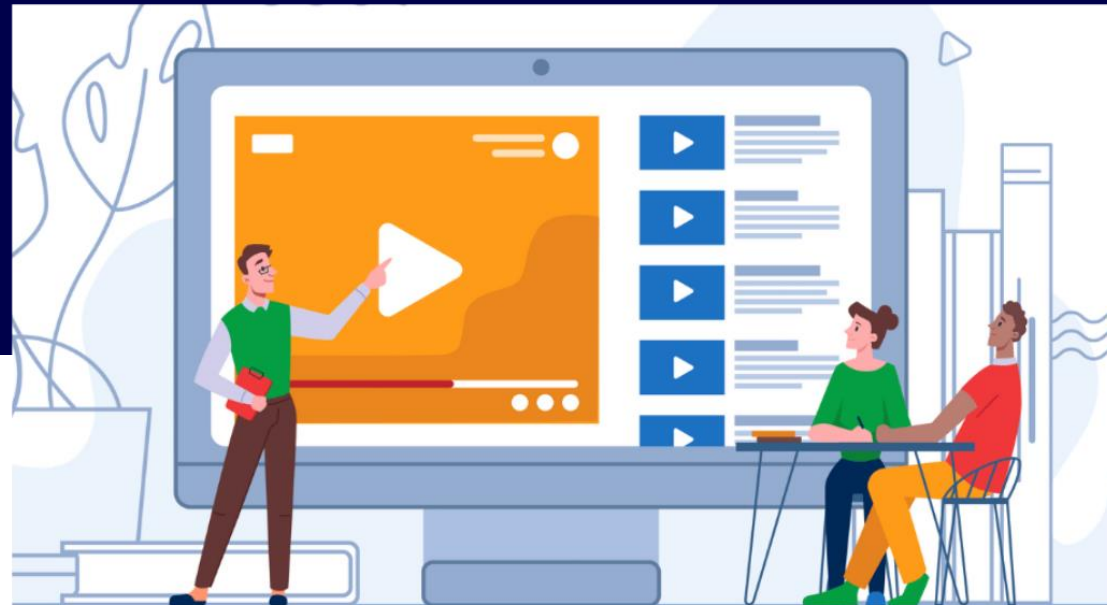




Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

24 April 2023 10:00 - 11:30 CEST

Health apps from a healthcare professional perspective



LabelRoundtable Event Series



Funded by the
European Union



label2enable.eu



[@label2e](https://twitter.com/label2e)



linkedin.com/company/label2enable



info@label2enable.eu

Webinar Housekeeping



Participants are muted by default. During the interactive parts of the webinar, organisers can unmute participants who wish to comment.



This is a recorded webinar. The recording will be published on the Label2Enable website.



Participants have two ways of interaction: by clicking on „raise hand“ and waiting for the organisers to call on them, or by submitting a comment/question via the chat.



The recording and slide deck will be made available to participants after the event, via a follow-up email.



Timeslot	Title	Presenter
10:00-10:15	How can Label2Enable foster adoption and trust in the use of health and wellness apps in clinical practice through the label based of CEN- ISO/TS 82304-2?	Antanas Montvila (European Junior Doctors Association)
10:15-10:30	Medical professionals' views on using wellness and health apps in clinical practice - insights from a pan-European survey	Ieva Biliūnaitė (Leiden University Medical Center)
10:30-10:50	Health Technology Assessment in Digital Health. Comparing approaches for health apps and technologies: CEN-ISO/TS 82304-2 and the Finnish Digi-HTA	Jarno Suominen (Digi-HTA)
10:50-11:10	Clinical assessment and evaluation of clinical evidence of Digital Health Technologies. Introduction to the approach used by the Review of Care and Health Apps (ORCHA)	Adam McCabe, Tom Micklewright (ORCHA)
11:10-11:30	Final discussion	

Webinar Panelists



Antanas Montvila

Vice-president at European Junior
Doctors Association



Ieva Biliūnaitė

Post-doctoral Researcher at Leiden
University Medical Center



Jarno Suominen

Biomedical Engineering and life
sciences



**Adam McCabe and
Dr. Tom Micklewright**

Senior Digital Health Reviewer



Antanas Montvila

Vice-president at European Junior
Doctors Association

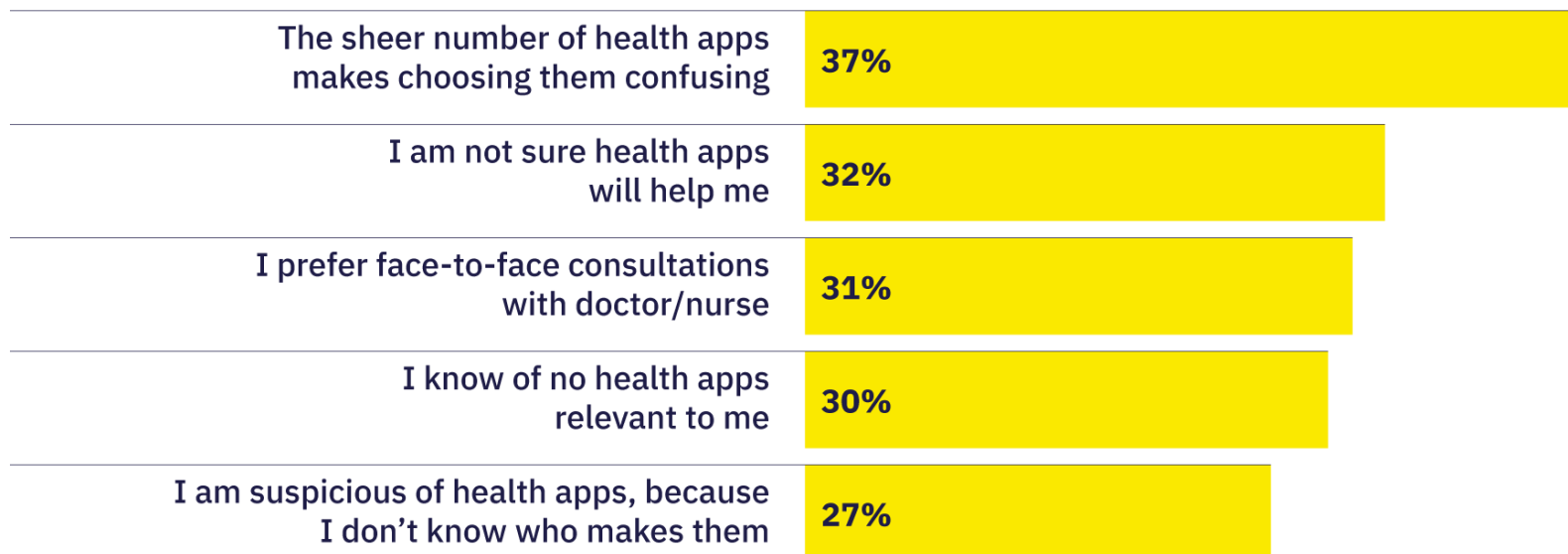
How can the Label2Enable project foster adoption and trust in the use of health and wellness apps in clinical practice through the label based on of CEN- ISO/ TS 82304-2 eHealth standard?

