

Health Apps From a Health Authority Perspective

Petra Hoogendoorn, Tatjana Prenda Trupec, Carme Pratdepàdua Bufill, and Liyousew Borga.

Part 1. Introduction 14:00

Part 2. Presentations and Q+A

- **Comparison of app assessment frameworks and country-specific requirements (Petra Hoogendoorn)**
- **Transforming Healthcare: A Journey Through Catalonia's Adoption of Health Apps (Carme Pratdepàdua Bufill)**
- **Real Value of Patient-centered Positive Health Effects of Digital Medical Devices: Lessons from the German DiGA (Liyousew Borga)**
- **Challenges and recommendations for the reimbursement of health apps (Tatjana Prenda Trupec)**

Part 3. Closing



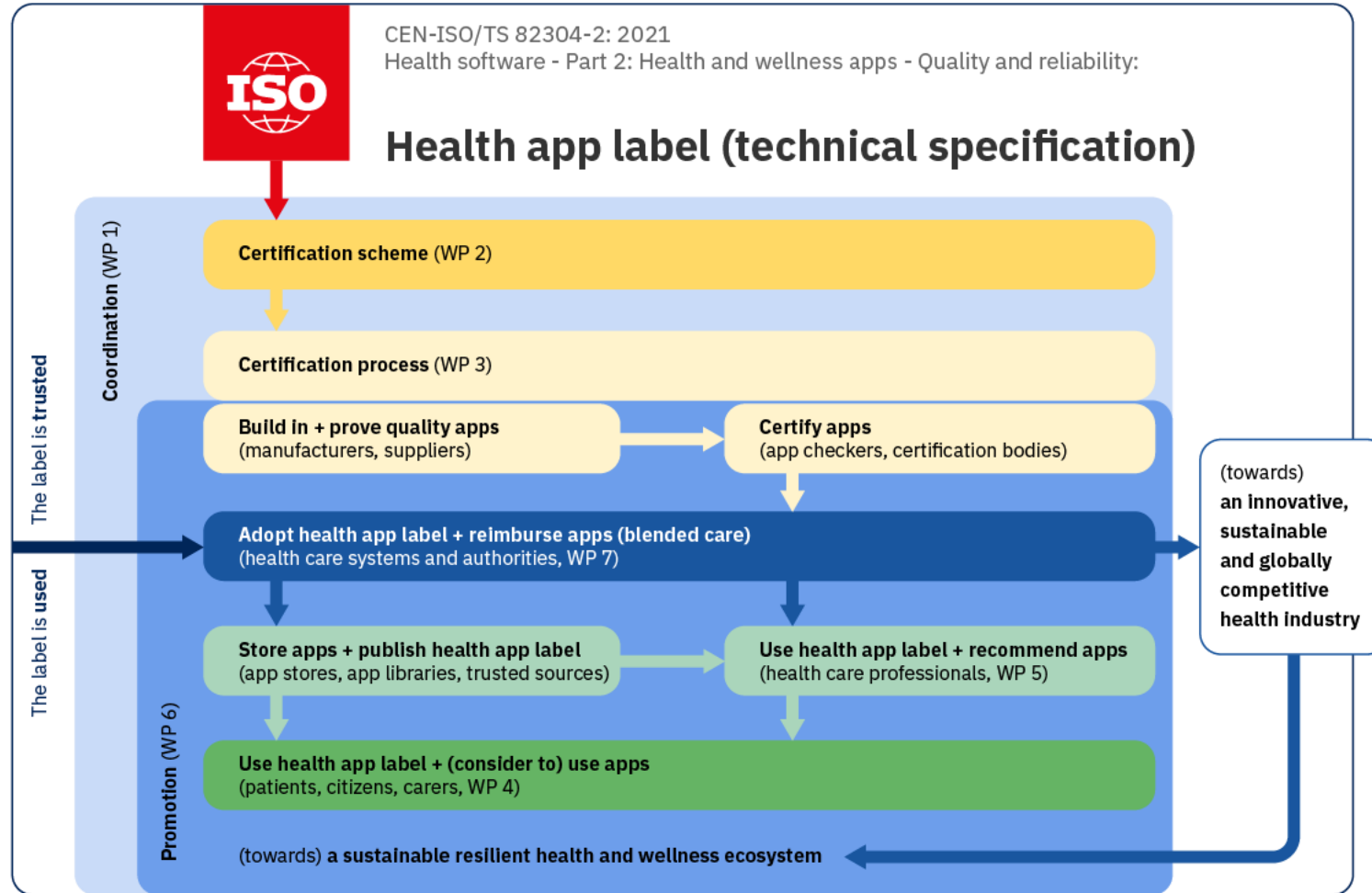
Comparison of app assessment frameworks and country-specific requirements

Petra Hoogendoorn
Coordinator of Label2Enable

Comparison of app assessment frameworks and country-specific requirements

Petra Hoogendoorn – Leiden University Medical Center / National eHealth Living Lab

multi-stakeholder: the importance

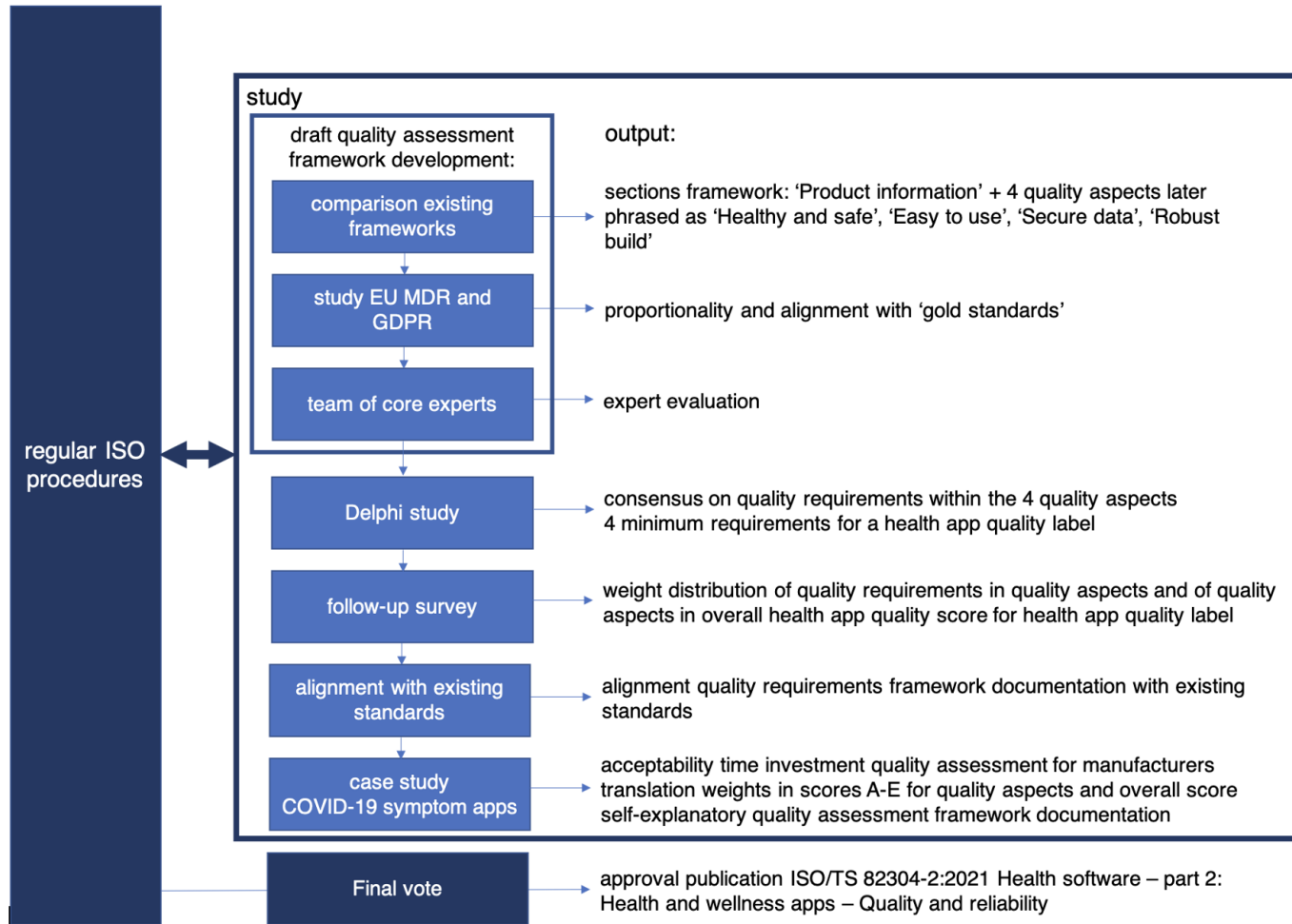


multi-stakeholder: the consortium

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

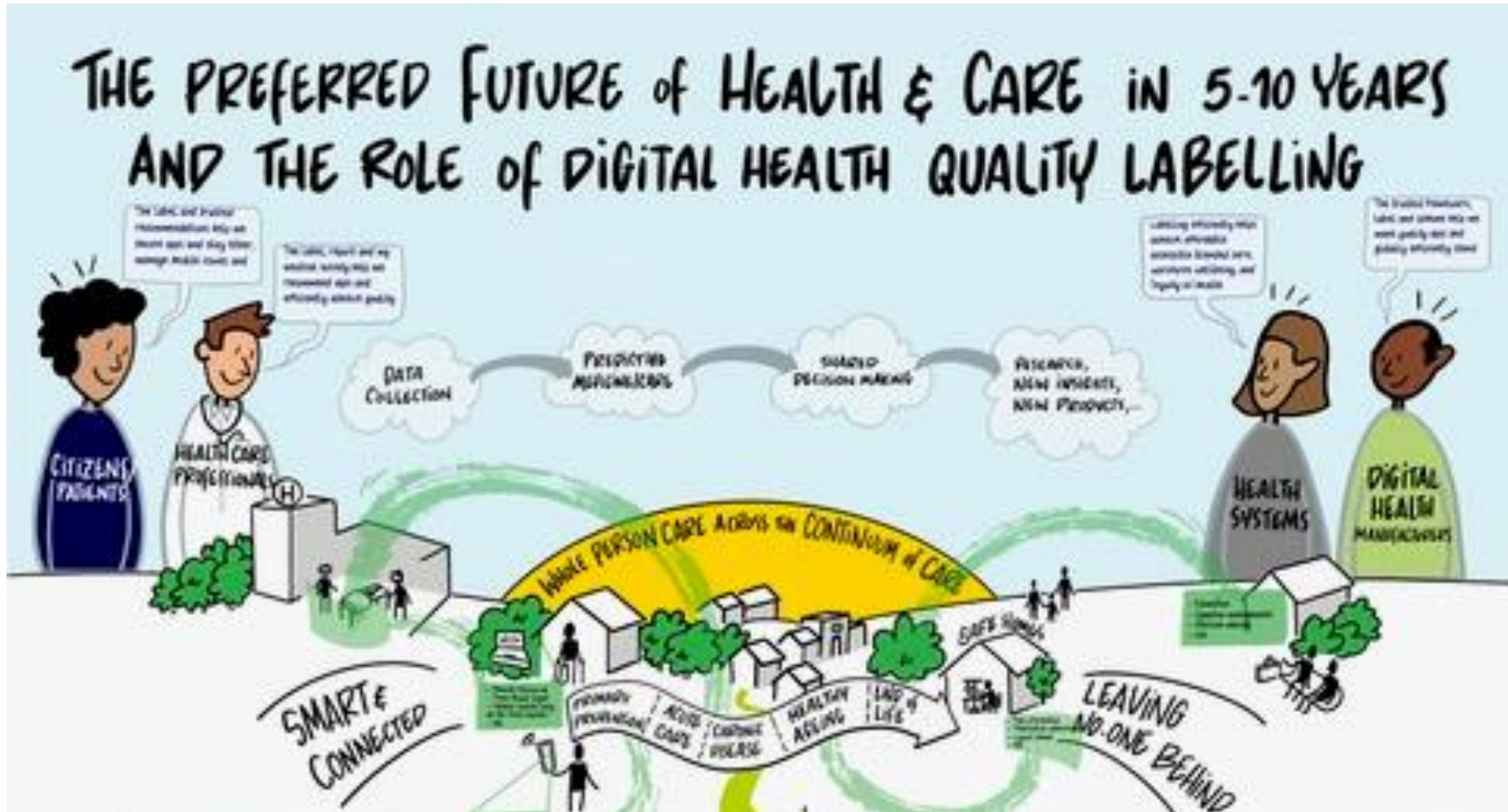


multi-stakeholder: the (Delphi) framework



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

multi-stakeholder: the preferred future



how to distinguish a “good” health app?

Flag or logo Health app quality label


App icon App name

Platform icons


Name app manufacturer

Benefit of the app
With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]
⚠ Check [here] when app requires approval from a health professional before use


Healthy and safe

	B	A
--	---	---


Easy to use

	E	D	C	B	A
--	---	---	---	---	---

Secure data

	C	B	A
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Robust build

	A
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Overall health app quality score





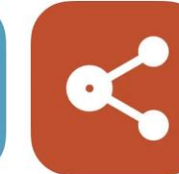
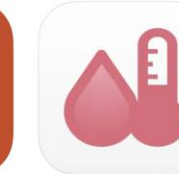












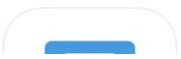





C	B	A
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App checked on [date]

CEN-ISO/TS 82304-2:2021

App Store Preview

mySugr - Diabetestracker-log
Suggesties voor jou

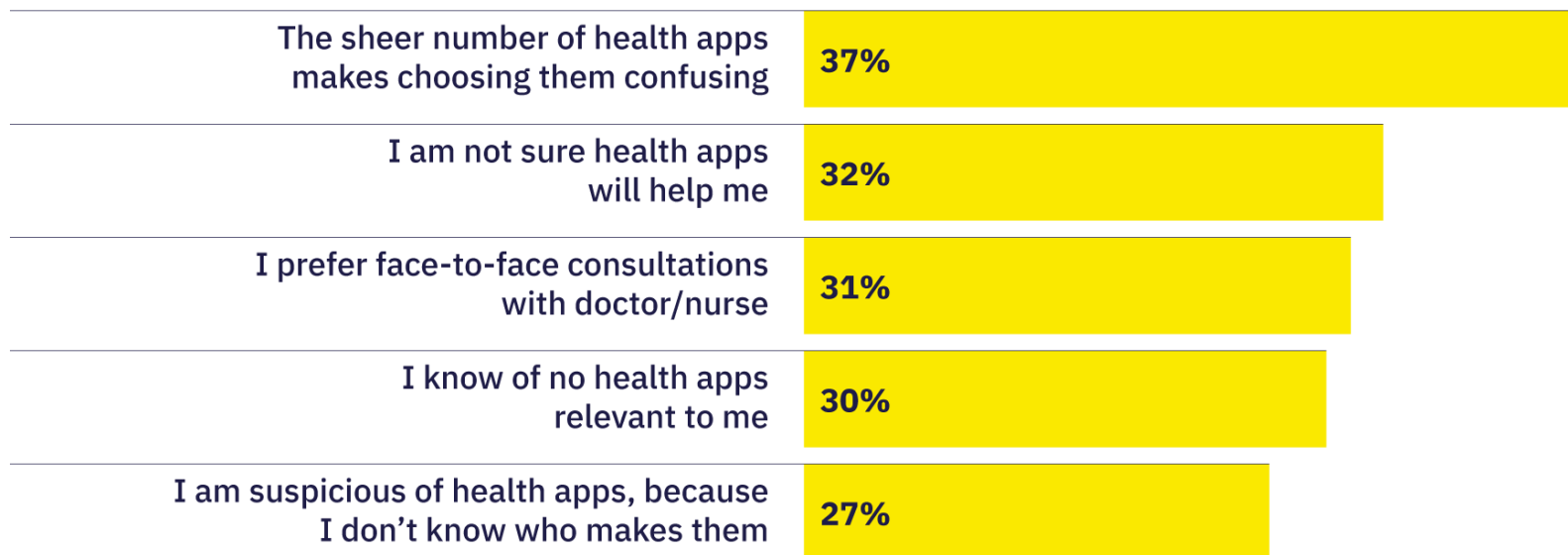
 Dexcom Clarity Geneeskunde	 Glycemische index. Diabetes Geneeskunde	 Glucose Blood Sugar Tracker Geneeskunde	 Diabetes:M Geneeskunde	 LibreLinkUp Geneeskunde	 Diabeto Log Diabetes Logboek Geneeskunde
 Glucose Buddy Diabetes Tracker Geneeskunde	 Dario Health Geneeskunde	 iHealth Gezondheid en fitness	 ONE DROP Gezondheid en fitness	 iHealth (Legacy) Gezondheid en fitness	 Klinio: Diabetes guidance app Gezondheid en fitness
 Glooko - Track Diabetes Data Geneeskunde	 Sugarmate Diabetes- tracker Geneeskunde	 Glucose tracker++ Geneeskunde	 Diabetes Food Tracker ~ Fittur Gezondheid en fitness	 Carbs & Cals: Diet & Diabetes Gezondheid en fitness	 DiabetesPal Geneeskunde
					

