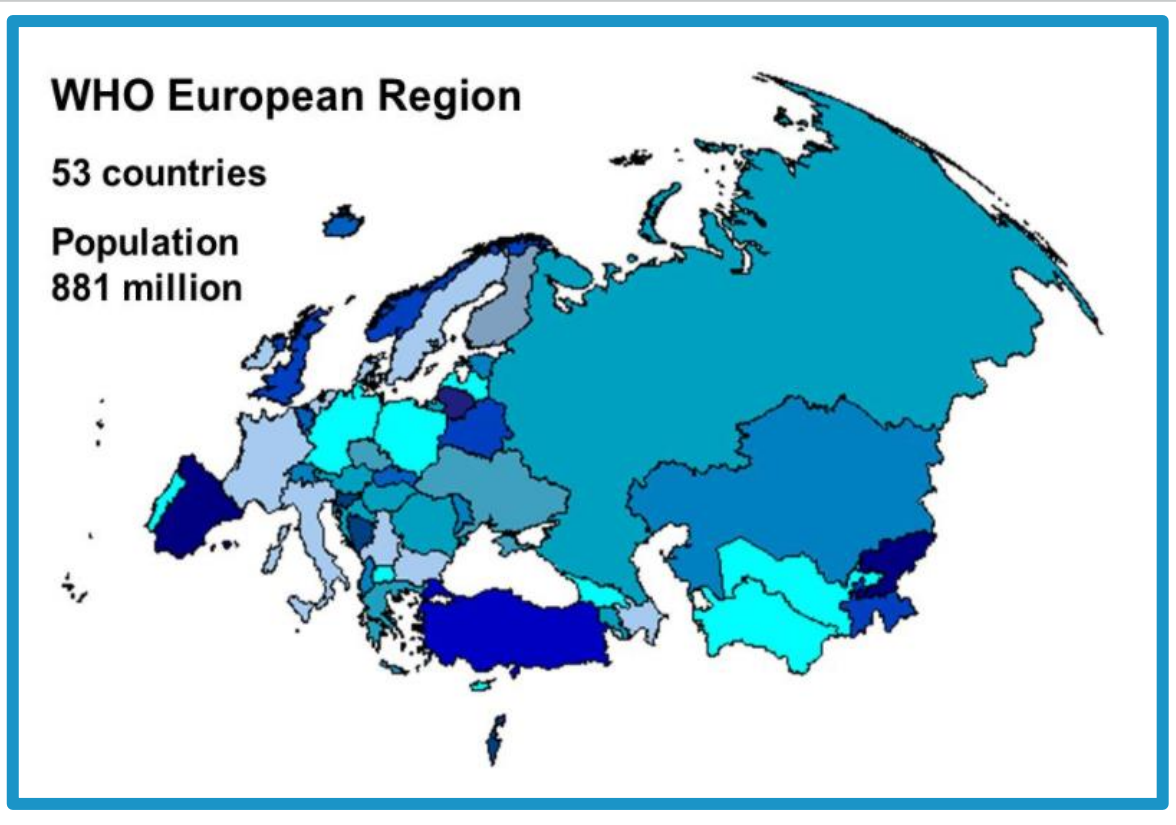
World Health Organization

WHO European Region

World Health Organization
REGIONAL OFFICE FOR Europe

Geographical scope





Declaration of Astana 2018

- Priority on Primary Health Care (PHC)
- Holistic view of health and wellbeing
- Emphasis on community engagement
- Multisectoral policies for health
- Integrated health services for resilience
- Universal health coverage (UHC)
- Commitment to better health outcomes
- The comprehensive approach and expanded roles in multi-disciplinary teams within PHC
- Greater integration of PHC and public health

World Health Organization
European Region

Source: WHO 2018

Digital Health and UHC

PERSPECTIVE

Prioritizing integrated mHealth strategies for universal health coverage

- **ACCOUNTABILITY COVERAGE**: the proportion of those in the target population known and registered in the health system
- **ACCESSIBILITY AND AVAILABILITY OF SERVICES**: includes ensuring availability of commodities, equipment and human resources and accessibility to health facilities
- **CONTACT COVERAGE**: proportion of clients who have contact with relevant facilities, health workers and services among the target population
- **CONTINUOUS COVERAGE**: the extent to which clients receive the full course of intervention required to be effective
- **EFFECTIVE COVERAGE**: the proportion of individuals receiving satisfactory health services among the target population

Fig. 3.4.3. **Health system needs for universal health coverage.**

PHC strengthened with integrated digital solutions

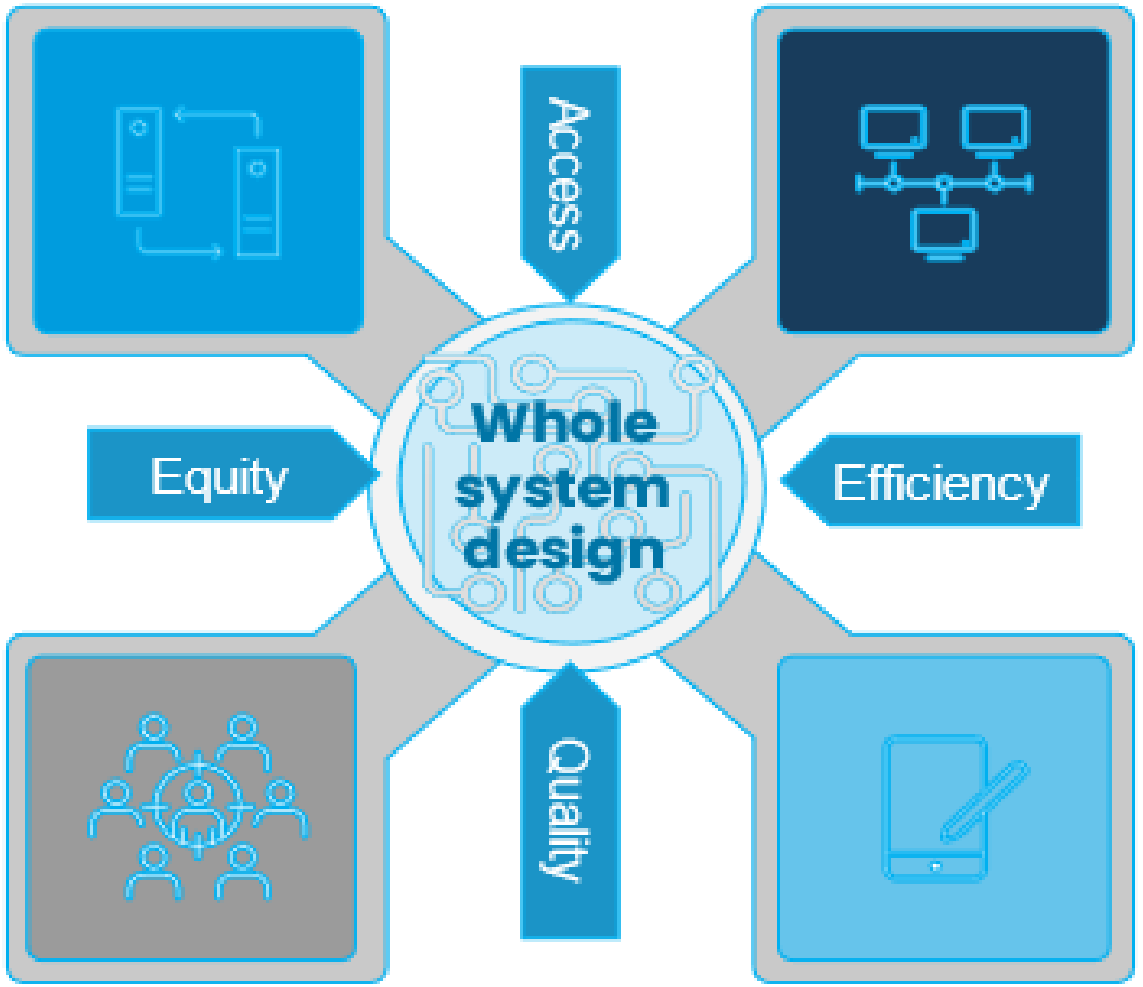
World Health Organization Europe

Remote service delivery Telemedicine & Telehealth

Telehealth and telemedicine solutions grounded in PHC

Tools to identify high risk and vulnerable

Population health management and risk stratification tools



Interprofessional EHR

Shared electronic inter-professional medical records to support multi-disciplinary PHC

SELF-MANAGEMENT

Digital self-management tools and technologies

Bringing services closer to people

People's needs

Face to face: facility

Face to face: mobile team

Remote delivery

How can multiple platforms be combined to reduce inequalities in access to health care and improve quality?

Chapter 3. The pillars of transformation

This chapter is divided into six parts

Part 1: the leaders – national digital health governance

Presents the significance of national digital health strategies and policies in unlocking the potential of digital health. This part of the chapter is informed by Strategic Priority 1 of the Digital Health Action Plan for the WHO European Region 2023–2030 and focuses on aspects like accessibility, quality, safety and efficiency, in addition to health information sharing and interoperability. Additionally, it emphasizes the role of national government agencies in supervising the uptake and application of digital health, the availability of funding, and the promotion of health literacy and digital inclusion.

Part 2: the lifelines – electronic health records (EHRs)

Carries forward the discussion on EHRs, touching upon the specificities of their use and implementation.

Part 3: bridging distances – telehealth

Delves into the utilization and advancement of telehealth services in the face of the recent pandemic. It expounds on the use of telehealth across Member States, reporting on national strategies, evaluations and barriers to telehealth implementation. It also examines the impact of the COVID-19 pandemic on the initiation or enhancement of telehealth services.

Part 4: health in your hands – mobile Health (mHealth) and mobile health applications (mApps)

Describes the role of mHealth and mApps in delivering various health services. It assesses the regulatory measures, challenges and impacts of the pandemic on the commencement or improvement of mHealth services.

Part 5: the power of knowledge – big data and advanced analytics for health

Reviews the employment of big data and sophisticated analytics in health services, as well as the challenges and regulations surrounding them.

Part 6: sharing is caring – access to and sharing of data

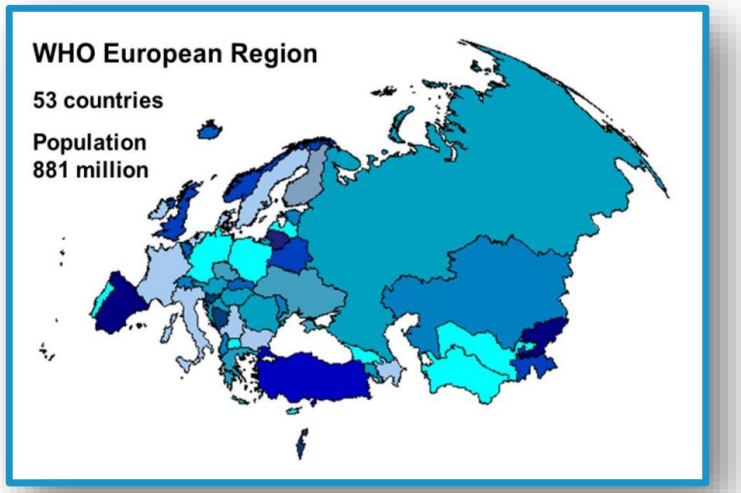
Data assesses the approaches Member States have employed to enable access to and sharing of health data, with a focus on privacy protection and control over health data.

Health in your hands

Mobile health (mHealth) and Mobile health applications (mApps)

Considerations to help move forward

1. Establish effective **governance**
2. Develop robust **evaluation guidelines** and increase **digital health literacy**
3. Ensure **sustainable financing** and **collaboration**
4. Address **interoperability** and **standardise** health data
5. Promote **patient-centred care** and **digital inclusion**



World Health Organization
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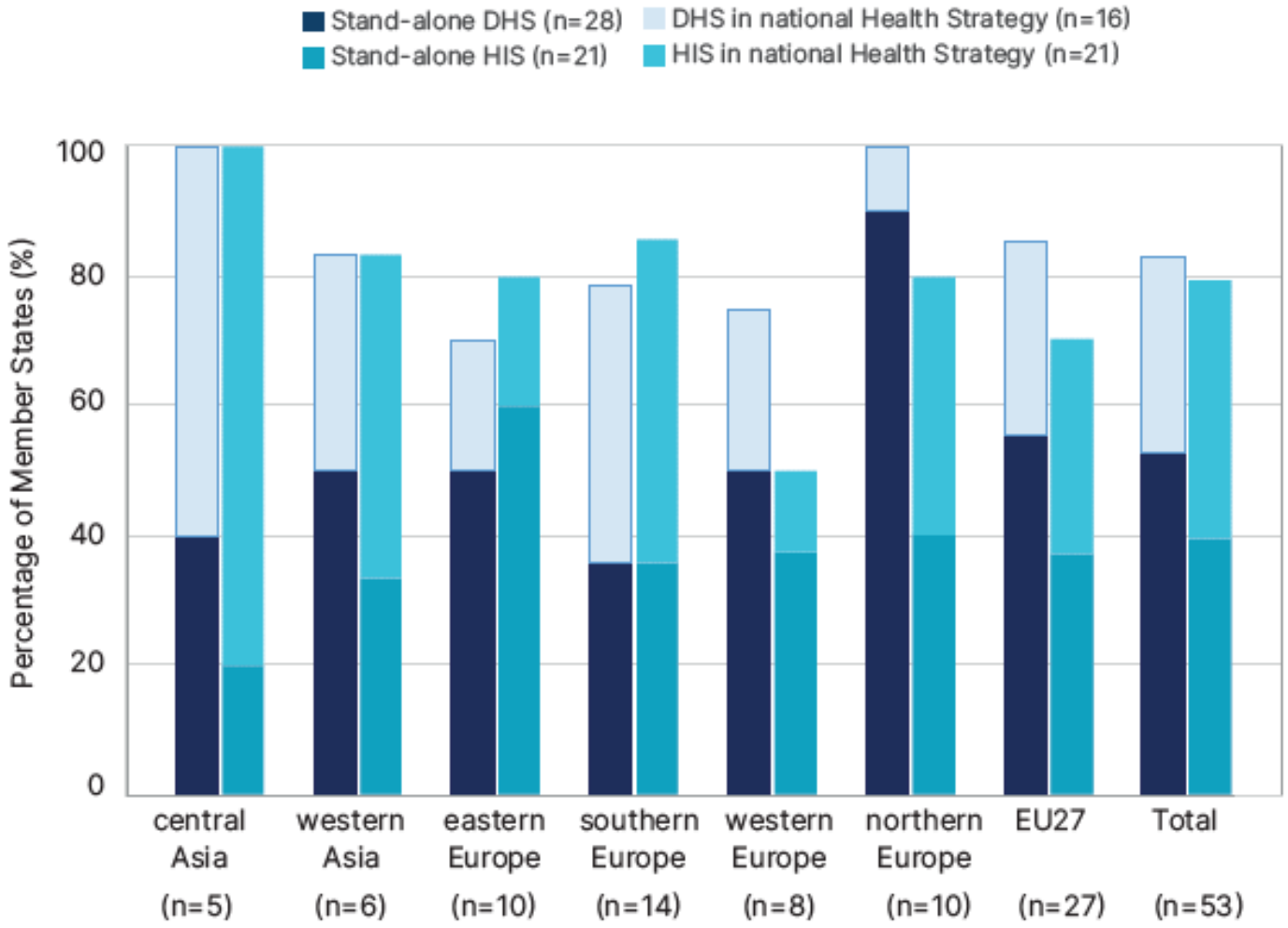
For Member States of the WHO European Region the geographic subregions are as defined by the United Nations Statistics Division and used in all United Nations publications and databases

WHO European Region Member States by Subregion

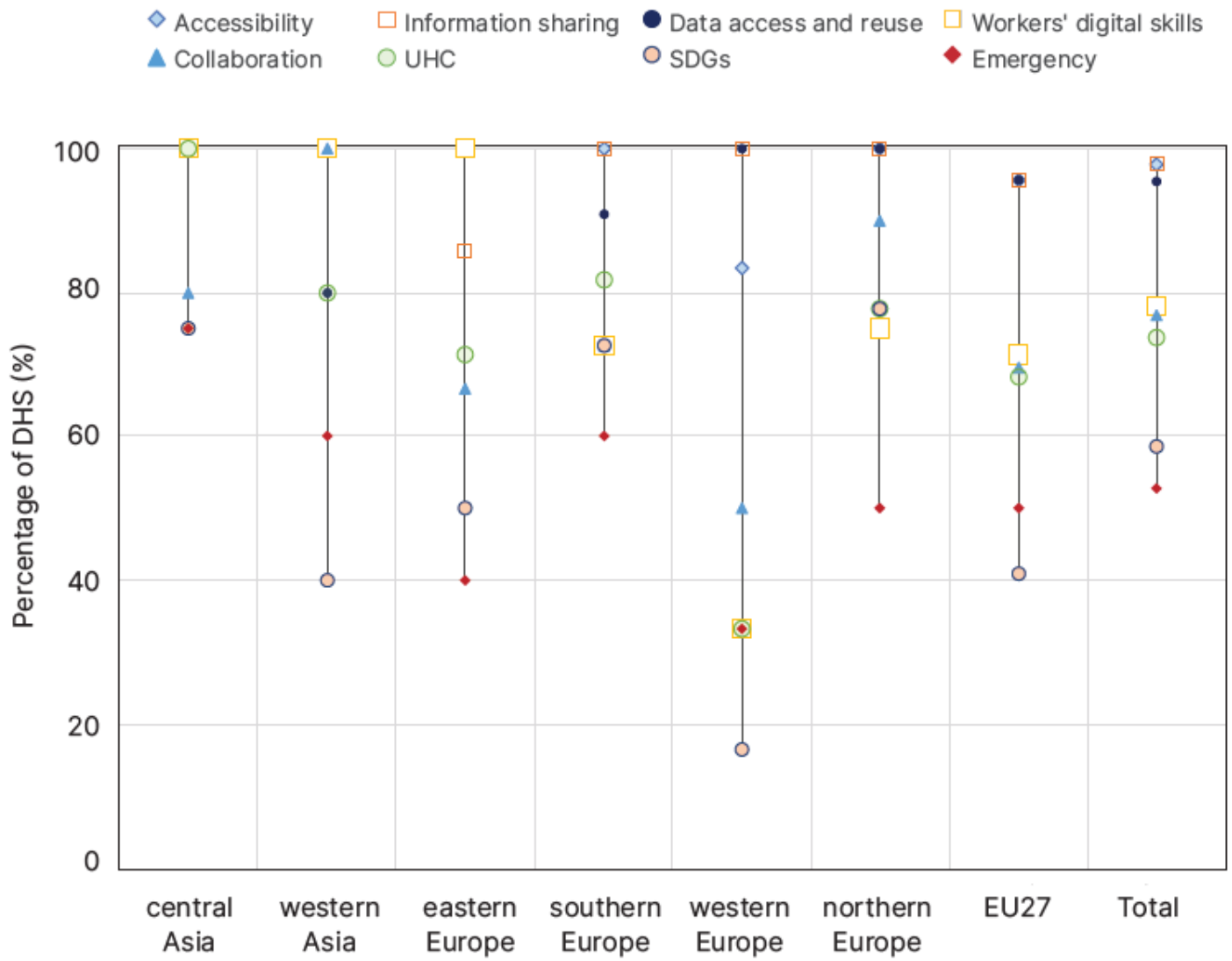
Subregion	Member States
central Asia	Kazakhstan, Kyrgyz Republic, Tajikistan, Turkmenistan, Uzbekistan
western Asia	Armenia, Azerbaijan, Cyprus, Georgia, Israel, Türkiye
eastern Europe	Belarus, Bulgaria, Czechia, Hungary, Poland, Republic of Moldova, Romania, Russian Federation, Slovak Republic, Ukraine
northern Europe	Denmark, Estonia, Finland, Iceland, Ireland, Latvia, Lithuania, Norway, Sweden, United Kingdom
southern Europe	Albania, Andorra, Bosnia and Herzegovina, Croatia, Greece, Italy, Malta, Montenegro, North Macedonia, Portugal, San Marino, Serbia, Slovenia, Spain
western Europe	Austria, Belgium, France, Germany, Luxembourg, Monaco, Netherlands (Kingdom of the), Switzerland

Member States with policies or strategies addressing digital health and HISs, by subregion