Label2Enable

Labelroundtable #2

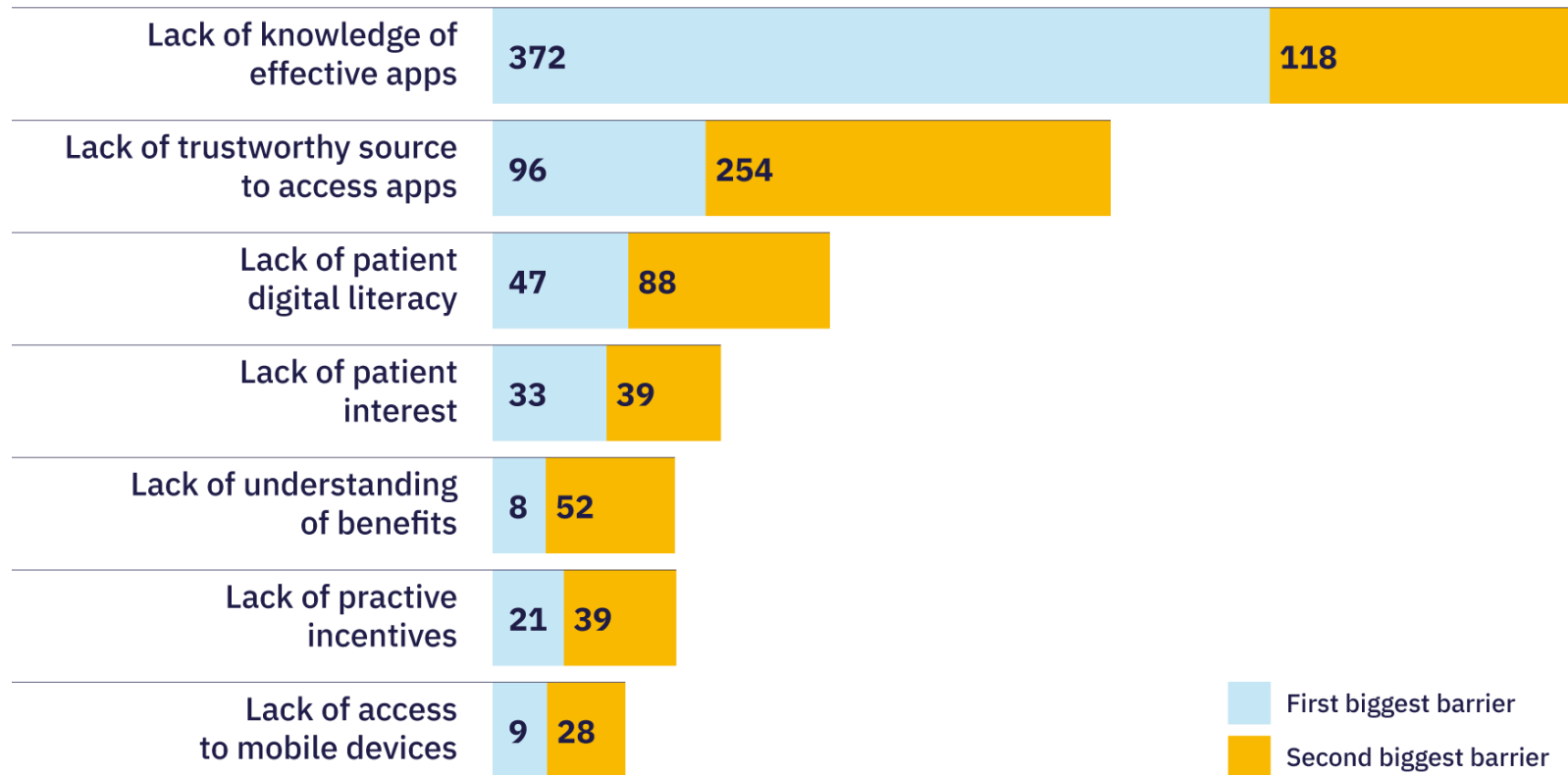
Why certification of medical apps is needed and how we can move forward?

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

Choosing a 'good' health app is difficult



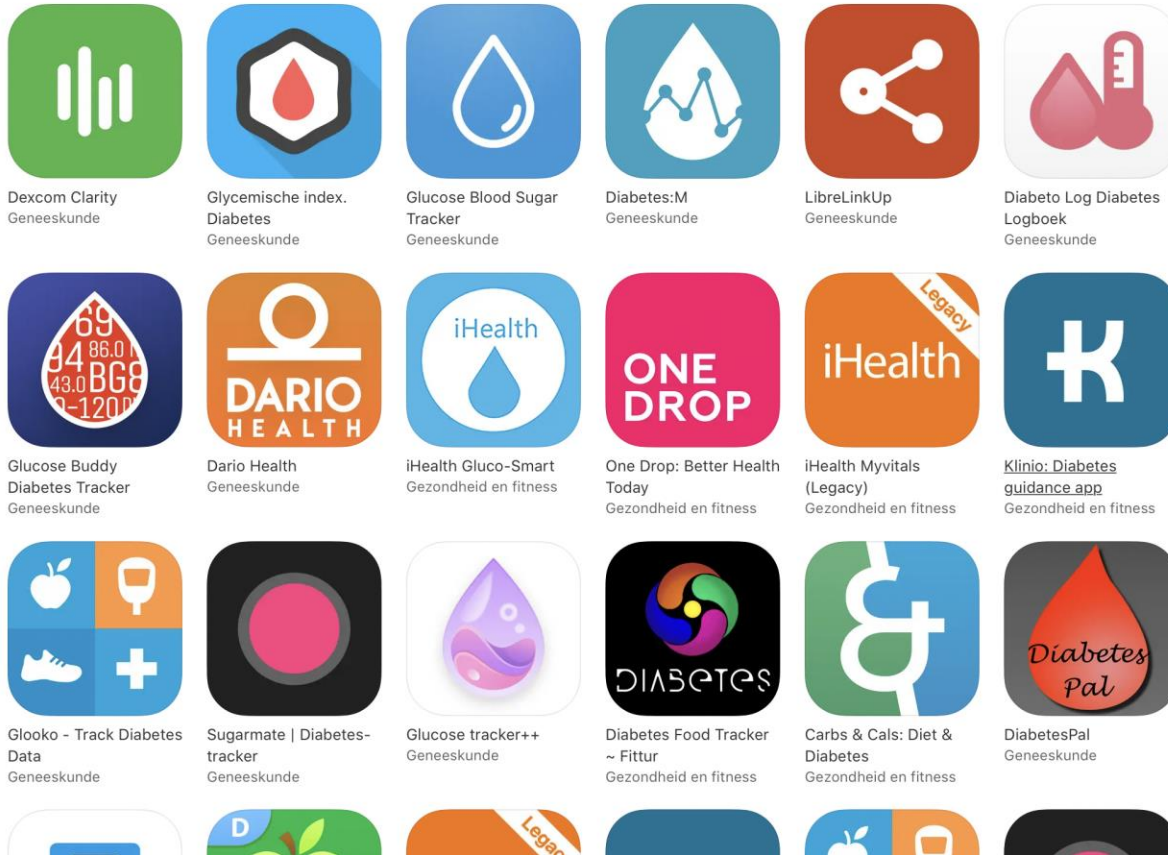
Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study

how to distinguish a “good” health app?

