

PFARRKIRCHEN, GERMANY

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GLOBAL DIGITAL HEALTH – TODAY, TOMORROW, AND BEYOND

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DigiHealthDay Keynote

Evaluation of Digital Products - Challenges, Functions and Opportunities
November 12, Friday, 2021, 9:40-10:20 (CET)

ABSTRACT

The generation of evidence in the evaluation of digital products repeatedly poses relevant challenges for science. Unlike classic medicinal products or medical devices, digital products are not developed once with a very high expenditure of resources and then scientifically investigated with regard to their effect, but are characterized by constant change and further development. Classical study designs, such as randomized controlled trials (RCTs), can quickly reach their limits here, so that the selection of more modern and flexible study designs can make sense depending on the product and healthcare context. These range from adaptive clinical trials, pragmatic trials to more exploratory approaches such as the use of Multiphase Optimization strategy (MOST) in the rather earlier stages of development.

Another aspect that makes the scientific evaluation of digital products and strategies so challenging is also one of their greatest strengths. Digital care concepts often actively involve, shape, and influence the patient's immediate environment and daily life. Creating a clinical and controlled study environment can consequently lead to a significant over- or underestimation of an effect. Obtaining and incorporating real-world evidence (RWE) into the overall evaluation can therefore be of great importance.

Finally, it should be noted that studies with digital products often have other functions than the pure proof of efficacy, beneficial effects or risks. Particularly if they are carried out or commissioned by the manufacturer, the studies also serve, among other things, as the basis for any approvals and price negotiations or as the foundation of marketing and sales strategies.

In summary, it can be concluded that the scientific evaluation of digital products poses challenges to the digital community and questions classic and traditional principles. On the other hand, these also offer new and exciting opportunities to investigate effects in everyday life and in the real environment of patients and thus, for example, to generate real world evidence. It is important to use this potential and to face the challenges in order to improve the digital healthcare of tomorrow.

