"TKP 2021-NKTA-36 Development and assessment of innovative digital technologies in the health industry"

Óbuda University Budapest, Hungary

### Recent Advances in Intelligent Engineering

Óbuda University, Budapest May 08, 2024 Room F09 (Pauli) ground floor Bécsi út 96/b, 1034 Budapest, Hungary

14:00-15:30

Link to the conference



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"TKP 2021-NKTA-36 Development and assessment of innovative digital technologies in the health industry"

### Recent Advances in Intelligent Engineering; increasing the societal value of medical innovation

Date and Time: 14:00 p.m.

May 08, 2024 (Wednesday)

#### Venue: Óbuda University, Room F09 (Pauli) ground floor Address: Bécsi út 96/b, H-1034 Budapest, Hungary

#### Introduction

The global digital health market in terms of revenue is estimated to be worth 180.2 billion US dollar and is projected to reach 549.7 billion US dollar by 2028.<sup>1</sup>

According to FDA "Providers and other stakeholders are using digital health technologies in their efforts to: Reduce inefficiencies, Improve access, Reduce costs, Increase quality, and Make medicine more personalized for patients. Patients and consumers can use digital health technologies to better manage and track their health and wellness-related activities."<sup>2</sup>.

Digital health tools are used to a large extent by the health sector, by health institutions, which are usually publicly funded. If a manufacturer wants to bring a new technology into public funding, it must provide scientific evidence of the efficacy and safety of the product and accurate data on the budgetary impact and cost-effectiveness of the product or service. In other words, it is not enough to call the product or service innovative, it must be shown that the

<sup>&</sup>lt;sup>2</sup> <u>https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health</u> 2



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<sup>&</sup>lt;sup>1</sup> <u>https://www.marketsandmarkets.com/Market-Reports/digital-health-market-</u>

<sup>&</sup>lt;u>45458752.html?gad\_source=1&gclid=CjwKCAiAuYuvBhApEiwAzq\_YiaGRXWquUftze99JDaopyKZLbQMX</u> <u>sR\_3fL0QpGhjOtGcU0lBQ5cxEBoCzLwQAvD\_BwE</u>

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benefits are greater than those of comparator products and that the cost side is as expected by the funder.

Digital (and other) healthcare manufacturers in Europe face increasingly detailed regulations, such as European Medical Device Regulation (MDR). However, the European MDR (2017/745) does not provide a definition and criteria of preferred measures for outcomes, but defines clinical benefit as 'the positive impact of a device on the health of an individual, expressed in terms of a meaningful, measurable, patient-relevant clinical outcome(s), including outcome(s) related to diagnosis, or a positive impact on patient management or public health'.

Our distinguished speakers will discuss how these legal requirements can be met and how health economics can help developers to work and enter the market smoothly.

For the third year, the Obuda University has been running a major research program named "Development and evaluation of innovative and digital health technologies" (TKP 2021 - NKTA - 36), one part of which is sub-project "Evaluation of digital medical devices (MDMs): efficacy, safety and social impact."<sup>3</sup> Some of its results will be presented at the conference.

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<sup>&</sup>lt;sup>3</sup> Thematic Excellence Programme (TKP2021-NKTA-36) 2022-2025





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#### Program

#### 14:00-15:30

#### **Conference Chairperson**

Moderator: Prof. Dr. László Gulácsi, DSc, Vice Rector for Research

### 14:00 - 14:15 Honorary Professor Diploma Award Ceremony: Prof. Dr. Levente Kovács, Rector

### 14:15 – 15:00 Health Economics – demonstrating and increasing the societal value of medical innovation

**Prof. Werner Brouwer**, Professor, Interim Dean of the Rotterdam School of Management (RSM) and as professor of Health Economics at the Erasmus School of Health Policy & Management (ESHPM), both of the Erasmus University Rotterdam; Honorary Professor of Óbuda University, Budapest

Abstract: Many countries aim to improve the affordability, efficiency and equity of their healthcare systems. Economic evaluations of health technologies can support funding decisions in line with these goals. This does require that these evaluations capture all societal costs and benefits adequately. Moreover, health economics can support the development of new technologies that offer value for money. In this lecture I will briefly discuss the developing methodology of health economic evaluations and how it can be used in developing and evaluating health innovations.