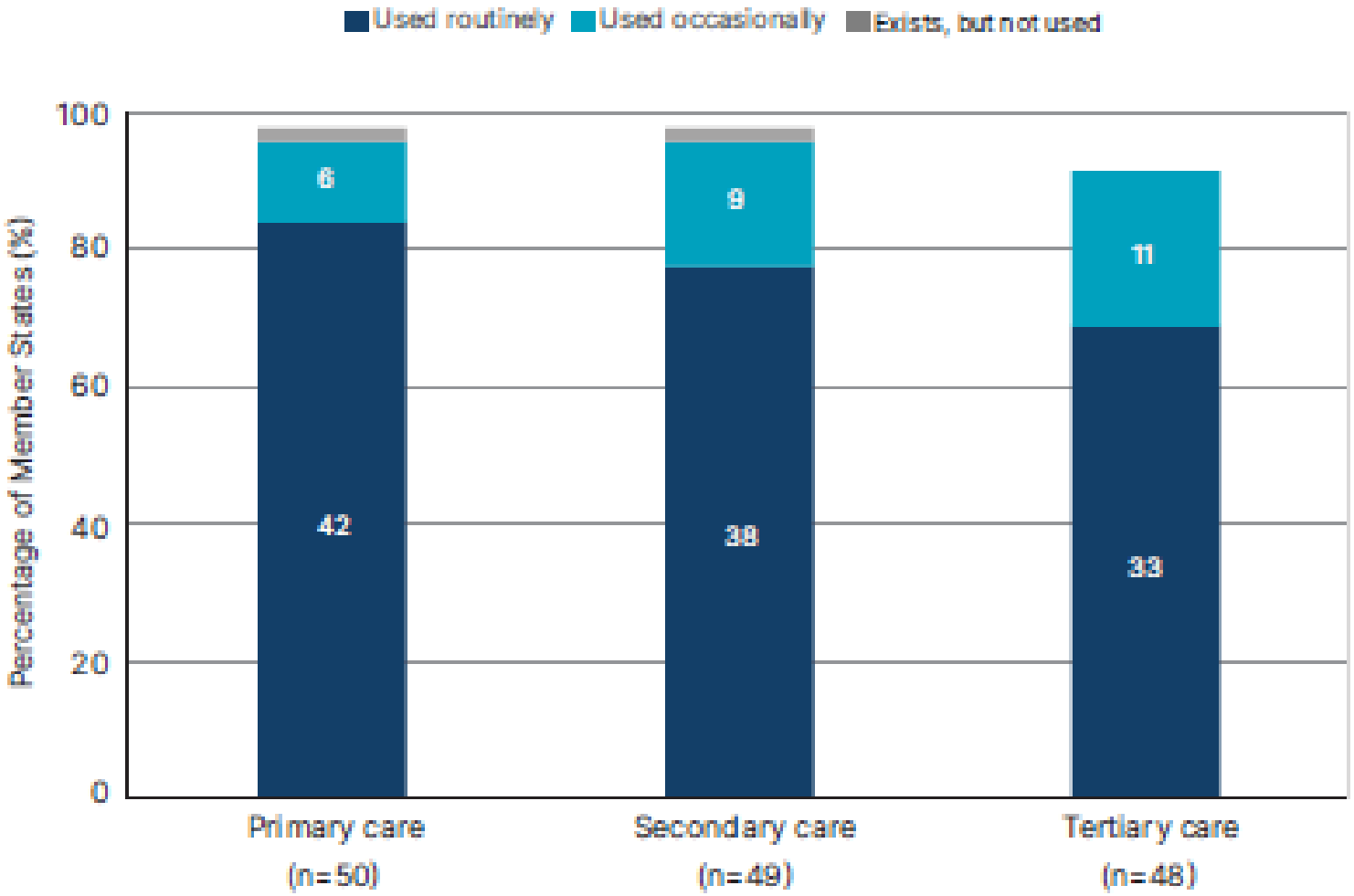


- **28** had developed a dedicated or stand-alone **DHS**
- **16** reported that their **DHS** was addressed within the scope of their national health strategy or policy or broader digital strategy
- **21** had developed a dedicated or stand-alone **HIS**
- **21 HIS** within a national health strategy

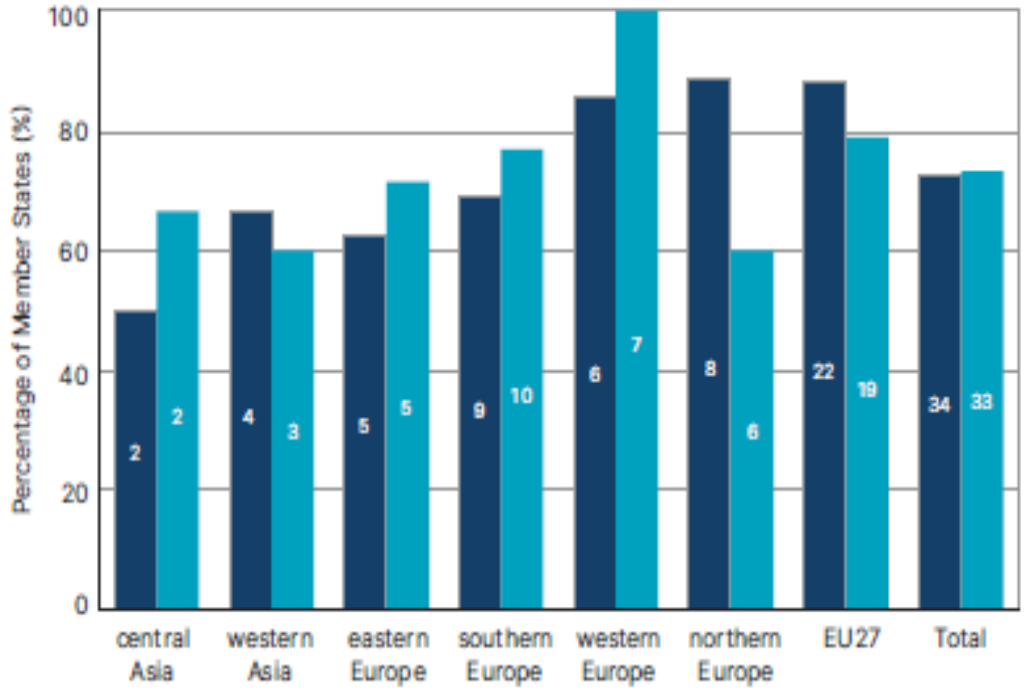
Priorities mentioned in national DHS by subregion



Use of EHR systems in primary, secondary and tertiary health care



Special funding allocation during the COVID-19 pandemic



Note: the number of responding Member States varies for telehealth and data sharing.

Out of **47** responding Member States

↓

34 reported having allocated

Special funding

to extend telehealth services during the pandemic

45 responding Member States

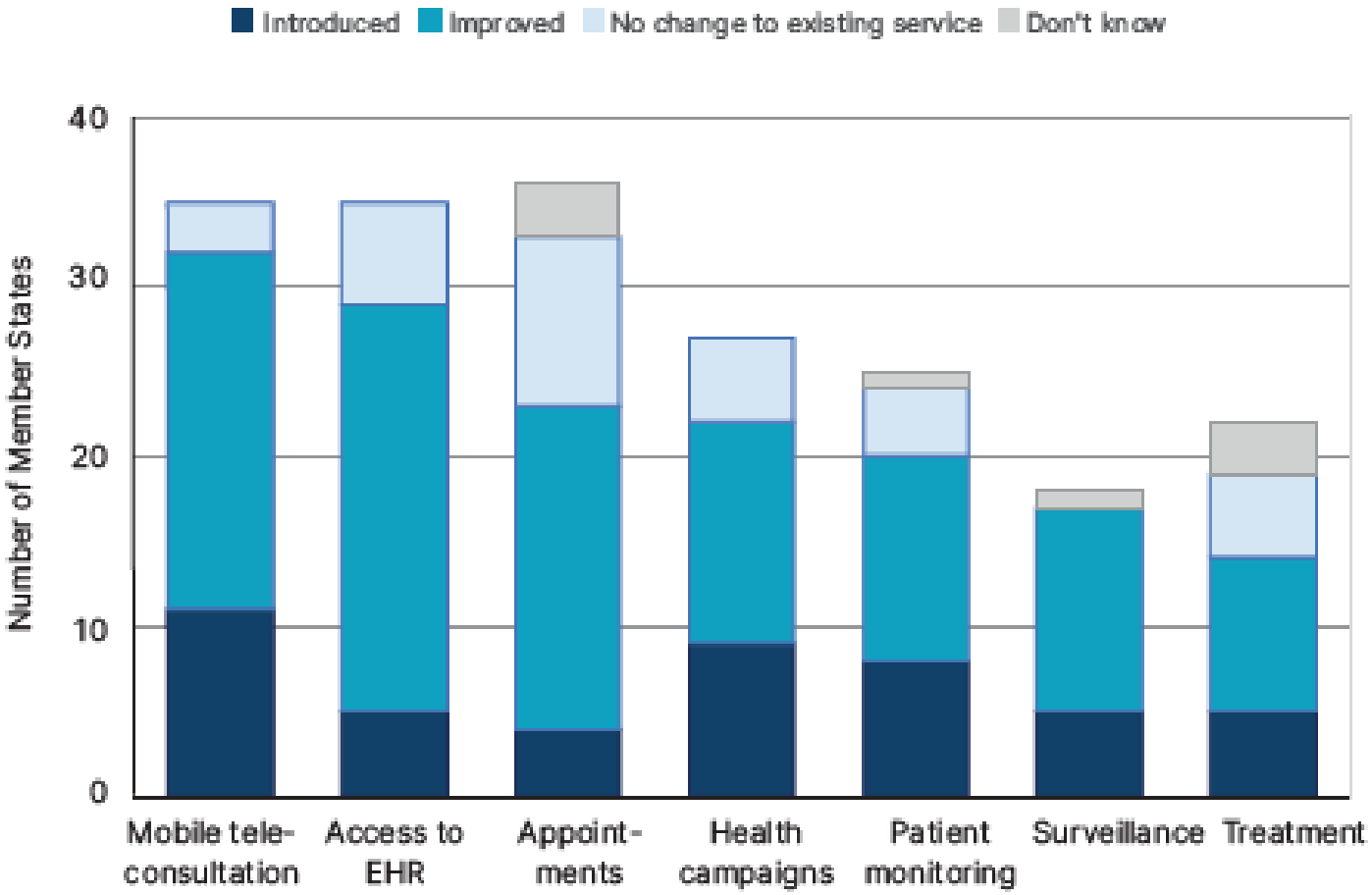
↓

33 for **data-sharing** and

data interoperability platforms

Many Member States introduced **new telemedicine services** and **schemes to pay** for them, which did not previously exist.

mHealth projects introduced or improved during the COVID-19 pandemic by type



Notes: "Do not know" responses are included in both numerators and denominators; denominators consist of the number of Member States where the services were implemented.

Examples of digital technologies used in the COVID-19 pandemic

COVID-19 context	Example technologies
Awareness, prevention and tracking	• Apps and websites for risk communication and dissemination of public health information • COVID-19 dashboards, mapping and forecasting utilities • Social media-based chatbots and online community forums • Case management software for contact tracing • Digital contact tracing apps • Infodemic management tools • Voluntary reporting tools • Self-management tools
Diagnosis, diagnostics and therapeutics	• Symptom assessment apps and online utilities • AI-based remote vital signs monitoring using devices or smartphone cameras • AI-powered computerized tomography imaging interpretation tools • Temperature-based diagnostic screening for border control
Management of contacts with the health system	• Online chat triage services • Online or app-based access to polymerase chain reaction test results • Telehealth or telemedicine use in primary health care
Surge management and protection in hospital settings	• Intensive care unit surge simulation tools • Inventory resource mapping and supply chain management tools • Telemedicine use in intensive care settings • E-learning platforms for health-care worker orientation • Robots (for disinfection, isolation ward communication and companionship, and medical waste transfer) • Volunteer databases
Testing and research	• Support to accelerated testing regimes • AI support to adaptive clinical trials
Recovery and re-establishment	• Smart vaccination certificates • Augmented reality-based temperature monitoring in public spaces

Source: (2).

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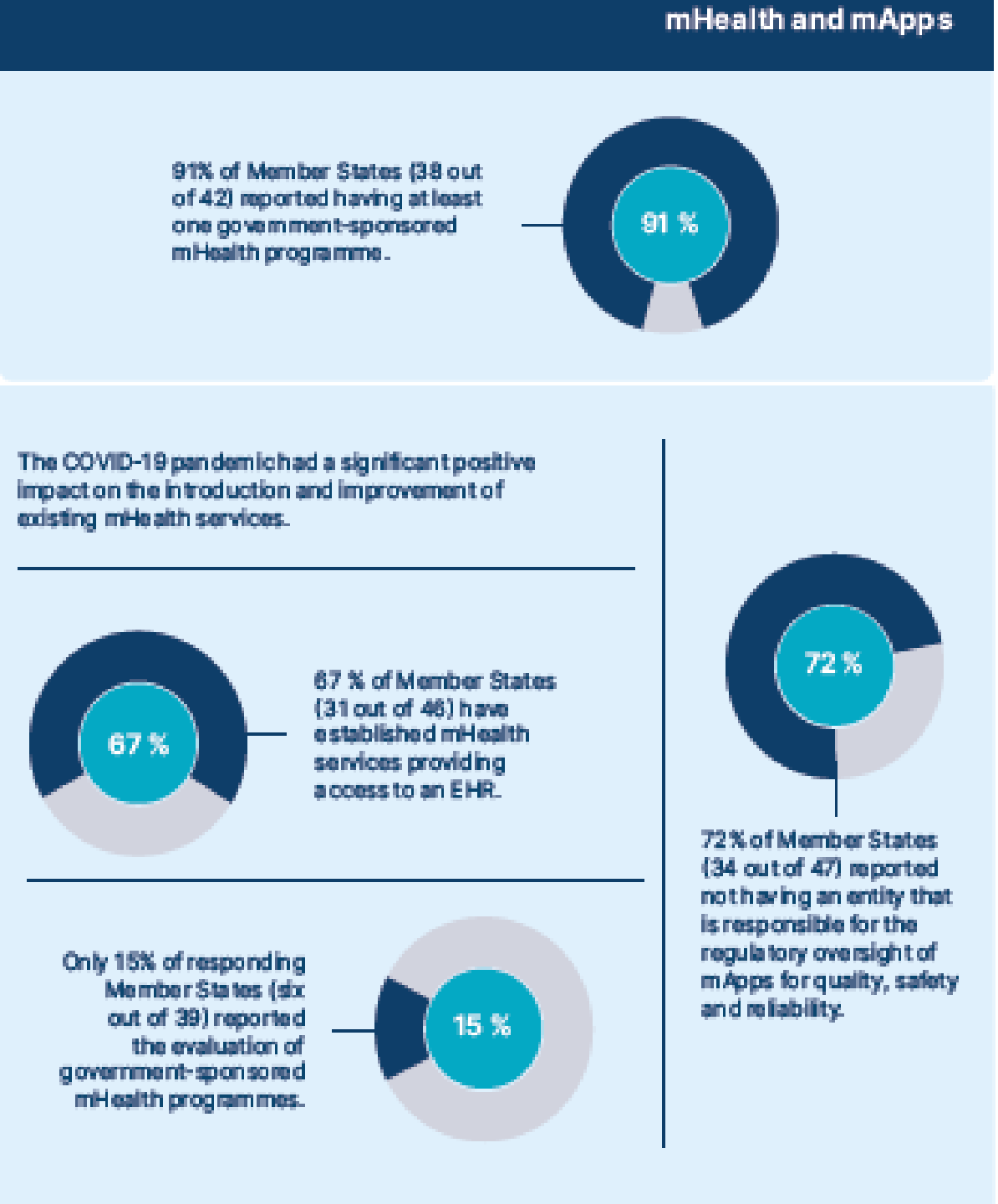
mApps

- ❑ Awareness, prevention and tracking
- ❑ Diagnosis, diagnostics and therapeutics
- ❑ Management of contacts with the health system



World Health Organization
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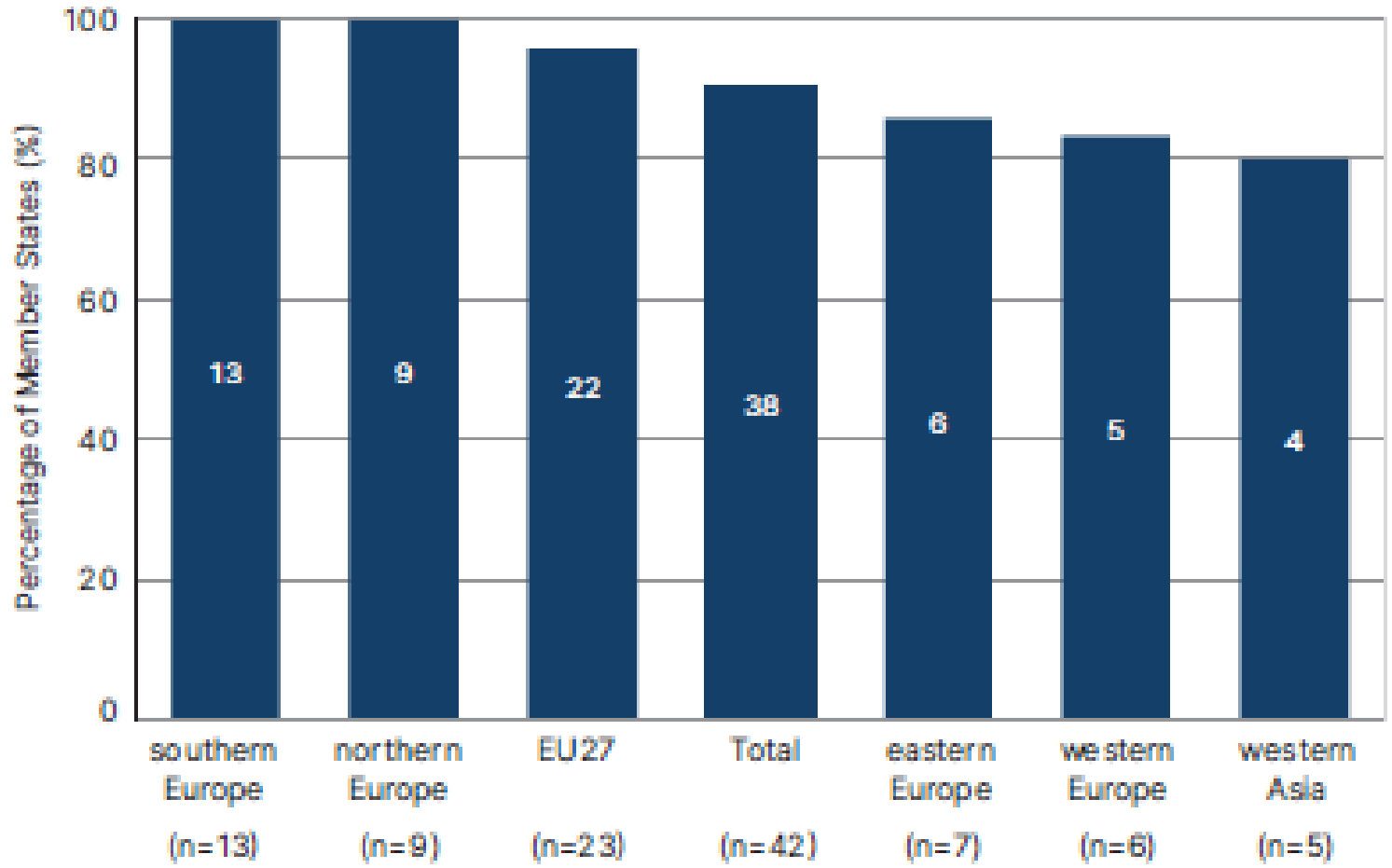
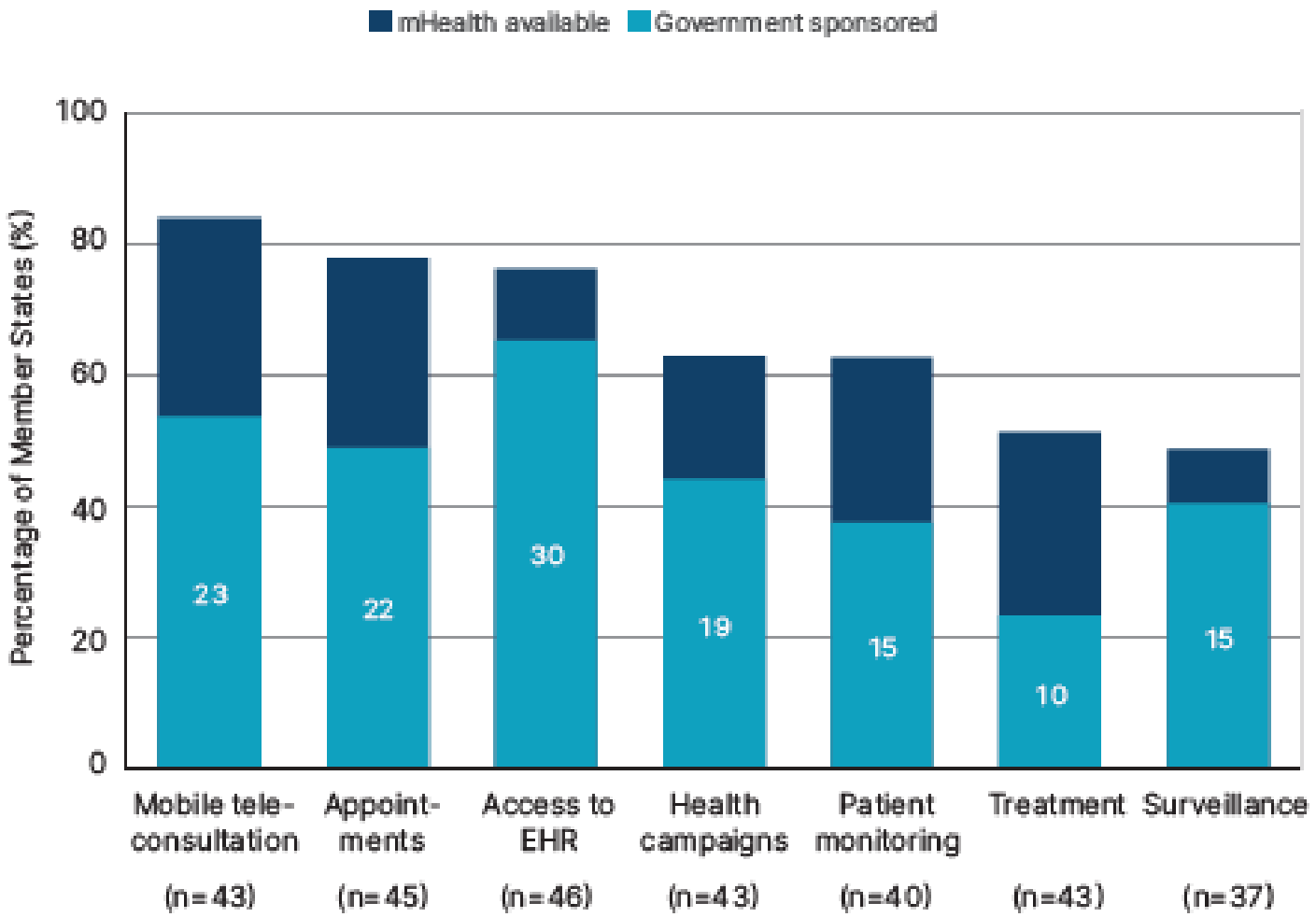
91%	Government sponsored mHealth programme
67%	The COVID-19 pandemic had a significant positive impact
15%	Only 15% of responding MS (6 out of 39) reported evaluation of mHealth programmes sponsored by the government.
72%	34 out of 47 MS reported not having an entity responsible for the regulatory oversight of mApps for quality, safety and reliability

