

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

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What is label to enable

What are the different work packages

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

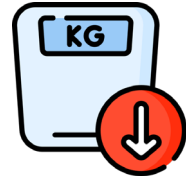
Work package 3

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

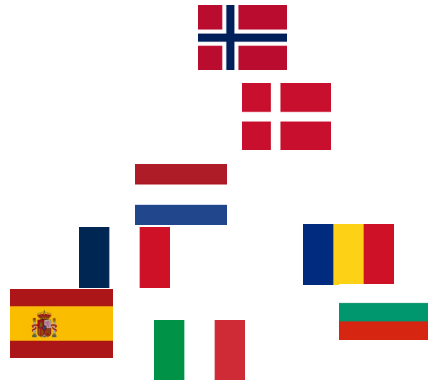
- Objective - Test the certification scheme with 24 apps in a group of 5 app checkers, that enables assurance the certification scheme results in useful efficient consistent app assessments, contributes to an implementation plan, and prevents duplication of work of notified bodies if the app is a medical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



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



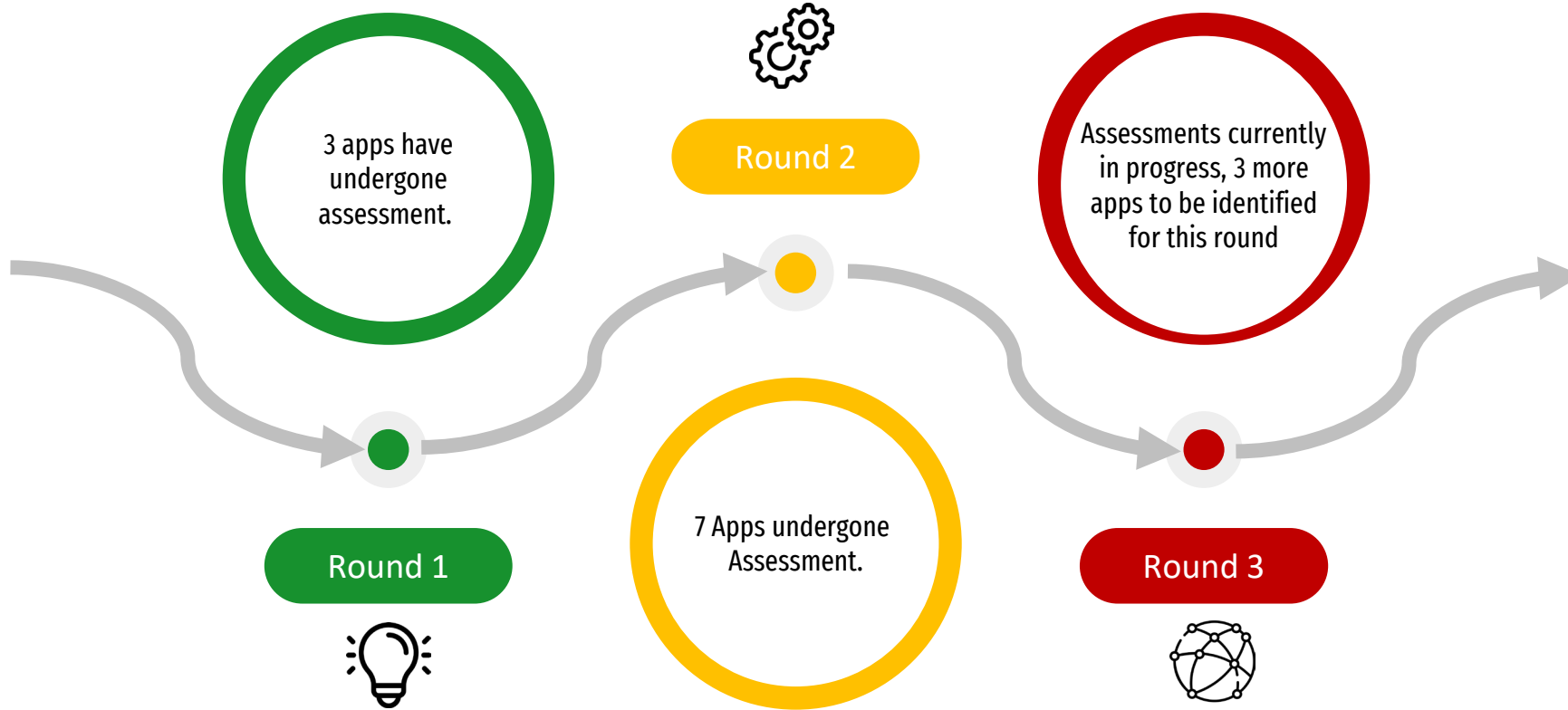
- Condition Areas
 - Over 15 conditions covered



- 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 on questionnaire: 1. procedure

- Companies were interviewed (25-35 minutes, on-line) after they had submitted evidence for the App-assessment.
- Selected round I companies: Fibrichек, Selfback and mKineticos
- Key representatives of the companies answered 10 open questions regarding their appreciation of the questionnaire, of the process and were encouraged to share additional suggestions and remarks.
- Round I observations and conclusions will be used to improve the assessment proces for companies (Apps) in the two subsequent rounds.

Feedback from companies

Outcomes of feedback interviews with round 1 companies

Menno Kok Consortium meeting 05-10-2023 (on-line)

Feedback on questionnaire: 2. results

- Companies completed the questionnaire and compiled the required documentation as a team effort (involving 2-3 people). They spent a self-estimated 8-40 hours to complete the submission. Although some of the companies considered this time investment considerable, they did not regret their participation. In fact, all three companies in round I offered to be further involved in the Label2Enable project.
- No unclarities were observed in the questionnaire. Suggestions for improvement included additional explanations (or a mock-up of a completed file) to ease the process (3x); indication of the key expertise required to answer certain questions (2x); more emphasis on cybersecurity (1x); use of an electronic form on-line (1x) and design of a process in which assessment and App development are aligned (1x).
- All companies recognize the relevance of the label for their credibility with stakeholders (end-users, medical specialist etc.).

Feedback on questionnaire: 3. conclusions (r1)

- The three round I companies did only suggested minor adaptations of process and the questionnaire (a full listing is available);
- At hindsight and considering the invested time and effort, the companies would all engage again with the Label2enable project and they are prepared to further collaborate with the project;
- All companies recognize the potential value of the label for their companies credibility and business.

Questions & Thank you for your attention

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