### 15:00 – 15:20 Innovative digital medical devices from the patients' perspective: from development to successful implementation

**Prof. Dr. Márta Péntek DSc,** Professor, Health Economics Research Center, University Research and Innovation Center, Óbuda University Budapest

**Prof. Dr. László Gulácsi DSc**, Professor, Health Economics Research Center, University Research and Innovation Center, Óbuda University Budapest, Hungary

Abstract: In the development of digital medical devices, the key questions are what the device is developed for, how the outcomes can be measured in clinical trials and in real world use, and to what extent the device and its outcomes are in line with patients' needs, attitudes and preferences. In this presentation, we will briefly describe and provide some examples of how the choice and assessment of patient outcomes can support the successful development, market entry and management of digital medical devices.

15:20-15:30 Discussion and take home message



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PROJECT

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Prof. W.B.F. (Werner) Brouwer, PhD



EDUCATION 1996 M.Sc. in (Micro) Economics at the Erasmus University Rotterdam, The Netherlands (average 8) 1999 PhD in Health Economics with a thesis entitled: 'Time and time costs in economic evaluations: taking a societal perspective.' (Promotor: Prof. dr. F.F.H. Rutten) at the Erasmus University Rotterdam, The Netherlands.

ACADEMIC POSITIONS 2011 - present Full Professor of Health Economics, Erasmus School of Health Policy and Management, Erasmus University Rotterdam 2016 - 2021 Full Professor of Health Economics, Erasmus School of Economics, Erasmus University Rotterdam 2012 - present Honorary University Professor, Faculty of Economics, Corvinus University Budapest, Hungary 2008 - 2010 Endowed Professor of Health Economics ('Economic Evaluation & Health Policy'), Institute of Health Policy and Management, Erasmus University Rotterdam 2005 - 2008 Associate Professor of Health Economics, Institute of Health Policy and Management, Erasmus University Rotterdam 2002 -2005 Assistant professor of health economics, Institute of Health Policy and Management, Erasmus University Rotterdam 2000 - 2001 Erasmus University Rotterdam-Fellow, Erasmus University Rotterdam, The Netherlands 1996 - 1999 PhD student, Institute of Health Policy and Management, Erasmus University Rotterdam, The Netherlands 1995 Studentresearcher, Dynamic Growth institute, Erasmus University Rotterdam, The Netherlands.

Prof. Márta Péntek, DSc



Main research areas of Prof. Péntek are the measurement and evaluation of health gains, healthrelated quality of life, with strong focus on their application in clinical, financial and health policy decision making and management of innovative health technologies.

So far, she has been the supervisor and co-supervisor of 8 successfully defended PhD students (Unversity of Amsterdam, Corvinus University, Semmelweis Unversity and is currently supervisor of 2 PhD students.

She is a member of the EuroQol Group (https://euroqol.org/). She is the Chair of the Section of Health and Health Economics of the Hungarian Economic Society since 2014.

She has successfully applied for and been the national leader / coordinator of seven international and 5 Hungarian research projects. Currently she is the Hungarian leader of the Bur-EB project (https://www.bur-eb.com/) and of the 'Development and evaluation of innovative and digital health technologies - Evaluation of digital medical devices: efficacy, safety and social utility' research project in Hungary. Her cumulated impact factor is 438,628, has a total of 4263 citations (3002 independent citations), Hirsch index of 31. She has has published 185 scientific articles, 8 books and 20 book chapters. She was guest editor of the 2019 supplement of The European Journal of Health Economics (https://link.springer.com/journal/10198/volumes-and-issues/20-1/supplement)

She has been awarded the Teacher of the Year (BCE, Health Economics Student Circle, 2012), Research Excellence Award (BCE, 2016), Most Cited Researcher of the Year (Óbuda University, 2021) and Researcher of the Year (Óbuda University, 2022).

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