

OPPONENT REPORT FOR PHD DISSERTATION

Title of PhD Thesis: Electronic clinical study management system with artificial intelligencebased data processing capabilities

Author: Ing. Miroslav Mužný Supervisor: Ing. Jan Mužík, PhD Opponent: Phuong D. Ngo, PhD Submitted thesis contains 70 pages, 20 figures, 2 tables and cited 58 publications.

Novelty, state of the arts and methodology

The thesis touches on the very demanding topic in clinical research by focusing on developing a new electronic clinical study management system to address the increasing amount of data generated by new technologies such as smart phone and wearable devices. The introduction provides a wide background of information and cover all the topics of the thesis including modern clinical trial, mobile applications and wearable devices.

The first section starts with several of the challenges in modern clinical trial. The candidate also mentioned about Hubro, an electronic management of clinical studies. However, there is little literature review on previous management system for clinical studies. This should be addressed since Hubro is the most important contribution of the thesis.

The connection between all the sections is not well defined. For example, how wearable sensor with health data exchange fits to the Hubro system needs to be clarified. Some parts of the information should be in the introduction or results chapter, while the methods used in conducting reviews of current technology or developing the Hubro system were not explained sufficiently. For example, the diabetes app has been developed before the project started and should be described as the background information in the introduction. The design of the Hubro platform was proposed with unclear connection with the smartphone/smartwatch integration.

State of the arts of artificial intelligence and the methodology in developing the system such that AI can be facilitated in data processing should be emphasized, since this is one of the main novelties and usefulness of the new system.

The reviewer thinks the last paragraph of the methods (page 20) which describes the development methodology for the Hubro system is too compact and can be further elaborated.



Chapter: Results

The results chapter provides a very good technical description of the developed systems and their usage in clinical studies. However, it is recommended that the materials and subsections in this chapter are better linked together to tell one whole thesis objective rather than independently written. The first part of the results chapter, where the author describes the aims and objectives of the design process, should be placed in the methods section. Similarly, the last paragraph of page 22, where the author describes the data sources used for reviewing current health data-exchange capabilities of wearable devices, should also be in the methods section. On the other hand, the conclusions of this review of data exchange, which was listed by bullet points at the end of page 23 and beginning of page 24, are not sufficiently described. The methodology of this review itself was also not found in methods section. Quantitative results of the review also need to be provided to make the conclusion more convincing.

The Design and Implementation of an Electronic Clinical Study Management System (Publication 3.) subsection also faces similar issues. The first part of this section ("State of the Art - New Evaluation Methods for eHealth and mHealth Services") should be in the introduction. The second part ("Identified Use Cases of Hubro System") should be in the methods. If this identification is considered as the results of the research, the appropriate knowledge review methodology to come up with this selection must be fully described in the methods chapter. The "Participant Recruitment, Enrollment and Staging" should be placed in the methods section. The remaining of the materials contain many technical details in which the reviewer thinks that needs more elaboration of methodological backgrounds (theory behind, choices of methods that lead to selection of the features).

The most important part of the results section is the evaluation of the Hubro system also contains much of the materials that should be placed in the methods chapter (e.g., design of study, questionnaires).

Chapter: Discussion and future research directions

This chapter provides very detailed information about limitations and future consideration of the systems. However, the opponent thinks the discussion of the results on page 61 is a bit short. Further elaboration on this subsection including connections with the results chapter should be added before discussing future research directions.

Other comments:

The following sentence seems to be an added as an error during the generation of the table of contents:



The English is relatively good but there are grammatical errors that can be fixed to improve the readability of the thesis.

The first sentence on page 19: "Figure 1. illustrates all steps of study:". The word "study" is not well defined. Reference should also be added.

In the statement of contributions, the candidate should emphasize more in details of the contribution in terms of which research ideas, the choice of methodologies, algorithms, implementation.

The three limitations of mobile devices by Piwek et al. on page 18 should be moved to before the last paragraph of page 19.

Opponent's Conclusions:

Having read through the dissertation thesis, I would like to summarize my opinions as follows: The thesis contributes to the development and applications of computer sciences and clinical research. The candidate is able to collaborate efficiently in a research team and conduct research independently. The amount of works is significant, and the results show proofs of improvement in efficiency of clinical study management through case studies. Some parts of the thesis can, however, be further improved, and the opponent recommends addressing the comments in this report. In general, the dissertation exhibits expectation for independent scientific work and for awarded of the academic degree doctor.

Tromsø, February 14, 2021



Phuong Dinh Ngo, PhD