

**5 October 2023 11:00 – 12:30 CET**

Health app certification from an app manufacturer perspective

**LabelRoundtable Event Series**



# Agenda

**11:00-11:05**

Welcome and introduction - Carola Schulz (empirica)

**11:05-11:25**

Evaluating and Certifying Products for Empowerment: Progress and Insights to date - Liz Ashall-Payne ( ORCHA)

**11:25-11:45**

Feedback from App Manufactures on certification scheme testing - Menno Kok (EIT Health Belgium & Netherlands)

**11:45-12:05**

Preferences and willingness to pay for health app assessments among healthcare stakeholders - Dr Anna Frey (ORCHA)

**12:05-12:25**

Market Access Pathways for Digital Health Solutions - Philipp Goedecker (COCIR)

**12:25-12:30**

Additional Q&A, closure

# 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.



Parts of the webinar require use of an interactive tool called Mentimeter. Be prepared to be given a URL to participate via the tool. Preferably use a second device (mobile phone).



Participants have two 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.

## Webinar Panelists



**Liz Ashall-Payne**

Founding CEO  
ORCHA



**Menno Kok**

Managing Director  
EIT Health  
Belgium & Netherlands



**Dr Anna Frey**

Research Associate  
ORCHA



**Philipp Goedecker**

Digital Health Senior Manager  
COCIR



## Evaluating and Certifying Products for Empowerment: Progress and Insights to date

**Liz Ashall-Payne**

Founding CEO - ORCHA

# Evaluating and Certifying Products for Empowerment: Progress and Insights to date

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**Liz Ashall-Payne and Menno Kok**

# What is Label2Enable

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# What are the different work packages

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WP1 - Coordination of the project

WP2 - Validation

WP3 - Certification

WP4 -Patients, citizens and carers

WP5 - Health Care professionals

WP6 - Promotion

WP7 - Health care system and authorities

WP 8 - Research and innovation

# Work package 3

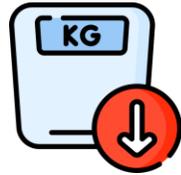
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The objective of the WP3 is to enable health systems and citizens to benefit from the supply and use of health apps facilitated by common pan-European principles for  
**CERTIFICATION**

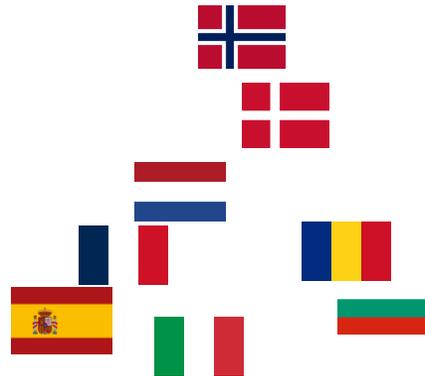
- Objective - Test the certification scheme with 24 apps in a group of 5 app checkers, that enables assurance the certification scheme results in useful efficient consistent app assessments, contributes to an implementation plan, and prevents duplication of work of notified bodies if the app is a medical device.



- Suggested by WP3 Members
- Suggested by Assessment Organisations
- Self-recommended



