Innovative and digital health technologies

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Obudai Egyetem, Budapest, Hungary

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Nowadays, the development and market entry of innovative digital medical devices (DMD) can only be successful if they offer real (added) value to users compared to existing alternatives and if there is scientific evidence to demonstrate their (clinical) efficacy, safety, social and economic benefits. This is clearly stated by the European Medical Device Regulation. Scientific evidence of clinical efficacy and safety is an official requirement of market entry permit.

In case a given medical technology such as device, software, or other piece of medical technology require public funding in the healthcare systems this information is required by law in the member states of the European Union, North America and elsewhere. Since health care systems in these countries are financed by public / insurance funds over 90% public funding has a key importance of profitability.

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https://uni-obuda.hu/tkp-en/

The research is divided into two subprojects:

Subproject I - Personalised digital physiological modelling and guidance for cancer therapy optimisation and artificial pancreas

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The research focuses on two key public health problems: cancer treatment and diabetes.

There is a lot of potential in personalising cancer treatment (professional tasks 1 and 2):

- increase the overall survival of the patient;
- to improve the patient's quality of life;
- reduce the cost of treatment;
- reducing the chance of resistance developing;
- reducing side effects.

Our research centre has been working on this problem for more than a decade, supported by an ERC grant from the European Union and a Competence Centre grant. In these projects we have demonstrated the concept in animal experiments.

To personalise the treatment, a mathematical model is needed to describe the effect of the drug on the tumour in the patient. We are developing algorithms that define this model (Professional Task 1). The structure of the mathematical model is given from previous research, the newly developed algorithms aim to determine the model parameters specific to the patient, and to identify the model.

Knowledge of the identified mathematical model is necessary for therapy optimisation. Based on the model, we can calculate the optimal treatment (professional task 2), which is tailored to the individual characteristics of the patient (using the results of professional task 1). We develop several optimisation algorithms based on different approaches. In practical applications, different algorithms may be needed in different settings; these algorithms are tested in silico experiments.

The development of physiological regulation algorithms (Professional Task 3) differs from the therapy optimisation task in that injections are given more frequently (in some cases even continuously), whereas in the therapy optimisation task in Professional Task 2, injections are given less frequently (e.g. twice a week). We develop control algorithms for artificial pancreas focusing on compensating for the effects of external perturbations such as food intake and physical activity. The algorithms developed will contribute to improving the quality of life of patients.

Subproject II - Evaluation of digital medical devices: efficacy, safety and social utility

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The aim of the research is to develop a methodology for measuring the health and socio-economic gains (benefit) of **digital medical devices** (DMDs) in order to support scientifically and economically successful domestic DMD development. In the first two years of our subproject (2022, 2023), we have focused on the first three research objectives out of the five technical tasks outlined in the proposals:

- Is DMD clinically effective and safe? How much more effective and safer than existing DMDs? (This is the input of cost-effectiveness and cost-utility studies – required by reimbursement and funding agencies) Literature evidence search and analysis, automated literature search;
- What is the outcome of DMDs from the perspective of patients, families, health care facilities, society in general: users? Outcome measurement (patients' user skills, knowledge, attitudes and preferences) is one of the key element of the innovation,
- How can digital data from DMDs be used (and re-used) for medical decision-making?

Further goal related to research objectives 4 and 5:

- cost-effectiveness analysis, health technology assessment of new digital medical devices, creating guidelines and offering trainings to the MedTech industry companies
- measuring innovation performance and competitiveness of DMDs

Why our research is useful...

... for innovators / developers of digital medical devices?

- They help to provide a systematic overview of existing DMD developments,
- a systematic literature analysis and evaluation of the effectiveness and safety of comparator DMDs in the field,
- the design of the DMD clinical trials to be developed and
- measuring and communicating results in a way that can be directly used to evaluate new technology and inform social inclusion decision-making.

... for doctors?

- It uses accepted methods of evidence-based medicine to provide sound information about DMDs, to help understand the value of DMD outcomes from the patient's perspective, and to use digital DMD data for clinical decision making.

... for patients?

- The methods developed as a result of our research provide an opportunity to take into account patient concerns in DMD development (patient preferences, device acceptability, usability) and to speed up the process of development, approval and social security certification of new devices, thereby improving awareness and access to DMD devices.

... the funder, the health policy makers?

- Our methodological developments will better measure the individual and societal benefits of DMDs, thereby supporting clinically and health-economically sound decision-making and financing decisions.