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

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

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

choosing a 'good' health app is difficult

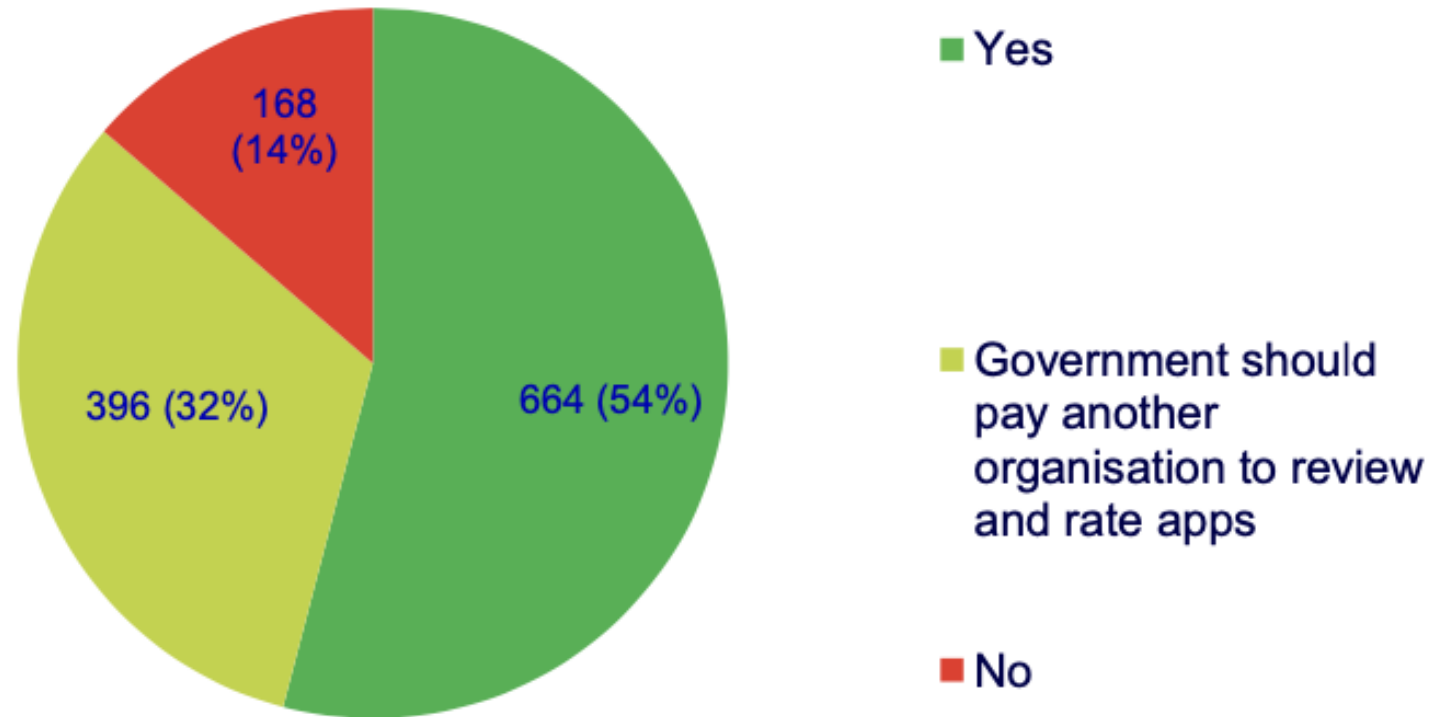


[Get-ehealth.eu \(2015\)](#) What do patients and carers need in health apps – but are not getting? Global survey of 1,120 patients and carers

should the government review and rate health apps?

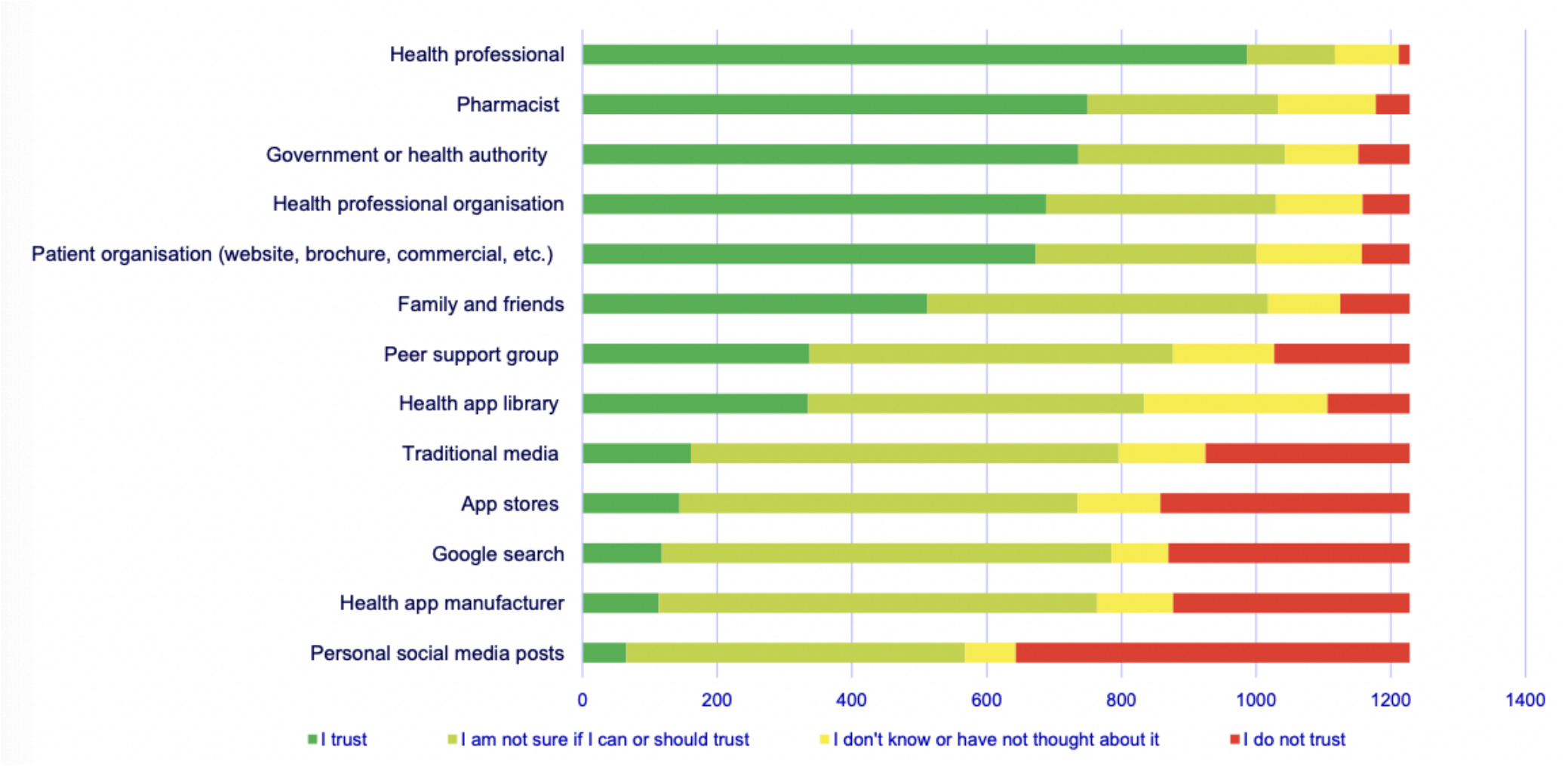
1228
respondents

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



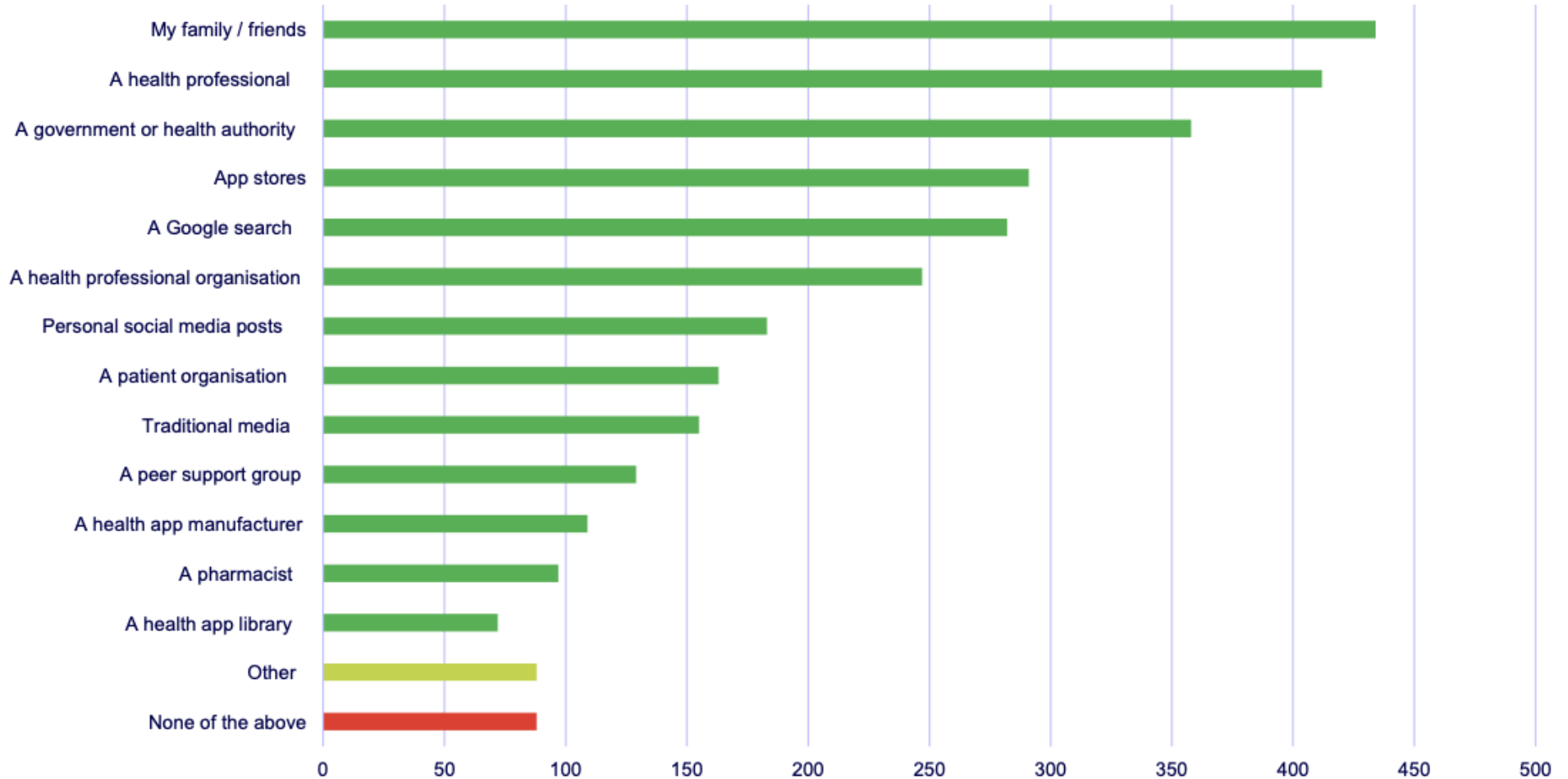
trusted advice to choose a health app

1228
respondents

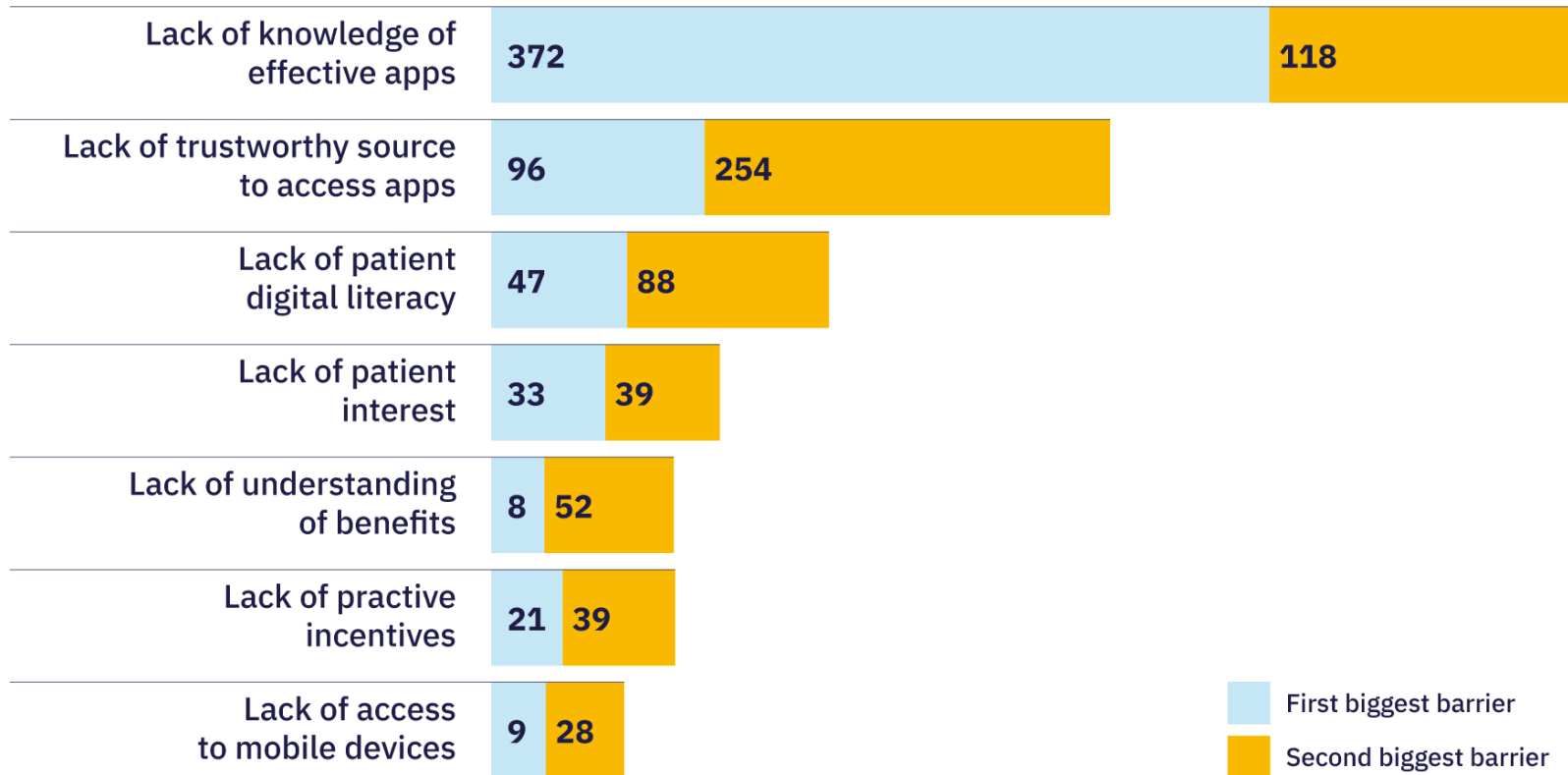


used advice to choose a health app

1228
respondents



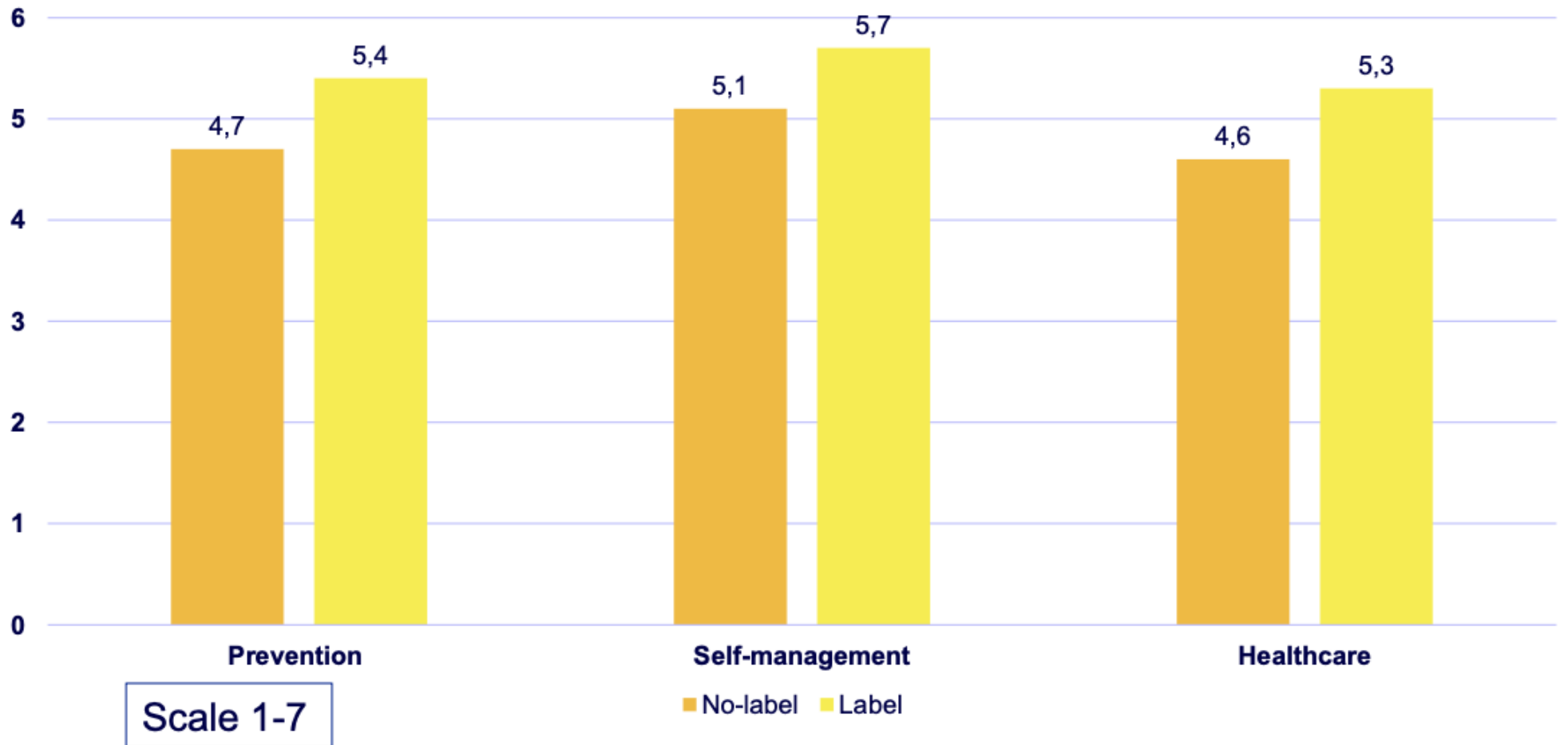
choosing a 'good' health app is difficult