App Store Preview

mySugr - Diabetestracker-log

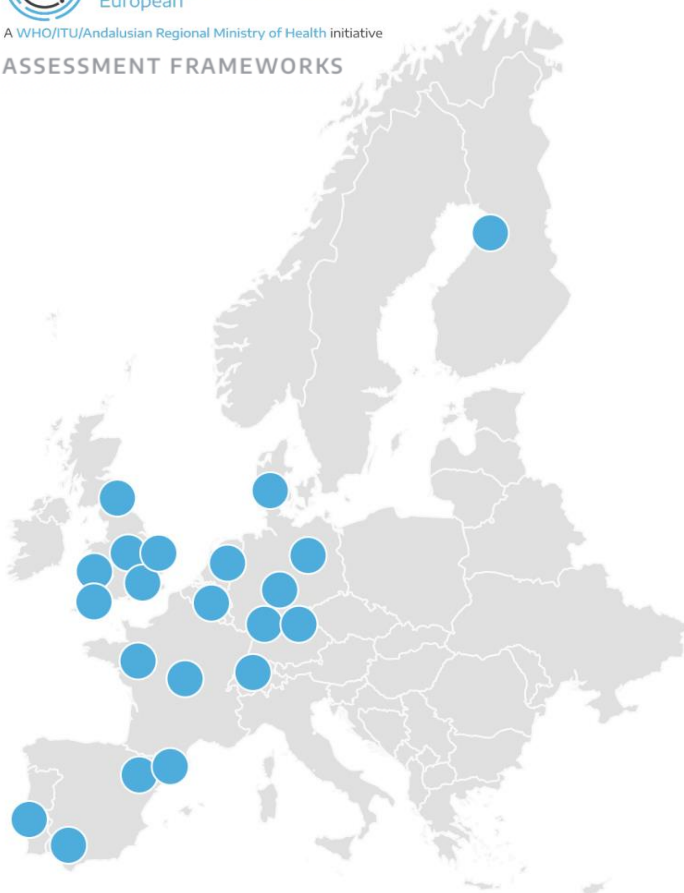
Suggesties voor jou



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

Delivering a 'good' health app is difficult



mHealth Hub (2022) Health App Assessment Frameworks



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

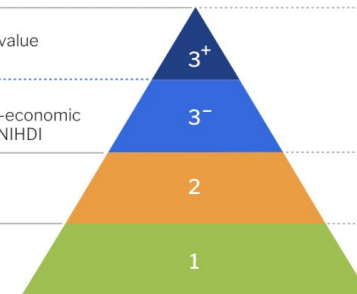


I have fully proven my social-economic value and I am definitely financed by NIHDI

I am in the process of proving my social-economic value and I am temporarily financed by NIHDI

I am safely connected

I am a CE certified medical device



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



EU policy context

The EU moves towards a common transparent assessment of health apps:

- 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 17065 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**

what: 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

Easy to use

Secure data

Robust build

Overall health app quality score

App checked on [date]

Zászló vagy logó

Egészségügyi alkalmazás minőségi címke

Alkalmazás ikon

Alkalmazás neve

Platform ikonok

Alkalmazás gyártójának neve

Az alkalmazás előnyei

Ezzel az alkalmazással [céltott felhasználók] [tervezett felhasználás] / Ezzel az alkalmazással [x 10-ből] [céltott felhasználók] [egészségre gyakorolt hatás] [használat esetén]

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

Egészséges és biztonságos

Könnyen használható

Biztonságos adatok

Robusztus felépítés

Általános egészségügyi alkalmazás minőségi pontszám

Az alkalmazás ellenőrzése [dátum]

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

Facile à utiliser

Données sécurisées

Design robuste

Score global de qualité de l'appli de santé

Appli vérifiée le [date]

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 utilizzata]

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

Sano e sicuro

Facile da usare

Dati protetti

Costruzione solida

Punteggio di qualità complessivo dell'app per la salute

App controllata il [data]

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

Let at bruge

Sikrer data

Robust konstruktion

Samlet kvalitetsscore for sundhedsapp

App tjekket den [dato]

the EU Energy score



5 jaar garantie

★★★★★ (91)

**Siemens WM14N295NL
iQ300 extraKlasse
wasmachine**

577,- Adviesprijs 759,-

✓ Op voorraad



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

☐ Vergelijk product



Ariel Allin1 PODS cadeau

★★★★★ (1)

**Whirlpool FFD6E 9638
BCEV F wasmachine**

497,- Adviesprijs 629,-

✓ Op voorraad



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

☐ Vergelijk product



Black Friday Deal

★★★★★ (84)

**AEG L8FEN96CAD OKOMix
AutoDose wasmachine**

866,- Adviesprijs 1.329,-

✓ Op voorraad



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

☐ Vergelijk product



Black Friday Deal

**Miele WED 174 WPS
wasmachine**

1.379,-

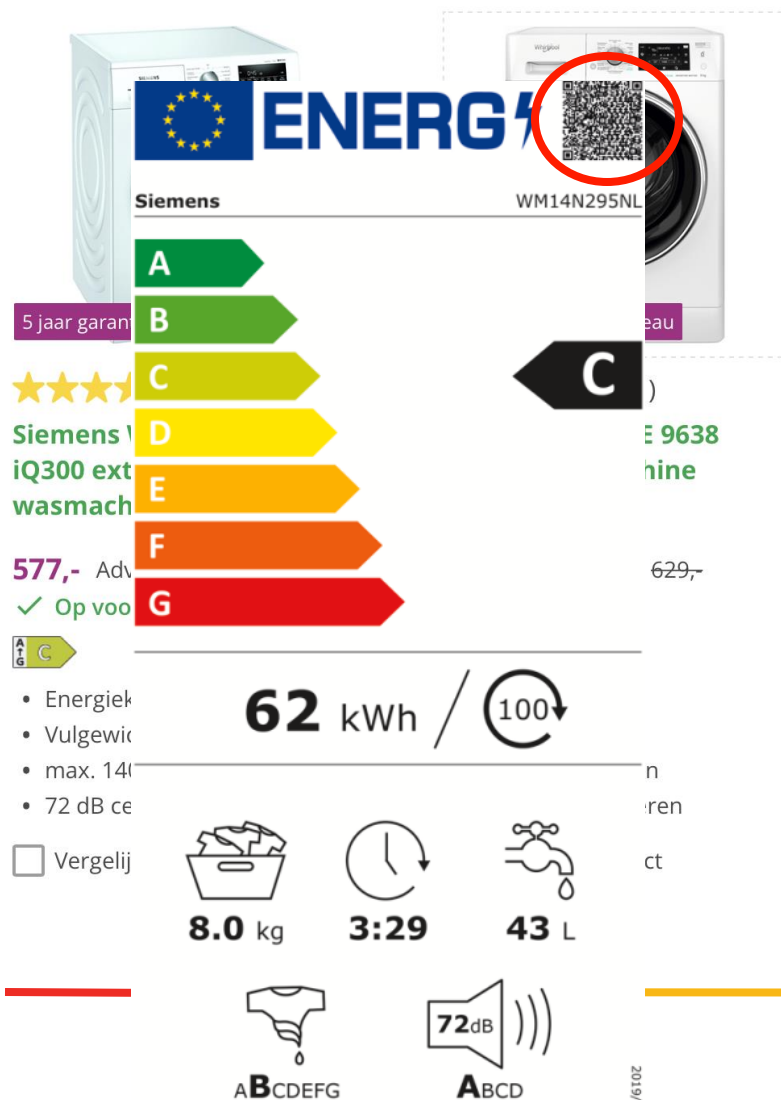
✓ Op voorraad



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

☐ Vergelijk product

the EU Energy label



★★★★★ (84)