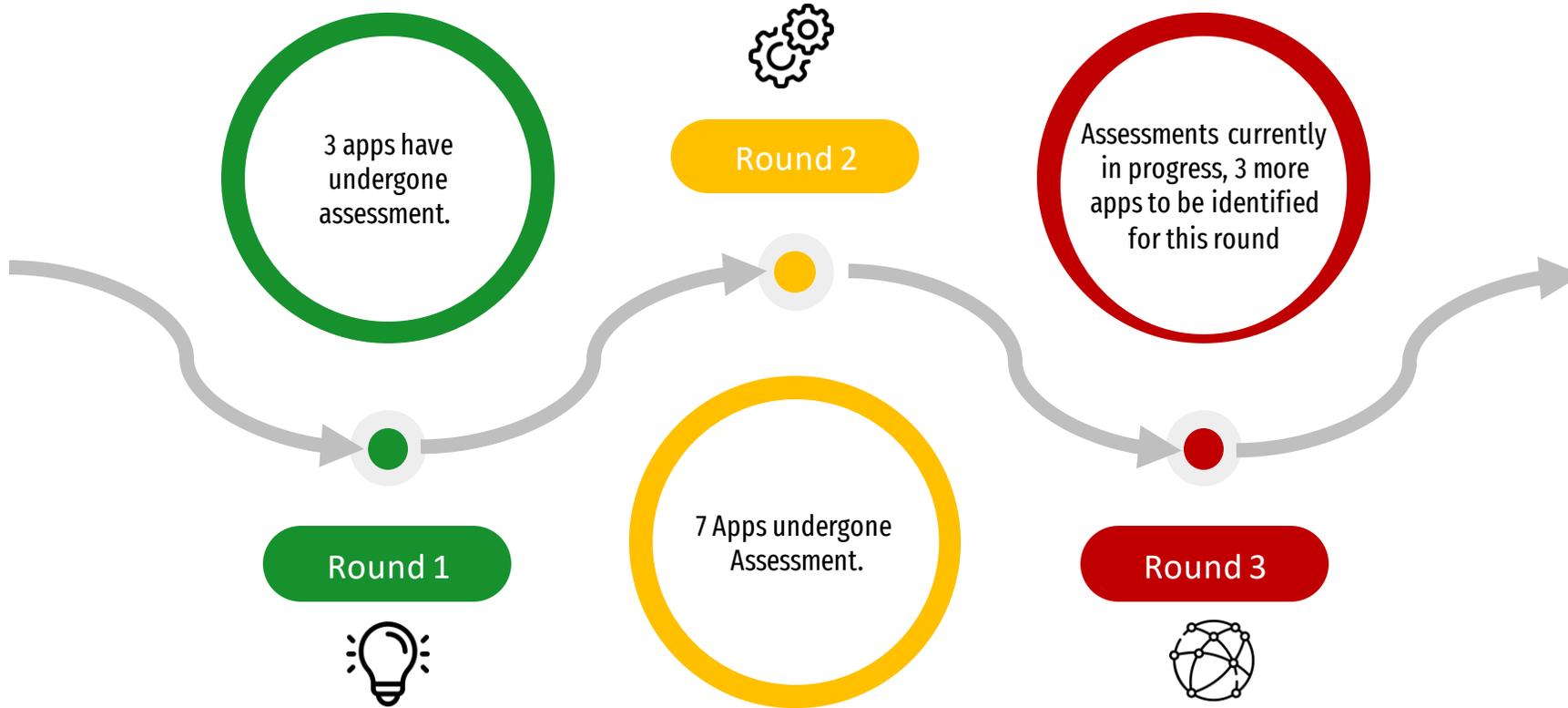
- Condition Areas
  - Over 15 conditions covered



- Country of origin
  - Over 11 countries



- Complexity
  - From simple self-management
  - To digital therapeutics





Invitation



Application



Assessment



Feedback



Improvement



- Initial Trends

- Inter-rater reliability
- Efficiency
- Self-explanatory





Feedback from App Manufactures on certification scheme testing

**Menno Kok**

EIT Health Belgium & Netherlands - EIT Health Belgium & Netherlands

# Reflections from companies

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Outcomes of feedback interviews with seventeen app producers WP 3.2