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

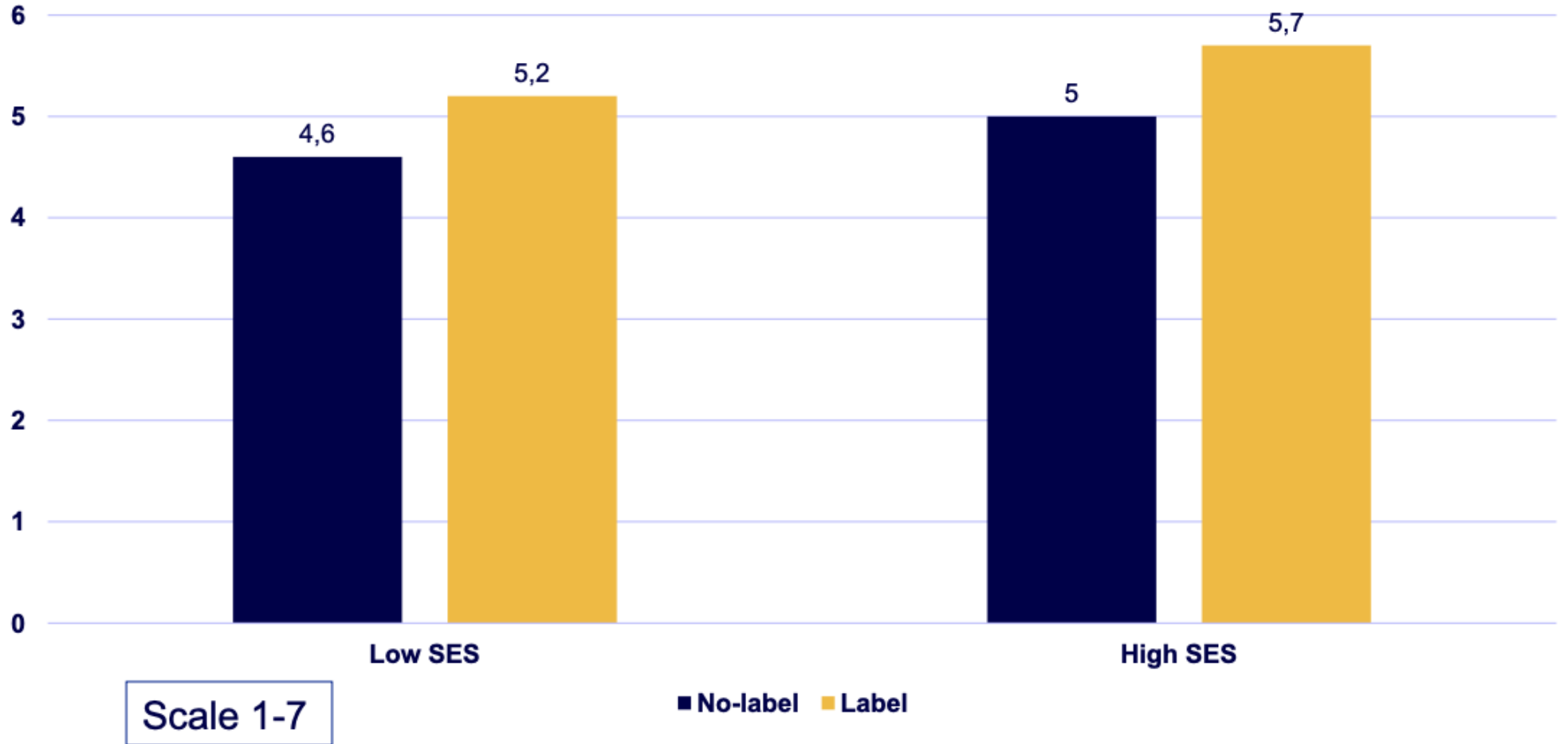
hcp willingness to recommend health apps

116
respondents

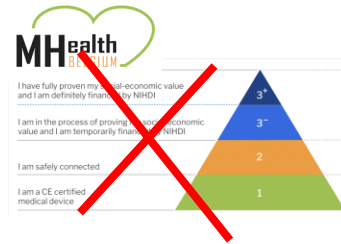
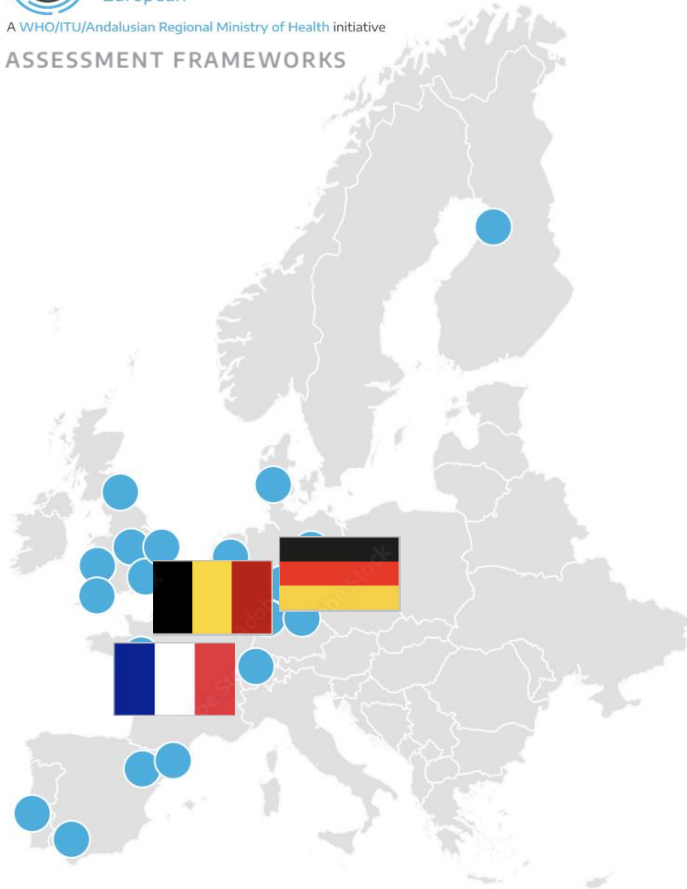


hcp willingness to recommend health apps

116
respondents



delivering a 'good' health app is difficult

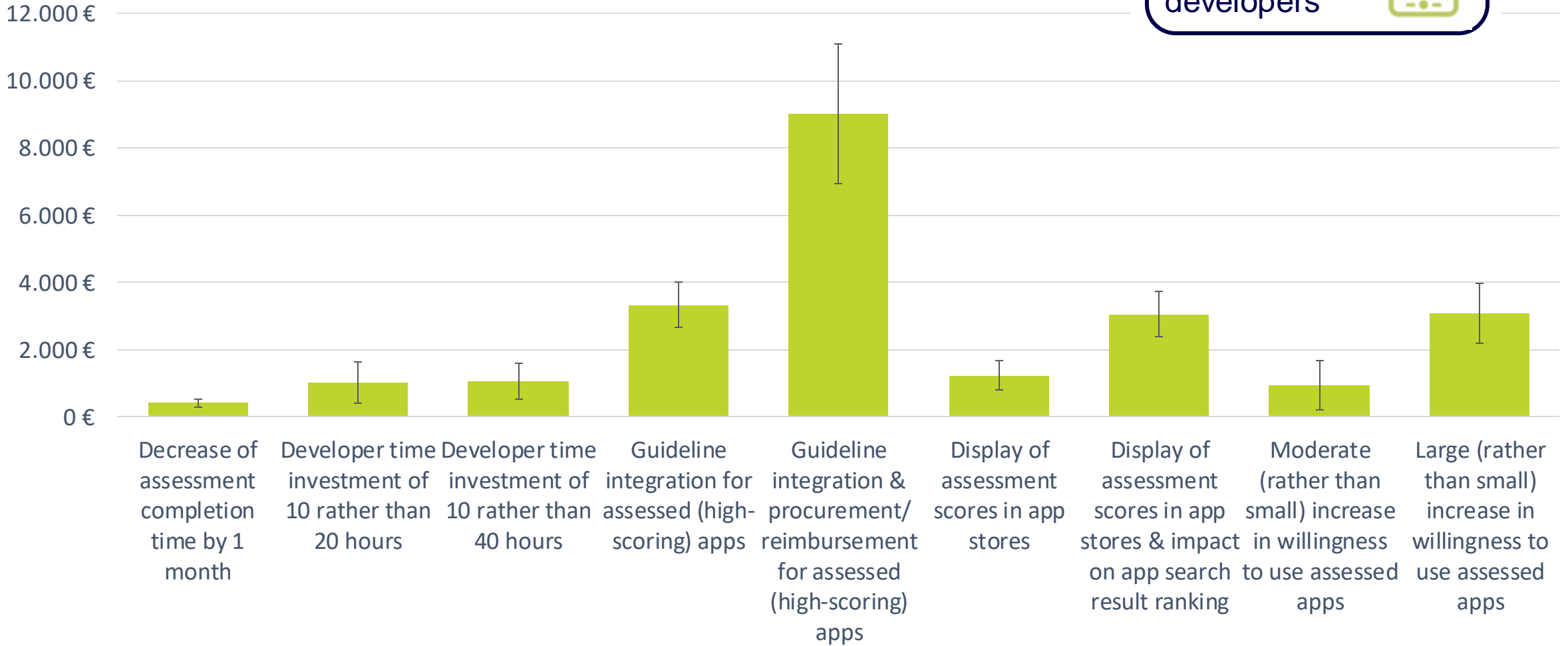


Early access to reimbursement for digital devices (PECAN)

mHealth Hub (2022) Health App Assessment Frameworks

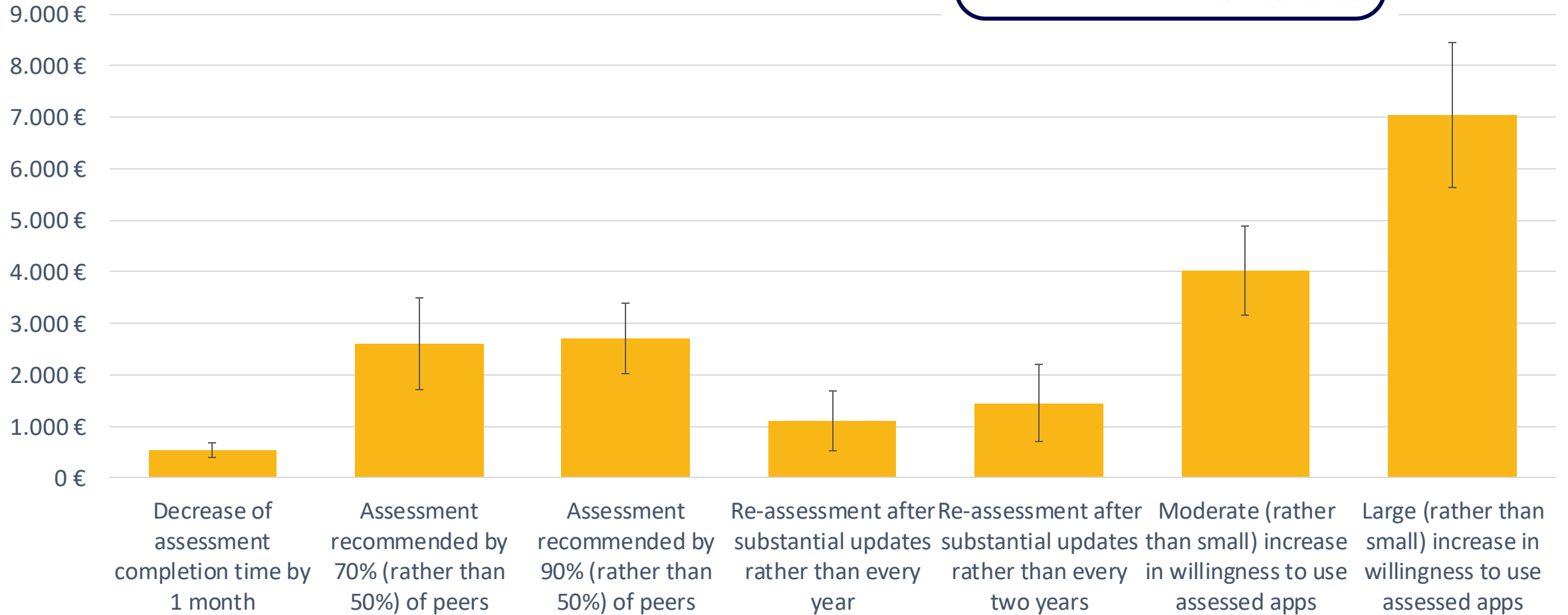
willingness to pay

41
health app
developers 



willingness to pay

46
health system
representatives 



reviewing a ‘good’ health app is difficult too

npj | digital medicine

Health app policy:

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

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

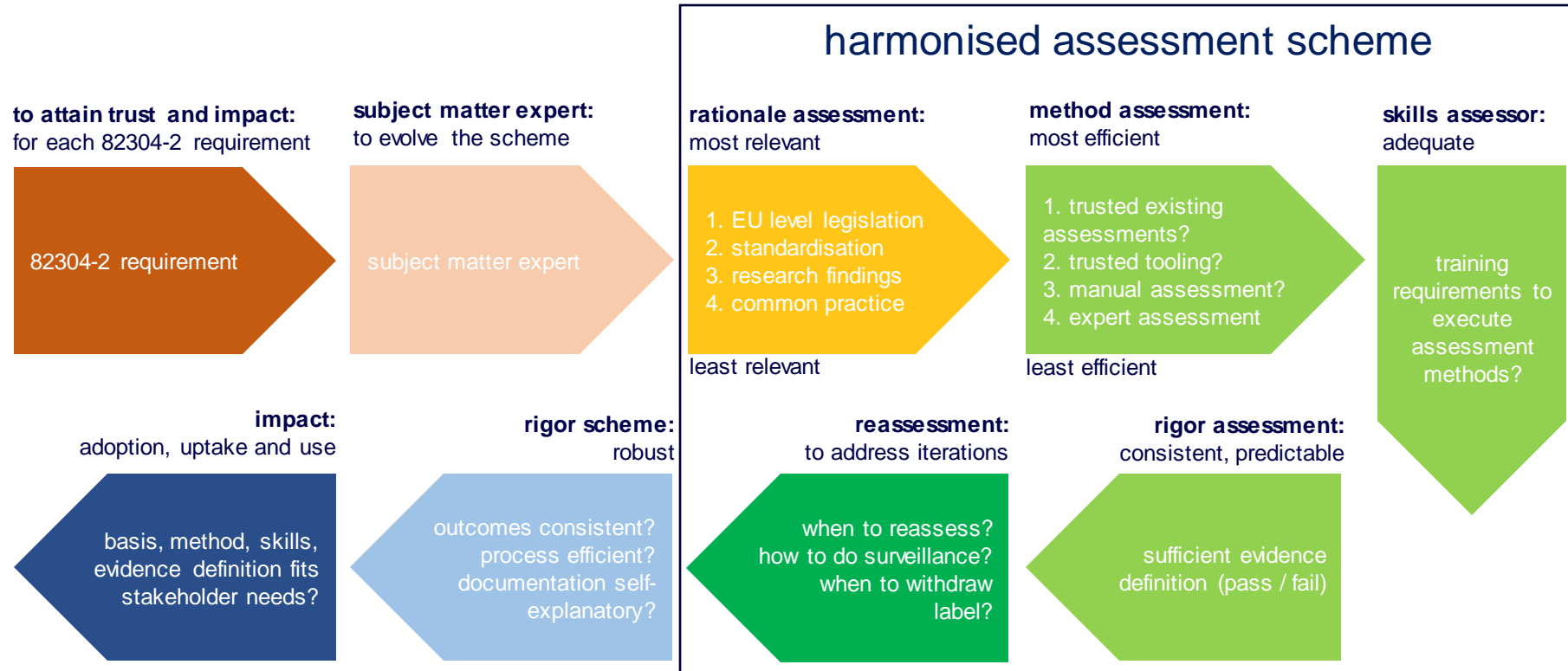
Cross-national efforts are needed around regulation and for countries to realize the benefits of these technologies.”