Percentage of Member States that reported at least one government-sponsored mHealth project by subregion

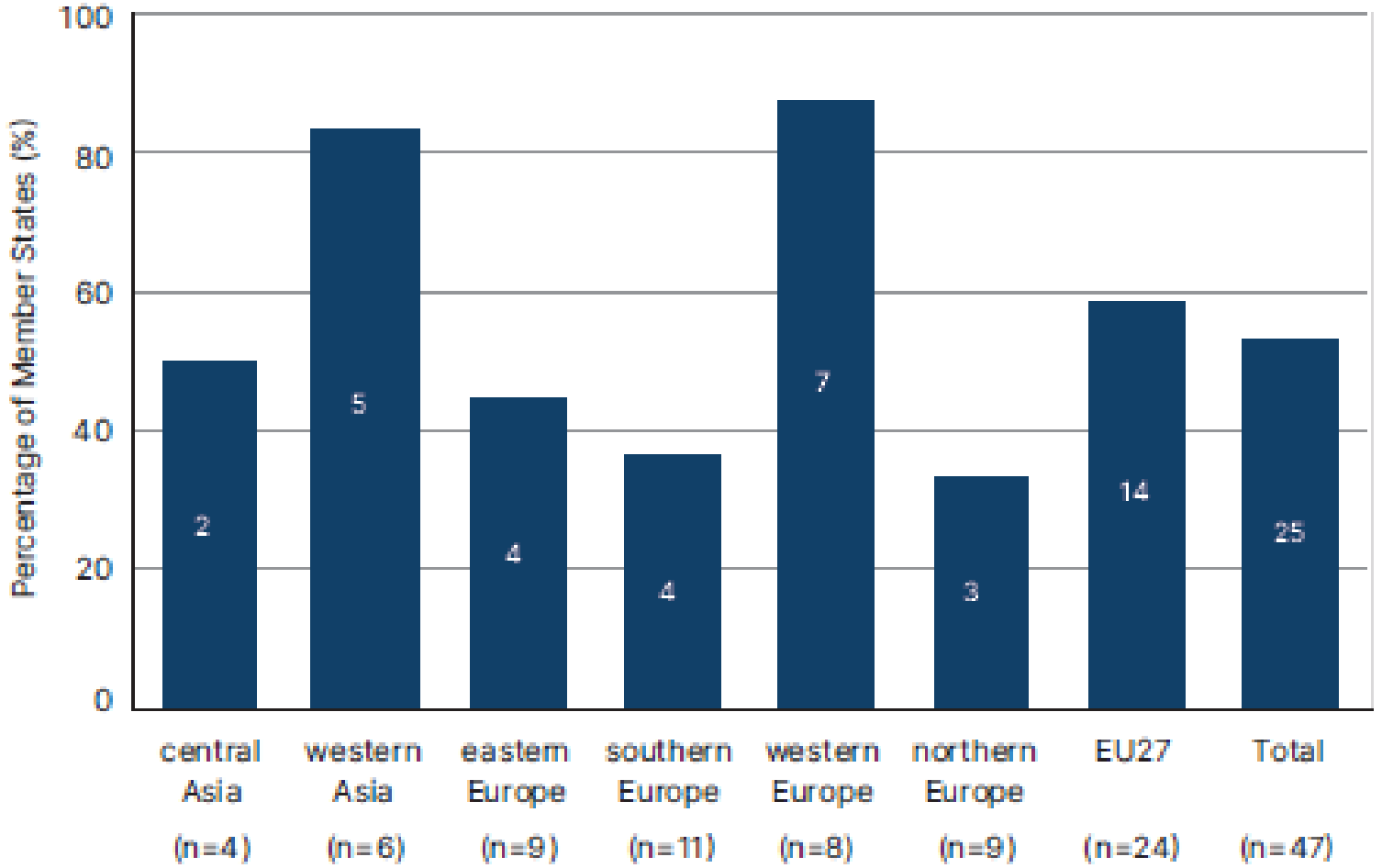


Note: central Asia is not included in the figure as only one Member State replied to this question.

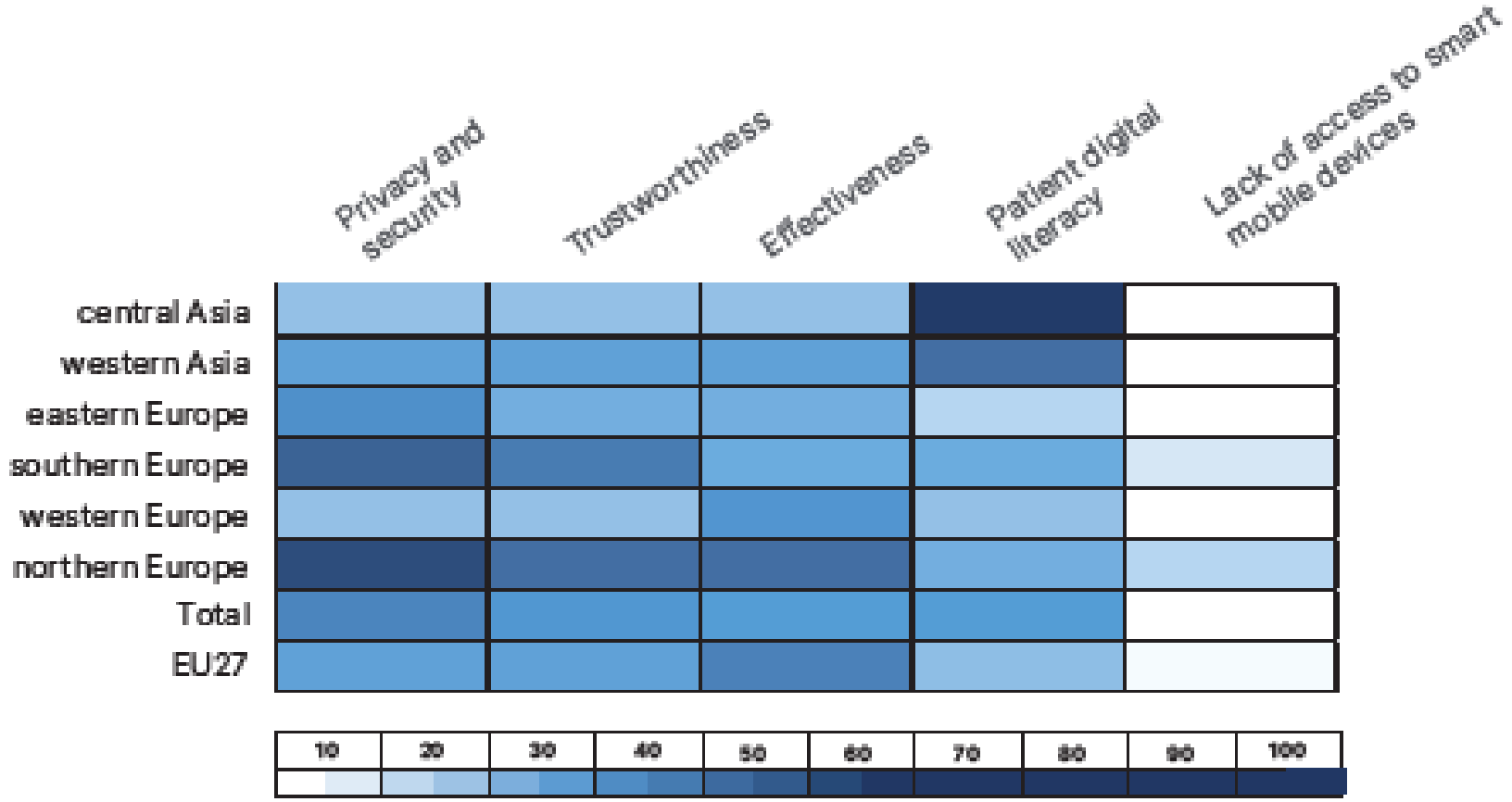
Most common types of mHealth programmes



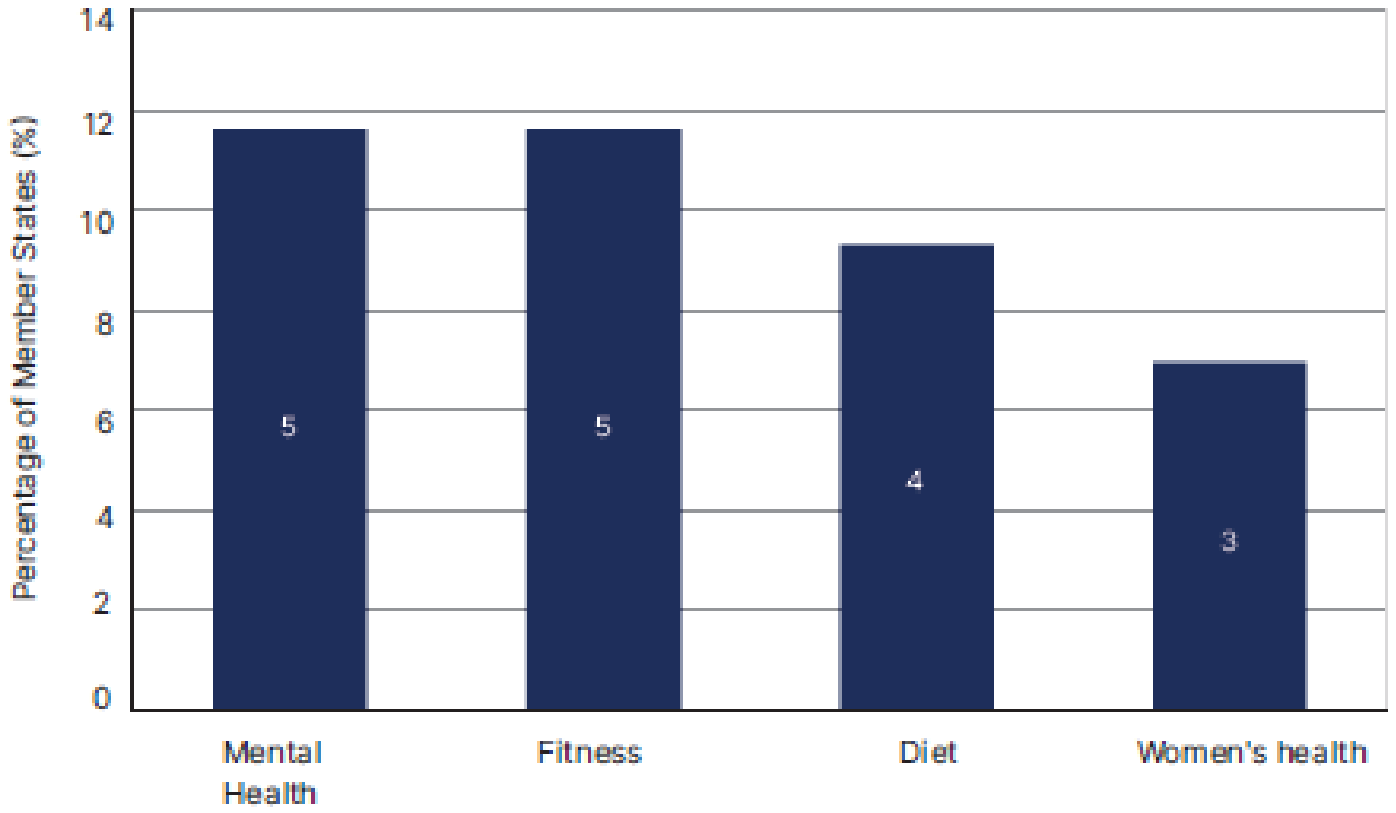
Incentives and guidance for innovation and research on mApps by subregion



Barriers to mApps integration into clinical practice by subregion



Types of mApps evaluated and approved (n=43)



Considerations

- Member States should consider **establishing entities** for mApp regulation and ownership security and privacy
- The **evaluation** of mHealth programmes and Apps should become the norm rather than the exception
- **Policy strategies** are needed to support the regulatory environment. National mHealth policies, strategies and regulations should be in line with those international
- Member States should have **national entities to promote the training** of health professionals, as well as of patients and citizens, to foster beneficial use of mHealth solutions

Thank you!

c. Towards the European Health Data Space

European Health Data Space

Roundtable on reimbursement of health apps
13 February 2024

Ole Gjerrestad
Policy officer DG SANTE
ole.gjerrestad@ec.europa.eu

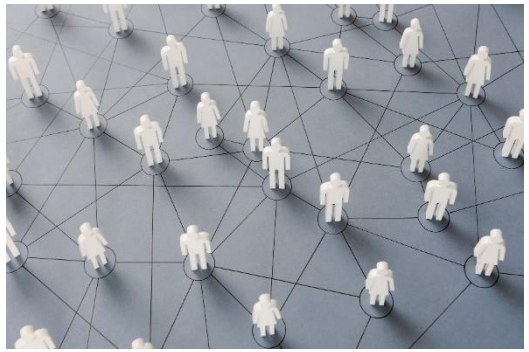
Why act now?

- **The 2020 European Strategy for Data** announced the Commission's plans for European data spaces, including EHDS
- The COVID-19 pandemic has clearly demonstrated **the importance** of digital services in the health domain, and has triggered **an important acceleration in the uptake** of digital tools. The European Digital Covid Certificate – positioned the EU as a **global leader and standard setter in digital health**
- The challenge now is **to maintain this momentum** on the importance of health data

Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data (Chapter II)



Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems) (Chapter III)

Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities (Chapter IV)

Secondary uses of health data

Primary uses of health data

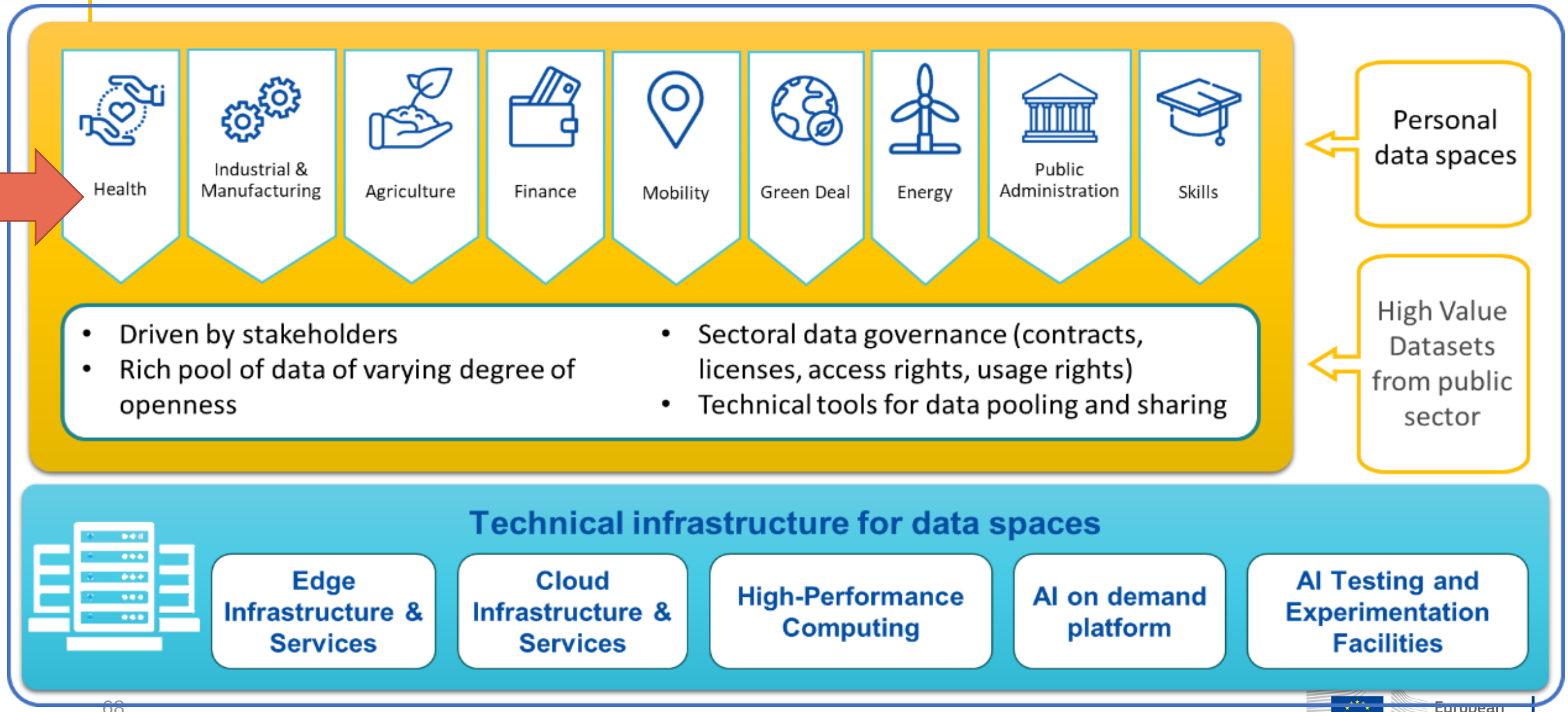
European Commission

Legal basis and scope of health data

- **Legal basis - Article 16 TFEU** and **Article 114 TFEU**
- **Article 16-** EHDS is building upon GDPR, strengthening the rights to the protection of personal health data and building on possibilities of EU law for processive sensitive health and genetic data
- **Article 114** - EHDS aims to improve the functioning of the internal market and the free movement of goods and services to avoid legislative fragmentation in the internal market and different rules and practices across the EU
- **Full respect of Article 168 TFEU –** EHDS does not intervene in organisation and delivery of health services and medical care of Member States

European Commission

EHDS – **the first** sector specific European Data Space



EHDS and wellness applications

European Commission

Definition in the context of European Health Data Space

‘wellness application’ means any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as well-being and pursuing healthy life-styles;

European Commission

Article 31 in CH III of the EHDS proposal

Where a manufacturer of a wellness application claims interoperability with an EHR system (C) **in relation to the harmonised components** of EHR systems and therefore compliance with the essential requirements laid down in Annex II and common specifications in Article 23, such wellness application (C,P) ~~may~~ shall be accompanied by a label, clearly indicating its compliance with those requirements. The label shall be issued by the manufacturer of the wellness application, (P) **and the competent market surveillance authority shall be informed**.

- Harmonized components are (1) interoperability (priority categories) and (2) logging
- When a manufacturer claims interoperability, it **must** use the label
- The label must be **registered** in the database of the competent market authority

- C- Council
- P - Parliament

European Commission

Implementing EHDS - Joint action on primary use (EX-EHR)

Scope of Work Package 8 in JA09 Ex-Ehr

- Establish Assessment Framework: Develop a framework for assessing the interoperability of EHRs, personal health data spaces, and wellness applications.
- Prepare Guidelines for Wellness Apps: Provide guidelines for app developers based on EHDS regulations and ISO/TS 82304-2.
- Evaluate Previous Initiatives: Assess results from previous initiatives (e.g., Label2Enable, EuroCAS) to inform the development of guidelines and assessments.