Menno Kok Consortium meeting 05-10-2023

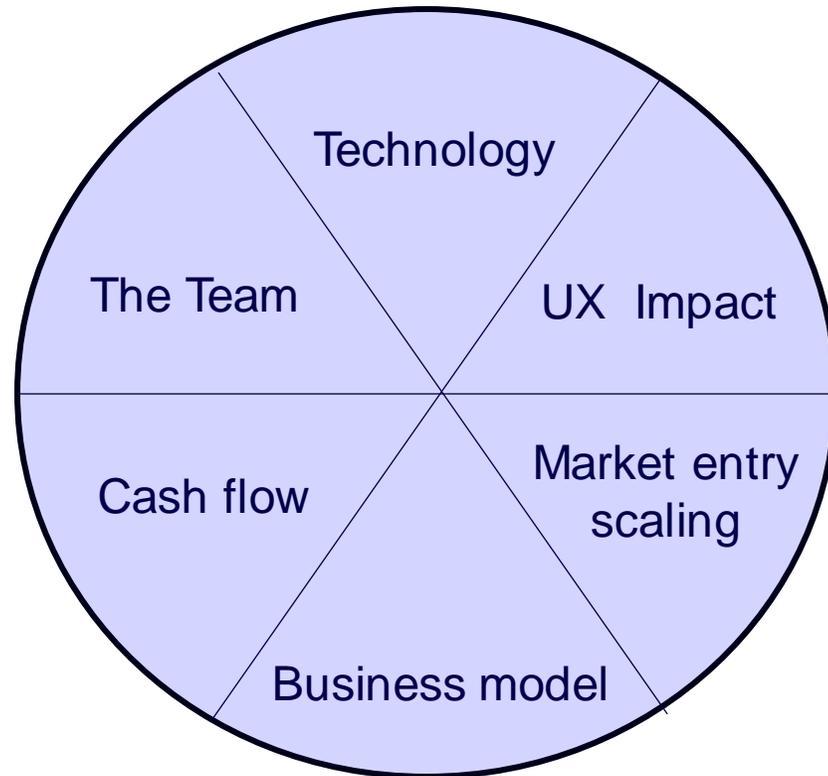
# The App manufacturers (N=17): who are they?

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## They...

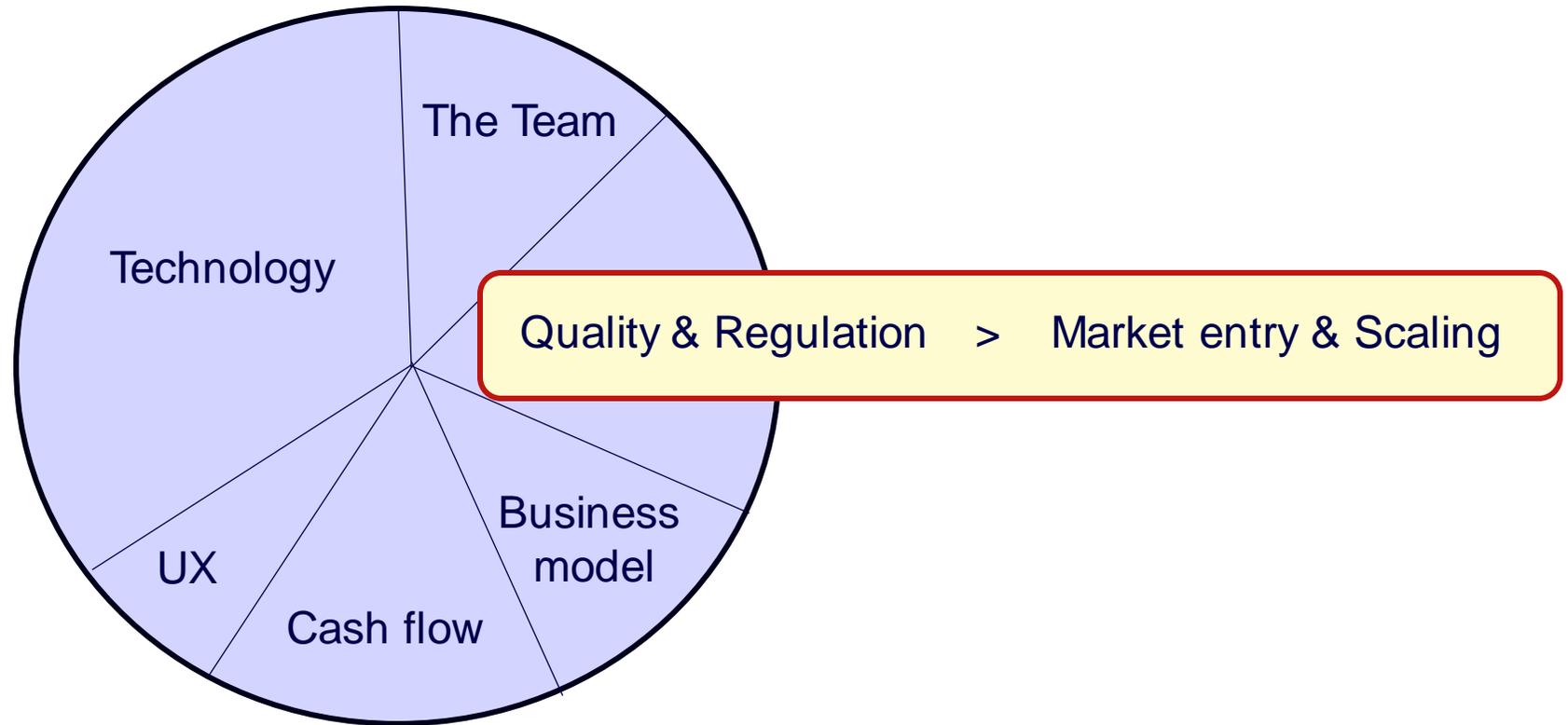
- are spread over Europe, some already conduct business in 2-3 continents;
- cover a variety of areas, from wellness to health care;
- are limited companies (15/17), a foundation and a corporate;
- are very positive about their own business (14/17) or positive (3/17);
- are ambitious and motivated to participate in the Label2Enable project;
- would enter the project again, if invited today;
- are ready to support the project further!