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

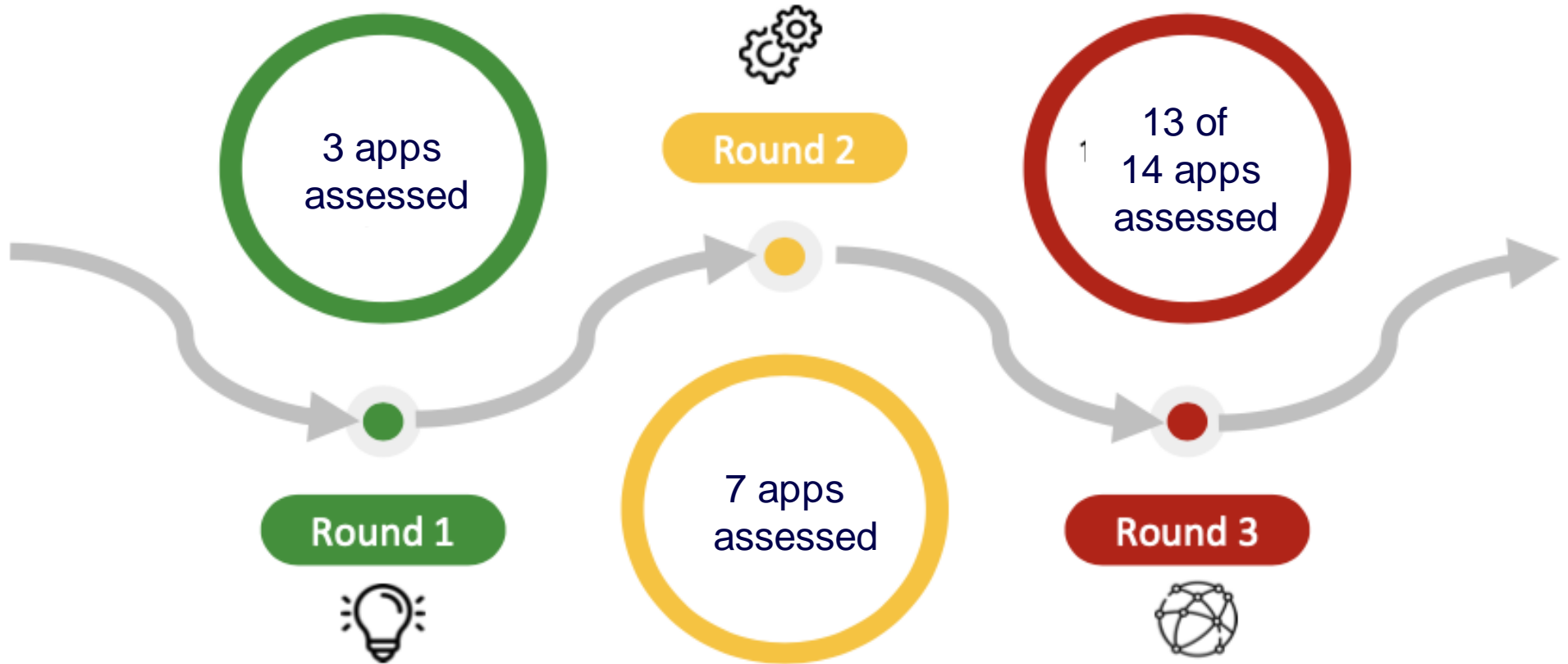
the context: EU policy

- 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

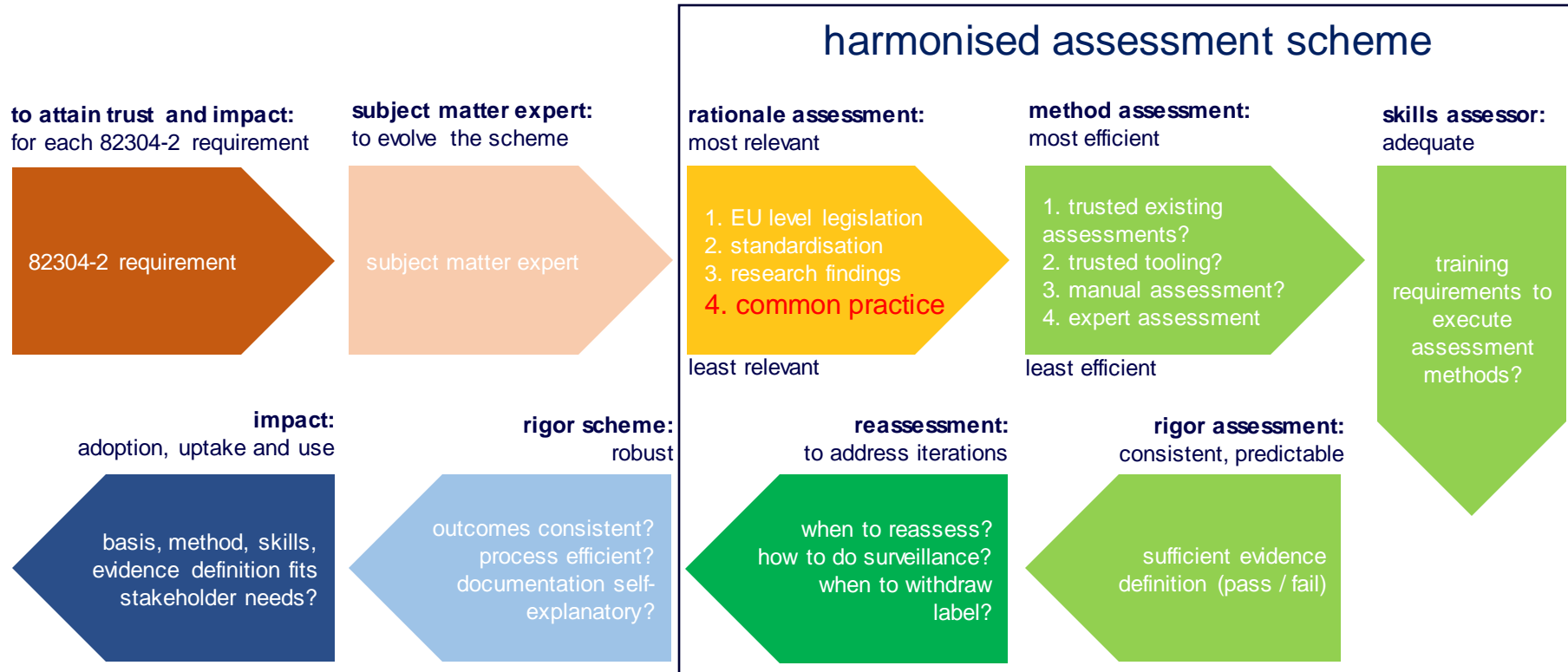
creating the common certification scheme



testing the common scheme: consistency+



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)
 - Assessment framework for mHealth apps (AU)
- }
 - 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 country-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.

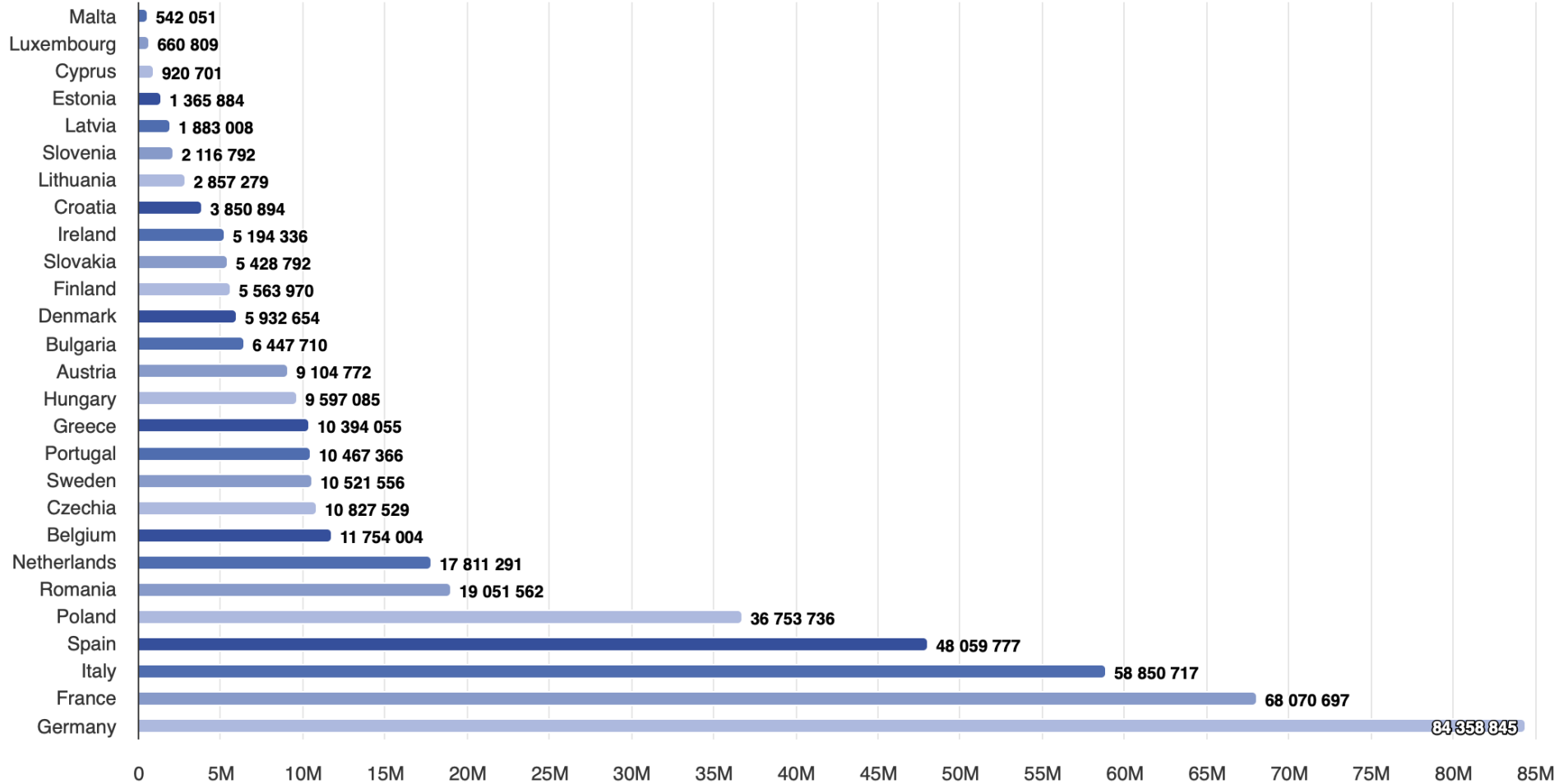
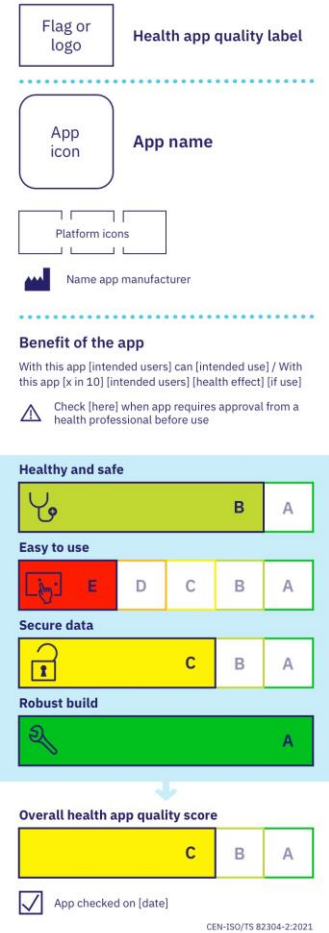
Phase 1: Triage

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.



duplication of efforts (27+) and size matters (mIn)



https://european-union.europa.eu/principles-count-ries-history/key-facts-and-figures/life-eu_en

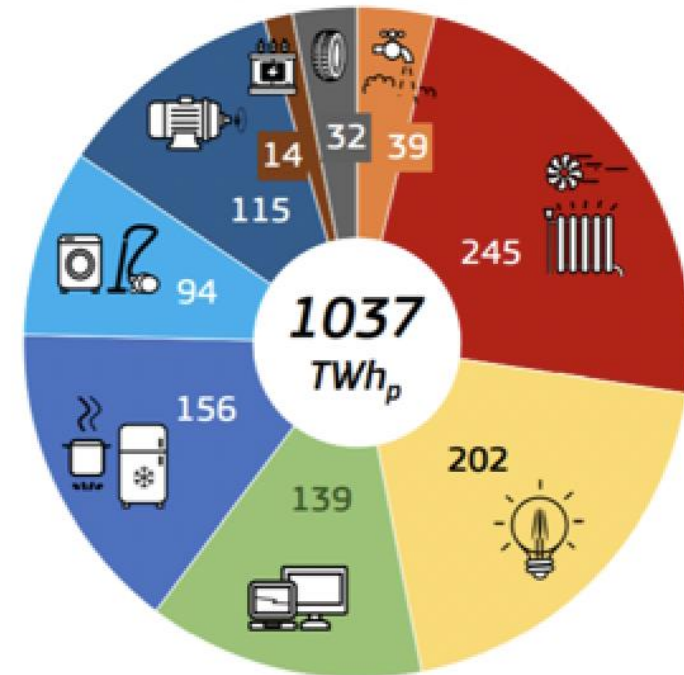
multi-stakeholder impact: EU energy label

Impacts estimates (2020 vs BaU)

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

Source: Ecodesign Impact Accounting 2020

Energy savings 2020



comparison – in more detail

- topics requirements
 - sub questions
 - pass / fail (sufficient evidence)
 - reassessment / surveillance
 - **context specific**
 - national legislation and standards
 - national systems interoperability
 - national authorities' registration
 - national reimbursement system specifics
 - national patient identifier
 - indigenous population
 - scope digital health
 - other items are considered for uptake in the proportional common scheme
-

over time more common? more proportional?