European Commission

Primary use of health data

European Commission

My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union

MyHealth@EU

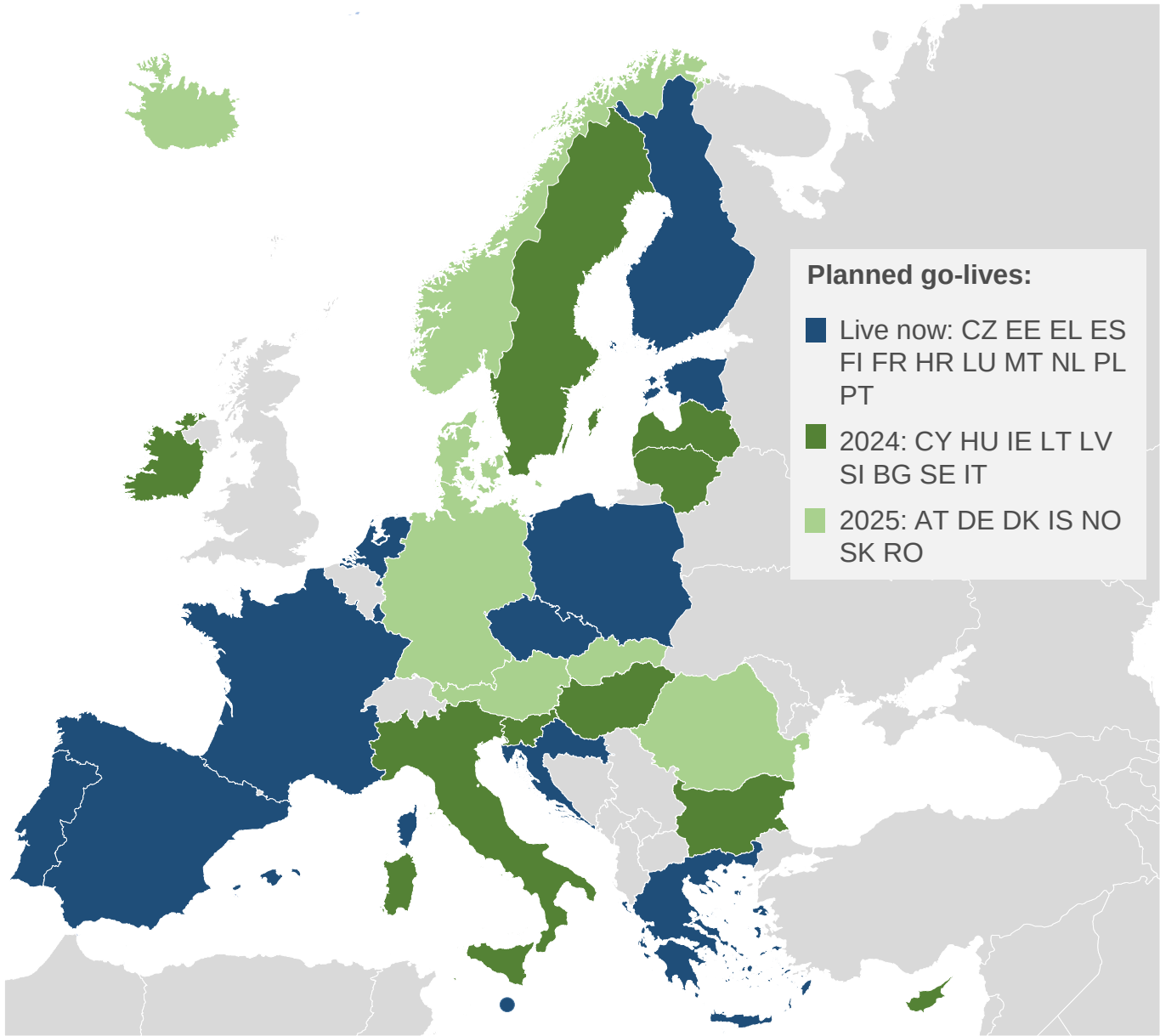
MyHealth@EU is the existing infrastructure that connects healthcare providers in 12 Member States.

The current live services are

(1) Patient Summaries and (2) ePrescriptions.

These services will be expanded to include (3)lab results, (4) hospital discharge reports and (5) medical images.

Together they comprise the priority categories in EHDS.



Cross-border electronic prescription in action

Illustration based on materials from: THL/FI

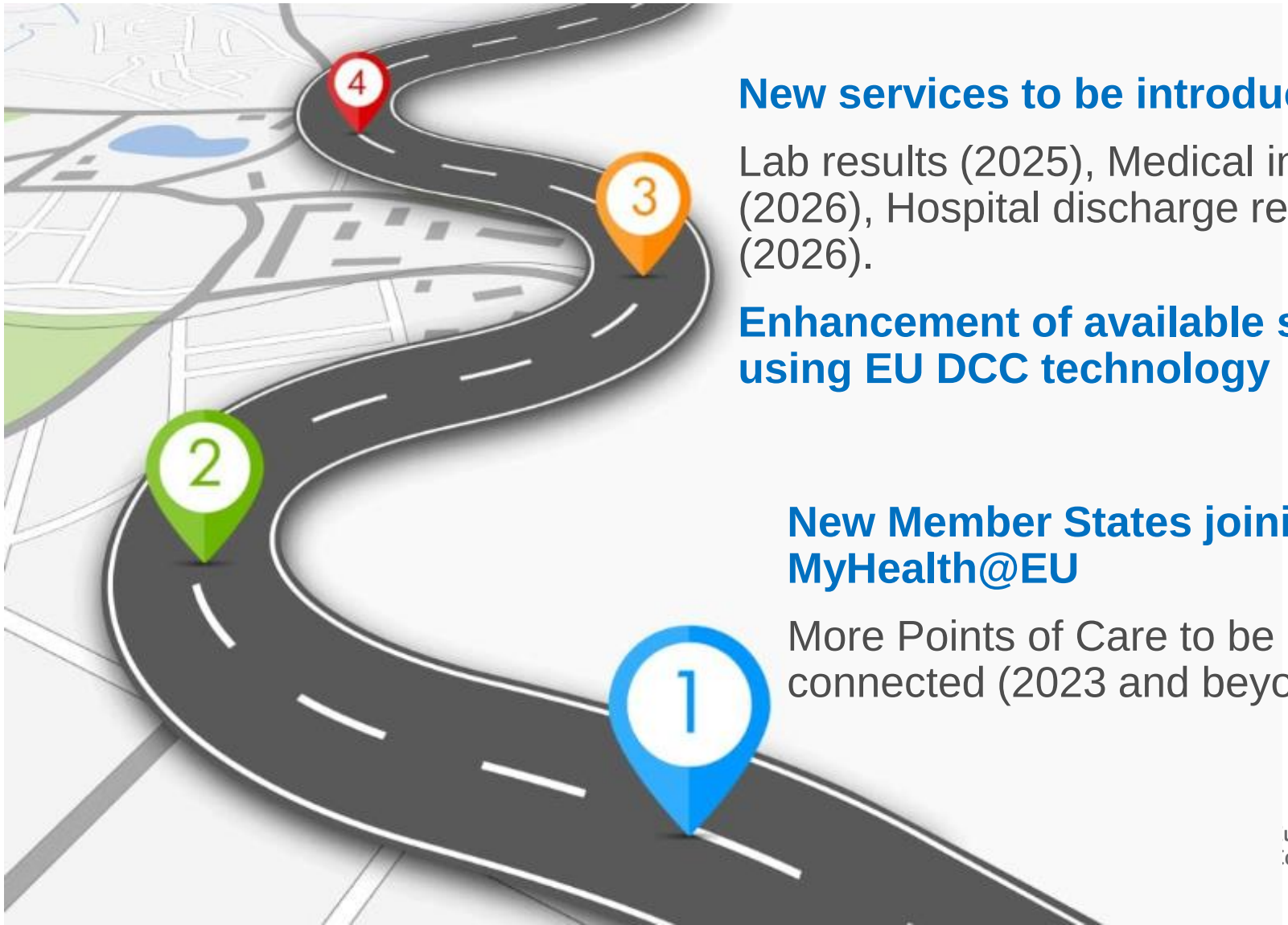
MyHealth@EU roadmap

Entry into force of EHDS regulation

Mandatory participation in MyHealth@EU for all Member States with transitional periods for the different services

Pilot on Patient Access

to enable citizens to access health data in MyHealth@EU (Jan 2023-Jun 2024).



New services to be introduced

Lab results (2025), Medical images (2026), Hospital discharge reports (2026).

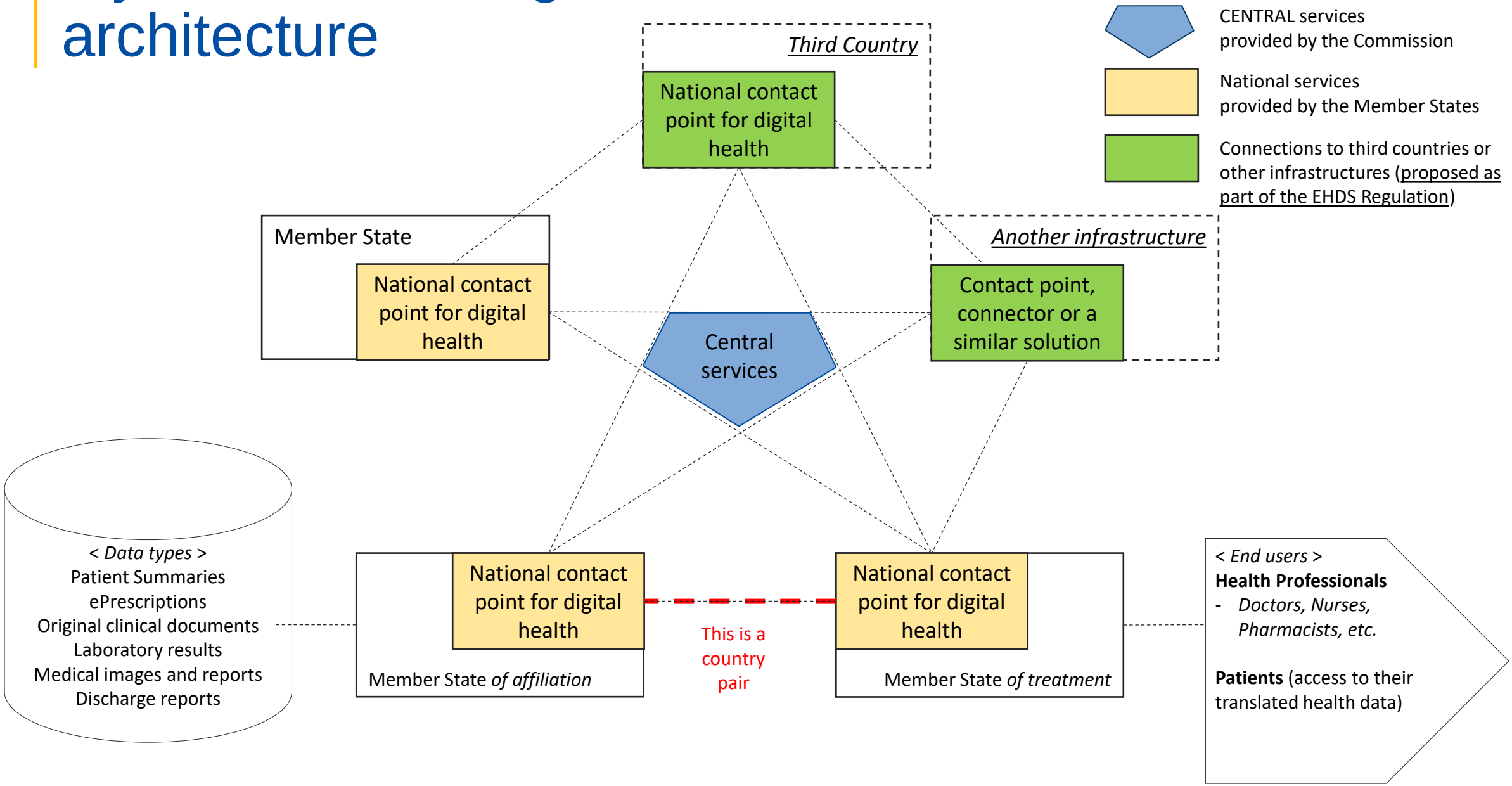
Enhancement of available services using EU DCC technology

New Member States joining MyHealth@EU

More Points of Care to be connected (2023 and beyond)

uropean
ommission

MyHealth@EU high-level architecture



Secondary Use of Health Data

European Commission

Data User journey

Data User

Data discovery — What health data exists to support my research?

Permit application — Can I use this data for my research project?

Data preparation — Issue permit and make data ready for use, ensuring data quality and privacy.

Health Data Holders

Health Data Access Body

Data provision — Give access to Secure Processing Environment

Data use — Analyse and process data

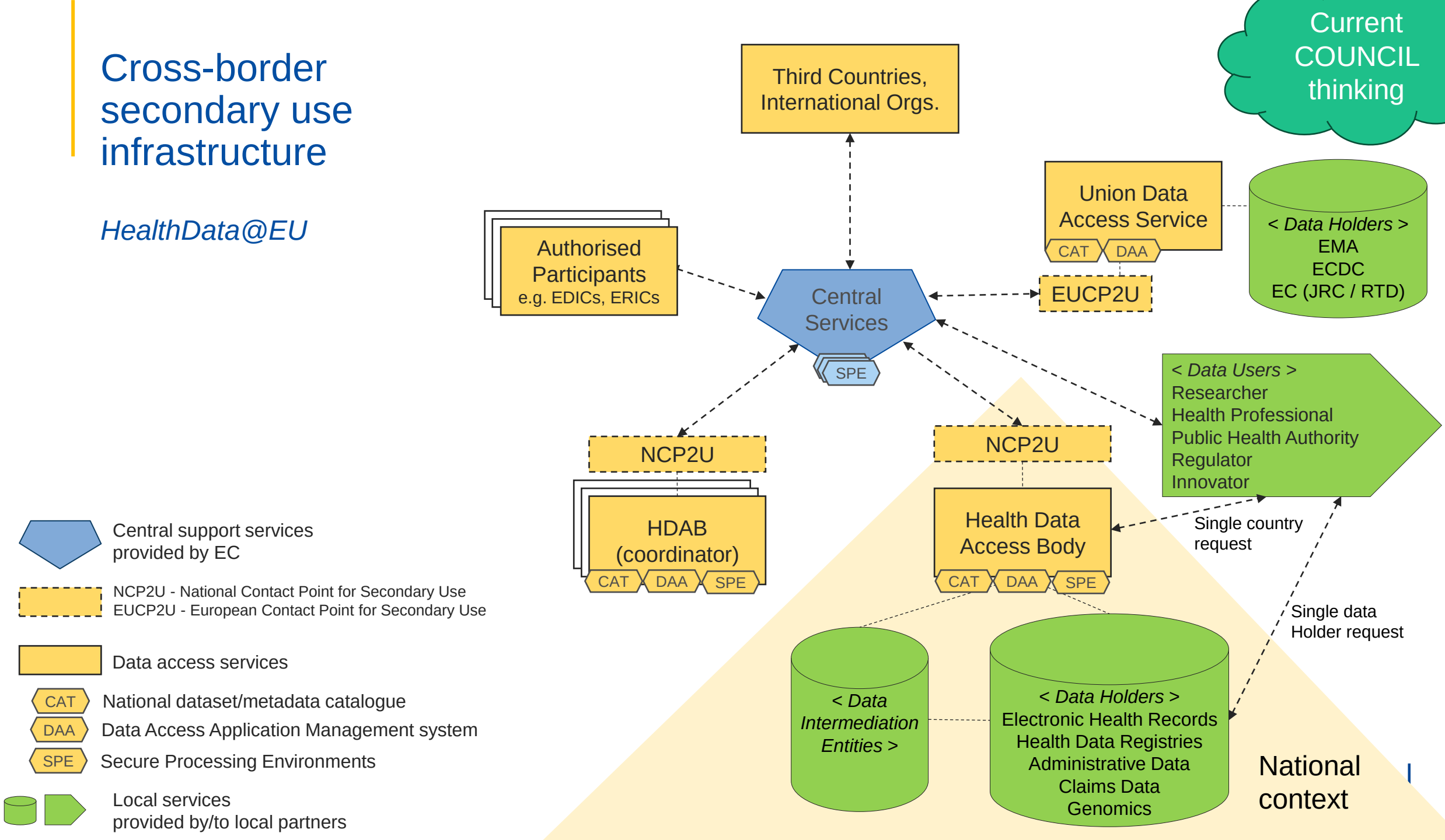
Data User

Results output — Publish of results, ensuring privacy and verifiability

European Commission

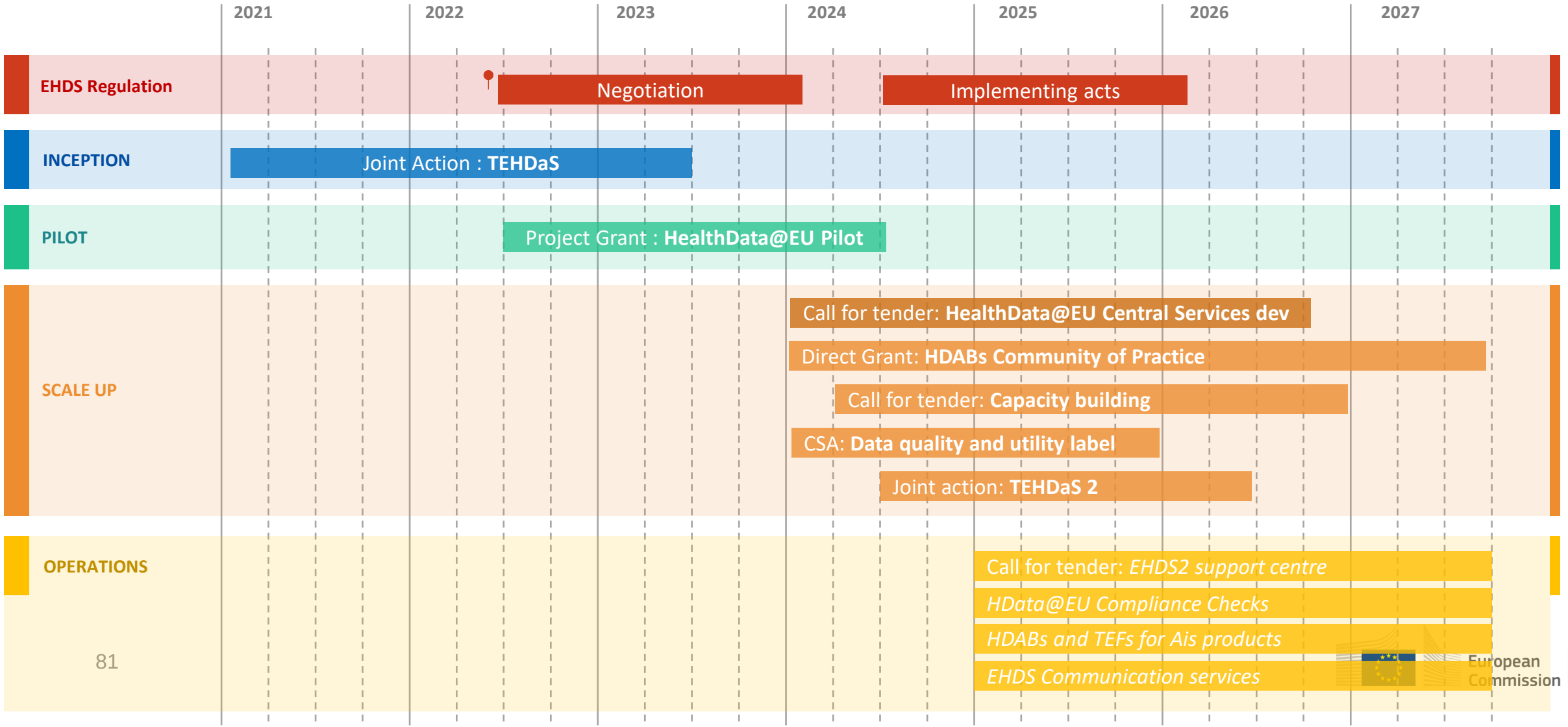
Cross-border secondary use infrastructure

HealthData@EU



Timelines are indicative.

EHDS2 – Overall timeline



European Commission

European
Commission

d. What is the role of EU level legislation in the pathway to health and wellness apps reimbursement

Petra Wilson, Senior Advisor, European Health Policy and EU affairs, HIMSS

Funded by the European Union

CONTENT

- **Current EU legislation**
- **Emerging EU legislation**
- **Where are Member States going?**

Current EU legislation I

Reimbursement of apps in the healthcare sector is <u>not</u> regulated at EU level

Why?

Public Health is a shared competences (Art 168 TFEU)

- **Member States** define and deliver healthcare, including allocation of resources
- **EU**'s actions are complimentary, focusing on cross-border aspects and harnessing new technologies for the benefit of efficient health systems

Current EU legislation II

LEGISLATION

Safety / Consumer protection	➢ Medical Device Regulation (MDR) ➢ Product Liability Directive
Data protection	➢ GDPR
Bring to market	➢ Regulation on HTA ➢ Transparency Directive of pricing and reimbursement of medicines
Data security	➢ Network and Information Security Directive (NIS2)

Impact on Apps

- Decide if a Medical Device, comply with MDR
- Liability for harm
- Protect app user data
- If publicly reimbursed transparency *could* apply
- Healthcare

≠

EU level legislation does not dictate levels of reimbursement

Emerging EU legislation

LEGISLATION

Creating Data Spaces	➢ Data Governance Act
Making non-personal data available, transferable	➢ Data Act
Making health data more useable, inc from wellness apps	➢ EHDS Regulation
Safeguarding data in cyberspace	➢ Cybersecurity Act ➢ Cyber Resilience Act
Safeguarding EU values, principles in AI systems	➢ AI Act

Impact on Apps

- Data interoperability and labelling (FAIR)
- Separation of personal and none personal data generated by apps
- Providers of app based services to ensure data security

≠

EU level legislation does not dictate levels of reimbursement

Reimbursement models are defined by national law

Existing approaches selected markets – as reported by EFPIA*

Country	National value assessment framework	National reimbursement pathway	Available funding mechanisms
Belgium	DTx clinical and/or socioeconomic value evaluated through Validation Pyramid	Apps in Level M3 of Validation Pyramid reimbursed by payers	Centralised funding for mHealth apps
Germany	DiGA process: Standalone DTx evaluated by BfArM	DiGA process: All listed DiGA are reimbursed	GKV-SV centralised funding for DiGA
France†		Apps in Level M3 of Validation Pyramid reimbursed by payers	Centralised funding for mHealth apps
Italy			

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* https://www.efpia.eu/media/677347/improving-access-to-digital-

Reimbursement models are defined by national law

Existing approaches selected markets – as reported by EFPIA*

Country	National value assessment framework	National reimbursement pathway	Available funding mechanisms
Netherlands			Covered by individual health insurers
Spain			Evidence of limited regional reimbursement
Sweden			
UK	NICE has developed evidence standards framework for digital health technologies		Can be funded locally by Integrated Care Systems

Funded by the European Union

* https://www.efpia.eu/media/677347/improving-access-to-digital-

What are the Common Challenges?