**AEG L8FEN96CAD OKOMix
AutoDose wasmachine**

866,- Adviesprijs 1.329,-

✓ Op voorraad

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

☐ Vergelijk product



**Miele WED 174 WPS
wasmachine**


1.379,-


✓ Op voorraad

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

☐ Vergelijk product

the EU Energy product information sheet

 An official website of the European Union [How do you know?](#) ▼

 European Commission EN English

EPREL - European Product Registry for Energy Labelling












[Home](#) > [Washing machines](#) > 335652

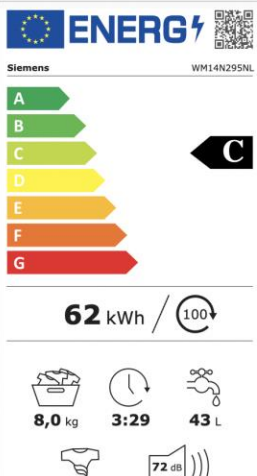
Washing machines

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

Siemens
WM14N295NL

General information

	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



Siemens WM14N295NL

ENERGY

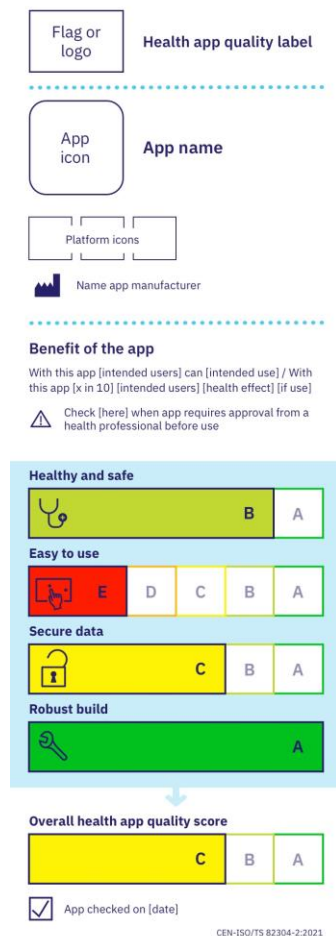
A B C D E F G

62 kWh / 100

8,0 kg 3:29 43 L

72 dB

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



- Comprehensive** For wellness and medical device apps, not duplicating the work of notified bodies
- Evidence-informed** Inspired by the EU energy label: used by 85% EU consumers and in 59 non-EU countries
- Inclusive** Label tested with people with low health literacy
- Informative** Score, label and report communicate quality in a glance to the needed detail
- Proportionate** At most 81 questions, of which at most 67 score-impacting yes/no questions
- Testable** Yes-answers require evidence to be assessed by accredited app assessors
- Relevant** Assessment framework founded in a Delphi study with 83 experts from 8 stakeholder groups
- Maintained**



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

CEN-ISO/TS 82304-2:2021 content

Flag or logo Health app quality label

App icon App name

Platform icons

Name app manufacturer

Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

Check [here] when app requires approval from a health professional before use

Healthy and safe

 B A

Easy to use

 E D C B A

Secure data

 C B A

Robust build

 A

Overall health app quality score

C B A

☒ App checked on [date]

CEN-ISO/TS 82304-2:2021

Healthy and safe

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

Easy to use

Accessibility, Usability

Secure data

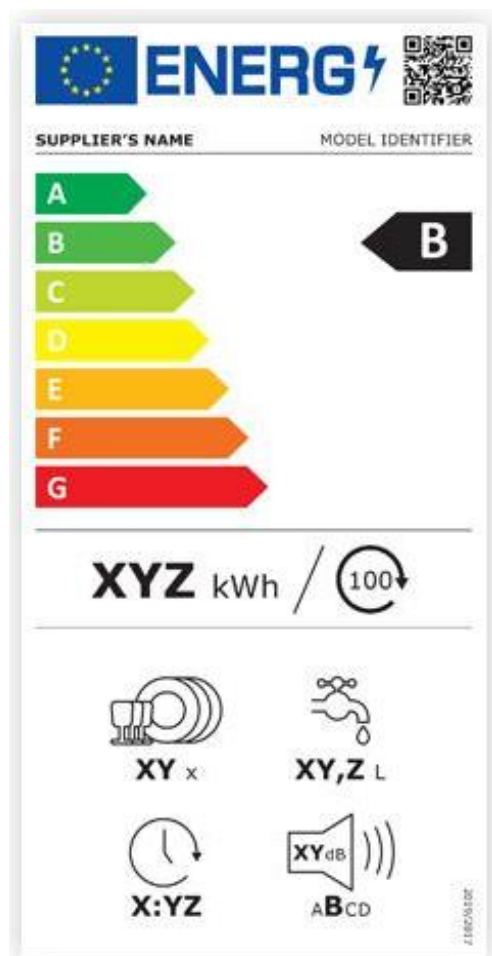
Privacy, Security

Robust build

Technical robustness, Interoperability

Original Paper

What Makes a Quality Health App—Developing a Global Research-Based Health App Quality Assessment Framework for CEN-ISO/TS 82304-2: Delphi Study



NUTRI-SCORE



Drug Facts

Active ingredient (in each tablet)

Chlorpheniramine maleate 2 mg Antihistamine

Purpose

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
■ trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

■ You may get drowsy ■ avoid alcoholic drinks
■ alcohol, sedatives, and tranquilizers may increase drowsiness
■ be careful when driving a motor vehicle or operating machinery
■ excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Other information store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Project pillars: trust, use and adoption

TRUST

Test handbook for accredited health app assessors

Co-create the trusted EU certification scheme (**handbook for accredited health app assessment**):

- Test scheme with 24 manufacturers and 5 app assessment organisations for **consistency and efficiency**
- Align **assessment methods** and **pass / fail** with **EU legislation, EU values** and **stakeholder trust**
- Analyse **business models** for app assessment and existing **label legislations** for applicability

USE

Addressing citizens' and health care professionals' needs

Co-create the communication citizens and health care professionals need:

- Survey whose recommendations on health apps **citizens trust** and what **health professionals need** to recommend health apps
- Test how to introduce the label with people with **limited health literacy**
- Propose level of detail **health app quality report**
- Test **label display** in app stores, app libraries and trusted sources

ADOPTION

Promoting uptake by health care authorities and systems

Co-create a single market (cross country recognition of EU certification scheme):

- **Involve relevant stakeholders** through various channels
- Document '**use stories**' of **pilots** with CEN-ISO/TS 82304-2 in Italy, Catalonia, the Netherlands, Norway, ..
- Explore with health insurers and health technology assessment bodies how the ISO assessment framework can **help in decision-making on reimbursement of health apps**

who can benefit from CEN-ISO/TS 82304-2:2021?

App manufacturers who seek to deliver quality apps



Patients, citizens, and carers who seek to use health apps



Health and care systems and authorities who seek to review / reimburse apps



Health care providers and professional societies who seek to recommend apps



Health app assessment organisations who seek to use a trusted, globally recognised assessment framework



App stores and libraries who seek to help their customers make informed decisions on health apps



- **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
- **Budget** 1,999.957.50 EUR
- **Partners**





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Ieva Biliūnaitė

Post-doctoral Researcher at Leiden University
Medical Center

Medical professional's views on using wellness and health apps in clinical practice -
insights from a pan-European survey

**Slides not shared at the request
of the author – final results will
be published soon**



Jarno Suominen

Biomedical Engineering and life
sciences

Health Technology Assessment in Digital Health. Comparing approaches to assessing digital health apps and technologies: CEN-ISO/TS 82304-2 (Label2Enable) and the Finnish Digi-HTA.

Health Technology Assessment in Digital Health

Comparing approaches for health apps and
technologies:

CEN-ISO/TS 82304-2 and the Finnish Digi-HTA

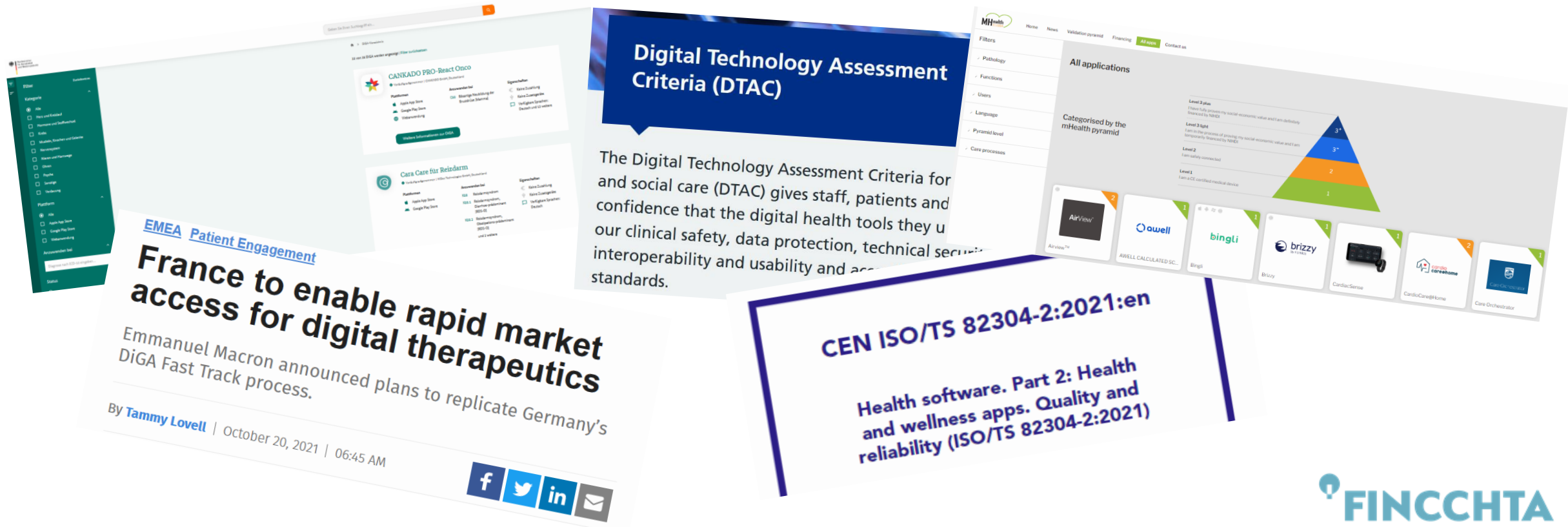


Funded by the European Union –
NextGenerationEU

Jarno Suominen
Senior Planning Officer, FinCCHTA

Trend in Digital Health

- Digital healthcare technologies are evolving rapidly.
 - Digital Medicine and Wellness technologies
- Need for fast assessment methods to support clinical decision making and health policy on required time frame.



Health Technology Assessment (HTA)

- Health Technology Assessment HTA is a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle.
- The purpose is to inform decision-making in order to promote an equitable, efficient, and high-quality health system.

Source: [HTA Glossary.net](https://www.hta-glossary.net)

The best available information is combined to support health policy and clinical decision making:

- Assessment is reliable, transparent and impartial
- Assessment includes new technologies and technologies that are already in use
 - Medicines, devices
 - Preventive, therapeutic and diagnostic interventions
 - Decision Support Systems (DSS)

Digi-HTA

- Method is developed by the FinCCHTA and the University of Oulu as the Ministry of Social Affairs and Health of Finland commissioned it.
- Published Digi-HTA recommendations can be found on FinCCHTA website: www.digi-hta.fi
- The assessment of data security and protection uses the criteria which is developed in the National Emergency Supply Agency's Cyber Health project.

Key assessment areas:

- Effectiveness
- Safety
- Costs
- Data security and protection
- Usability and accessibility

Other assessment areas:

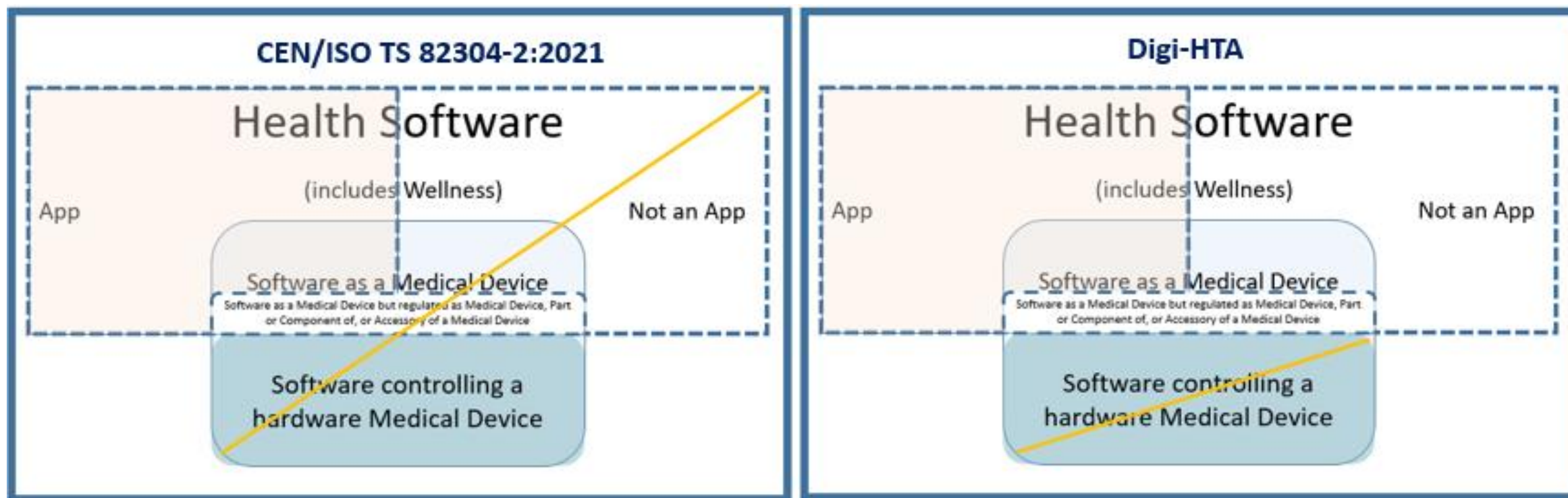
- Interoperability
- Technical stability
- Artificial intelligence
- Robotics



*Haverinen J, Keränen N, Falkenbach P, Maijala M, Kolehmainen T, Reponen J. (2019) Digi-HTA: Health technology assessment framework for digital healthcare services. Finnish Journal of eHealth and eWelfare, 11(4), 326-341. <https://doi.org/10.23996/fjhw.82538>



Comparison between the scope of criteria



Digital Health solutions, including Digital Medicine and Wellness technologies

*Adapted from Värri, A 2021. SFS. What Health Apps ISO/TS 82304-2 specification contains. Available online: <https://urly.fi/37R6>

Comparison between criteria

CEN/ISO TS 82304-2:2021

The screenshot shows a vertical form for a 'Health app quality label'. It includes fields for a flag or logo, app icon, app name, platform icons, and app manufacturer. Below these is a section for 'Benefit of the app' with a text area and a warning icon. The main part of the form consists of five rows, each with a category name, an icon, and a score box. The categories are: 'Healthy and safe' (score B), 'Easy to use' (score D), 'Secure data' (score E), 'Robust build' (score A), and 'Overall health app quality score' (score C). At the bottom, there is a checkbox for 'App checked on [date]' and a reference to 'CEN-ISO/TS 82304-2:2021'.







Category	Score
Healthy and safe	B
Easy to use	D
Secure data	E
Robust build	A
Overall health app quality score	C

Digi-HTA




The screenshot shows a vertical form titled 'Areas of assessment'. It contains a list of assessment criteria, each with a colored circle, a text description, and a dropdown arrow. The criteria are: 'Effectiveness: Promising, but more evidence is needed' (yellow circle), 'Safety: Sufficient' (green circle), 'Costs: Reasonable' (green circle), 'Data security and protection: Sufficient' (green circle), 'Usability and accessibility: Sufficient' (green circle), 'Other things to consider when using the product', 'References', and 'Assessment team'. Each row has a dropdown arrow on the right side.