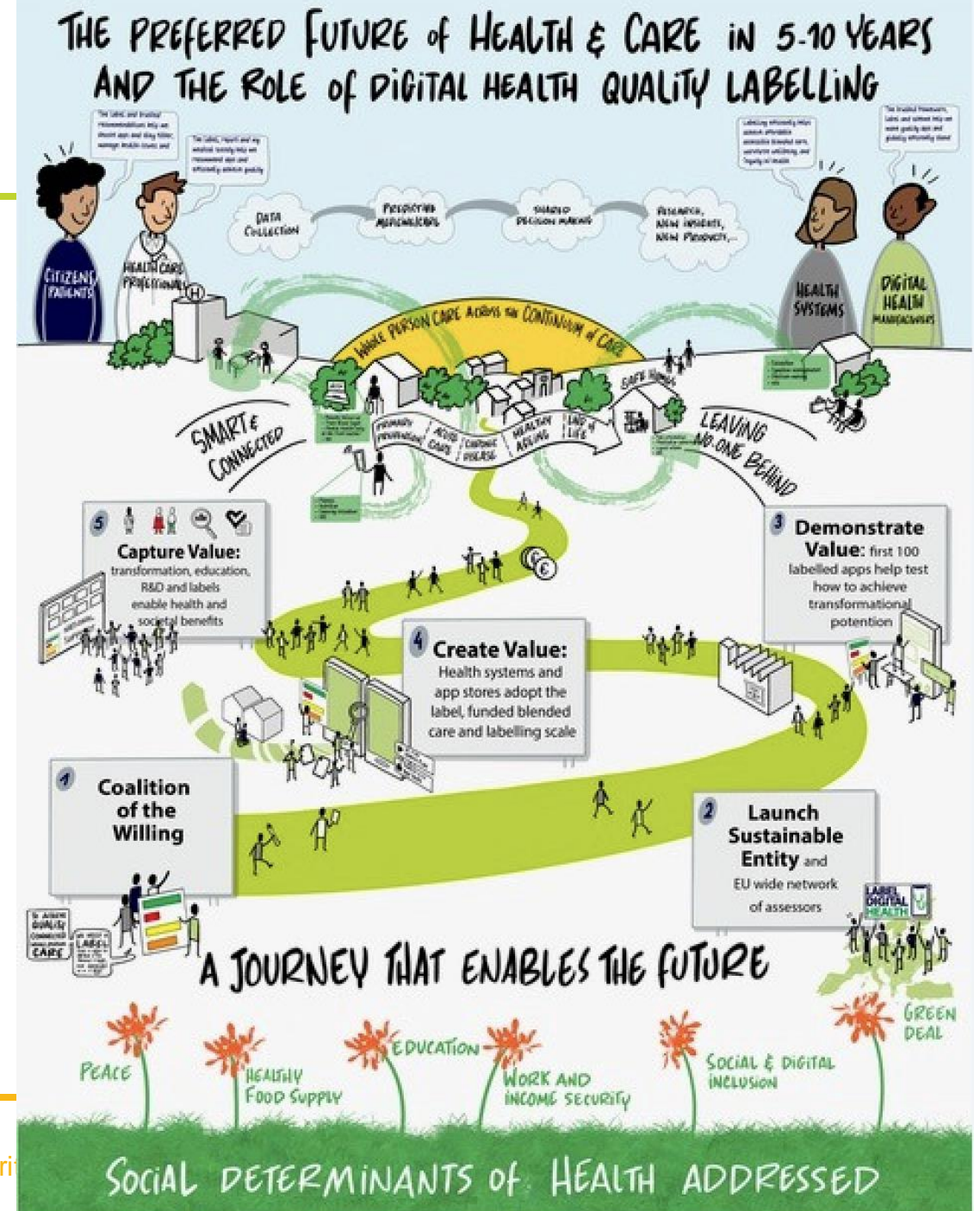
Stakeholders and Expert Organisation

maintains scheme

EU network of:

- Certification Bodies
- Conformity Assessment Bodies

issues labels and reports



country-specific interest? do contact us



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Website label2enable.eu

Twitter (X) @label2e

LinkedIn linkedin.com/company/label2enable

Facebook facebook.com/label2enable



Transforming Healthcare: A Journey Through Catalonia's Adoption of Health Apps

Carme Pratdepàdua Bufill

Leading the mHealth Office at TIC Salut Social Foundation

TIC Salut Social

Innovation and Digital Transformation

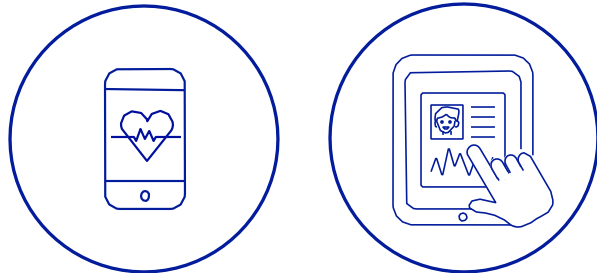
Transforming Healthcare: A Journey Through Catalonia's Adoption of Health Apps

LabelRoundtable 4 - Health Apps from a Health Authorities perspective

March 21, 2024



Digital Health Solutions



App

WebApp

Substantial rise
in availability and popularity



Importance in healthcare

- Management of personal health
- Support to clinical practice



Redefinition of relationship



Patients



Professionals

About Catalonia – Who we are?



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 funds 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

About Catalonia – Organization



Regional Ministry of Health → Sets policy



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**



**Digital transformation → Promote innovation
through the digital transformation**

Digital Health Solutions in Catalonia



Personal Health Record



Health Care and Promotion

Specific Medical Specialties

Digital Health Solutions in Catalonia

Main Personal Health Record



Some individual hospitals solutions
Added functionalities



- Add value in the management of Health
- Foster Healthcare Equity in Rural Areas
-

Promoting Digital Health Solutions in Catalonia



Salut/ Servei Català de la Salut



Aim

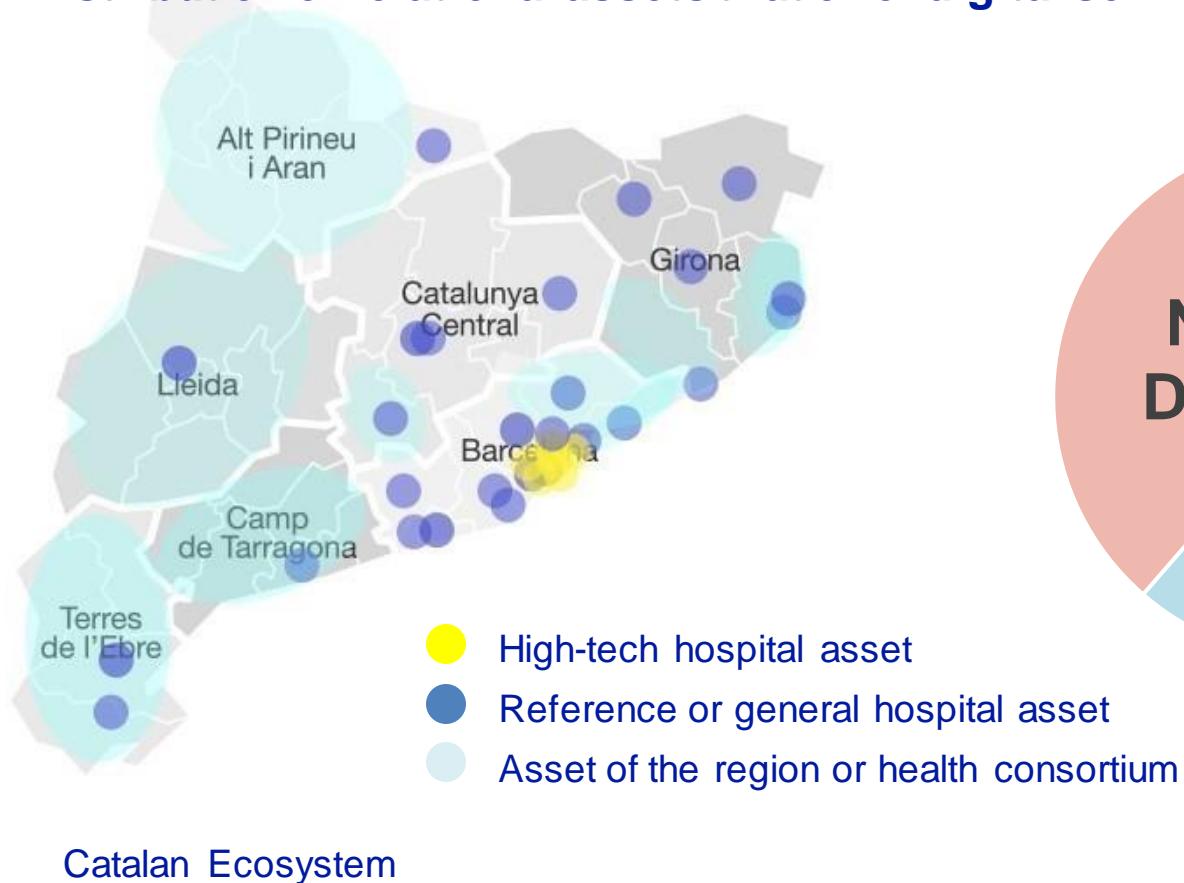
Identify, adopt and upscale Digital Health Solutions in the public system

What do we present?

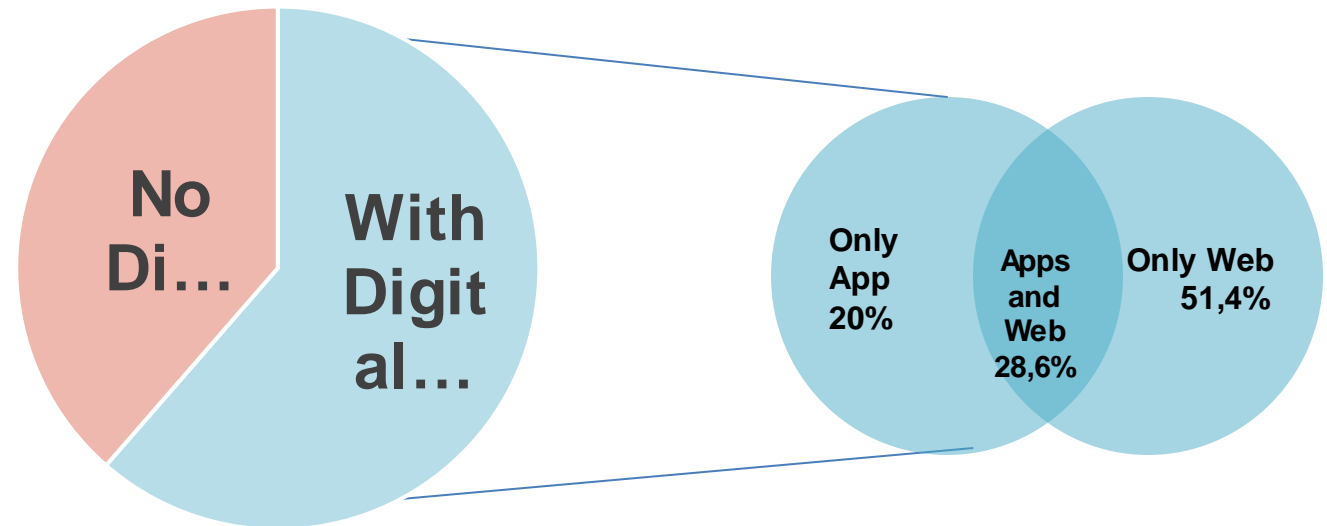
- **Radar ADC** – Inventory of Solutions that exist in SISCAT
- **Analysis of the services offered** - by public and private centers
- **Good practice guide** - to develop solutions for Citizenship

Digital Patient-Centre Solution Radar for citizens

Distribution of relational assets that offer digital services

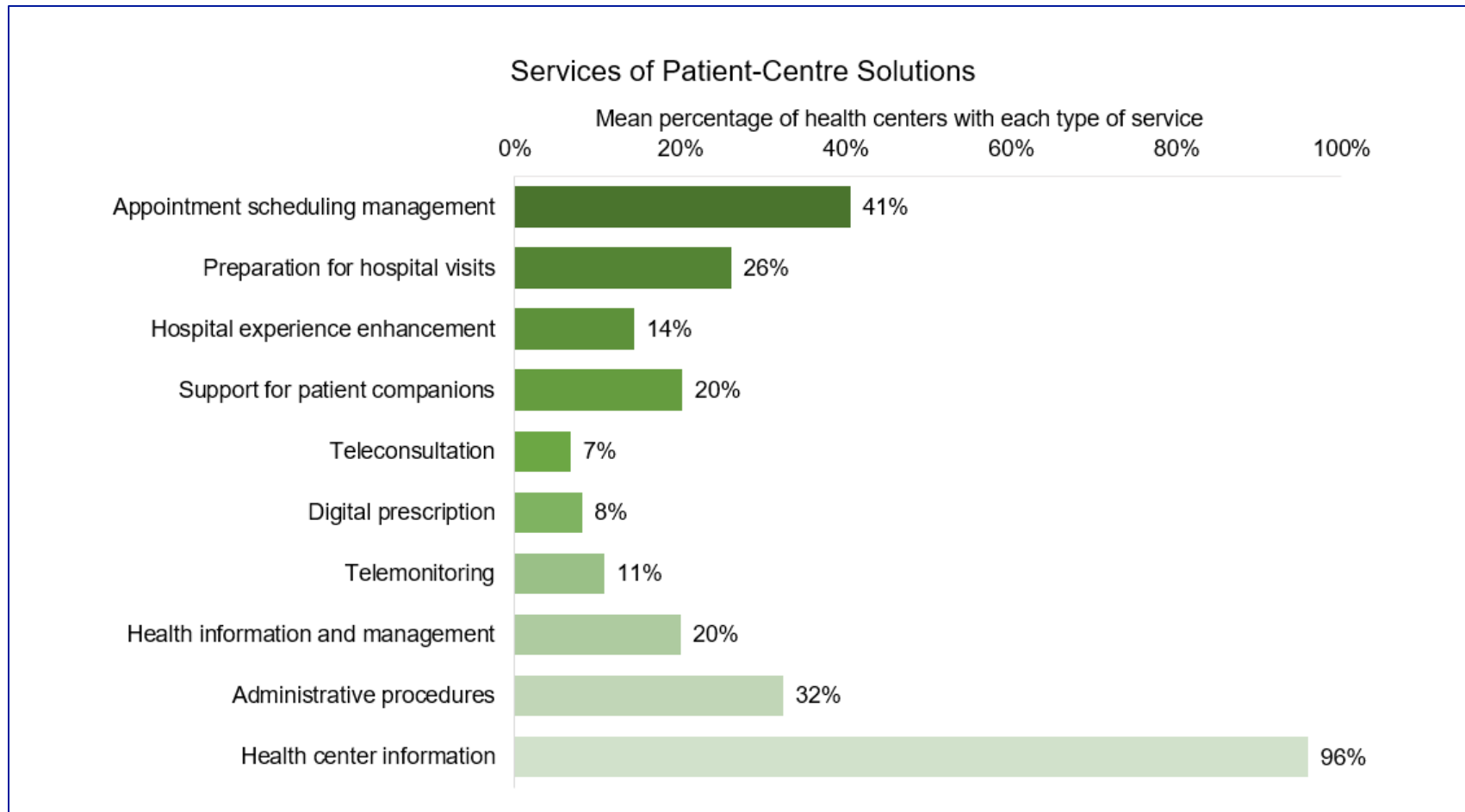


100%*
SISCAT centers analyzed



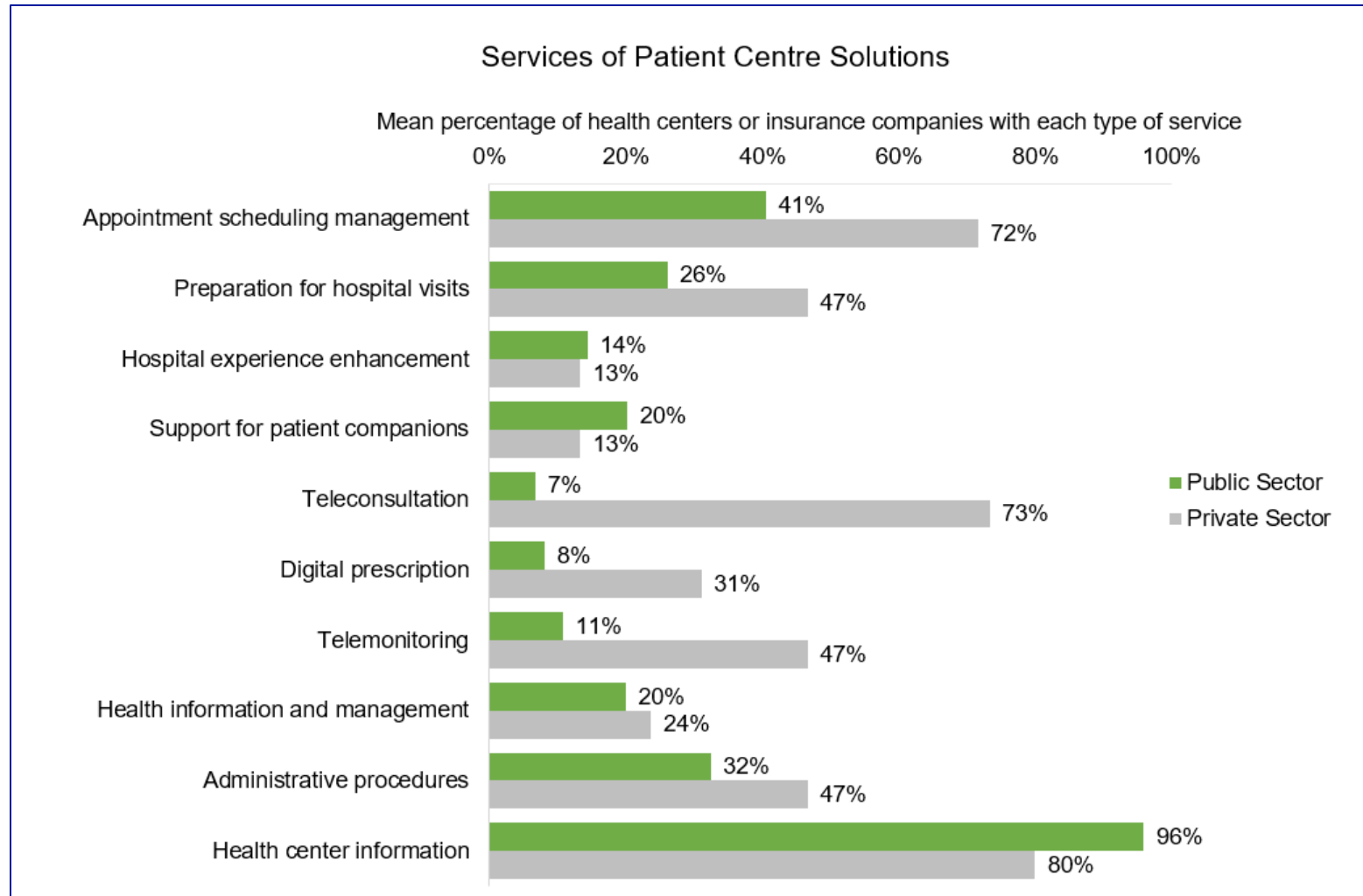
61,4%
of hospitals offer digital services

