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Evaluation of a Regulatory Orientation Guide for Young Entrepreneurs in the Field of Digital Health

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Abstract. Background: The number of software products in the field of health and medicine increases excessively. Self-tracking, fitness, dose calculation, and analysis of physiological data – apps are popular and commonly used. For young entrepreneurs, it is difficult to recognize and understand the distinction between software as medical product and health software products. A product-related orientation guide was developed to help start-ups to understand the difference and to find the right strategy for placing their product on the market. Objectives: An initial evaluation of this orientation guide to improve the comprehensibility, the simplicity, and to validate the benefit. Methods: The evaluation was performed using a questionnaire. In total, 15 employees from start-ups or those in foundation phase and in regulatory affairs positions or comparable were interviewed. Results: the orientation guide was rated as very helpful and comprehensible. 80 % would highly recommend it to others. Conclusion: The orientation guide was positively evaluated and can be used in field. Nevertheless, further investigations must be performed, and a post-market surveillance will be necessary.

Keywords. Software, Biomedical Engineering, Medical Device Legislation

1. Introduction

Software products for smartphones and tablets, so called apps, are widespread and popular, even in the health sector and it is to be expected that the market for apps in this field will prospectively grow [1].

In the third quarter of 2020, the Google Play Store contained 47,140 mHealth apps (for comparison: Q3 2015 ca. 27,417) and the mHealth apps market grew at a rate of 14.3% from 2019 to 2020. A rising number of healthcare professionals recommend mHealth applications and platforms for patient care. [2]

The scope of apps ranges from self-tracking, through fitness and healthcare information to the analysis of physiological data or the calculation of drug dosages. There are general concerns about the quality and safety of those apps. Additionally, there are uncertainties, whether and when an app is a medical device and thereby the Medical Device Regulation (MDR) will be applicable [1]. For entrepreneurs, especially for start-ups and unexperienced or small enterprises, it is often unclear which regulatory requirements must be met in detail and what legal consequences arise from the

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classification as medical device [1]. Furthermore, the terminology is not unambiguous. It is not trivial to understand the difference between medical app and health app. Both terms are often used synonymously, or distinction is vague [3]. Apps related to the health care sector are not necessarily medical devices, therefore a clear definition of the terms is very important [1].

The MDR provides substantial changes for the development and distribution of medical devices, including and notably for software and mobile apps as medical device. Legal manufacturers need to know the regulatory framework exactly. [4]

In particular, the new classification rule 11 of the MDR Annex VIII states, that software "…intended to provide information which is used to take decisions with diagnosis or therapeutic purposes…" must be at least class IIa. If there might be a serious deterioration of a person's state of health, it must even be class IIb [5]. Combined with the definition of a medical device (Article 2, MDR), it can be anticipated that most medical stand-alone software will be classified as class IIa or higher.

1.1. Challenge for young entrepreneurs

The overall goals of the MDR (see Preamble 1 and 2), among others, are to provide a positive effect on innovations and a smooth functioning of the internal market, taking the small- and medium-sized enterprises into account. [5]

The Neue Zürcher Zeitung and Conceplus estimate that due to MDR, up to 30,000 additional professionals will be needed (despite shortage of specialists) and financial damage up to 18 billion Euros is caused. They conclude that small companies might disappear and that thereby the MDR's goal was missed [6]. Hagen and Lauer have published a survey of start-ups that indicates that 67% of the enterprises consider the duration of the CE-certification process as significant barrier and 66% are not well informed regarding the role of the notified body and the conformity assessment procedure [7].

Funding lines for young entrepreneurs usually flank supporting processes using advisors or coaches e.g., business plans and foundation preparation [8]. In contrast, regulatory know how and approval processes are hardly considered while the demands continuously increase.

1.2. Orientation guide for young entrepreneurs

Due to this initial situation, Lukas et al. developed an orientation guide for young entrepreneurs based on a decision tree using plain questions to identify whether the planned software product is a medical device or a health software product [9]. Additionally, the terminology was clarified and the necessary competences were pointed out. Thereby, it was created to help the young entrepreneurs or unexperienced small enterprises to find the right strategy for placing their product on the market.