COMMON CHALLENGES AT NATIONAL LEVEL

- Lack of clear conceptualization of digital health
- Limited applicability of HTA models
- Lack of value-based pricing and reimbursement mechanisms
- Slow development of reimbursement models and pathways in healthcare funding

COMMON CHALLENGES AT EU LEVEL

- Limited EU level regulation of Apps and Dtx – only those in scope of MDR, lack of MDR harmonisation on dossier interpretation
- No harmonised EU level evidence requirements for HTA, esp. on use of RWE – potential expansion on HTA Regulation to apps and DTx

- *van Kessel R, Srivastava D, Kyriopoulos I, Monti G, Novillo-Ortiz D, Milman R, Zhang-Czabanowski WW, Nasi G, Stern AD, Wharton G, Mossialos E. Digital Health Reimbursement Strategies of 8 European Countries and Israel: Scoping Review and Policy Mapping. JMIR Mhealth Uhealth 2023;11:e49003 doi:* 10.2196/49003
- EFPIA - https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf

Thank you for your attention

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13/2/2023

Disclaimer
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Break

Part 2 Decision-makers' perspectives on the reimbursement of health apps

a. Sussex

b. Croatia

c. Catalonia

d. Portugal

a. Sussex

Humber and North Yorkshire
Health and Care Partnership

Empowering Health Care

Unlocking the power of digital health Apps in collaboration with NHS Humber & North Yorkshire ICB

Presented by: Carrie Cranston – Digital Programme Support Manager

ORCHA

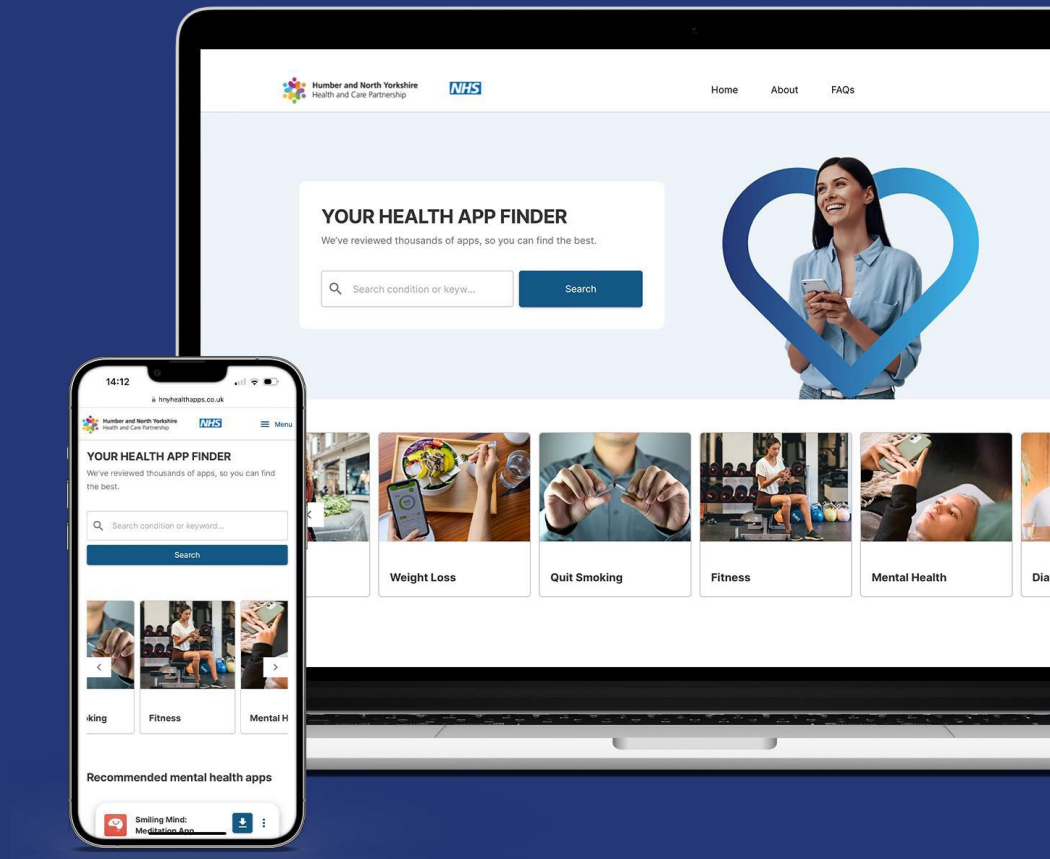
Introduction

Humber and North Yorkshire
Health and Care Partnership

- NHS Humber and North Yorkshire Integrated Care Board looks after the NHS spending and performance across a region home to 1.7million people

- A key priority within the Humber & North Yorkshire Health & Care Partnership Digital Strategy is to be able to empower citizens to better manage their own health and wellbeing, via the use of digital solutions.

- This is driven by citizen need across all health and care services and ultimately, supports with a reduction in capacity and demand for other services which is at an all-time high.



Partnership and Collaboration

Humber and North Yorkshire
Health and Care Partnership

Our partnership with ORCHA has allowed us to identify pain points across the ICB where digital health solutions can allow for support and self-management of identified condition areas.

Utilising digital health solutions and the assurance provided through the ORCHA platforms has enabled us to design safe tailored health campaigns for specific target populations.

ORCHA

Supporting demands on services

Humber and North Yorkshire
Health and Care Partnership

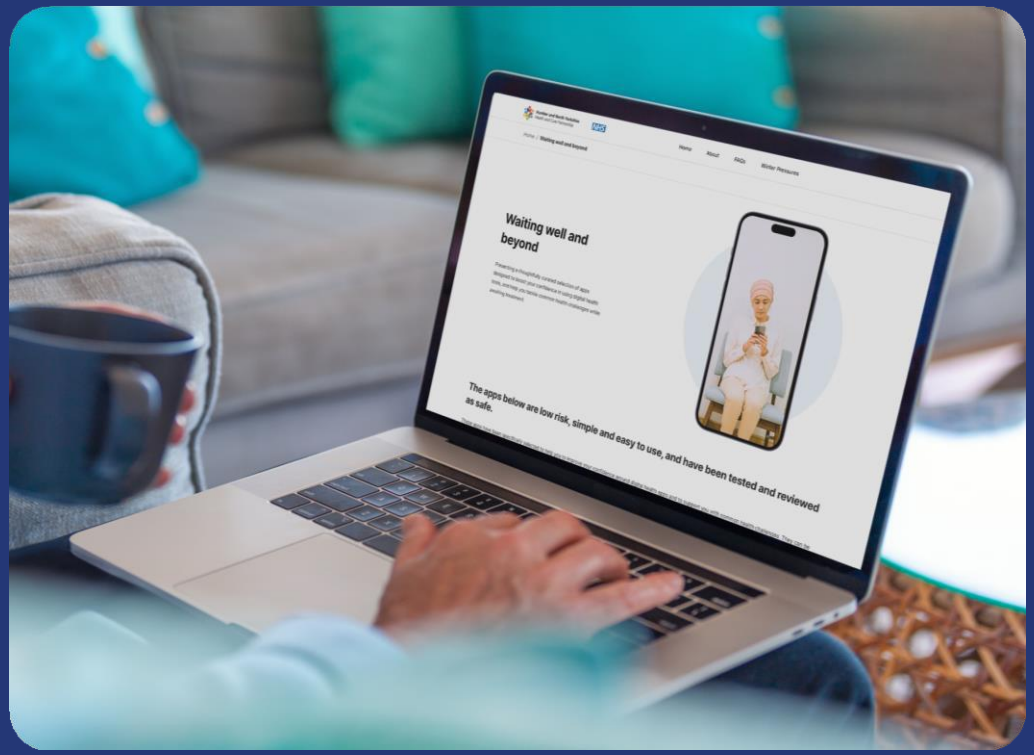
One of the key needs identified, was to support our acute trusts across Humber and North Yorkshire around their Elective Care Recovery Programme.

- Cardiology
- MSK
- Ophthalmology
- Dermatology

Waiting well and beyond

Humber and North Yorkshire
Health and Care Partnership

- A carefully selected number of apps were chosen with guidance from ORCHA's Clinical team.
- All apps were then verified by ORCHA's assessment team to make sure they met the ORCHA Baseline Review adding an additional layer of assurance.
- ORCHA's Product and Development team supported building the landing page to ensure it was a space that was easy to navigate and engaging to the population.
- ORCHA's team collated digital collateral including Posters and QR codes so that we could widely promote the campaign.



Activation and Deployment

Humber and North Yorkshire
Health and Care Partnership

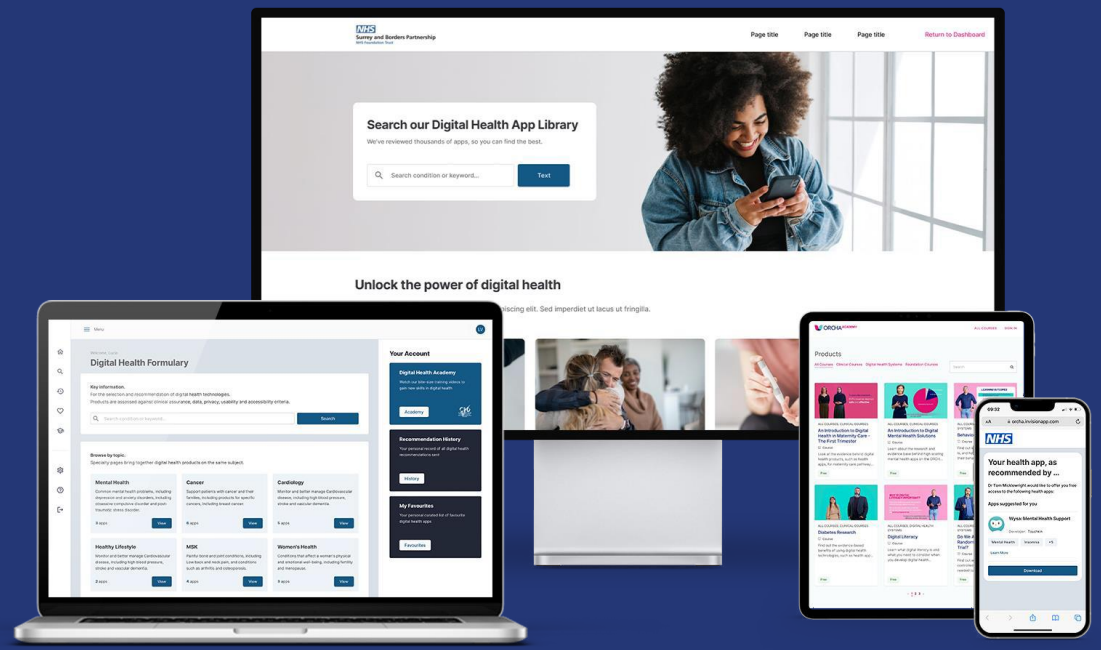
So, what have we been doing locally to deploy and encourage the use of the HNY Elective Care Campaign?

Direct to population via the patient facing library

- Social Media engagement
- GP Text Messages
- Digital collateral in GP Surgeries and hospital waiting areas
- Promoted on ICB intranet sites and newsletters
- Included on outpatient letters to patients

Professionally supported through the digital formulary

- Digital collateral to be shared with patients
- QR Codes given to professionals for patients to scan
- Professional training to support direct app recommendations to patients



Outcomes and Results

Humber and North Yorkshire
Health and Care Partnership

7,648 Page Visits

27% Downloads

During August and September, the programme saw 7,648 people visit the page, and approximately 27% of these people download a health app as a result

(1,021 on page downloads and an equal number of off-site downloads).

£93 Saving Per App

£189,906 total saving

Based on NICE evidence, each download helps save the NHS £93 in costs. And so over eight weeks, this campaign not only helped provide support to people when they needed it, improving their health, but also saved the NHS £189,906.

Over £1 million potential saving per year

If this continues over one year, the saving could be over one million pounds (£1,006,706).

Future Outlook

Humber and North Yorkshire
Health and Care Partnership

- Continuation of Elective Care Support
- Humber and North Yorkshire Swap and Stop Campaign
- Diabetes and Long-Term Condition Support
- Virtual Wards
- Mental Health Support

b. Croatia

Why and **How** TO DECIDE to start reimbursing health apps

Siniša Varga, former Minister of Health Croatia

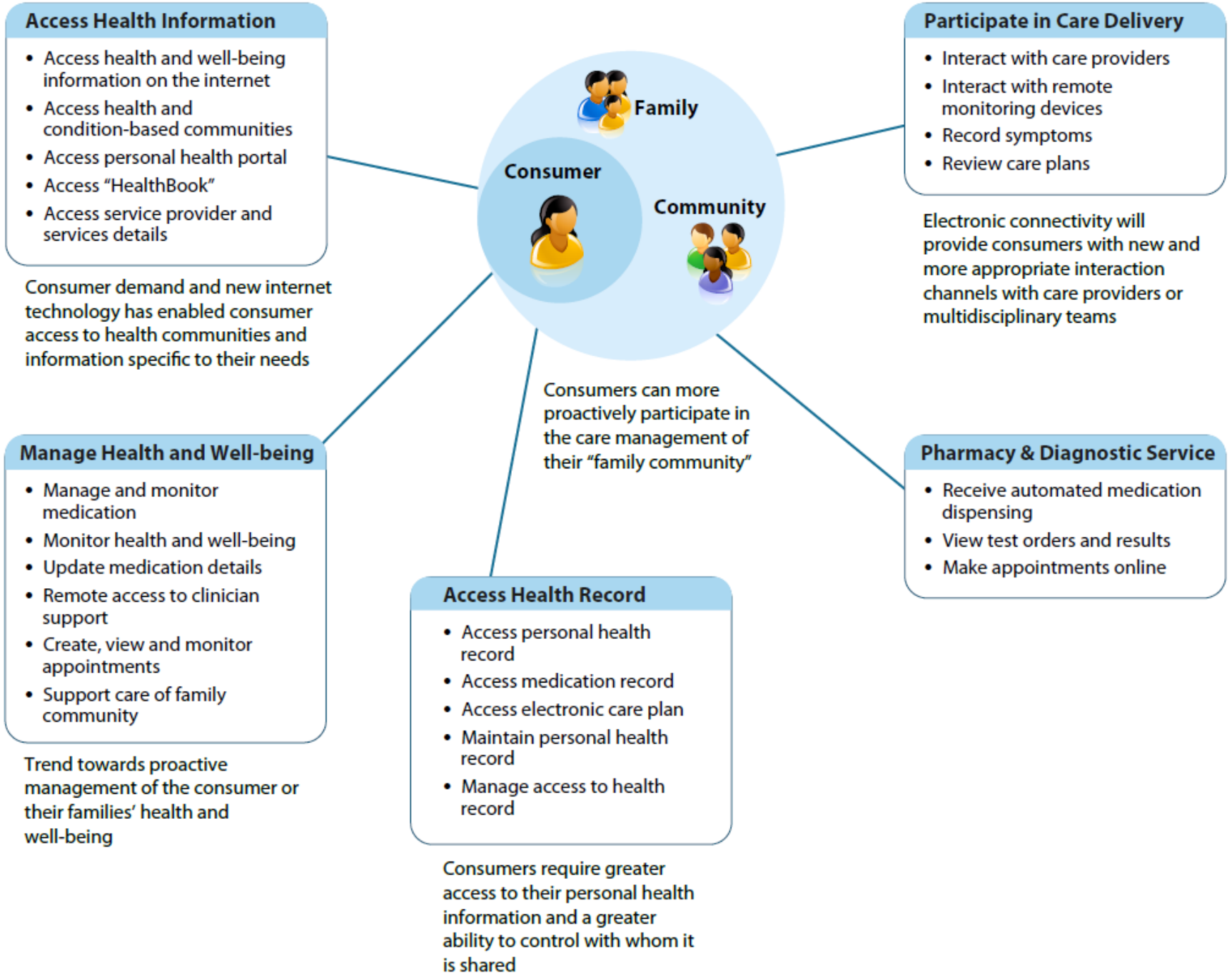
3rd roundtable on the reimbursement of health apps

February, 2024

WHY

– for patients

- Access Health Information
- Manage Health and Well-being
- Access Health Record
- Participate in Care Delivery
- Pharmacy &Diagnostic Service



Source: WHO National eHealth Strategy Toolkit

WHY – for other stakeholders (HP and HCP)

- Enables **communication** and data exchange between **patients** and **providers**
- **Supports treatment** (health apps as part of the integrative approach)
- Allows **remote consultations** with patients, for second opinions, and with professional networks
- Improves **integration of care** and multidisciplinary healthcare providing
- Supports healthcare professionals with **knowledge base** within the apps, especially if integrated in guidelines
- Improves **digital health literacy**
- Improves **shared decision making** with patient
- Increases **adherence to therapy**

WHY – for other stakeholders (government)

- Delivers more **reliable, responsive and timely reporting** on public health; as health becomes increasingly central to economy, security, foreign affairs and international relationships.
- Creates **enabling environments** rather than technology limitations.
- Offers **new roles** for stakeholders, health professionals, authorities, citizens and others.
- Improves **business processes**
- Compensates for **lack of doctors**
- Compensates **unlimited demand** with limited resources (time/people/money)

WHY – for other stakeholders (public health)

- Monitors **quality and safety**; improves care processes and reduces the possibility of medical errors
- Assists **mobility of citizens and their medical records** – providing patient information when and where needed
- Opens new opportunities in **basic and applied research**; from health knowledge to policy and action (providing evidence for public health interventions)
- Identifies **disease and risk factor trends**; analyses demographic, social and health data; models diseases in populations

HOW – leadership, governance and multi-sector engagement

- Direct and coordinated **implementation at the national level**; ensure **alignment** with health goals and political support; promote awareness and engage stakeholders.
- Use mechanisms, expertise, coordination and partnerships to develop or adopt all components (e.g. **certification scheme, standards**).
- Clearly **define roles and responsibilities** (certification body? HTA?)
- Support and empower required **change**, **implementation** of recommendations and monitoring results for delivery of expected benefits.
- Enable **transparency**, Measure **results**, Manage **information** flow
- Take special care of the **vulnerable group** (education, equipment)
- Engage **professional associations** to implement health apps in **guidelines**

HOW – strategy and investment

- Ensure a **responsive strategy** and plan for the national implementation.
- **Lead planning**, with involvement of major stakeholders and sectors.
- **Align financing** with priorities, government, patient and private sector funding identified for medium term.
- Plan **creative payment schemes** (incentives for the stakeholders involved):
  - doctors who are **prescribing** health apps,
  - patients who are regularly **using** health apps,
  - healthcare providers who are **promoting** health apps,
  - manufacturers who are providing **innovations** (carefully assess the value compared to price)

HOW – legislation, policy and compliance

- Adopt **national policies** and **legislation** in priority areas.
- Ensure **safety and proper use**
- Review **sectoral policies** for alignment and comprehensiveness.
- Establish **regular policy reviews**.
- Create a **legal and enforcement environment** to establish trust and protection for consumers and industry.
- Align with **EU** (best) **practice**
- **Regulate use** and sharing of collected data for research and the public interest

HOW – standards and infrastructure

- Adopt **national policies** and **legislation** in priority areas.
- Review **sectoral policies** for alignment and comprehensiveness.
- Establish regular **policy reviews**.
- Create a **legal and enforcement environment** to establish trust and protection for consumers and industry.
- Set clear **interoperability requirements**
- Integrate with **EHR**
- Take care of the **network coverage** in rural parts (60 inhabited islands)

CONCLUSIONS

- **WHY** – clear necessity for patients and other stakeholders
- **HOW** - national level coordinated implementation aligned with health goals and political support
- **REIMBURSEMENT** of health apps will happen, this is the only way forward for any country.
- It is important to choose a good path adapted for each countries situation/possibilities where **CERTIFICATION** is at utmost importance to ensure primarily safety and efficacy for the patients.
- The value is clear, however good **GOVERNANCE** is a key success factor.

Thank you

c. Catalonia

S/Catalonia: Assessing the Landscape of Health App Reimbursement and Providing Recommendations

13th of February 2024

Label2Enable 3rd roundtable discussion

/Salut Generalitat de Catalunya

S/ Agenda

1. About Catalonia
2. Background
3. Current status
4. Reflections and recommendations

S/ About Catalonia – Who are we?

8,001,703

Population in Catalonia on January 1, 2024.

Universal coverage

The publicly health care system of Catalonia was founded in 1990 under the principle of universality; so all individuals and communities are able to receive the health services.

12,500 M€

Catalan Health Service budget for 2020. The system is funded from general taxation and government founds and contributions.