# The young App manufacturer (N=15): concerns



- Competitors
- Payers
- App stores
- Users
- Health care providers
- Consultants, mentors
- Investors
- Regulators

# The young App manufacturer: reality shock



# Feedback on questionnaire 1.: procedure

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- Companies were interviewed (20-75 minutes, on-line) after they had submitted evidence for the App-assessment (before receiving assessment outcomes).
- Representatives of the companies answered 10 open questions regarding the time and effort they invested in providing evidence and filling in the questionnaire; their appreciation of the questionnaire (clear, confusing, difficult...) and of the process and app producers were encouraged to share additional suggestions for improvement and remarks.
- The company input is used to optimize the assessment process.

# Feedback on questionnaire 2.: results

- Submitting evidence was team-work for the large majority of the companies. They would appreciate indications of the type of expertise that would be required for specific questions.
- The time invested in completing the questionnaire varied considerably (between 5 and 160 hours).
- Despite the variable levels of difficulty experienced by the 17 companies, all manufacturers remained committed to the Label and are looking forward to receive feedback from the assessors.
- No large unclarities were observed in the questionnaire.
- Suggestions for improvement that were recorded quite often included: additional explanations (or a mock-up of a completed file) to ease the process; use of an electronic form on-line instead of a spread-sheet.
- Some companies suggested two parallel paths for health Apps and wellness apps respectively.
- Interestingly, many companies would like to look for approaches that would more strongly integrate the assessment procedure into their critical path.
- Most companies recognize the relevance of the label (16/17) for their credibility with stakeholders (end-users, medical specialist etc.), all recognize it as a means to establish quality and trust (17/17).

# Feedback on questionnaire 3.: specific inputs

- **Missing:** Cybersecurity issues merit even more attention in the assessment process; in addition to the expertise vested in the company team, the user appreciation provides insight into the quality of the app; “our app is strongly embedded in the regional healthcare system, which provides extra quality assurances”.
- **Harmonization:** there is a great need for harmonization of procedures in Europe;
- **Critical path:** The questionnaire triggered internal discussions about the development of the app: how can the assessment process be aligned with the app development process so as to derive more value from the assessment process for the company?
- **Re-use:** There is overlap between assessment procedures, “can you develop a higher level structure of the questionnaire that would help us (App producers) to interlink various procedures?”
- **Level of detail:** companies feel uneasy about questions that “do not apply” or seem to require extensive explanations. This may be solved by indicating the extent of detail requested and/or word count
- **Relevance:** The assessment procedure stimulates further harmonisation of standards in Europe, which is vital for the dHealth (sub-)sector.