1.3. Objective

The aim of this paper was the initial evaluation of the orientation guide to improve the comprehensibility, the simplicity, and to validate the benefit. Based on the feedback, the decision tree might be improved as well.

2. Methods

In total, we interviewed 15 (f = 2, m = 13) professionals in the field of digital health software/app development. The age of the participants ranged between 20 and 40 years. Ten of the participants were developers (67%), four (27%) were from executive management, and only one person had regulatory background. We handed out the one-page orientation guide to the participants. After the participants indicated that they had worked through the orientation guide, they were asked to answer the questions.

The questionnaire was subdivided into the following nine items:

1. The guide is expressed in an understandable way.
2. The guide provides an understandable overview of the terminology.
3. The guide helps to assess when the application is a medical device.
4. Using the decision tree, I was able to assign my app to a category.
5. The guide changed my assessment (A, B, C).
6. The guide does not help determine if the application is a medical device.
7. I believe I am well informed in the regulatory field.
8. The guide has a relevant insight and benefit for start-up companies.
9. I would recommend the guide to others.

Item 6 was used as control question to check whether the answers are consistent.

The measurement was made by means of a four-point Likert scale without neutral option (forced choice), so for each item, participants could choose between the following answer options:

- [1] “strongly agree”,
- [2] “agree”,
- [3] “disagree”
- [4] and “strongly disagree”

2.1. Data analysis

All items, except item 6 (control question), are displayed as bar chart with absolute frequencies. The Likert scale is interpreted as ordinal data but can approximately be interpreted as an interval-level measurement and therefore the arithmetic mean is calculated for each item for orientation purposes only. Item-based statements are presented as percentages.

3. Results

All 15 participants answered all nine questions. The control question (item 6) was answered correctly in all cases. So, we can assume that all participants read the questions attentively and answered truthfully. The results of all items are summarized in Table 1. The highest level of agreement was achieved with the items 1 and 9 followed by items 3 and 4.

Table 1. Summary of the item based results of the evaluation of 15 participants

N°	Item	mean
1	The guide is expressed in an understandable way.	1.27
2	The guide provides an understandable overview of the terminology.	1.53
3	The guide helps to assess when the application is a medical device.	1.40
4	Using the decision tree, I was able to assign my app to a category.	1.33
5	The guide changed my assessment (A, B, C).	2.93
6	The guide does not help determine if the application is a medical device.	3.80
7	I believe I am well informed in the regulatory field.	2.67
8	The guide has a relevant insight and benefit for start-up companies.	1.60
9	I would recommend the guide to others.	1.27

Figure 1 shows that all participants found the guide understandably written a) as well as helpful answering the question whether the application is a medical device or not c) beyond to assign the app to a category d), and 93% found the overview of terms understandable b).

