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Abstract:

Digital tools including data-driven diagnostic and therapeutic applications and sensors are moving into healthcare. Already, the first telemedical services support patients life and the work of healthcare provider. Nowadays, new wearable sensors, smartphone application as well as intelligent algorithms ("artificial intelligence") developed by researchers are moving into the field of healthcare. The anticipated effects for patients as well as the market for new digital healthcare services seems endless.

However, the healthcare ecosystem including certification, regulation and reimbursement is different from other fields of services in our society. Quality assurance is of great importance and the EU-based Medical Device Regulation (MDR) and the General Data Protection Regulation (GDPR) have been established to ensure the technical quality of the new digital healthcare services, as well as the data safety/privacy issues on this very relevant topic of healthcare data management. Nevertheless, a European definition of the evidence for the medical and societal benefits of digital healthcare service is missing. Thus, market access and reimbursement procedures are extremely diverse within Europe and even within each country. Germany has moved forward by filing a new law (Digital HealthCare Act) that defines this evidence generation process linked to the reimbursement by the German healthcare system. Luxembourg considers this concept to be a strong basis to generate a coherent regulatory process on an European Level and is willing to contribute proactively to the development of such a process.

In the presentation the concept will be explained and especially the future consequences for researchers, patients and their Healthcare Provider, as well as for the society will be envisioned: open for discussion and shaping of our digital healthcare future.

Short Vita Prof. Dr. med. Jochen Klucken

Prof. Dr. med. Jochen Klucken is the head of the Digital Medicine (dMed) Group that works in very close collaboration with the NCER-PD project (National Centre for Excellence in Research on Parkinson's Disease https://parkinson.lu/) and is supported by the FNR-PEARL Programme at the LCSB (Luxembourg Center for Systems Biomedicine) of the University of Luxembourg, the LIH (Luxembourg Institute of Health) and the dMed Research Clinic at the CHL (Centre Hospitalier de Luxembourg). The dMed group led by Prof. Klucken focuses on I) shaping and innovating personalised digital healthcare solutions, and II) understanding and evaluating the new benchmarks of a new ecosystem for digital medicine.

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Digital medicine is a new field Medicine that aims to understand how patient-centered technology can be used in everyday medical practice, and which evidence assessment is needed to not only understand the medical benefits of healthcare technologies, but also their patient- and social acceptance and economical efficacy. Here, the major goal lies in clinical studies for healthcare technologies providing evidence for their medical, social, ethical and legal benefit as well as economic efficiency ultimately generating a concept of “clinical validation of healthcare technologies and services”.

Prof. Klucken earned his MD in Laboratory Medicine and specialized in Neurology. He finished his habilitation thesis in 2009 in translational neuroscience in Parkinson’s disease including work at the Massachusetts Institute for Neurodegenerative Diseases, **Harvard Medical School,** Boston, USA on neurodegenerative processes in Parkinson’s disease. In 2004 he also started translational research projects in the field of medical technology (m/eHealth) applying sensor-based motion detection in movement disorders. Jointly with engineers and data-scientists, he developed novel gait-specific instrumented movement analysis concepts for **Parkinson’s disease, multiple sclerosis, osteoarthritis, sarcopenia, oncology and healthy well-being of the elderly**. From 2008 until 2021 he was a senior physician and PI at the Movement Disorder Unit (Department of Molecular Neurology, University Hospital Erlangen, Germany) and developed sensor-based gait analysis for patients with movement disorders. From 2018-2021 he also lead a group at Fraunhofer IIS, Erlangen, Germany with the focus on developing digital health pathways that enable technology integration into healthcare workflows. In 2019 he also established a contract research organization (Medical Valley Digital Health Application Center - dmac) supporting personalized healthcare technologies in order to get access to the German healthcare market. Within the scientific community he initiated and leads the task-force “**Telehealth Services” of the Germany Parkinson Society (DPG**), he is a founding member of the task-force “**technology” of the international movement disorder society (MDS**), and he is the chairman of the advisory board “e-health, telematics methods) of the **Professional Association of German Neurologists (BDN**). On political and societal level including patient-support groups he promotes the use of mobile healthcare technologies and innovations for comprehensive digital healthcare services, clinical studies and care. In addition, he participates in spin-offs/start-ups in the field of sensor-based movement analysis, and is advising several pharmaceutical companies and healthcare insurances/services on the topic of wearable derived objective outcomes.