> 160

Health care entities to provide health care services.

HIT fragmentation

Huge fragmentation of HIT across the Catalan Health System:

- 1 EMR for primary care.
- > 29 EMR products in the Intermediate care hospitals.
- At least 10 different systems for social care records.

699

Facilities that range from primary health care centres to hospitals and intermediate care centres.

- 369 Primary Care Centers
- 69 Hospitals
- 96 Intermediate Care Centers (long-term)
- 165 Mental Health Centers

/Salut Generalitat de Catalunya

S/ About Catalonia - Organisation

Generalitat de Catalunya
Departament de Salut

Regional Ministry of Health → Sets policy

CatSalut
Servei Català de la Salut

Public insurance → Health planning and allocation of resources

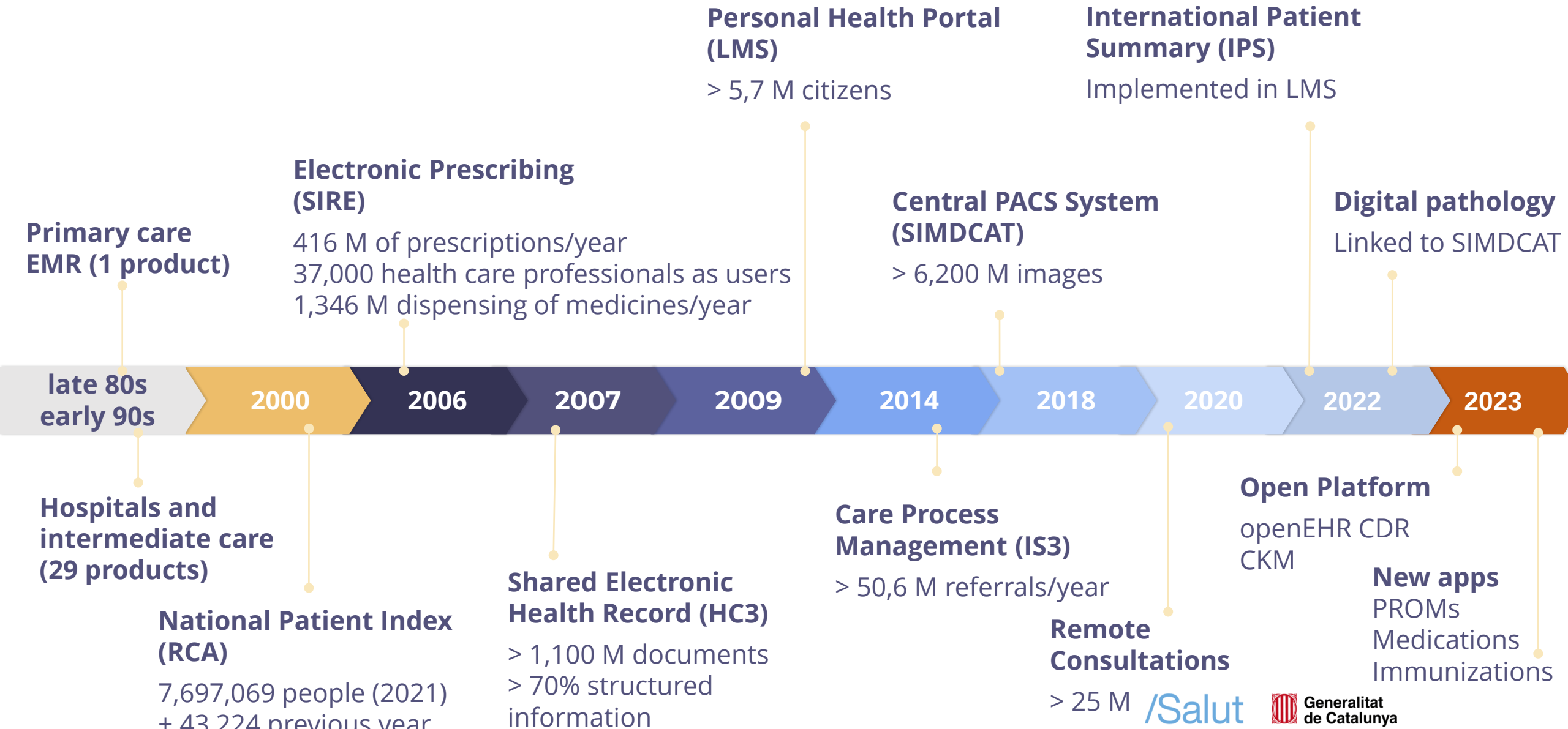
Agència de Qualitat i Avaluació Sanitàries de Catalunya

Health Technology Assessment Agency → Quality and evaluation of new therapeutics

TIC Salut Social

Digital transformation → Promote innovation through the digital transformation

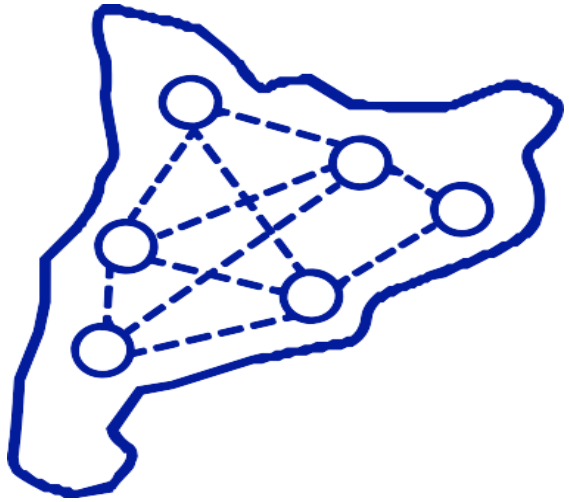
S/ Background – The Digital Health Platform



/Salut

Generalitat de Catalunya

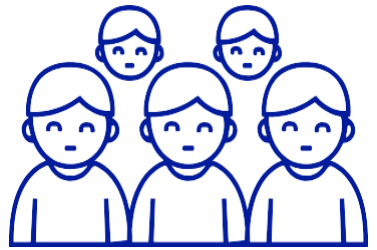
S/ Background – mHealth (2015)



Catalan Ecosystem

mHealth

- **Promote mHealth solutions**
- **Observatory**
- **Assessment Process**
- **Interoperability framework**
- **New guidelines and requirements**

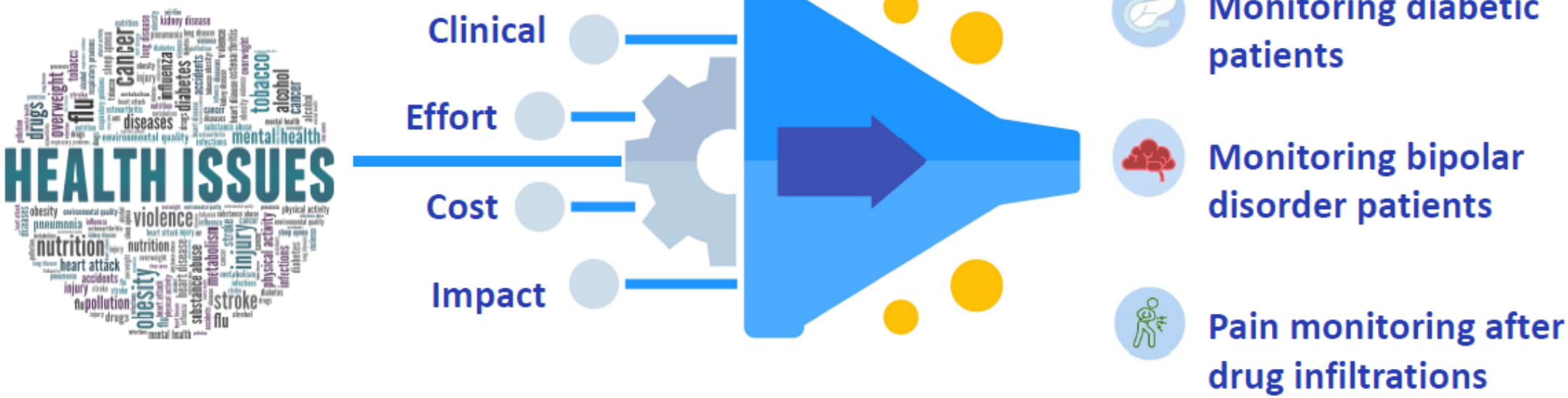


Citizens

S/ Background – how to set priorities?

Generalitat de Catalunya
Departament de Salut

CatSalut /Salut



S/ Current status – assessment of mHealth

1. **Comparison of the FTSS and ISO Evaluation Framework –** Production of an adaptation guideline for countries having their own assessment framework.

2. **Dual Assessment** – Evaluation of 2 apps following the FTSS and ISO Evaluation Frameworks to compare results.

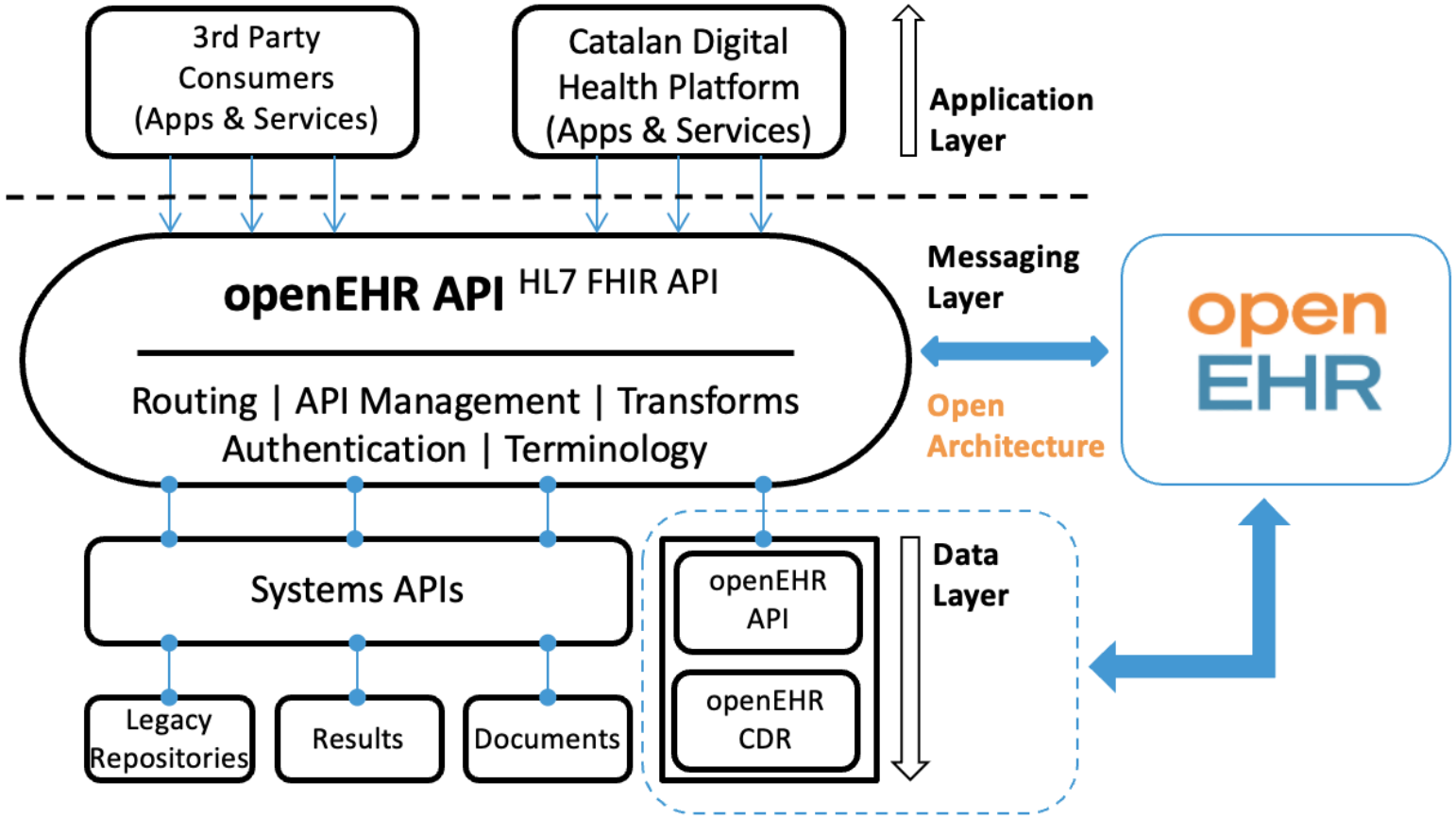
3. **Publication of the Requirements Guide for Digital Assets to all Providers** – Guidelines for providers in Catalonia, including security, usability, and accessibility requirements, also adapted to ISO.

S/ Current status - reimbursement

1. Catalonia is not directly reimbursing the deployment of mHealth solutions.

2. Service provider organisations have found alternative ways to introduce such solutions in routine care under the umbrella of the current reimbursement system.

S/ Current status - interoperability



The open platform approach for Catalonia (source: adapted from the Apperta Foundation – United Kingdom)

S/ Reflections and recommendations

1. **Strategy towards the adoption of mHealth solutions** → FTSS in charge of promotion, observatory and assessment.
2. **Generating evidence** → The assessment process produces results that generate transparency and trust.
3. **Scaling up beyond pilots** → Providing the capabilities for mHealth solutions to interoperate with the Catalan Digital Health Platform.
4. **Participation in international activities** → FTSS participates in international projects to bring in new evidence.
5. **Import the learning from other therapeutic areas** → Pharmacotherapeutics have clearly established pathways towards moving their products into routine care. Let's copy!

Thank you!

Jordi Piera-Jiménez, PhD, MBA, FHIMSS
Director of the Digital Health Strategy for Catalonia

Director, openEHR International

Professor collaborator, Faculty of telecommunications, informatics and multimedia, Open University of Catalonia

jpiera@catsalut.cat
@jpieraj

d. Portugal

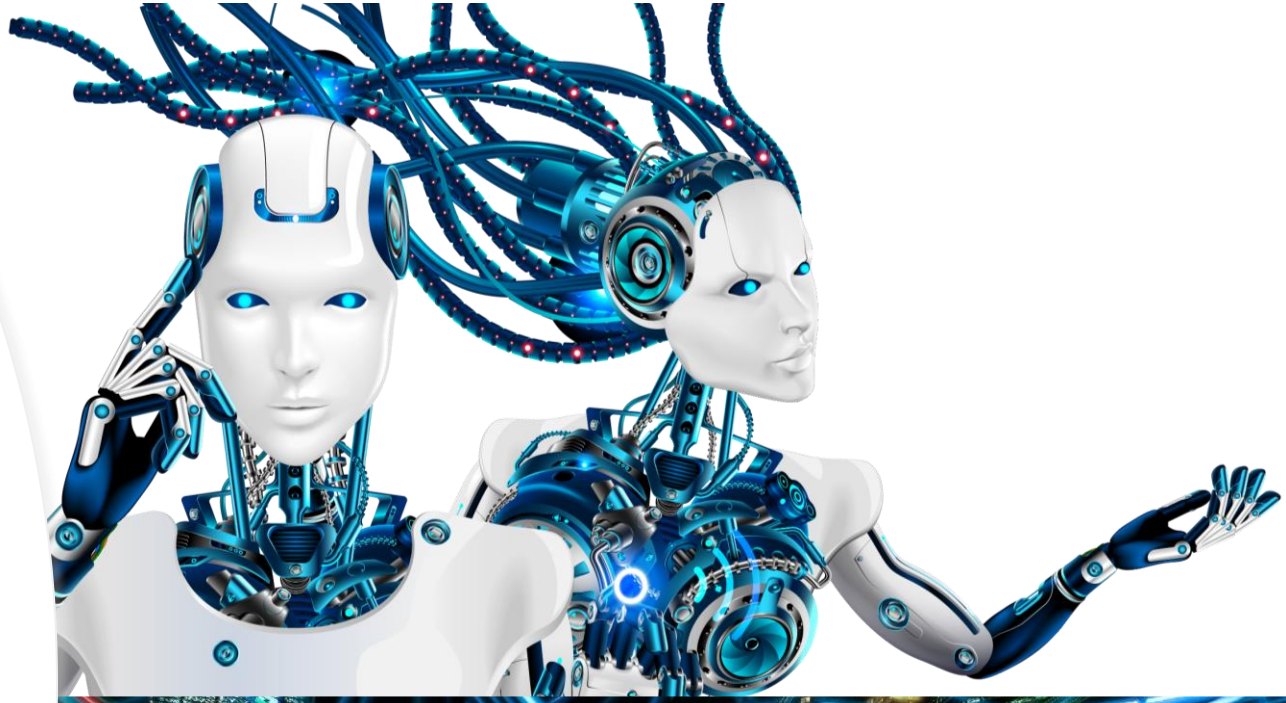
Healthcare transformation

Henrique Martins

ex – “enabler, labeller (procuring), creator of Digital Health mAPPs at the MoH. SPMS

10min Summary…

- Enable for what?
- Digital Health Systems and Healthcare Transformation
- G-EHR and Global Treaty on Digital Health
  - Labelling in Africa (next work)



XXI Century Health & Main Advanced Digital Health Challenges

+ age

+ tech

+ Knowledge

Data - Open and FAIR principles, (the NEW GOLD)
Information – Sharing is key (content interoperability)
Knowledge – is rare (involves Hybrid-I and Advanced-I)
Meta-knowledge – network and strategy (know who knows what and how it knows)

Aims for Health Care Delivery System

- Equitable
- Safe
- Effective
- Patient-Centered
- Timely
- Efficient

- **Digital Inclusion** - Capacity to ensure advanced tech is equitably accessible to organizations/citizens
- **Minimally disruptive Tele/meta health services –** Tele/metahealth services that offer high Quality-of-Care
- **Trustworthy Digital Clinical Services –** Including mHealth APPs; AI-based Solutions; Digital Therapeutics
- **Health data economy & health innovation –** Health data spaces for data exploration and care integration/innovation
- **Digital sovereignty & sustainability –** Creation of digitally advanced infrastructures and processes that cybersecurity, governmental sovereignty and cost-effective architectures

Digital Health Systems

- **Vision...**

- **Preventive, paperless, empowering, personalised, and accountable**. Digital healthcare strengths lay not in technology but rather that digital technology will be present in processes, professionals and people, in ways such that **everyone can be a healthcare creator**.