Area of assessment	Status
Effectiveness: Promising, but more evidence is needed	▼
Safety: Sufficient	▼
Costs: Reasonable	▼
Data security and protection: Sufficient	▼
Usability and accessibility: Sufficient	▼
Other things to consider when using the product	▼
References	▼
Assessment team	▼

Baseline between the criteria

Cross-tabulated characteristics, criteria and requirements	ISO/TS 82304-2:2021	Digi-HTA
Publication year	2021	2019
Region	Global	National: Finland
Readiness level and application	Standardization criterias published 2021, assessment process under implementation	In production since 2020
Assesment level/Zooming	Emphasis especially end users point of view. The evaluation process is based on materials provided by the vendor providing the product or service.	Emphasis especially organizational perspective and end user point of view. The evaluation process is based on materials provided by the vendor providing the product or service with additional assessor based literature review process.
Suitable for evaluating medical devices	 All classes	 All classes
Suitable for evaluating non-medical devices		
Suitable for evaluating digital health products in the form of native apps, web apps or websites		










Explanations for table interpretation

-  Includes
-  Includes partially
-  Doesn't include

Similarities within the criteria

Cross-tabulated characteristics, criteria and requirements	ISO/TS 82304-2:2021	Digi-HTA	Explanations for table interpretation
Effectiveness/Clinical evidence patient and end-user point of views	●	●	● Includes
Effectiveness organizational point of view	●	●	● Includes partially
Country of origin of evidence	Not specified	Not specified. Will be evaluated case by case. The results of studies conducted in other countries must be transferable to the Finnish health care context.	● Doesn't include
Safety	●	●	
	Describes when the health app requires approval from a health professional before use	The company must have processes and responsible person available to ensure product safety. Includes national references for safety supervision	
Usability	●	●	
	Evidence about end-user testing. Considers if the app is age-appropriate	Evidence about end-user testing.	
Accessibility	●	●	
	WCAG 2.1. AA or AAA guidelines. Doesn't require published accessibility statement.	WCAG 2.1. AA and AAA guidelines. Requires published accessibility statement.	
Technical stability	●	●	

Differences between the criteria

Cross-tabulated characteristics, criteria and requirements	ISO/TS 82304-2:2021	Digi-HTA	Explanations for table interpretation
Cost-utility/Cost effectiveness	 <p>Information about cost for end user for using the product</p>	 <p>Costs for the organization and end-user for using the product assessed. Considers if the costs are reasonable and align with the benefits of the solution when compared to the standard of care or comparable solution.</p>	 Includes  Includes partially  Doesn't include
Artificial Intelligent (AI) and Robotics			
Ethics	 <p>Considers if ethical challenges of the health app are assessed with intended users and health professionals</p>	 <p>Doesn't include separate ethical aspect</p>	

Suominen, J., Veikkolainen, P., Kaksonen, R., Voutilainen, M., Haverinen, J. FinCCHTA. 2023. Comparison report of Digi-HTA and CEN/ISO TS 82304-2:2021.
<https://urly.fi/32CZ>

The importance of harmonization of Digital Health assessment

I. On regulatory basis, the safety, performance, risks and benefits of medical devices are strongly regulated before market access



Strong regulation-based approach can create the impression that market penetrated solutions are uniformly applicable. However, market access in itself does not guarantee the effectiveness or applicability of the device.

The same applies to wellness technology, in which regulation is clearly at a lower level compared to medical devices.

II. With harmonized assessment of Digital Health solutions, including Digital Medicine and Wellness technologies, it is possible to support health policy and clinical decision-making in evolving health care by producing objective information of safe and effective interventions.



The assessment criteria should not silo innovations or research but support them to ensure quality on high standard. Nevertheless, It has been recognized that the criteria for reimbursement can remain at the national level.

Thank you!

fincghta.fi
twitter.com/fincghta

Clinical assessment and evaluation of clinical evidence of Digital Health Technologies.
Introduction to the approach used by the Review of Care and Health Apps
(ORCHA).

**Adam McCabe and
Dr. Tom Micklewright**
Senior Digital Health Reviewer



The ORCHA Baseline Review and Clinical Assessment

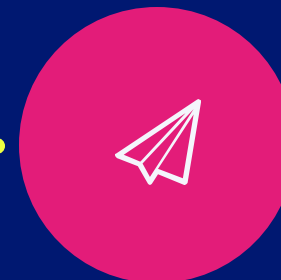
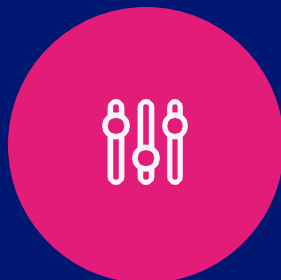
Dr Tom Micklewright and Adam McCabe
24th April 2023

THE ORCHA BASELINE REVIEW PROCESS

A revolutionary approach to technology assessment

Auto Filtering

We filter out apps not available in relevant languages and apps that haven't been updated for over 18 months. We auto-categorise those remaining Apps into over 250 condition and category areas.



Weekly Monitoring

We monitor all of the apps in this space on a weekly basis to identify new apps, apps that have new releases and apps that have become out of date.

350 Point Evaluation PLUS

Our reviewers analyse each app through a 350+ point evaluation which assesses an app's compliance with relevant standards, regulations and best practice.

Developer Checks

We notify developers of our review findings ahead of publication and allow them 10 days to challenge any area of the review.

Publication & Further Monitoring

Following the developer check period, the review is published on all relevant platforms and we start to gather further information for our 'Advanced Review' phase.

DATA PRIVACY



Privacy Policy

When writing a privacy policy the more transparent the better!

Data Use

Thinking about the data you are collecting next consider how it is used & shared

Standards & Management

Serious about information security?

GDPR

UK General Data Protection Regulations

Other Considerations

Best practice for all users data protection

USABILITY & ACCESSIBILITY



Design & Development

Application of standards & user involvement

Accessibility

Consideration of all users regardless of need

Usability

Ensuring positive user experience

Support

How can users contact you effectively



DIGITAL HEALTH. UNLOCKED.