# Feedback on questionnaire 4.: more specific inputs

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- **Make the questionnaire easier to use:** Indicate level of detail expected; allow extra tekst elements to explain the context of the answer; oral introduction to the questionnaire; example-responses.
- **Learning experience:** Assessors to provide critical comments to individual questions; improve overlap with other assessment procedures; manufacturers can use the questionnaire to critically look at their own development process (identify caveates).
- **Assessment outcome:** Allow repair of insufficient answers or evidence; reveal how the label is calibrated.
- **Repeated assessment:** Companies agree that this would be required regularly (up to 2-3 times per year) with any major update of the app. Could we design a methodology for updates, that would only re-assess the relevant changes in the app?
- **Relevance 2:** 16 out of 17 app manufacturers tell us that “carrying the label (with a good score) would be great for awareness, visibility, trust and market access”



## Preferences and willingness to pay for health app assessments among healthcare stakeholders

**Dr Anna Frey**

ORCHA - Research Associate

**This presentation will  
not be recorded**





## Market Access Pathways for Digital Health Solutions

**Philipp Goedecker**

COCIR - Digital Health Senior Manager

# Agenda

- Introduction COCIR
- COCIR Living Repository
- Digital Health Solutions: Framework
- Scope of Digital Health Solutions
- Digital Health Solutions and placement Requirements
- Digital Health Solutions and Security
- Digital Health Solutions and Health Technology Assessment
- Evaluation of Evidence
- Economic Evaluation
- Country Report: Spain



# Introduction



## MEDICAL IMAGING

- Computed Tomography scanners
- Ultrasound
- Nuclear Imaging
- Radiation therapy equipment
- Magnetic Resonance Imaging
- Imaging Information Systems
- Medical X-Ray equipment

## RADIATION THERAPY

- Brachytherapy
- Nuclear Medicine
- Proton Therapy
- Systemic Radiation Therapy
- External Beam Radiation



- Patient Monitoring
- Intensive Care equipment
- Electro Surgery

## ELECTROMEDICAL EQUIPMENT

- Medical Imaging Information Technology
- Enterprise Information Technology
- Hospital Information Systems
- Clinical Information Systems
- Electronic Health Records
- Telemedicine
- Mobile Health

## DIGITAL HEALTH



- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe.
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle

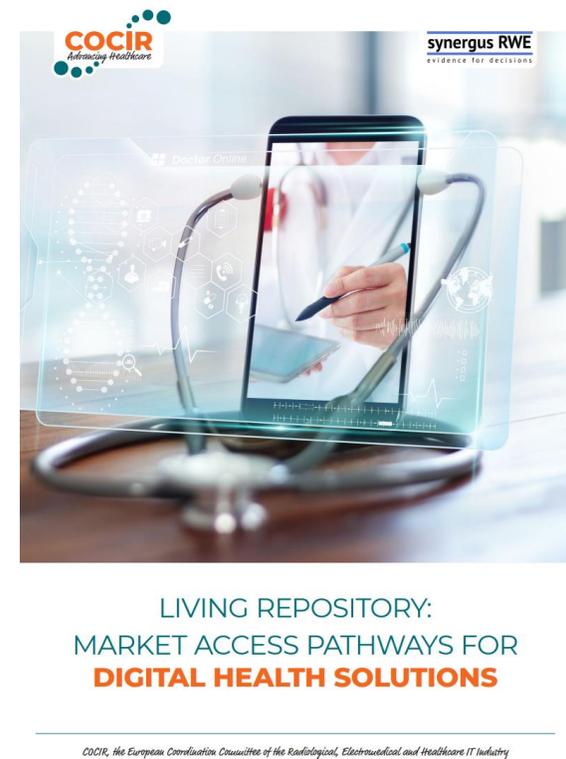


- COCIR covers 4 key industry sectors
  - Medical Imaging
  - Radiotherapy
  - Health ICT
  - Electromedical



# COCIR Living Repository: Market Access Pathways for Digital Health Solutions

- Purpose: Analysing digital health reimbursement in 6 countries
- Scope: Stand-alone digital health solutions.
- Countries included:
  1. *Belgium*
  2. *France*
  3. *Germany*
  4. *Spain*
  5. *Sweden*
  6. *United Kingdom*
- The Report is available at: <https://www.cocir.org/>