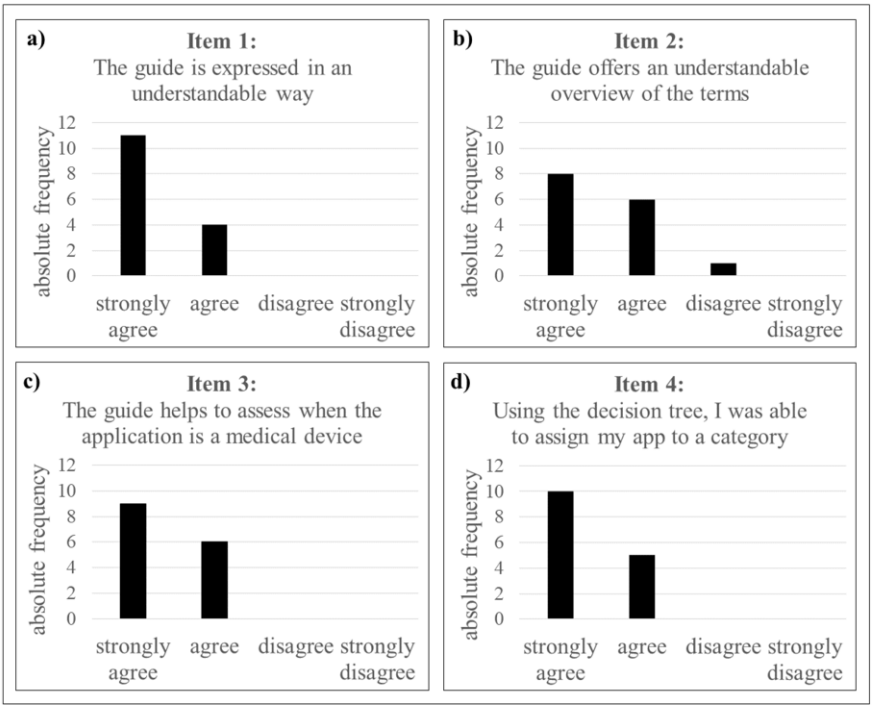

Figure 1. Bar charts for the Items 1 to 4.

Figure 2 shows that the guide did only change the assessment of the category in 26% a). All but one participant (93%) see a relevant insight and benefit of the guide for start-ups c) and would recommend the guide to others d). Only 40% belief that they are well informed in the field of regulatory affairs, and no one answered item 7 with "strongly agree" b).

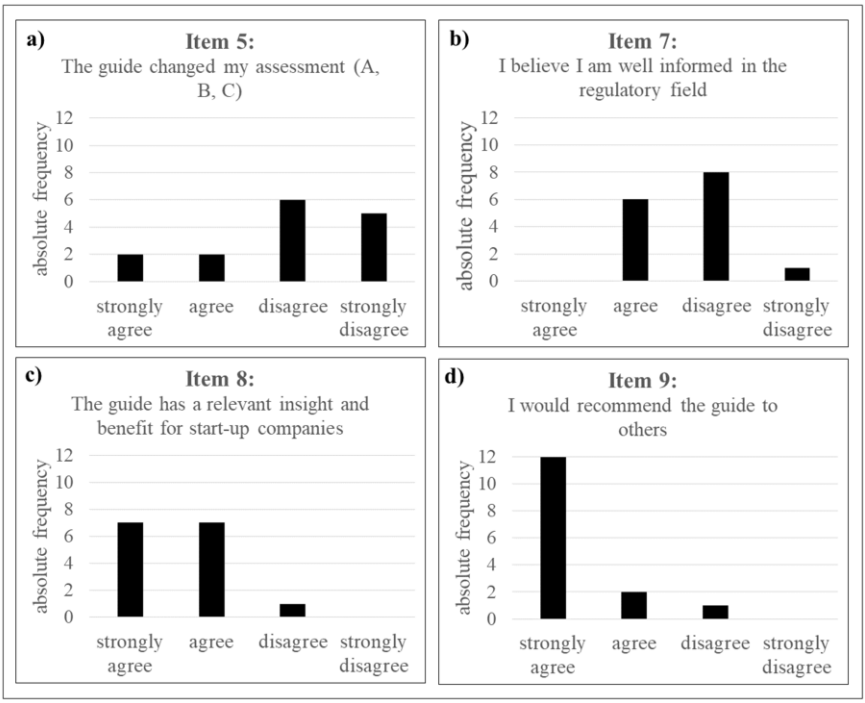

Figure 2. Bar charts for the Items 5 and 7to 9.

4. Discussion

The developed orientation guide [9] could prove that it is written in an understandable way and gives an understandable overview of the terminology. Also, its purpose to categorize whether the application is a medical device or a health application or neither of them seems to be fulfilled. Most participants see the benefit and would recommend the guide. As expected, 60% of the participants do not believe, that they are well informed in the regulatory field. This result is consistent with the results of Hagen and Lauer [7]. The personal feedback of the participants that was not part of the protocol crystallized that the explanations of terminology should be more explained for layman, and the fact, that hardware-related software is excluded in the guide should be more highlighted. These constructive remarks will be integrated into further development of the orientation guide.

To sum up, the initial evaluation of the orientation guide was successful and informative.

Prospectively, we will keep on testing the decision tree with the startups, spin-offs and other small enterprises that contact the University of Applied Sciences searching for support and clarification for the development process of their innovative applications in the field of health care. In addition, on one hand we plan to re-evaluate the orientation guide on a larger collective of possible users and on the other hand we plan to evaluate the orientation guide with experienced experts from the field of regulatory affairs.

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