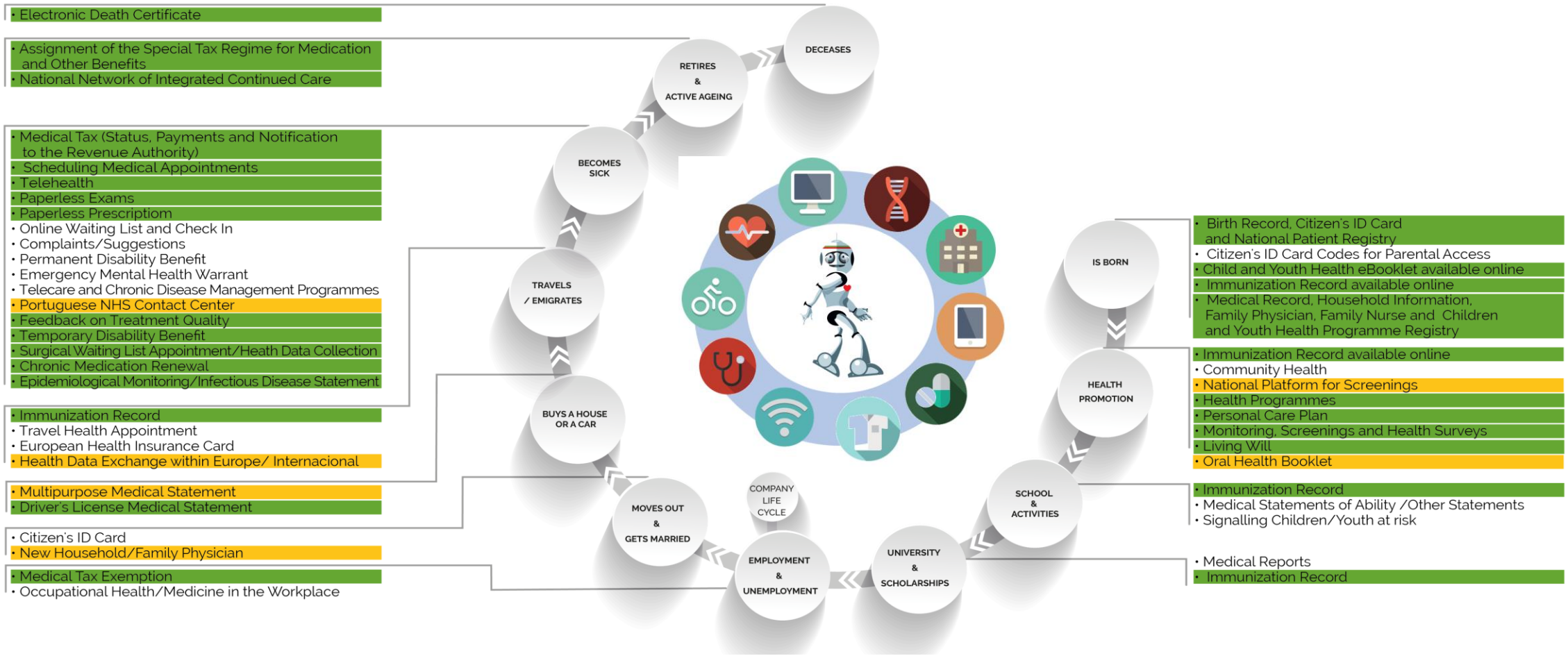
- He/she can be a prevention specialist; care for him/herself and family with the best scientific support; access digital therapeutics by default. Moving to any form of needed physical care, drug therapy, surgery, hospital admission, or ventilation support, etc, as last resource

SHARED SERVICES FOR MINISTRY OF HEALTH (SPMS)

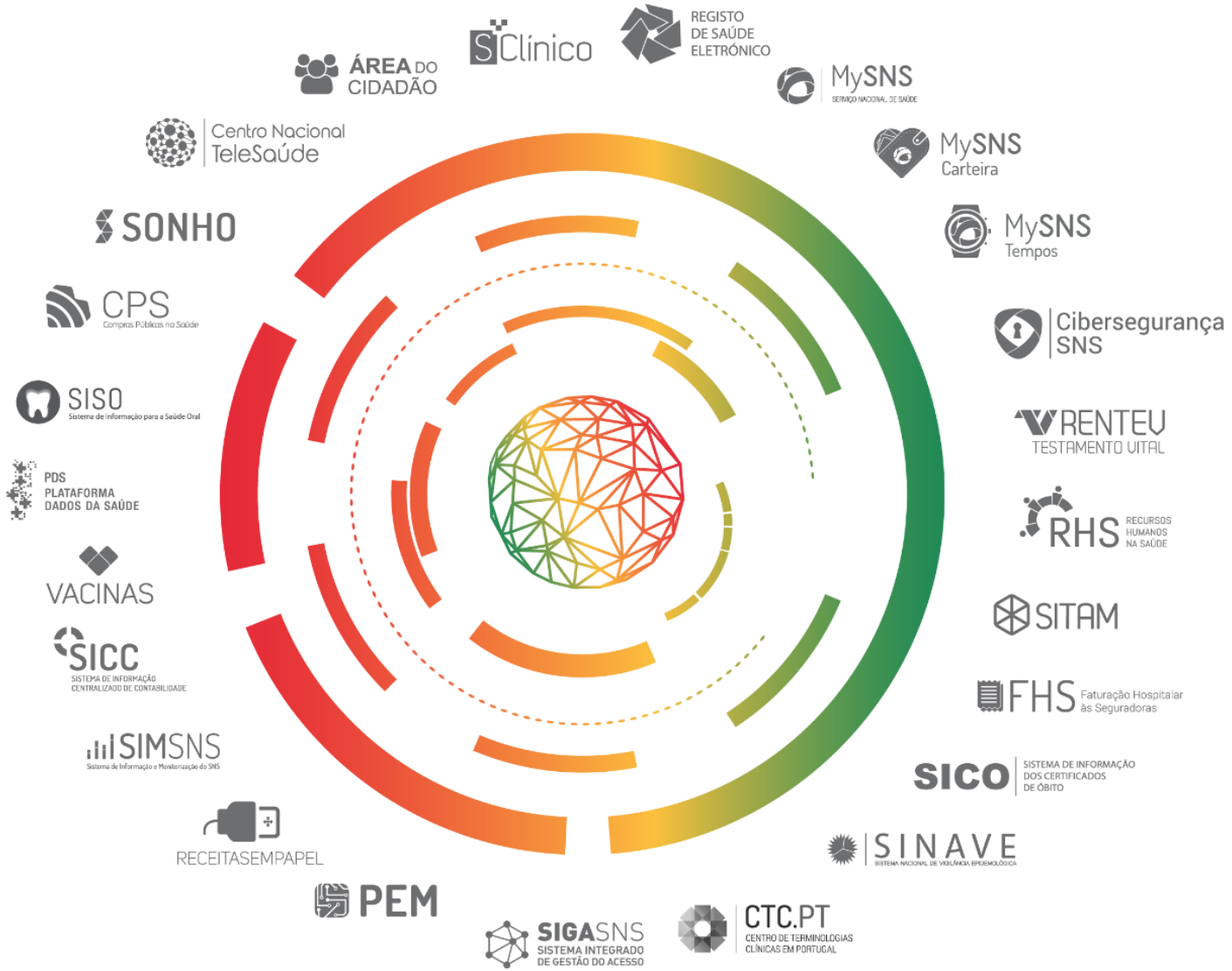
Citizen Life Cycle

CITIZEN'S LIFE CYCLE
IT Health Events

- Accomplished
- Under Development



ICT Solutions – SPMS Portfolio (some examplars)



Paperless Prescription (PEM)

To promote the complete dematerialization of the prescription of medicines throughout the national territory through authenticated electronic accesses to:

Healthcare Profissionals

Citizen as a Patient

Policy #205

SIMPLEX+
Ainda mais simples

PEM
Prescrição Eletrónica Médica

9 draft recommendations – HM Comments

1. **Govern** – Establish governance: who within the health authority is responsible for exploring and decision-making on assessment and reimbursement of health apps?
2. **Value** - Acknowledge **apps can do things that drugs can't and vice versa**. Both in their own way potentially add to health, wellbeing and can affect citizen, patient, carer and health system burden.
3. **Focus** - Determine which types of apps may deliver this value for which health issues and if applicable which types of patients. Consider these apps for payment / reimbursement.
4. **Create** - Create the habitat in which apps can deliver value. Integrate the quality assessed health apps of choice in care pathways to optimize value and to ensure potential for substitution / cost reduction is achieved.
5. **Fund** – Allocate related funds, consider innovative payment models, and explore need further policies.
6. **Assess** - Decide how to quality assess health apps or outsource such activities. Consider using a trusted EU framework with your own additional national requirements if applicable. Make the assessment results easily available, also to patients (e.g. label in frequently used / trusted sources.
7. **Enable** - Educate health care professionals (medical school, post graduate, MOOCs, also by professional societies and manufacturers,
8. **Support** - Explore a support role for patients of / similar to pharmacists for drugs, alongside efforts from manufacturers to create easy to use apps and of insurers and hcps to require and reward such ease of use. Involve professional societies to provide guidance for health professionals
9. **Measure** –Measure value transparently. Publish reports and explore what else needs to be arranged to capture the attainable value of health apps.

10. ADD ENABLE FOR TRANSFORMATION OF HEALTH SYSTEMS

Label FOR WHAT type of ENABLEMENT ?
The need for a Healthcare Transformation Model

Healthcare Org that transform people, processes for health, and seek to continuously transform themselves

Adapted from Kotter "Leading change" 8 steps

Label FOR WHAT type of ENABLEMENT ?
The need for a Healthcare Transformation Model

Innovation in Quality-of-Care

	Uses establish technology and known (social) methodologies	Explores new Technology or new (social) methodology
New/(significant changes to the) Business model	(Potentially Disruptive: a new way of providing care (disruptive care process) or even a new healthcare business model but not exploring new technological basis	Architectural: Technological/methodological base changes AND healthcare businesses models/care process (potential) disruption
No changes to the Business model	Routine/Incremental: slowly builds on existing technological/process competences incrementally using established technology and known methods of working	Radical: There is a visible effort to create new technology or methodology to provide care differently with higher levels of quality

(WHO Europe QoC Office Proposal adapted for QoC from Pisano, 2015*)

**Pisano GP. You need an innovation strategy. Harv Bus Rev. 2015;2015(June).)*

Why and how on Global EHR?

- A global electronic health record (G-EHR) is achievable with focus, concrete steps, value creation and determination to explore certain elements.
- To reach a truly global digital healthcare system, however, we need to work much more profoundly and more decisively on real worldwide cross-border eHealth services, like a global ePrescription system or sharing of minimum sets of data (e.g. the ISO International Patient Summary) and progressively bigger components, such as a vaccination passport, summary or e-cards. For example, medical devices (e.g. insulin infusion pumps, or non-invasive home ventilators) are increasingly globally produced and standardised, yet, the information that they require and generate seems to get ‘chained’ to local, regional or national health systems, in turn, chaining citizens down to their institutions, often their homes. People fear to travel to a remote location where access to their device or health data is not possible. They know healthcare may not be equally safe, which makes them feel unsafe to travel and ‘chained’.
- Digital Health Diplomacy refers to the concentrated international efforts towards supranational interoperability in eHealth/Digital Health. These may include international agreements for mutual health data transmission, recognition of information systems or common approaches to the use of international standards.

What is the Global EHR?

- A global electronic health record (G-EHR) is **a set of interconnected digital systems and services that support the sharing of personal health data across the globe** to support primary use of health data regardless of geographical, jurisdictional and language barriers creating an electronic health record support environment as similar as possible to that experienced by the individual and his/her caregivers in is home country. It is based on standards and is a de facto promotion of data harmonization leading up to a potential "Global Health Data Space" of nominal/anonymized health data for it potential secondary and tertiary use.
- A global electronic health record (G-EHR) is not something utopic. It requires focus, concrete steps, value creation and determination to explore the following elements.
  1) Creating a worldwide voluntary patient and health professionals' registries
  2) Setting up a global regime/governance forum for the advancement of agreements and common creations
  3) Using a common exchange format (possibly inspired in the European EHR exchange format?)
- Source: H. Martins 2020: https://healthmanagement.org/c/healthmanagement/issuearticle/digital-health-diplomacy-in-chained-globalised-health-context

Worldwide eHealth cross-border services

The following worldwide eHealth cross-border services serve as initial steps:

1) Global ePrescription system
2) **Global sharing of minimum sets of data** (for example, the ISO International Patient Summary) and, progressively, bigger components, such as vaccination passports/summary/e-cards
3) exploring Globally with the EU European EHRxFormat
4) Internationally approved **minimum information sets** for advanced data-rich medical devices
5) Internationally approved and maintained digital information leaflets for prescribed drugs.
6) International sharing of larges datasets for research/public health based on Commonly agreed minimum sets of data

Global Treaty on Digital Health

Prof. Dr. Henrique Martins, MD, PhD, FCS-UBI ISCTE-IUL – www.henriquemartins.eu | Henrique@henriquemartins.eu

THANK YOU!

Questions?
(now or via email/website)

Part 3. Discussion

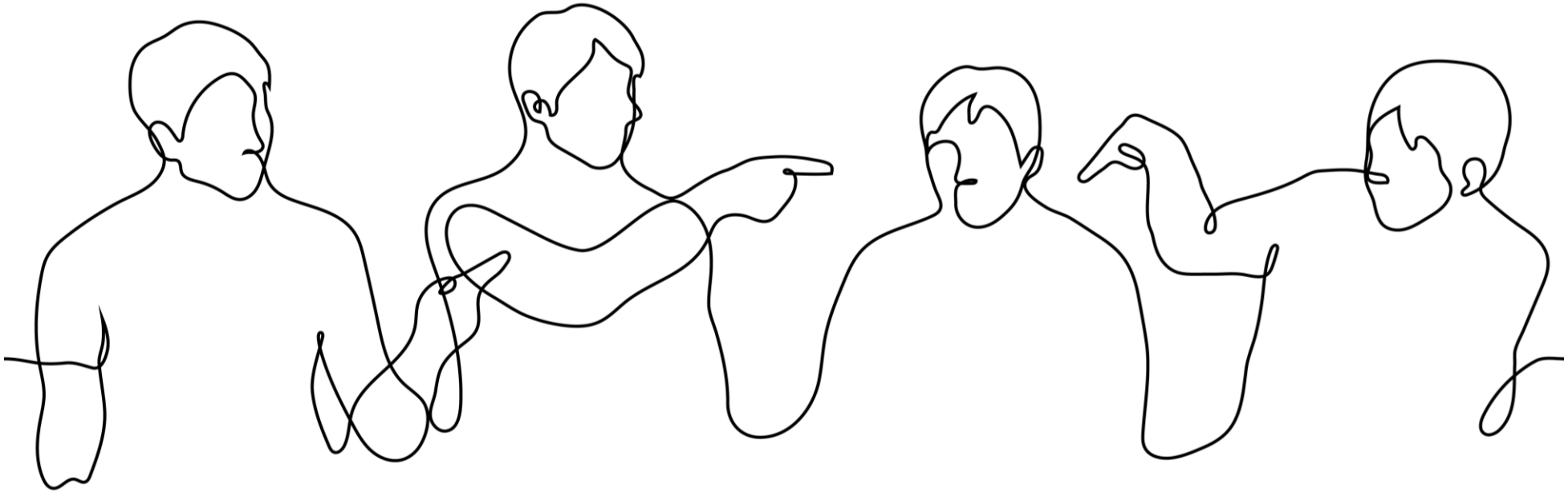
a. Discussion: Recommendations on the reimbursement of citizen / patient-facing health apps

draft recommendations for reimbursement of apps

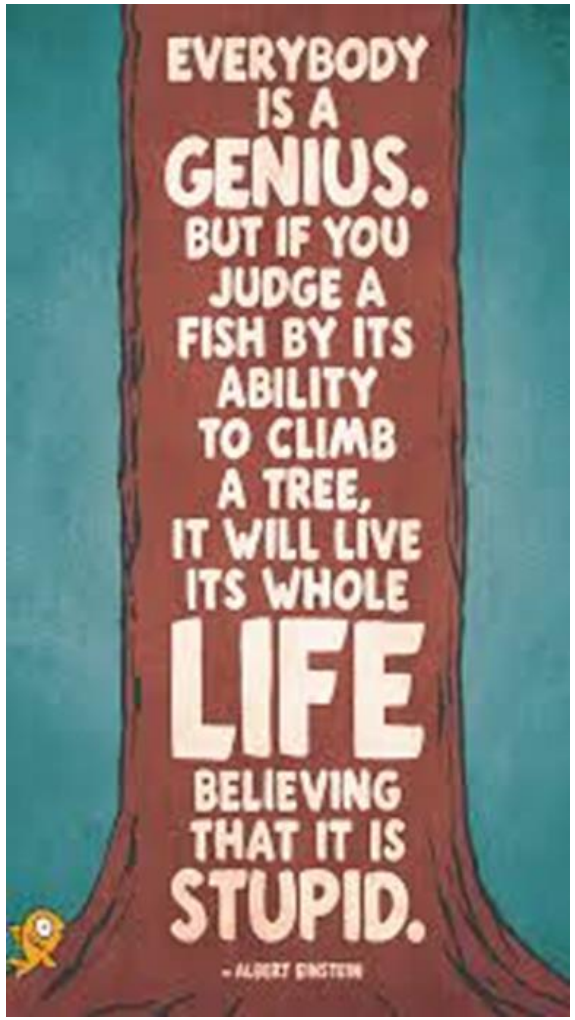
1. **Govern** – Establish governance: who within the health authority is responsible for exploring and decision-making on assessment and reimbursement of health apps?
2. **Value** - Acknowledge ap**ps can do things that pills can't and vice versa**. Both in their own way potentially contribute to health, wellbeing and can impact citizen, patient, carer and overall burden of the health system. Assess both the positive value and potential adverse effects or risks of apps, whether integrated in hybrid care pathways or not, for your public health and health system, now and in the future. Examples may include advances in prevention, early diagnosis, patient self-management, treatment adherence, health literacy, health professional efficiency, cost-effectiveness, primary and secondary data. Adverse effects, for which assessment can be a mitigation, may span privacy and security, regulatory compliance, user engagement, disparities, and technology lifetimes.
3. **Focus** - Identify types of apps that can deliver this value for specific health issues in which care pathways and if applicable for which types of patients. Evaluate these apps for potential payment or reimbursement in these care pathways.
4. **Assess** – Establish a framework for assessing health apps through internal processes or outsourcing. Consider incorporating a trusted EU framework within your own additional national requirements, creating an accelerated more efficient assessment. Ensure the assessment results are easily accessible, also to patients and citizens (e.g. label in frequently used trusted sources).
5. **Create** - Create the environment in which apps can deliver value. Integrate properly evaluated high-quality health apps in care pathways to maximize their value and facilitate potential substitution or cost reduction. If the value requires a role of a health professional, fund that role. Facilitate and provide incentives for industry to deliver quality products, addressing present and future needs. Ensure that reimbursement rates consider added value, quality, societal benefits, investments needed to acquire the indicated evidence, sustained equitable use, seamless integration of app data in EHRs, etc. and enable further investments to meet future demands. Set up the needed infrastructure. Enable interoperability and safe data exchange between EHR systems and patient-facing health apps. Use standards.
6. **Fund** – Foster reimbursement of quality apps, making them part of a new normal and accessible to all. Allocate related funds, consider innovative payment models, and explore need for further policies.
7. **Specify** - Recognizing that if you judge an app by its ability to be a pill or vice versa we will believe either one is stupid, explore and communicate appropriate outcome measures and potentially also comparators (standard of care, if possible with an EU perspective, waiting list, other digital / hybrid care) and scope to consider (e.g. wider value of behaviour change and literacy) to capture the true value and thus make adequate decisions on initial and final reimbursement. Consider that beyond individual benefit, apps can progress societal benefit with the data they produce for secondary use.
8. **Enable** – Promote the education of health care professionals (medical school, post-graduate, Massive Open Online Courses, also by professional societies and manufacturers). This education should include how to analyse app data to safely capture the value of data in primary use and ultimately secondary use. Educate citizens and patients on benefits and risks associated with health apps and how to recognise trusted sources.
9. **Support** – Co-create a support role for patients and consumers similar to pharmacists for drugs and consumer organisations for consumer products, alongside efforts from manufacturers to create easy to use apps and of insurers and hcps to require and reward such ease of use. Involve professional societies to provide guidance for health professionals on how to identify apps to recommend and their recommended use, also in relation to other health interventions. Integrate this guidance in regular clinical guidelines.
10. **Measure** –Measure value transparently. Publish reports and explore what else needs to be arranged to capture the attainable value of health apps. Enable and incentivise such results. Realise that without quality apps, integrated in care pathways, users trained and resulting data being used, adequate outcome measures and ditto scope, etc. the measurements do not reflect attainable value.

recommendation 1: Govern

1. Govern – Establish governance: who within the health authority is responsible for exploring and decision-making on assessment and reimbursement of health apps?



recommendation 2: Value



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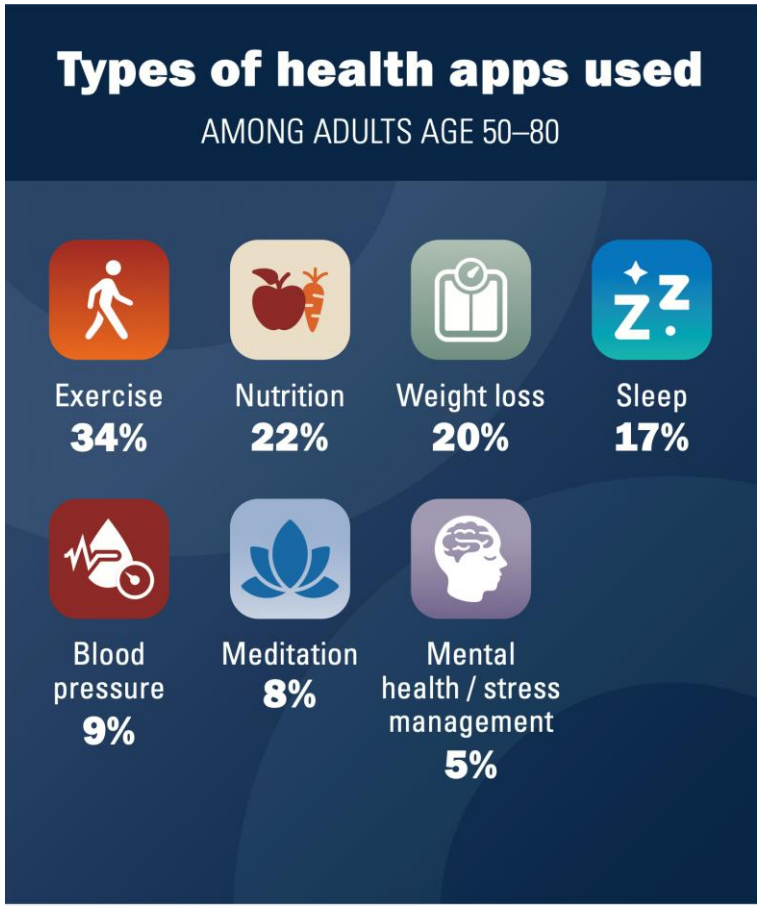
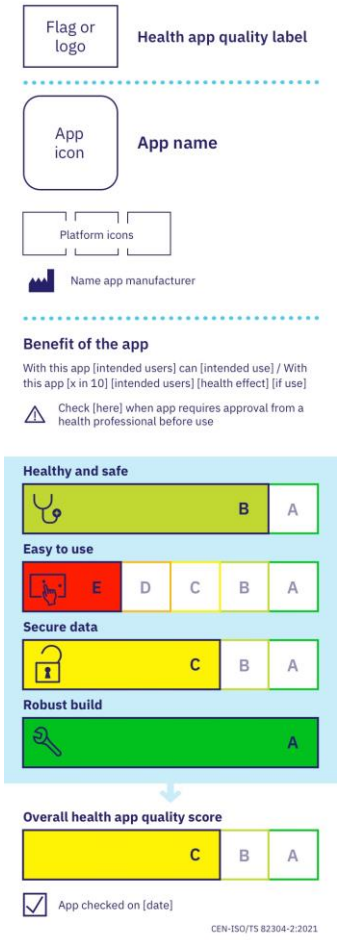
recommendation 3: Focus



University of Michigan, National poll on healthy ageing, 2022

3. Focus - Identify types of apps that can deliver this value for specific health issues in which care pathways and if applicable for which types of patients. Evaluate these apps for potential payment or reimbursement in these care pathways.

recommendation 4: Assess



4. Assess – Establish a framework for assessing health apps through internal processes or outsourcing. Consider incorporating a trusted EU framework within your own additional national requirements, creating an accelerated more efficient assessment. Ensure the assessment results are easily accessible, also to patients and citizens (e.g. label in frequently used trusted sources).