# DIGITAL HEALTH SOLUTIONS: FRAMEWORK

PATHWAY (COUNTRY)	OUTCOME	IMPACT ON UPTAKE / REIMBURSEMENT
Evidence standards framework for digital health solutions (UK) (6)	Guidance to DHS developers regarding methodological considerations.	No direct link to uptake or reimbursement.
Mhealth – Level 1 (BE) (7)	Apps are registered on a list with products fulfilling CE-mark and GDPR requirements.	No direct link to uptake or reimbursement.
Digital Health Application Regulation (DiGA) (DE) (8)	Conditional reimbursement for one year while evidence is generated. OR Reimbursement	Direct link to reimbursement

**Table 2** Examples of pathway outcomes and impact.



# SCOPE OF DIGITAL HEALTH SOLUTIONS

DHS FUNCTIONAL SCOPE	REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)			
	BELGIUM	GERMANY	FRANCE	
<p>This comparison aims to broadly capture the functional scope of the different pathways that exist.</p> <p>Combining the functional scope with the limitations based on the regulatory classification may lead to a rather narrative definition, whereas there is also the example of Digital Health Solutions with a therapeutic benefit and no limitation in the regulatory classification and thus providing a broad potential scope.</p>				
	REMOTE MONITORING	X		X
	DHS WITH THERAPEUTIC BENEFIT			X
	PATIENT DHS LINKED TO ACTION BY HEALTHCARE PROFESSIONAL			
	DHS CENTRED AROUND PATIENT		X	
DIGITAL ASSISTANTS IN LONG-TERM CARE		X		

**Table 3** Compared scope of Digital Health Solutions included in 3 EU Member States.



# DIGITAL HEALTH SOLUTIONS AND PLACEMENT REQUIREMENTS

DHS REGULATORY CLASSIFICATION	REIMBURSEMENT PATHWAY FOR DIGITAL HEALTH (Bismarck)		
	BELGIUM	GERMANY	FRANCE
With the revised Medical Device Regulation, there was a significant change in the classification of software based medical devices, leading to alignment with traditional medical devices.			
<b>MDCG 2019-11</b> Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746 - IVDR			
I	X	X	X
IIa	X	X	X
IIb	X		X
III	X		X

**Table 4** Comparing Digital Health Solutions scope based on regulatory classification in 3 EU member states.



# DIGITAL HEALTH SOLUTIONS AND SECURITY

- inform patients of their physical condition while dispatching this information to specific health-care professionals
- patients of their physical condition while dispatching this information to specific health-care professionals
- many countries apply further requirements on the safe use of Digital Health Solutions, while others require independent testing



# DIGITAL HEALTH SOLUTIONS AND HEALTH TECHNOLOGY ASSESSMENT

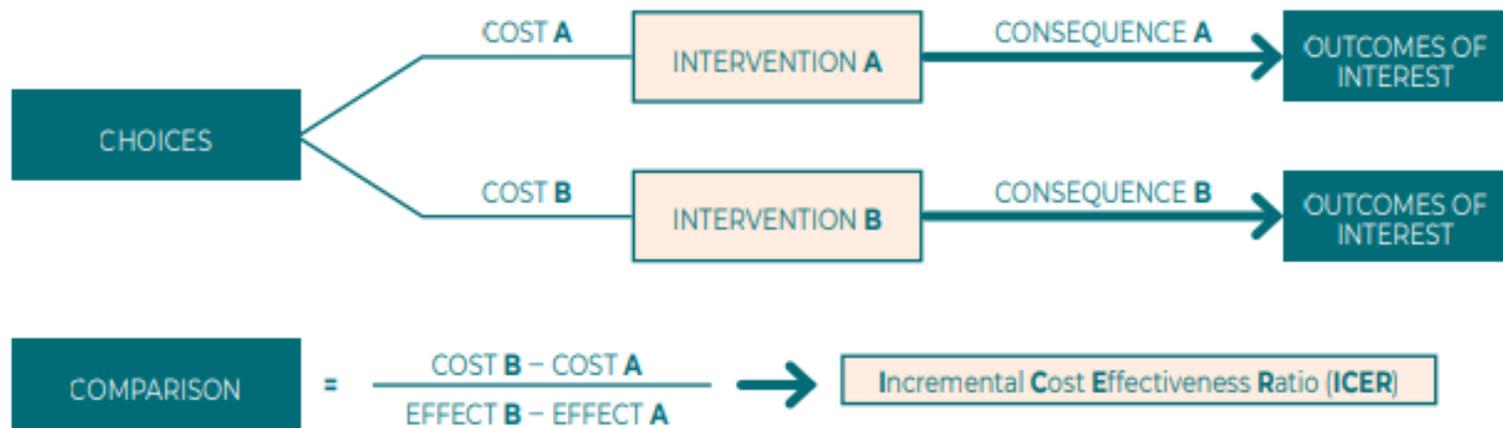


Figure 1 Cost effectiveness methodology.