Services of Patient-Centre Solutions



**30 services
grouped into
10 groups**

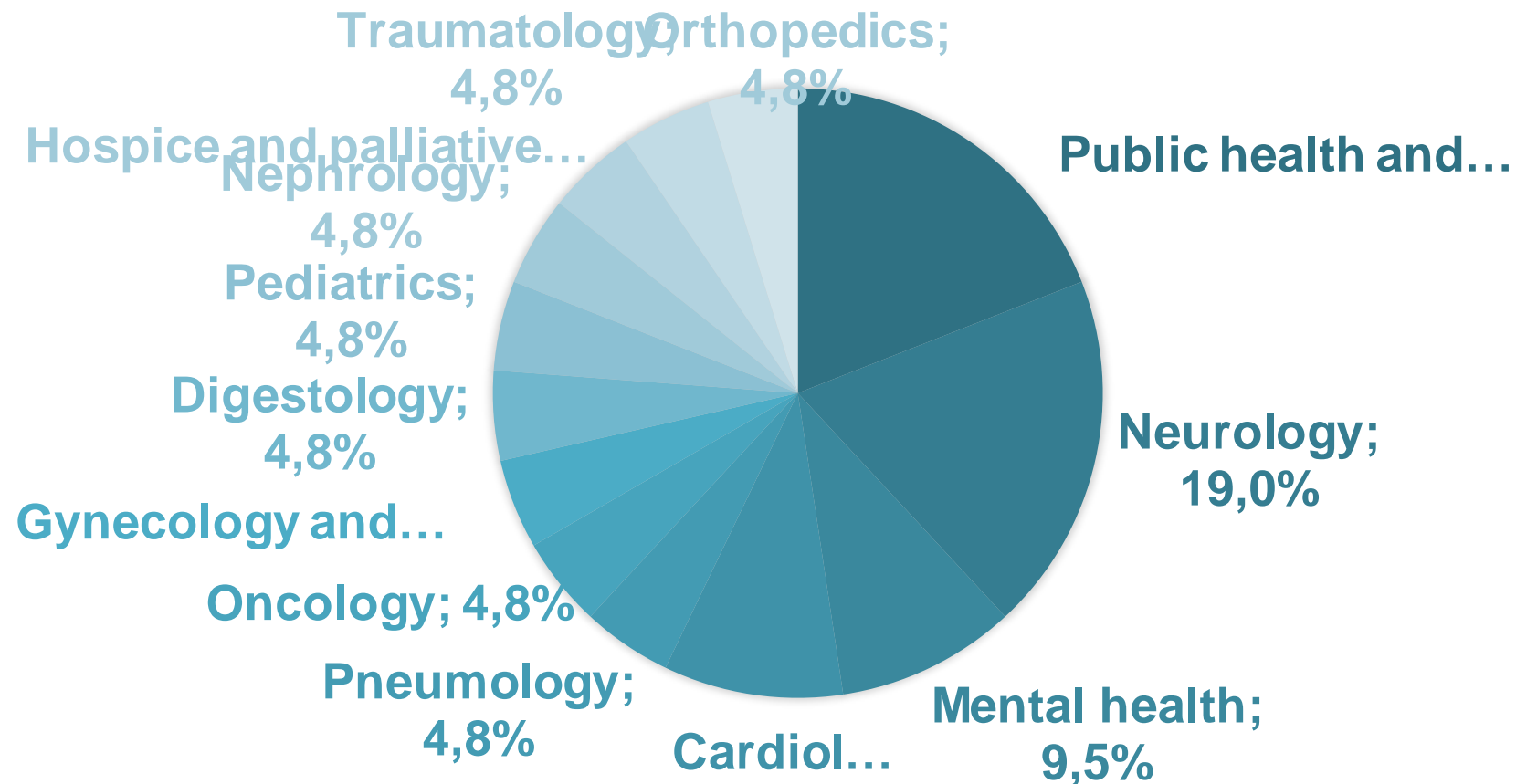
Services Private vs Public



Health & Wellness Solutions

Classification according to specialty

Centers within the Public Health System



mHealth Adoption Journey



2015-2016

- **mHealth plan**
- Action Plan
- mHealth office

2017-2018

- AppSalut project
- **Assessment Framework for Health Apps**
- Apps Pilot in Primary Care (4 centers)

2019-2020

- mConnecta Platform
- Pathways models:
 - **Diabetes**
 - Bipolar Disorder
 - Post-surgery

2021

- **Diabetes tender**
- Requirements for Health Apps

2022-2024

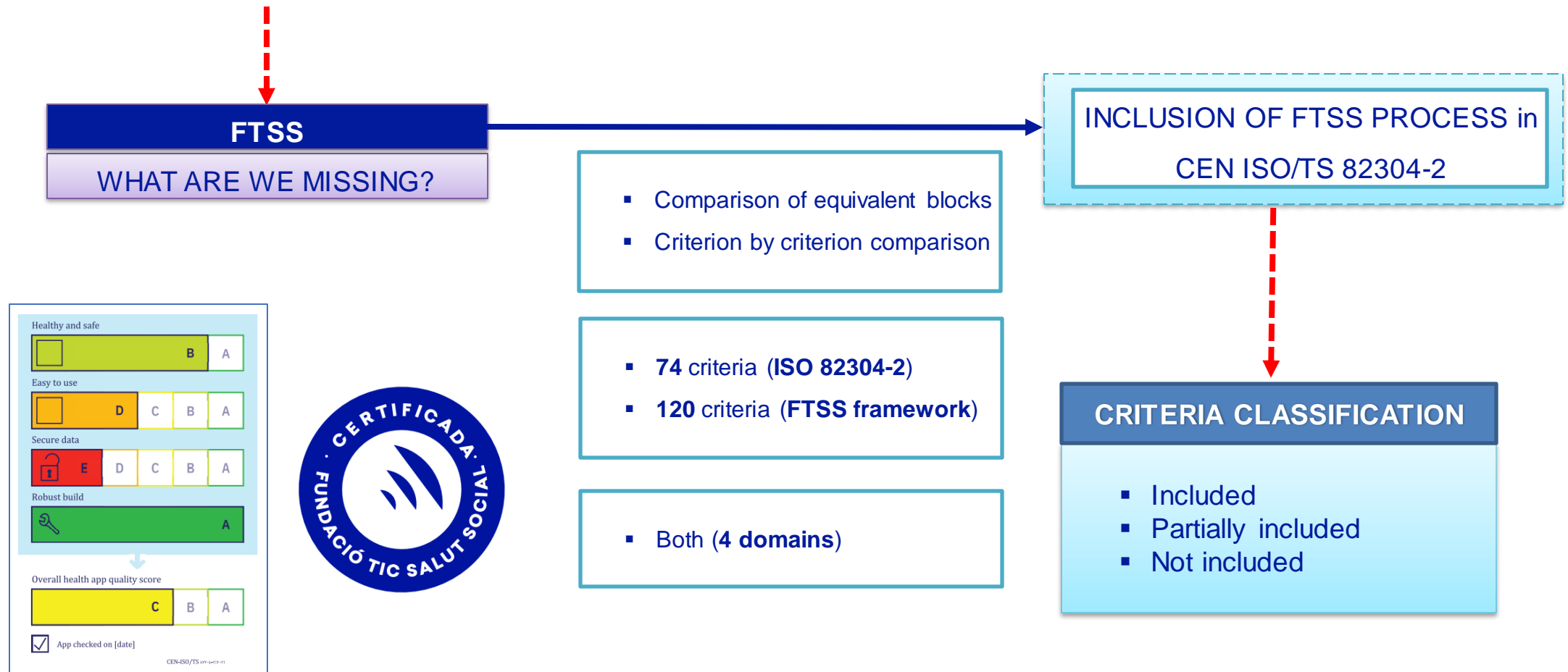
- **Comparison ISO 82304-2 – FTSS assessment framework**
- **Guidelines based in ISO for all providers**



mConnecta
Solucions de mobilitat en salut i benestar

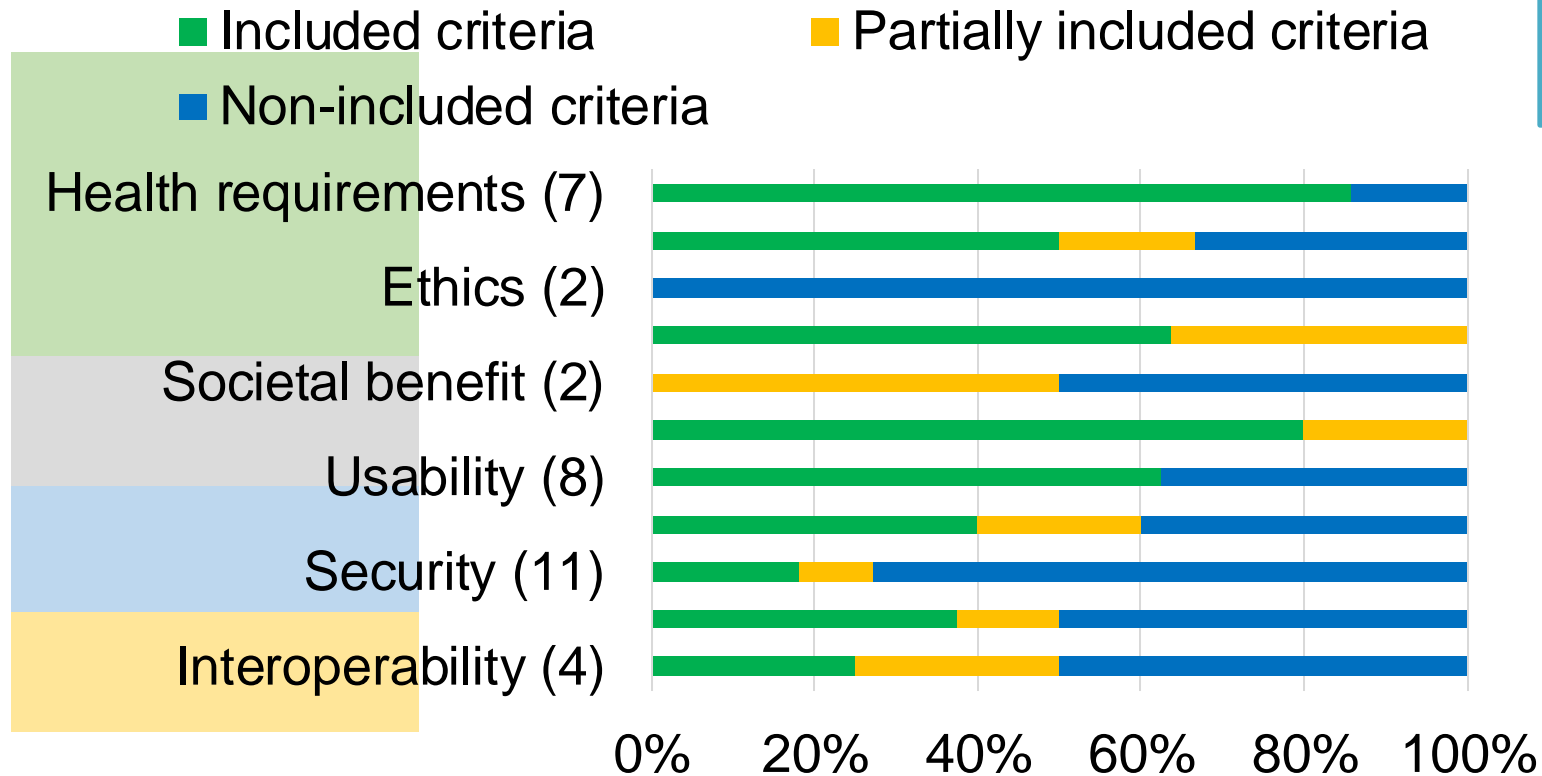


Comparison between CEN ISO/TS 82304-2 and FTSS framework



Transforming Healthcare: A Journey Through Catalonia's Adoption of Health Apps

Inclusion of CEN-ISO/TS 82304-2 requirements in the FTSS certification

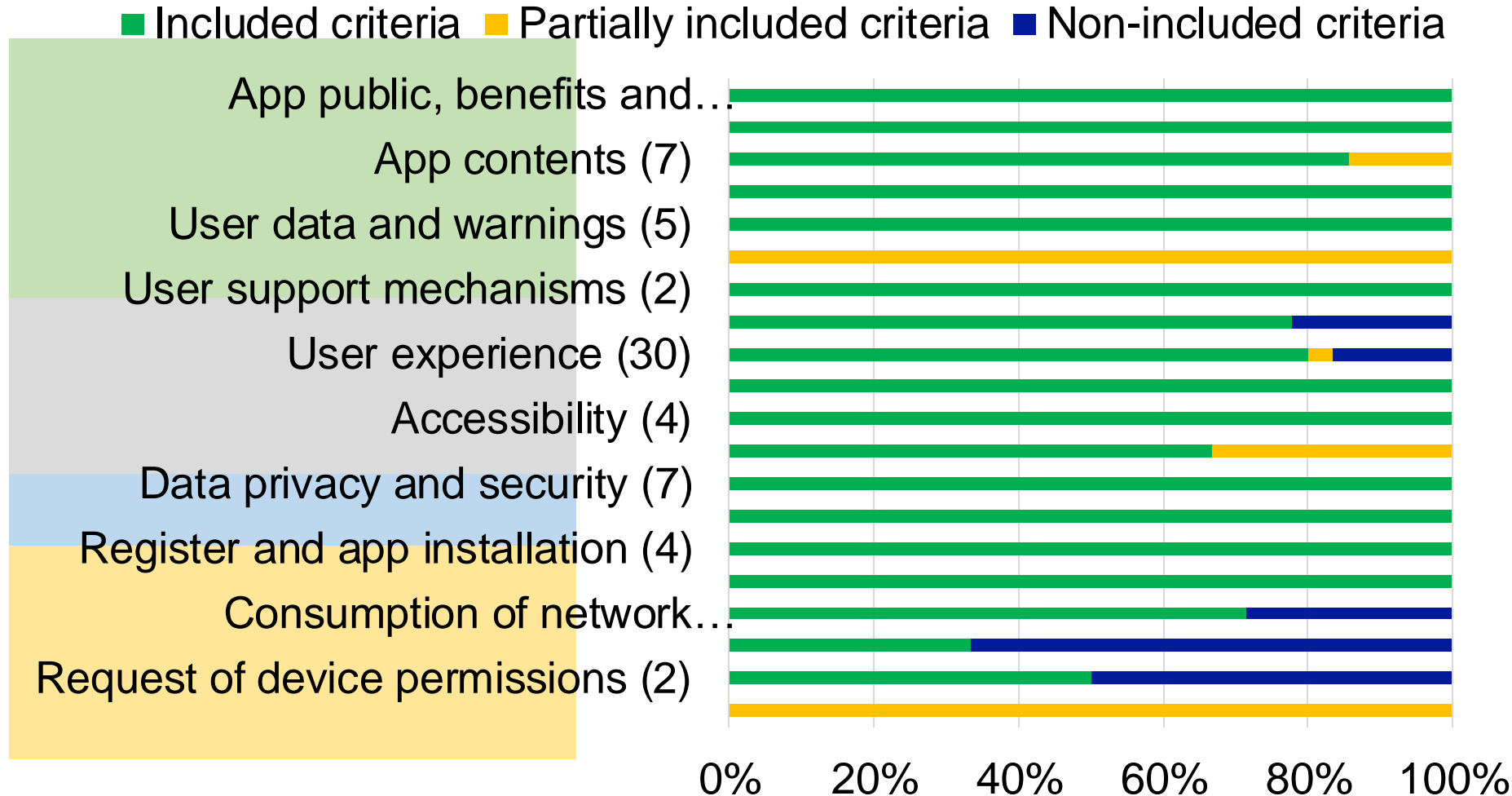


TOTAL
55.4%
of inclusion

- WHAT IS NOT COVERED?**
- **Ethics** (Solution has been evaluated by a Committee of ethics?)
 - **Societal benefits** (evidence)
 - **Health risks** (in FTSS sometimes ask AIPD not all apps accomplish)
 - **Health benefit** (ask about that but we don't ask for any evidence)
 - **Clinical evidence** (more restrictive in evidence about articles)
 - **Security**

Transforming Healthcare: A Journey Through Catalonia's Adoption of Health Apps

Inclusion of FTSS criteria in CEN-ISO/TS 82304-2

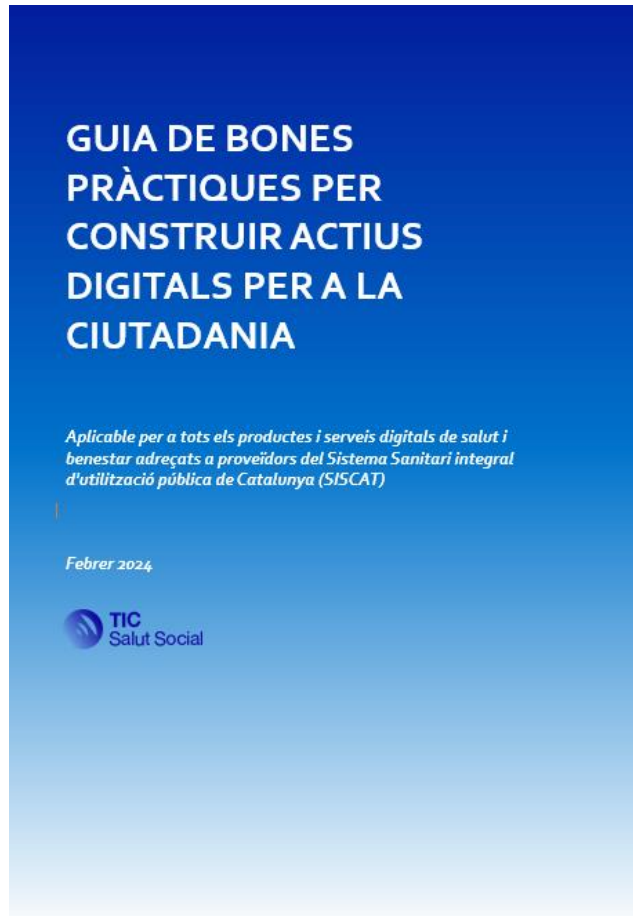


TOTAL
87.5%
of inclusion

WHAT IS NOT COVERED?