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5. Create - Create the environment in which apps can deliver value. Integrate properly evaluated high-quality health apps in care pathways to maximize their value and facilitate potential substitution or cost reduction. If the value requires a role of a health professional, fund that role. Facilitate and provide incentives for industry to deliver quality products, addressing present and future needs. Ensure that reimbursement rates consider added value, quality, societal benefits, investments needed to acquire the indicated evidence, sustained equitable use, seamless integration of app data in EHRs, etc. and enable further investments to meet future demands. Set up the needed infrastructure. Enable interoperability and safe data exchange between EHR systems and patient-facing health apps. Use standards.

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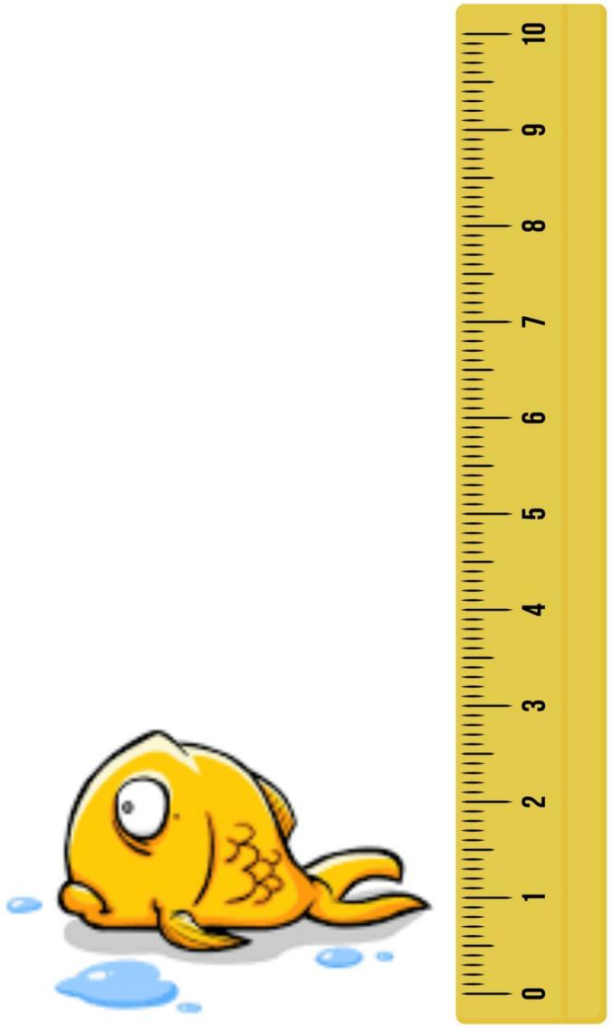
6. Fund – Foster reimbursement of quality apps, making them part of a new normal and accessible to all. Allocate related funds, consider innovative payment models, and explore need for further policies.

recommendation 7: Specify



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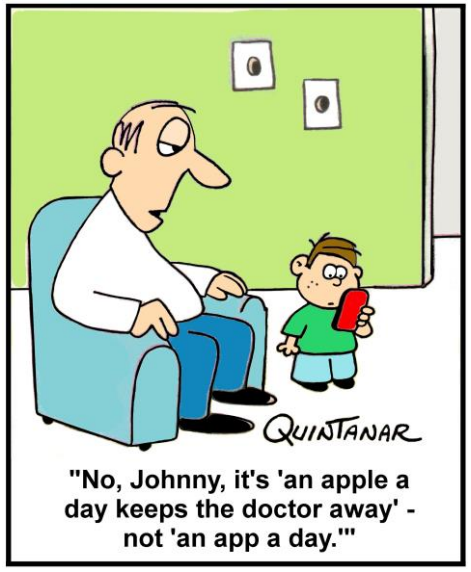
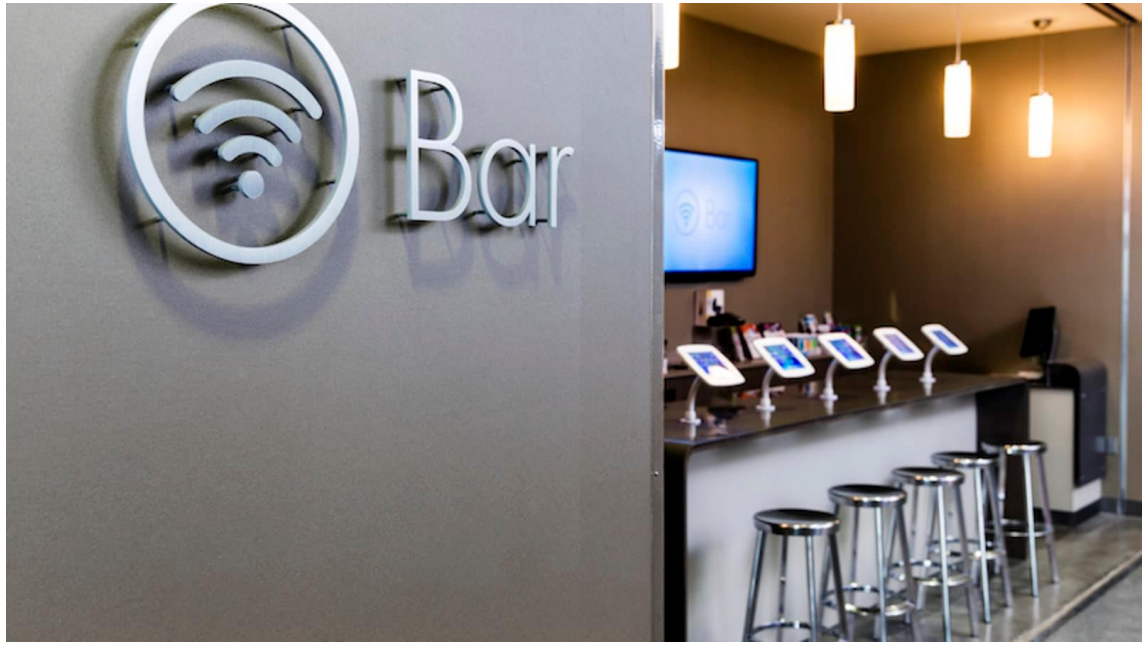


recommendation 9: Support



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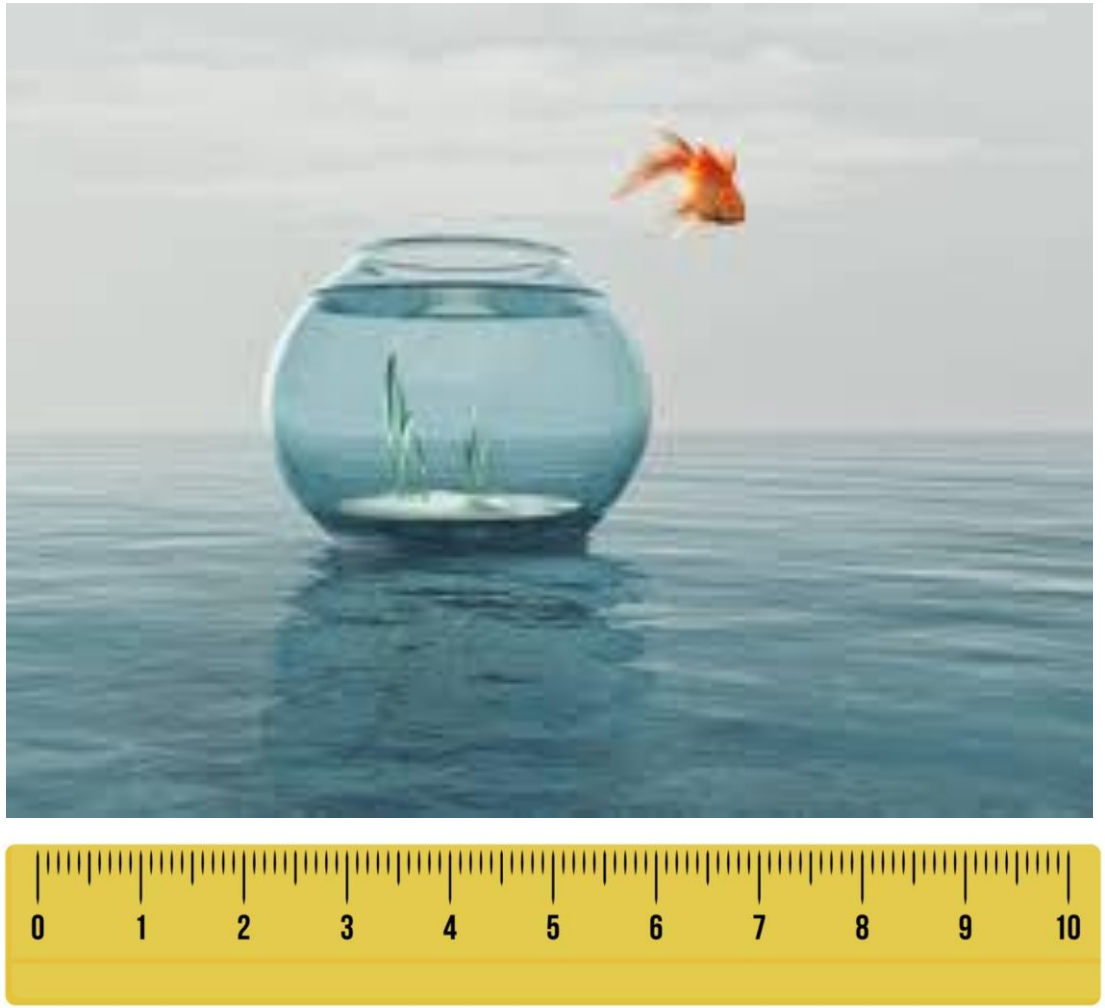
ESC
European Society of Cardiology
mHealth Taskforce

recommendation 10: Measure



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b. Conclusion of all 3 roundtables

3rd roundtable on reimbursement and payment of patient / citizen-facing health apps – February 13, 2024

draft recommendations for reimbursement of apps

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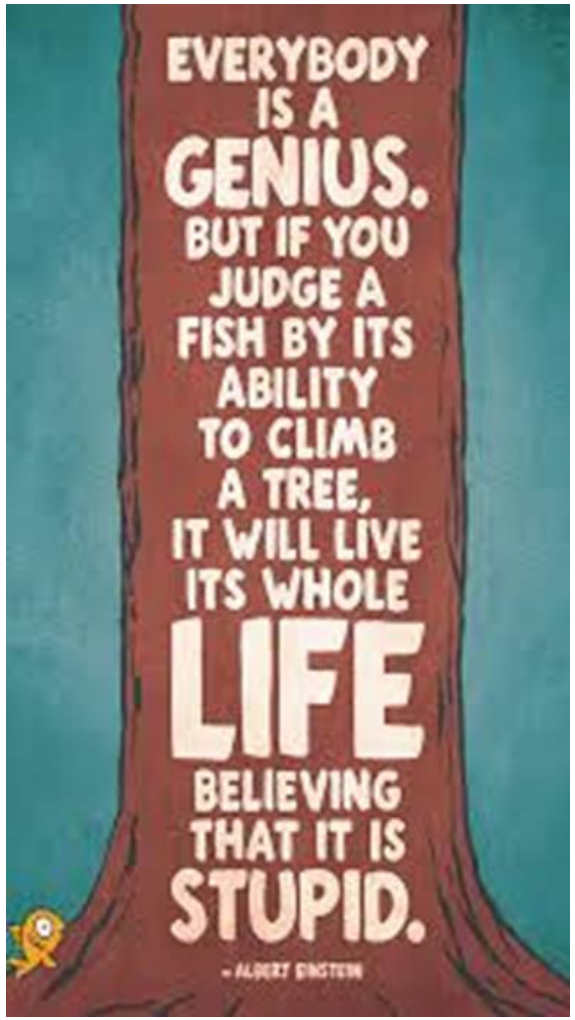

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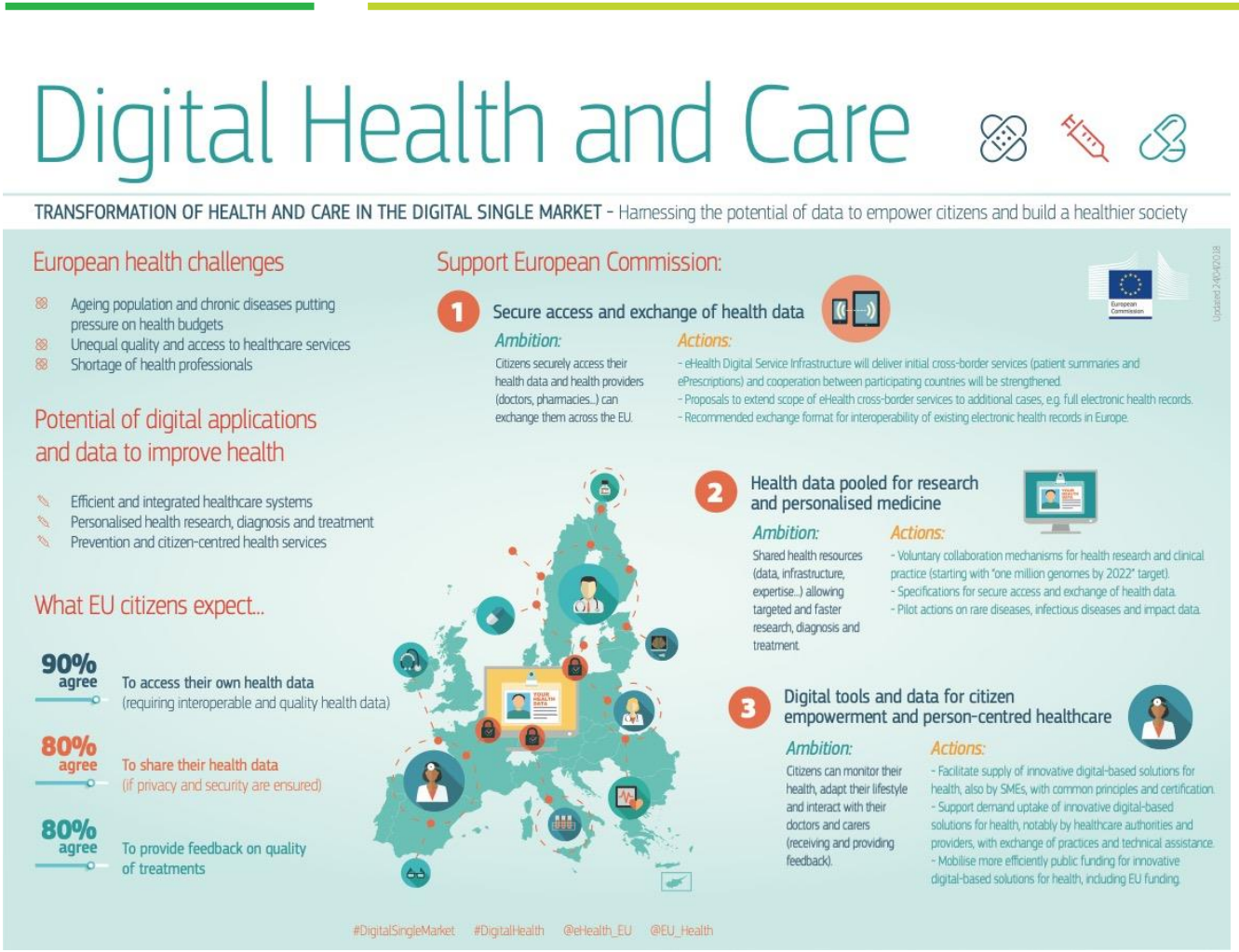
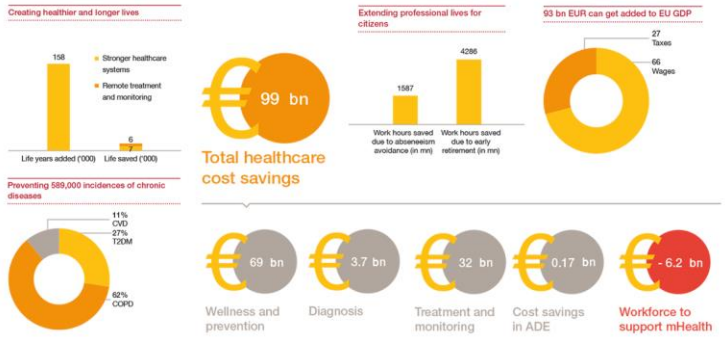
potential and needs for health apps



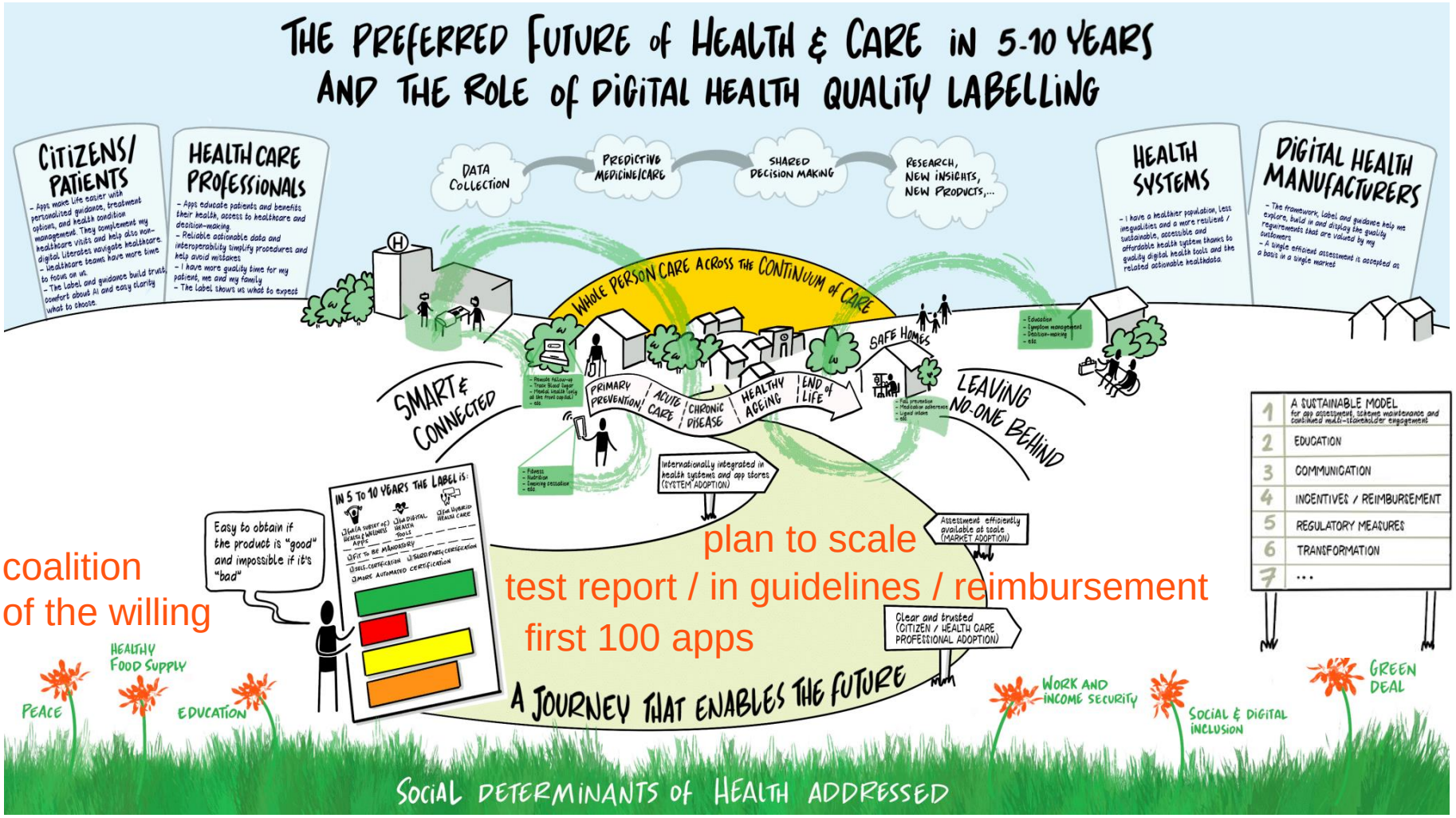


PWC (2013)
Socio-economic impact of mHealth – An assessment report for the European Union

Basch et al. (2016)
Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial

WRR (2021)
Kiezen voor Houdbare Zorg. Mensen, middelen en maatschappelijk draagvlak

multi-stakeholder success in 5 to 10 years



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LABEL2ENABLE invites you to join the coalition of the willing

Email	info@label2enable.eu / a.p.y.hoogendoorn@lumc.nl
Website	label2enable.eu
Twitter (X)	@label2e
LinkedIn	linkedin.com/company/label2enable
Facebook	facebook.com/label2enable

Thank you for your attention

More information person@label2enable.eu

Website label2enable.eu

Funded by the European Union

3/6/2024

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