PROFESSIONAL ASSURANCE



Registration Requirements

Consideration of services you will provide

Medical Devices

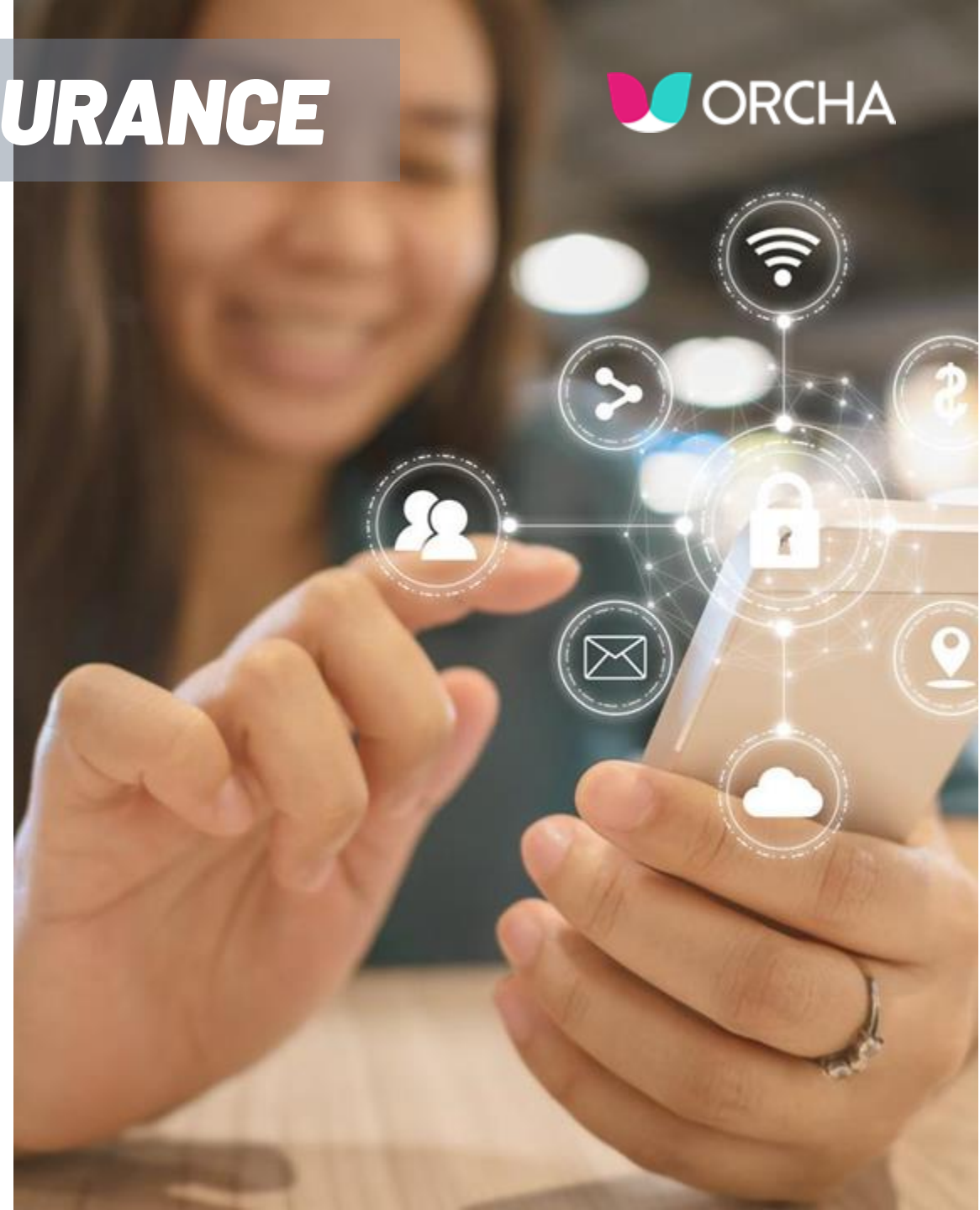
Ensuring safety and quality

Professional Backing

Establishing credibility

Effectiveness & Impact

Essential for products within healthcare



THE CHALLENGE

NOT ALL HEALTH APPS ARE THE SAME

THE ORCHA Baseline Review

THE CHALLENGE: NOT ALL APPS ARE THE SAME

OBR is intelligent, adapting to the wide nature of health apps, from the simple to the complex. This slightly changes the scoring makeup, with section weightings differing depending on functionality



**Preventative or
Independent of pathway**



Pathway Replacement



**Integrated pathway
support**



Administrative support



PROFESSIONAL ASSURANCE

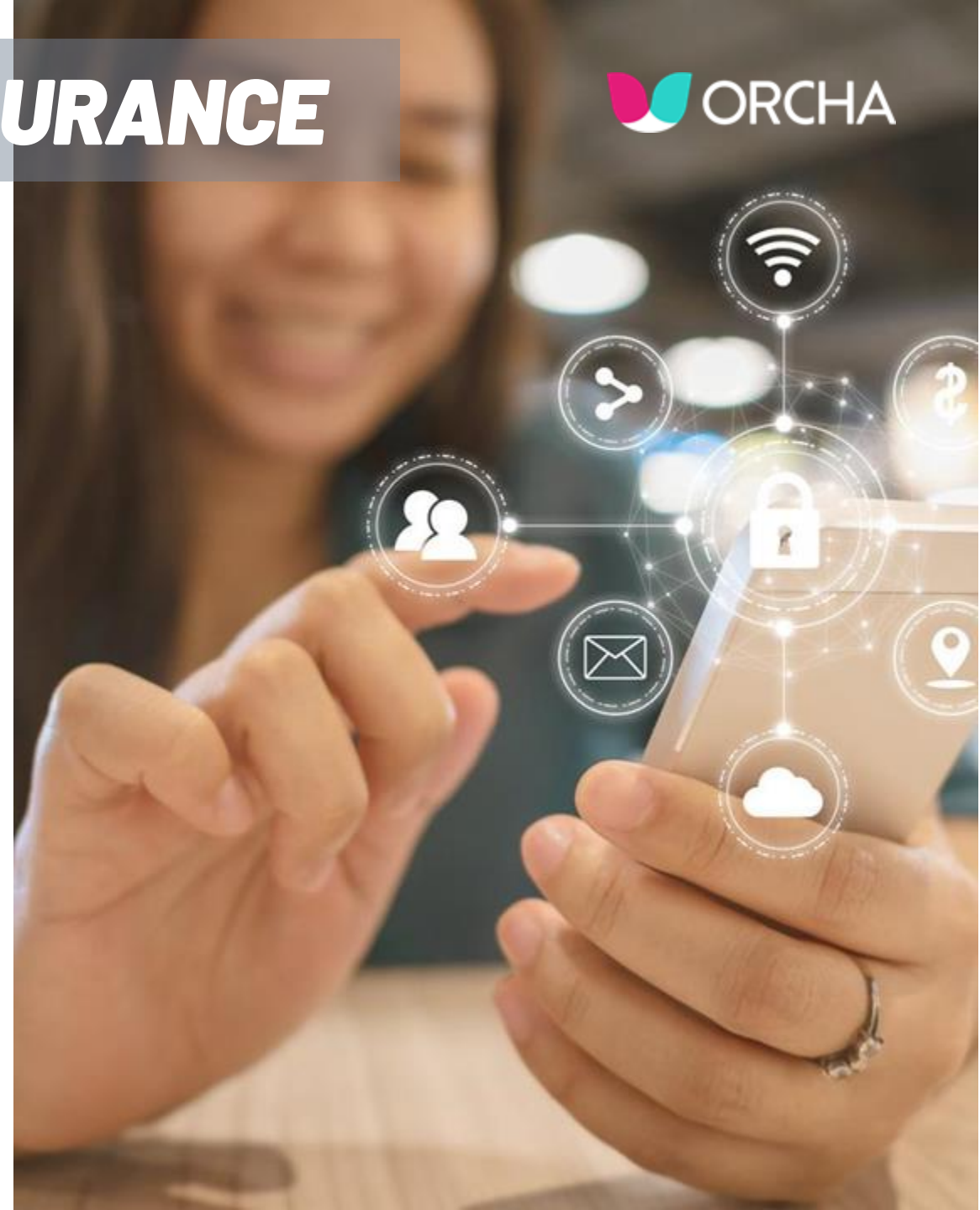


ORCHA's Adapted ESF

To pull together the professional backing, and the effectiveness information around the app, we apply our adapted ESF

