

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.

Input from companies

Outcomes of feedback interviews with seventeen app producers WP 3.2

Menno Kok Multistakeholder Workshop 03-11-2023

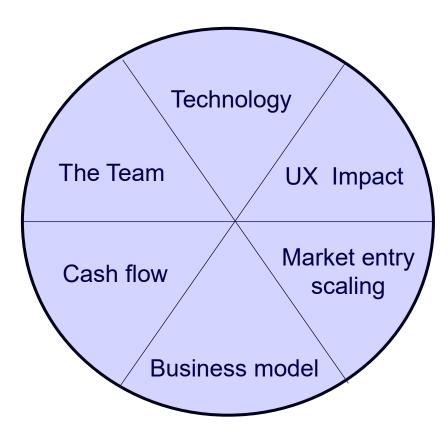


LABEL2 U The App manufacturers (N=17): who are they?

They...

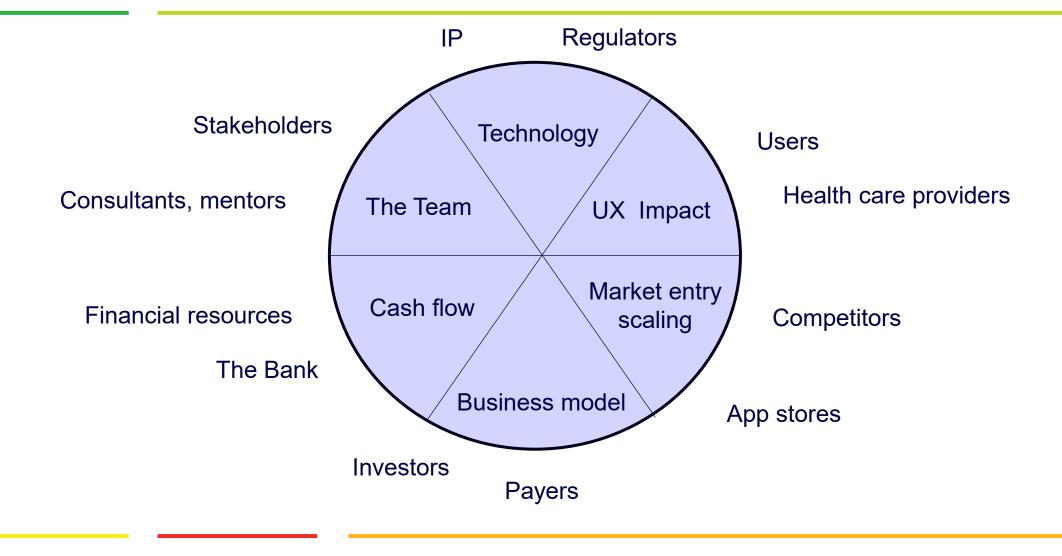
- are spread over Europe, some already conduct business in 2-3 continents;
- cover a variety of areas, from wellness to health care;
- are limited companies (15/17), a foundation and a corporate;
- are ambitious and motivated to participate in the Label2Enable project;
- would enter the project again and ready to further support the project.

LABEL2 C The young App manufacturers (N=15)



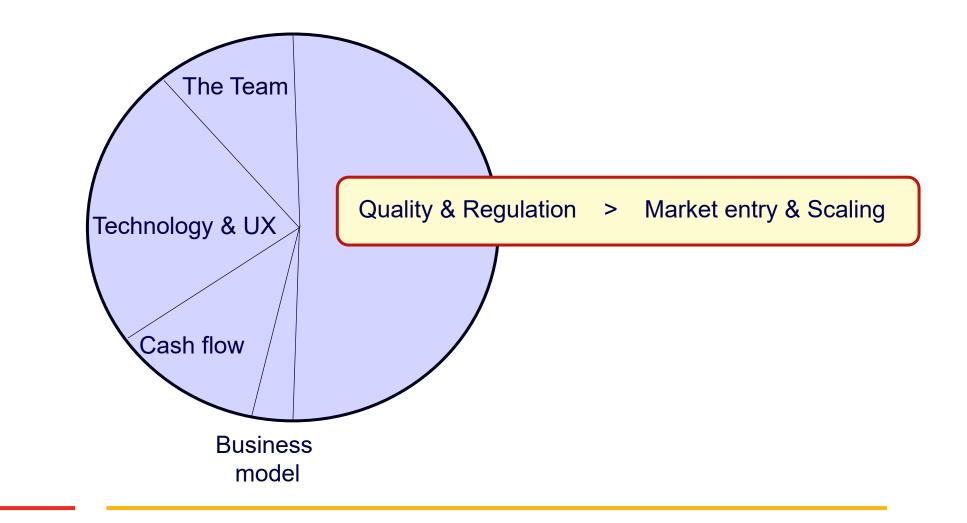


LABEL2 C The young App manufacturers: environment





LABEL2 ENABLE The young App manufacturer: reality shock





LABEL2 Feedback on questionnaire 1.: procedure

- 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;
- The App manufacturers were encouraged to share additional suggestions for improvement and other remarks and ideas.

LABEL2 Feedback on questionnaire 2.: results

- **Submitting** evidence was team-work (stratification of questions?);
- The time invested in the questionnaire varied considerably (5 to 160 hours).
- Improvements suggested: additional explanations / level of detail / electronic form on-line;
- Manufacturers suggest to look for approaches to more strongly integrate the assessment procedure into their companies' critical path (identify caveates);
- Missing: the values of (1) user appreciation and (2) integration into the regional healthcare system;



LABEL2 V Feedback on questionnaire 3.: results

- Exploit overlap between assessment procedures, "can you develop a higher level structure of the questionnaire that would help us to interlink various procedures?"
- Repeated assessment: would be required regularly. Can we make it focussed on changes?
- Relevance of the label: credibility, awareness, visibility and market access;
- Harmonisation: The assessment procedure stimulates further harmonisation of standards in Europe, which is vital to the succes of dHealth



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.

Thank you for your attention

More information menno.kok@eithealth.eu

Website label2enable.eu





Disclaimer

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HaDEA). Neither the European Union nor the granting authority can be held responsible for them.