- **Usability** (FTSS – Affordance buttons, user experience)
- **Technical robustness** (Consumption of network, behavior in front an event,
- **Clinical content** (minor and dependent people info)
- **Wearables** requirements
- **Interoperability framework** specific from Catalan System

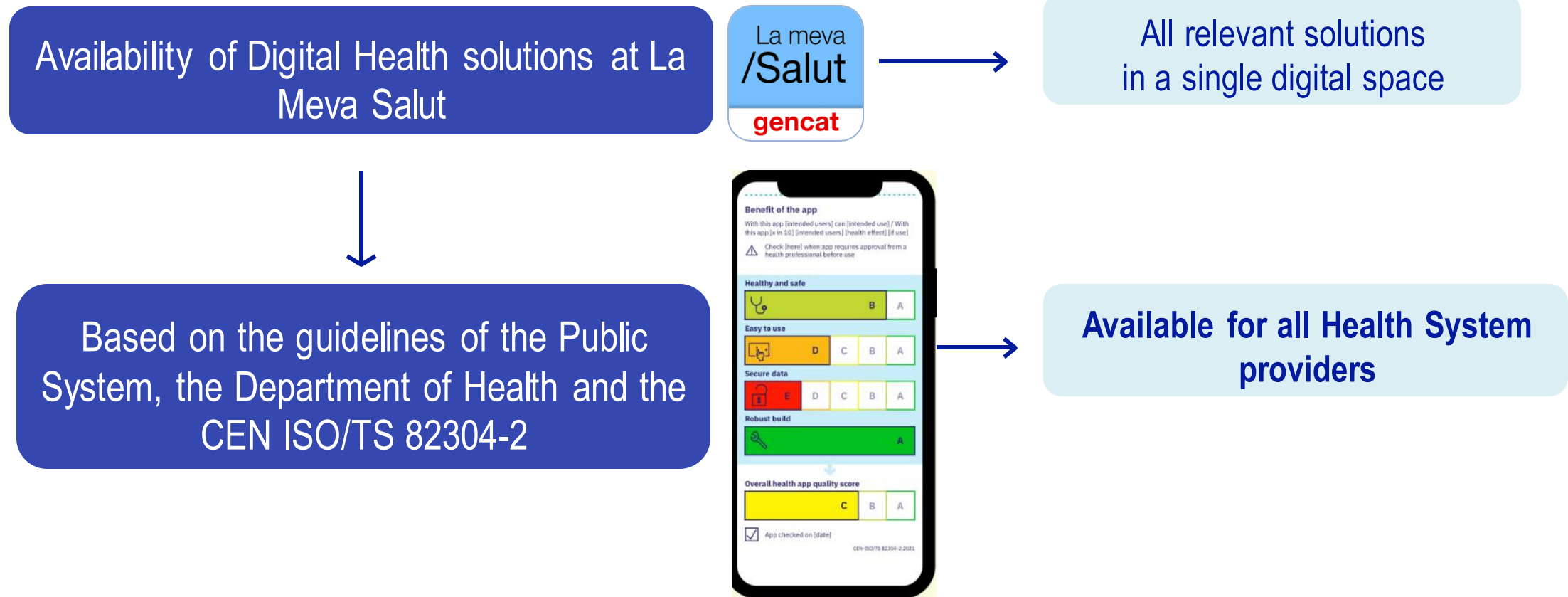
Guidelines for developing Health Solutions for SISCAT



Aimed at SISCAT providers to develop **validated and secure digital solutions** with the requirements and good practices established in La Meva Salut and, thus, facilitate access to all citizens.

Robust, secure, reliable, easy-to-use digital assets that preserve data privacy and are accessible to all citizens.

Guidelines for developing Health Solutions for SISCAT



Guidelines for developing Health Solutions for SISCAT



Health Apps Library

270

<https://ticsalutsocial.cat/es/que-fem/activos-digitales-para-los-ciudadanos/actius/>

The screenshot displays the TIC Salut Social website interface. On the left, a table lists three health apps. On the right, a detailed view of the IConnecta't app is shown, including its description, target audience, and screenshots of the app's interface.

Icono	Nombre	Categoría	Público	Descripción	Ámbito
	HumanITcare	Monitoreo de la salud	Paciente Profesionales sanitarios	Aplicación que permite a los médicos controlar de forma remota el estado físico y psíquico de sus pacientes, a través de tests y medidas de variables clínicas.	Salud
	IConnecta't	Oncología	Paciente Profesionales sanitarios	La App IConnecta't es una herramienta de cribado, monitorización y manejo de síntomas en Oncología.	Salud
	Infermera Virtual	Prevención Monitoreo de la salud	Ciudadanía Paciente Profesionales sanitarios	La aplicación de Enfermera virtual es una aplicación móvil gratuita, dirigida tanto a ciudadanos como a profesionales de la salud, con el fin de promocionar la autonomía y la independencia de las personas en la toma de decisiones respecto a su salud.	Salud

Apps destacadas de salud y social

IConnecta't

Oncología

Dirigido a: Paciente, Profesionales sanitarios
Paciente

La App IConnecta't es una herramienta de cribado, monitorización y manejo de síntomas en Oncología.

Forma parte de un ecosistema digital más amplio que aporta acceso a los PROMs (Patient Reported Outcomes Measures) clave para una atención centrada en el usuario (ej. Calidad de vida).

Está dimensionada por el trabajo multidisciplinar de todos los profesionales en cáncer, pero en la actualidad se ha iniciado en el ámbito psicosocial y educativo.

Permite detectar y monitorizar de forma sostenida variables psicosociales y de agarre farmacológico para ofrecer una atención sanitaria ajustada a las necesidades específicas detectadas en población oncológica. Por otra parte, facilita el acceso seguro a información de calidad sobre cáncer. Esta aplicación también permite a los usuarios contactar de forma directa con sus profesionales sanitarios de referencia mediante un sistema de mensajería segura y privada.

Más información

Desarrollador: Socioemprende SL (Grupo Trilema)
Cost: Gratuita
Versió revisada: 3.9.14 (iOS) y 3.9.7 (Android)
Data revisió: 29/07/2022
Marc de referència: Fundació TIC Salut Social / Instituto Catalán de Oncología (ICO)
Especialidad: Oncología
Adreçat a: Paciente

Accede al Activo

DISPONIBLE EN **App Store**
DISPONIBLE EN **Google Play**

Adoption of CEN ISO/TS 82304-2

- ✔ More objective, the result should be the same independently of the assessor.
- ✔ Increases the certification's value: global standard promoted throughout Europe.
- ✔ Designed so that everyone can benefit from it. The ISO empowers patients, healthcare workers, and healthcare systems to use and recommend healthcare apps
- ✔ Saving time and cross-border recognition - Developers won't have to apply for a different certification in each territory.
- ✔ Easy for early adopters, saving costs due not to start from scratch.
- ✔ Including digital solutions in the same space as citizens' health records seems a good technique to promote them and improve their equity

Thank you!

Carme Pratdepàdua Bufill
cpratdepadua@ticsalutsocial.cat

Fundació TIC Salut Social
www.ticsalutsocial.cat





Real Value of Patient-centered Positive Health Effects of Digital Medical Devices: Lessons from the German DiGA

Liyousew Borga
Luxembourg Institute of Health

Real Value of Patient-centred Positive Health Effects of Digital Medical Devices: Lessons from the German DiGA

Liyousew Borga

Postdoctoral Fellow

Digital Medicine

Luxembourg Institute of Health

Positive Care Effects of DiGAs

Digital Healthcare Act (DVG)

– One or more “positive healthcare effects”



Medical Benefit

Outcomes that are known from trials of clinical or pharmaceutical interventions:

- based on the corresponding standards for the evaluation of drugs
 - improvement of the **state of health**,
 - reduction** of the **duration** of a disease,
 - prolongation of **survival**, or
 - improvement in the **quality of life**.



Patient-relevant improvement of structure and processes (pSVV)

Outcome core area in the context of proof of benefits:

- offer good and new possibilities for improving care, especially regarding processes in the patient
 - detection, monitoring, treatment or alleviation of disease / injury / disability
 - supporting the health **behaviour**
 - integrating** processes between patients and providers

pSVV: Untapped Potential

The motivation behind adding **pSVV** was to **empower patients** to become more active and informed, encourage shared decision-making, and promote health literacy.

- ❑ It increases patient-centeredness in healthcare delivery and contributes to the principles of **value-based** healthcare.
- ❑ Patients have low-threshold **access** to quality-assured digital health applications.

Lack of widespread understanding of **pSVV** among stakeholders



1

pSVVs are **underutilized** by DiGA applicants

2

Established methods for **measuring pSVV** outcomes are limited

3

Economic **value** of **pSVVs** not fully demonstrated

Domains of Patient-Centred Improvement

ADHERENCE

Involves patients actively following parts of the therapy agreed with their physician, with DiGA increasing adherence by integrating health behaviours into daily activities.

COORDINATION OF TREATMENT

Supports coordination between healthcare providers and patients, leading to improved care through adapted therapies and accessible communication.

FACILITATING ACCESS

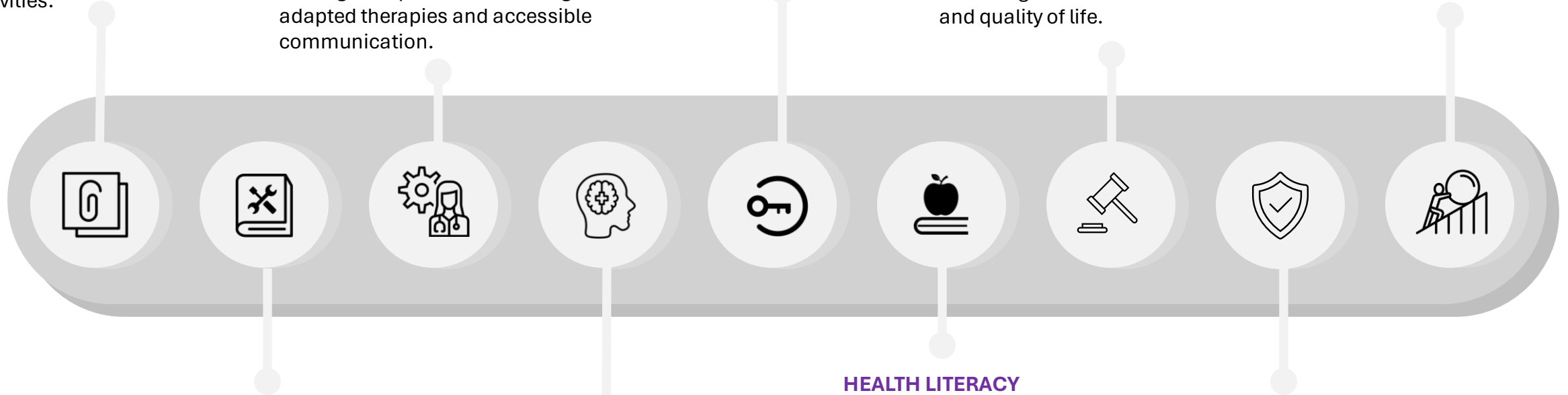
Improves access to healthcare services, ensuring reliable and equitable health support.

PATIENT AUTONOMY

Empowers in health management and decision-making, utilizing their knowledge for better outcomes and quality of life.

REDUCTION OF EFFORTS

Streamlines treatment and disease management, reducing stress and improving safety through simplified procedures and targeted physician visits



ALIGNMENT OF GUIDELINES

Ensures treatments align with guidelines and standards by translating medical instructions into patient-friendly formats.

COPING WITH ILLNESS

Helps manage daily challenges by utilizing technology for early warnings, facilitating remote monitoring, and developing coping strategies.

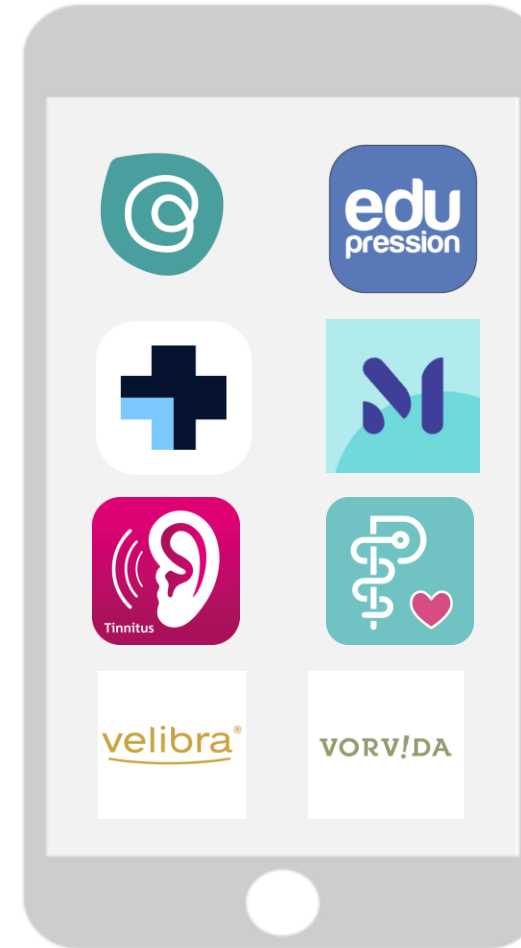
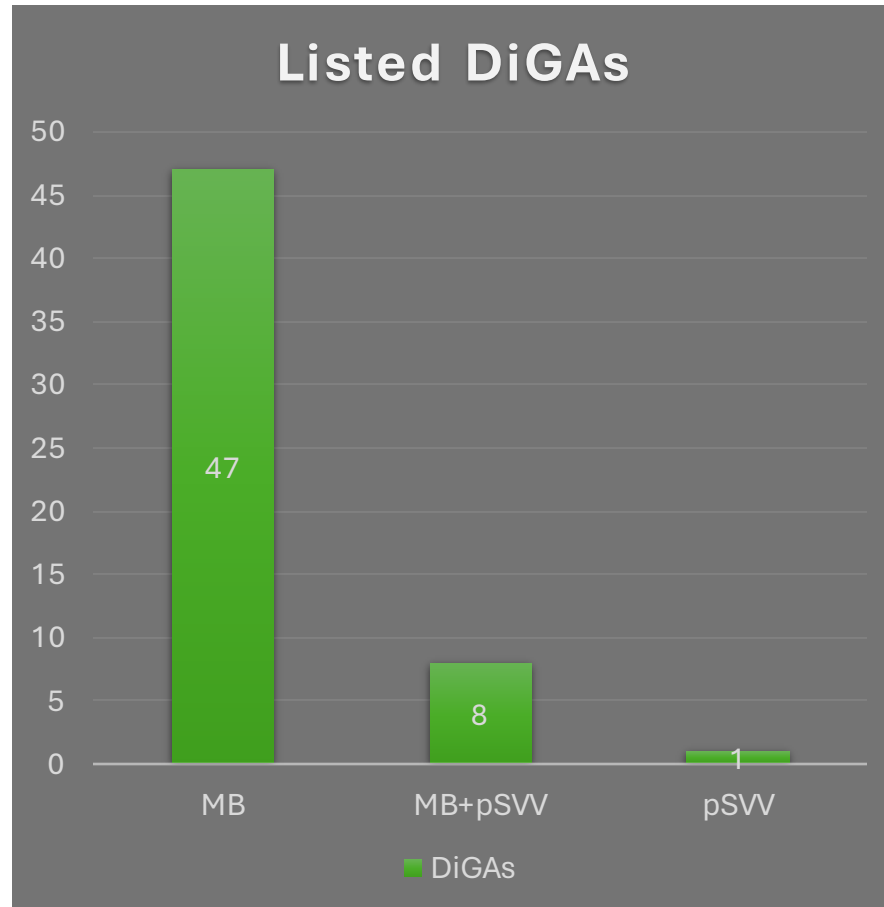
HEALTH LITERACY

Enhances understanding and application of health-related information, crucial for informed decisions and successful therapy outcomes.