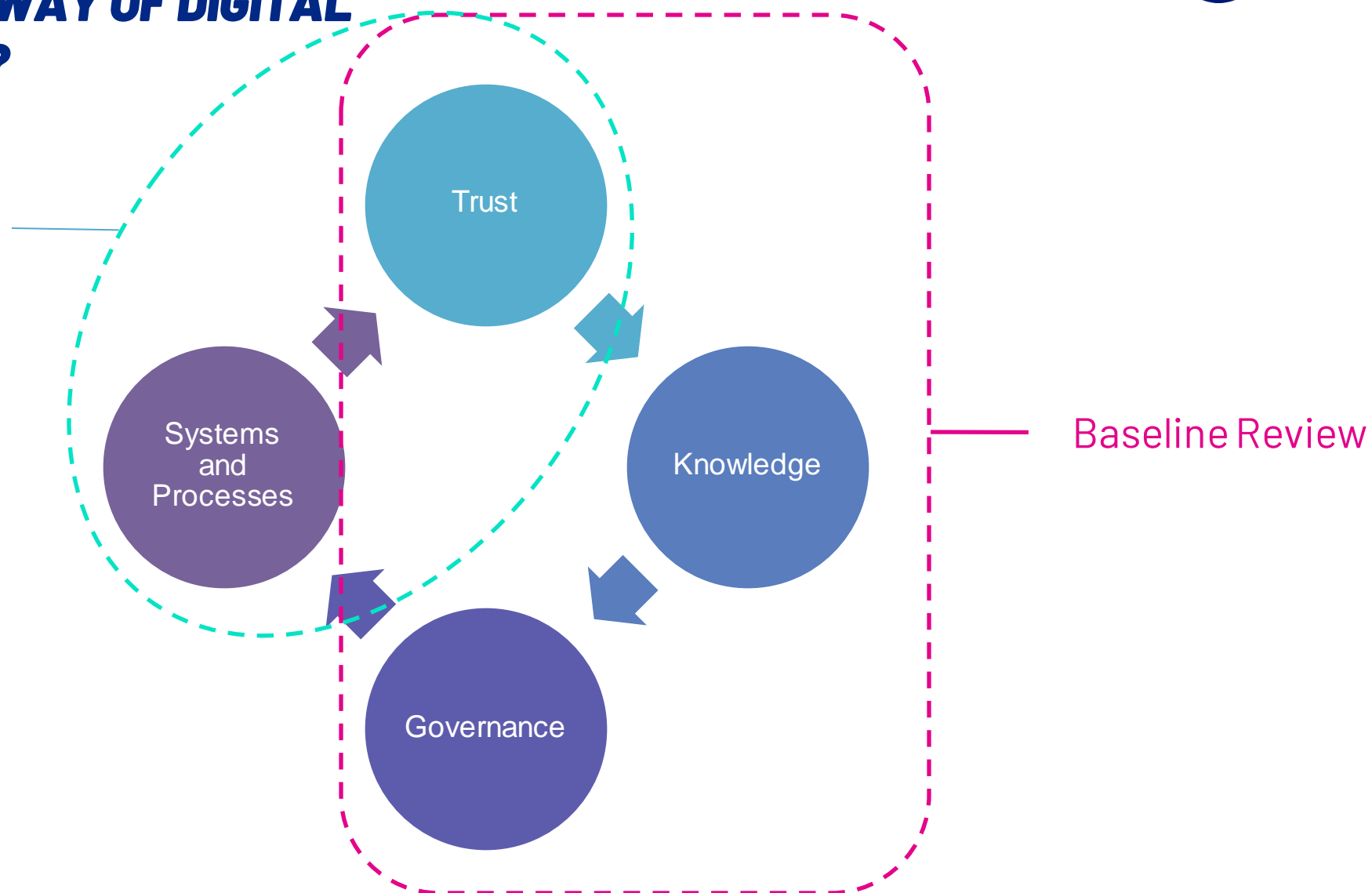
Scoring Outcomes

Meeting requirements will be reflected in the score. Failure to meet requirements will have a noticeable impact on the section and overall score.



WHAT GETS IN THE WAY OF DIGITAL TRANSFORMATION?

Clinical Assessment



Baseline Review

Trust

"Health apps were **most likely to be prescribed** to patients if they had an NHS stamp of approval or if they were **recommended by another HCP**"

> JMIR Mhealth Uhealth. 2020 Jul 6;8(7):e17704. doi: 10.2196/17704.

Barriers and Facilitators to the Adoption of Mobile Health Among Health Care Professionals From the United Kingdom: Discrete Choice Experiment

Simon Leigh ¹, Liz Ashall-Payne ¹, Tim Andrews ¹

ORCHA CLINICAL ASSESSMENT



Systems
and
Processes

- Indications
- Contra-indications
- Clinical cautions
- Pathway targets
- Limitations

Supports **real-world**, clinical decision making and the digital transformation of **clinical pathways**

ORCHA CLINICAL ASSESSMENT



Clinical Use Case

Intended patients. Pathway integration. 'Contra-indications'. Impact on marginalised patient groups.

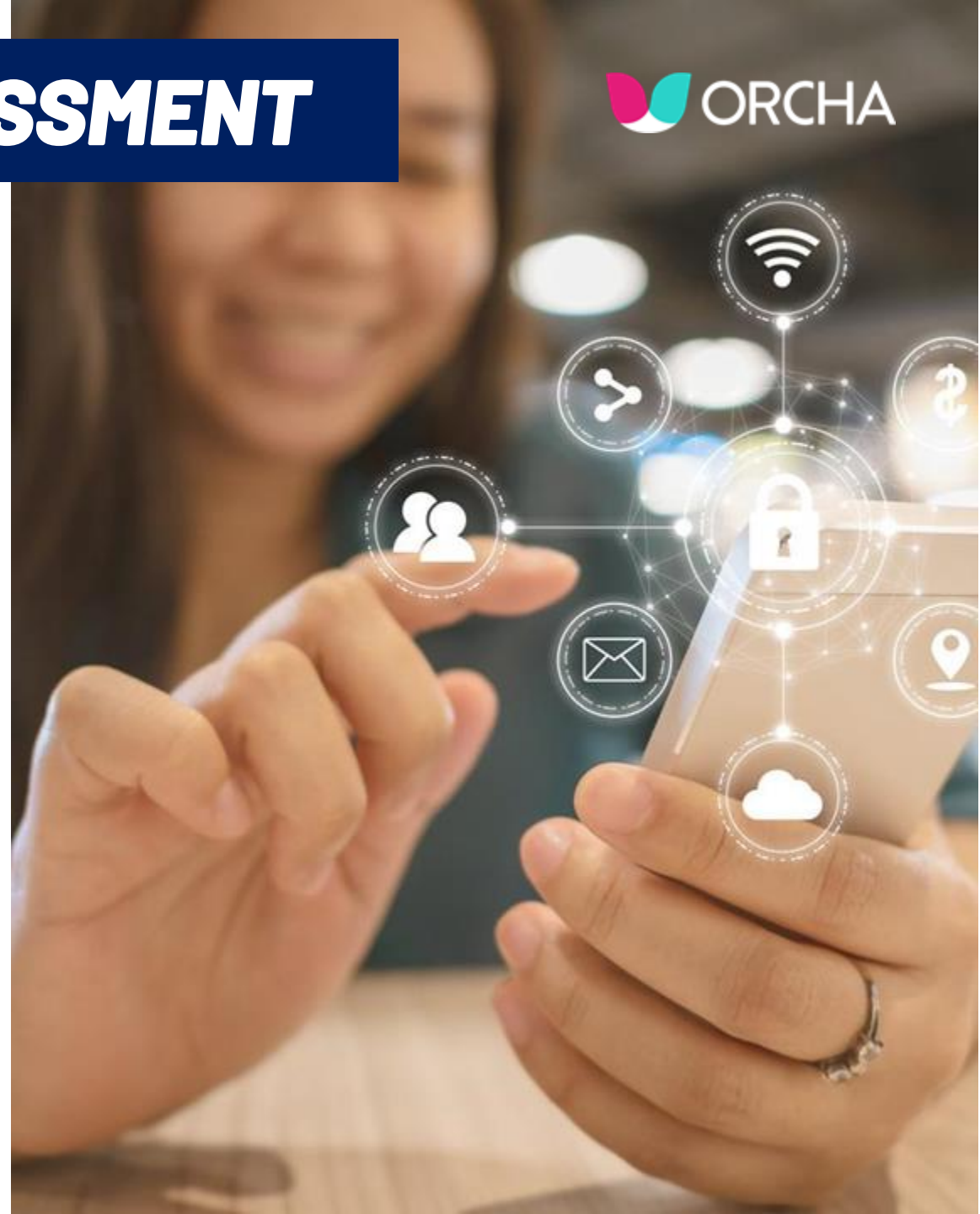
Clinical Validity

Alignment with national guidelines or recognised best practice.

Clinical Risk

What risks are apparent? What mitigations are in place?

High Complexity Products
(Tier 3)



THANK YOU ***ANY QUESTIONS?***

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Thank you for your attention

More information info@label2enable.eu

Website label2enable.eu