# EVALUATION OF EVIDENCE

EVIDENCE REQUIREMENTS	EVIDENCE REQUIREMENTS		
	BELGIUM	GERMANY	FRANCE
For HTA evaluations, Randomized Clinical Trials (RCT) are considered the gold standard.			
While all countries recognise that different study designs could be used, the question still remains. What approach is methodologically justifiable to inform the decision about viable efficacy?			
This will in many instances result in the need for RCT's or very well-designed Real-World Evidence (RWE) studies.			
<b>RCT</b>	X	X	X
<b>Non-RCT studies</b>	(X)	(X)	(X)
<b>RWE</b>	(X)	(X)	(X)

**Table 6** -Comparison of evidence requirements in 3 EU Member States.



# ECONOMIC EVALUATION

- Economic evaluation is a tool to identify, measure, value, and compare the costs and consequences.
- There are four types of economic evaluation which can be used to evaluate the economic consequences of introducing a new DHS.



# Country Report: Spain

COUNTRY PROFILE (REGION optional)	SPAIN	
SCOPE	<input checked="" type="checkbox"/> Medical devices (CE Mark)	<input type="checkbox"/> Other
REIMBURSEMENT	<input checked="" type="checkbox"/> Statutory Health Insurance	<input type="checkbox"/> Private insurance
REIMBURSEMENT (additional)		
DHS - TYPE	Any type of DHS that the local healthcare unit determines to buy. No regional or national process exists.	
DHS - DEFINITION / DESCRIPTION	No definition related to digital health solutions and the decision to fund.	
LEGAL FRAMEWORK	None related to reimbursement or funding of digital health.	
INVOLVED AUTHORITIES	Any healthcare organisation choosing to purchase a digital health solution.	
ASSESSMENT DOMAINS	Not defined.	
PROCESS	Not defined.	
Criteria on Value Based Care	Not defined.	
ACCEPTANCE OF CLINICAL DATA	<input type="checkbox"/> Data from populations outside the local market	<input type="checkbox"/> Data from a similar device
RELEVANT COCIR NTA	Fenin	<a href="http://www.fenin.es">www.fenin.es</a>
REFERENCES	In the absence of relevant framework, no references.	



## Key Requirements:

- Interim reimbursement of promising solutions so that the tech developer to have time to provide evidence
- Be able to use EHDS and patient data
- To start using Real World Evidence instead of or in addition to Randomised Clinical Trials





A word cloud featuring the phrase "thank you" in various languages and colors. The central and largest text is "thank you" in red. Other prominent words include "gracias" in green, "danke" in blue, "merci" in orange, and "obrigado" in green. Smaller words include "dziękuję", "sukriya", "terima kasih", "grazie", "arigatō", "dank je", "ngiyabonga", "teşekkür ederim", "spasibo", "hvala", "mauruuru", "sagolun", "kop khun krap", "go raibh maith agat", "mochchakkeram", "tapadh leat", "takk", "dakujem", and "мерси".

спасибо  
danke 謝謝  
ngiyabonga  
teşekkür ederim  
dank je  
gracias  
tapadh leat  
bedankt  
hvala  
mauruuru  
thank you  
mochchakkeram  
dziękuję  
sukriya  
kop khun krap  
go raibh maith agat  
obrigado  
sagolun  
grazie  
arigatō  
takk  
dakujem  
merci  
merси  
terima kasih  
감사합니다  
ευχαριστώ





# Quotes

- All pictures Copyright © 2023 COCIR - Synergicus RWE





# Final Q&A

# Thank you for your attention

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**Website** [label2enable.eu](https://label2enable.eu)



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