PATIENT SAFETY

Extends quality and safety measures to the home, enabling recognition and response to treatment risks, errors, or side effects.

pSVV: Underrepresented in Current DiGAs



Are DiGA Developers Embracing pSVV?

DiGA	Condition	Core pSVV Area	Endpoint	Instrument
 Cara Care	Irritable bowel syndrome	Coping with illness-related difficulties in everyday life Health literacy	Work Impairment Health literacy	Work Productivity and Activity Impairment questionnaire (WPAI:IBS) European Health Literacy Survey Questionnaire (HLS-EU-Q16)
 education.com®	Mild depressive episode Recurrent depressive disorder	Health literacy	Health literacy	Depression Literacy Questionnaire (D-Lit)
 Kranus Edera	Impotence of organic origin	Patient sovereignty	Patient sovereignty	Patient Activation Measure-13 (PAM-13)
 Meine Tinnitus App	Tinnitus aurium	Coping with illness-related difficulties in everyday life	Change in perception, behaviour and dealing with tinnitus	Bochum Change sheet 2000 (BVB-2000)
 Mindable	Agoraphobia Panic disorder	Patient sovereignty	Patient sovereignty	Anxiety Control Questionnaire (AKF)
 ProHeart	Heart failure	Alignment of treatment with guidelines and recognized standards	Alignment of treatment with guidelines	9-item European Heart Failure Self-Care Behaviour Index (EHFScBS)
		Health literacy	Health literacy	Atlanta Heart Failure Knowledge Test (AHFKT)
 velibra	Agoraphobia Panic disorder Generalized anxiety disorder	Reduction of therapy-related expenses and burdens on patients and their relatives	Patients' general psychological stress	Brief Symptom Inventory (BSI)
 vorvida	Mental and behavioural disorders caused by alcohol	Patient sovereignty	Patient sovereignty	Alcohol abstinence self-efficacy questionnaire (AASE-G)

The Measurement Hurdle?

Evaluation Framework

Relatively new focus within the digital health evaluation landscape.

Broad Domains

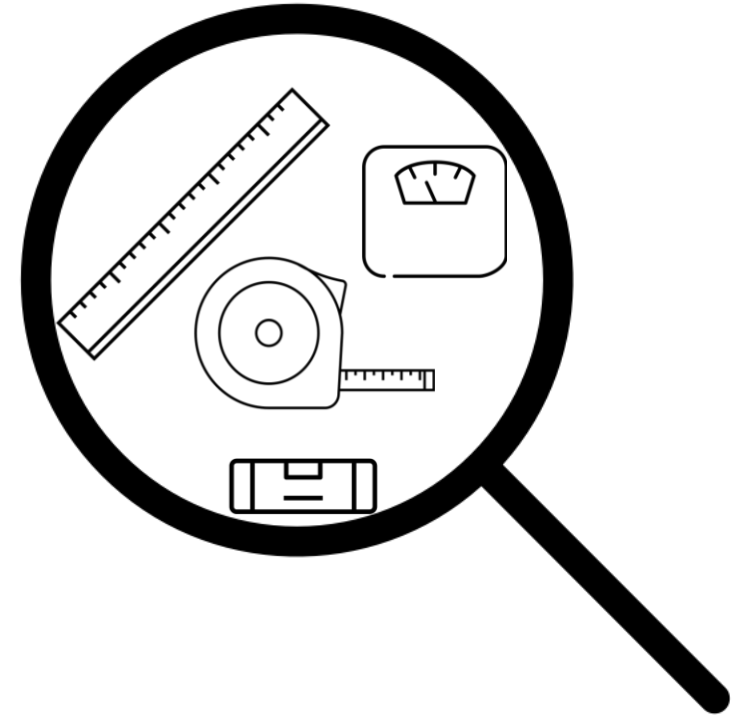
Some domains are broad and multifaceted (e.g., "Coordination of Treatment Processes").

Standardized Tools

For some *pSVV* outcome categories, validated outcome measurement instruments are lacking.

Evidence Generation

pSVV evidence can be more challenging to generate → less clear path to reimbursement.



The Real Value of *pSVV*



Up to a **FIFTH** of health spending in OECD countries is at best **ineffective** and at worst, **wasteful***

Failures of care delivery

Failures of care coordination

Overtreatment

Administrative waste

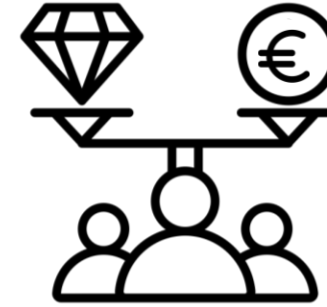
Pricing failures

Fraud and abuse

Patients do not receive the right care

Benefits could be obtained with fewer resources

Resources are unnecessarily taken away from patient care



- pSVV*'s have potential for long-term cost savings and improved health outcomes.
- Economic value hidden in patient outcomes
 - Undervalued potential in healthcare efficiency
- Challenge in quantifying economic benefits of *pSSVs*

*OECD (2017), *Tackling Wasteful Spending on Health*, OECD Publishing, Paris

Conclusion: The Path Forward

Quantify Impact:

- ❑ Standardize methods to measure *pSVV*'s healthcare outcomes and economic benefits.

RWD/RWE:

- ❑ Promote novel study methodologies.

Reimbursement:

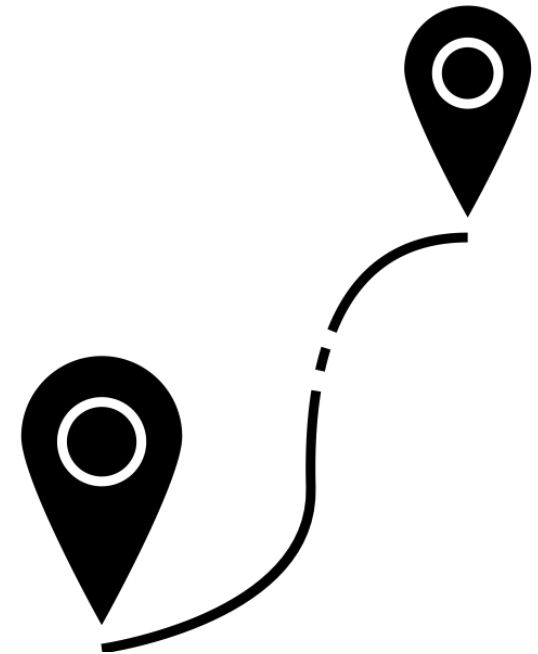
- ❑ Rethinking reimbursement models to reward patient-centred innovation.

Engagement:

- ❑ Greater support for DiGA developers targeting *pSVV* outcomes.
- ❑ Engage all stakeholders in all phases: development, testing, policy dialogue.

Harmonisation:

- ❑ International harmonisation of best evidentiary practices





THANK YOU

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Challenges and recommendations for the reimbursement of health apps

Tatjana Prenda Trupec
International Consultant

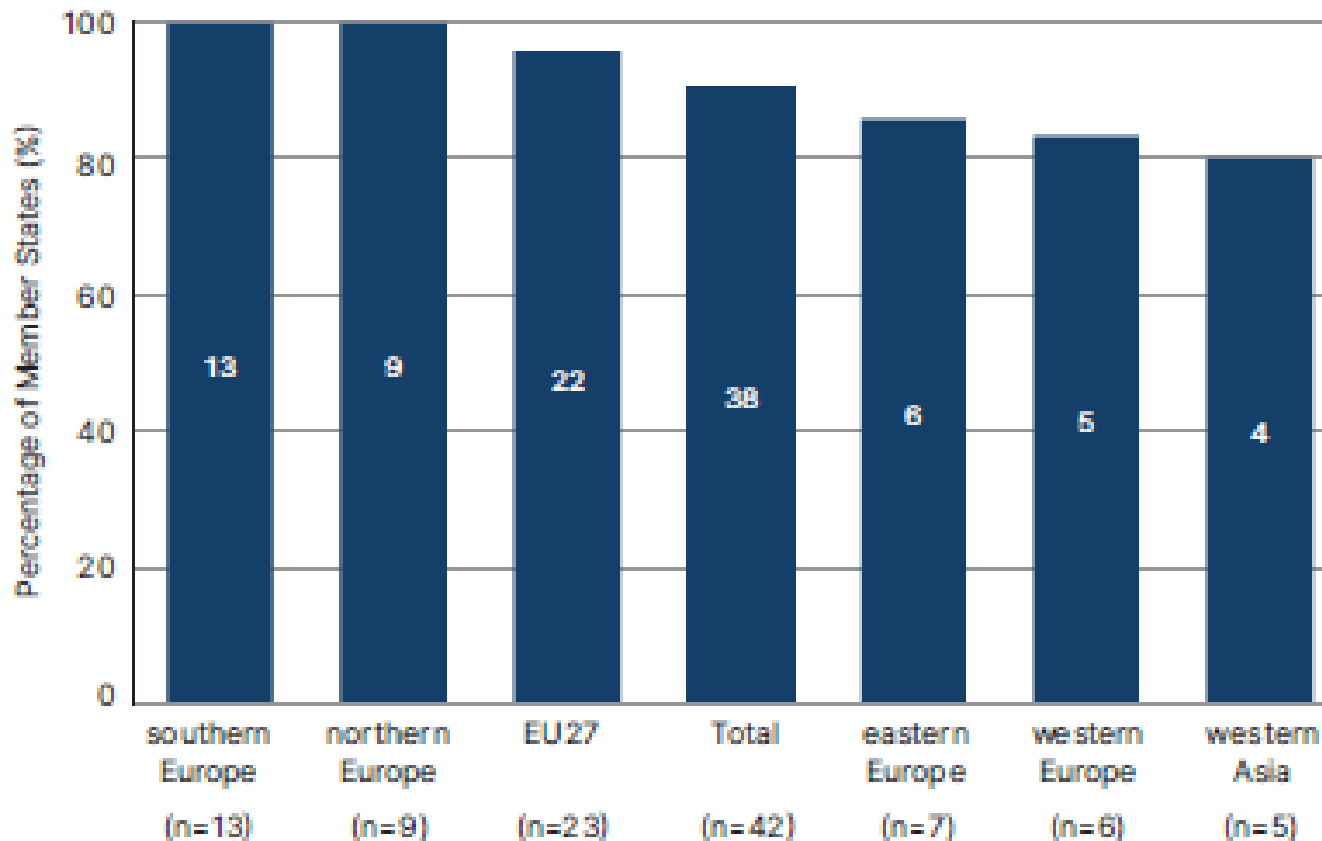
Challenges and recommendations for the reimbursement of health apps

Tatjana Prenda Trupec, international expert (OptimIT)

Label2Enable_4th Roundtable on Health Apps from Health Authority Perspective

March 21, 2024

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



91% of WHO EU Member States (38 out of 42) reported having at least one government-sponsored mHealth programme.

from Toni Dedeu's presentation for the 3rd roundtable on the reimbursement of health apps Feb 13

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

https://cdn.who.int/media/docs/librariesprovider2/data-and-evidence/english-ddh-260823_7amcet.pdf?sfvrsn=4c674522_2&download=true



Challenges

why are health and wellness apps rarely reimbursed ?

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**
- care pathway integration**
infrastructure
time constraints
disruption workflow
interoperability
- assessment scheme**
what is sufficient evidence
assessment methods
when to reassess / surveillance
- transparency process**
awareness roles and responsibilities
predictability outcome
rigor / scoring mechanism

challenges solutions
procedure / process

people
challenges solutions

- equity**
(patients)
device ownership
platform availability
internet access
affordability / SES
language / translations
cultural sensitivity
disability
literacy
hcp support
- trust**
(patients, hcps)
trusted assessment
trusted recommendations
complement to in person care
- skills / training**
(patients, hcps)
- (financial) incentives**
(patients, hcps)
- regulation**
not EU but national responsibility
copy paste front runners not feasible
regional/municipal healthcare
- standardisation**
- uptake in clinical guidelines**
- assessment framework**
scope
requirements
maintenance

challenges solutions
policy

product
challenges solutions

- abundance of apps**
CE marking
AI, including equity
clinical evidence
- patient safety**
- data security**
- sustained use**
- evolving nature**
- capacity**
smaller countries/languages:
- lack of HTA body
- other priorities
- market influence

challenges solutions
place

Current EU legislation on the reimbursement of health apps

Reimbursement of apps in the healthcare sector is not regulated at EU level

Why?




Public Health is a shared competences (Art 168 TFEU)

- ⑨ **Member States** define and deliver healthcare, including allocation of resources
- ⑨ **EU's** actions are complimentary, focusing on cross-border aspects and harnessing new technologies for the benefit of efficient health systems

from Petra Willson's presentation for the 3rd roundtable on the reimbursement of health apps Feb 13

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





[*https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf](https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf),

European Federation of Pharmaceutical Industries and Associations

from Petra Willson's presentation for the 3rd roundtable on the reimbursement of health apps Feb 13

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

*<https://www.efpia.eu/media/677347/improving-access-to-digital-therapeutics-in-europe.pdf>,
from Petra Willson's presentation for the 3rd roundtable on the reimbursement of health apps Feb 13

Recommendations for the reimbursement of health apps

Results of three 3-hour roundtables in 2023/2024 with 135 participants from 34 countries, focussing on 1) EU Member States' challenges in reimbursement of health apps, 2) multi-stakeholder solutions to these challenges, and 3) Member State decision-makers' perspectives.



1. Value

Acknowledge **apps can do things that pills can't** (and vice versa). Approximate with key stakeholders the added value of apps for health, public health and care (e.g. for health literacy, healthy behaviours, early diagnosis, personalized shared decision-making, self-management, remote consultations, symptom monitoring, multidisciplinary care delivery, treatment adherence, recovery, efficiency, primary and secondary use of (big) data), suggest accepted endpoints for studies and revisit this effort periodically.

2. Focus

Identify which (packages of) types of apps or their functional components for which health issues and which patients, and if applicable integrated in which care pathways are likely to add value. Prioritize these apps according to value added and explore existing policy goals, political support and day-to-day challenges. Start small, consider a pilot and assess the need for changes in or additions to policies and legislation.

3. Govern

Establish who or more specifically which multidisciplinary collaboration within or beyond the health authority is responsible for policymaking, evidence generation, innovation promotion, assessment, reimbursement, transparency, education and transformation (data usage). Manage change.

Overall health app quality score



4. Create

Enable manufacturers, clinicians and researchers to achieve more evidence-based, effective, value-adding apps and care pathways. Use adequate outcome measures to quantify the (potential) value of individual health apps and blended care pathways, and study how to create, capture and measure it. Harmonise accepted endpoints, comparators etc. where possible.

Healthy and safe



5. Assess

Determine quality requirements, assessors (internally and/or trusted third parties), assessment methods and what is sufficient evidence. Consider the trusted EU-initiated global CEN-ISO/TS 82304-2 framework as a basis, adding country specific requirements on top, to increase health system and manufacturer efficiency and avoid a duplication of efforts.

Secure data



6. Inform

Ensure intended users and prescribers are aware of and able to easily access positively assessed value-adding apps (e.g. quality label in app stores and frequently used trusted sources).



7. Fund

Allocate funding for value-adding apps and / or related blended care pathways. Consider innovative payment models, transparent criteria, and incentivizing all stakeholders involved (manufacturers, users, prescribers, providers) to achieve equitable sustainable use of value-adding apps at scale. Have pricing reflect the added value and needed investments.



8. Transform

Create the environment in which quality apps can deliver value: integrate into clinical guidelines, pathways, prescription practice, and care delivery. Educate and support health professionals and citizens to increase digital literacy, attain equitable sustained app use and capture value of data. Enable internet access, interoperability and safe data exchange with EHR systems. Use standards.

Easy to use



WHO European Member States: most important barriers to mApp integration into clinical practice ¹

(72% of European Member States (MS) lack regulatory oversight entity for mApps)

61% MS: lack of evidence effectiveness of mApps in clinical practice

75% MS: privacy, security (15% MS reported evaluating mHealth)

77% MS: lack of a trustworthy source to access effective mApps

WHO: evaluations should inform investment and implementation decisions

73% MS: lack of patient digital literacy

9. Measure to scale

Identify key value indicators and measure and present value transparently. Realise that the measurements will only reflect the attainable value when apps are quality-proven effective, where applicable integrated into care pathways, if users are sufficiently enabled, if the resulting data is used, if appropriate outcome measures, scope, comparators are utilised, etc. Explore, again in a multi-stakeholder effort, what are the promising next steps to capture the attainable value of health apps.



Thank you for your attention

Country-Specific Interest? Do Contact Us



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