How digitalization can boost participation in clinical studies

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Only about 5% of patients participate in clinical studies. Pharma and MedTech companies face time-consuming and costly processes when recruiting participants. Patient centric thinking in combination with digitalization can solve the problem.

Regulatory authorities require that Pharma and MedTech companies provide clinical evidence that medical devices as well as new medicines deliver what they claim. These so called clinical studies are performed by enrolling volunteers to test the medicine or device. Without these scientific trials, new developments cannot get approval and consequently cannot obtain market access. Companies that have brought a new device or medicine as far as the starting point of a clinical study lose millions if the innovation cannot access the market.

There are a couple of severe and increasing challenges for the pharma and medical device companies with regards to clinical studies, including the increasing regulatory requirements, the need for international studies and the complexity and costs of these studies. The major problem, however, is the recruitment of appropriate volunteers to participate in clinical studies.

Patients without optimal care

As only about 5% of patients participate in clinical studies, pharmaceutical companies face a time-consuming and expensive recruitment process. As a result, around 80% of clinical studies fail to meet their enrolment deadlines and more than 35% of research sites do not reach their enrolment targets. For 10% of all clinical studies not even a single patient can be recruited, often because they target a specific condition which means there is a smaller patient population.

Additionally, the international requirements for clinical studies increase the obstacles even further, especially considering the fact that five billion people do not have access to proper health care. These issues result in delays and hinder the approval of new and innovative treatment options ultimately leaving patients without optimal care.

Digitalization meets patient centric thinking

They key question is: Why are patients so hard to recruit? There are some great examples that demonstrate the willingness of patients to participate in clinical studies. For example,
the mPower App which allows the digital diagnosis of Parkinson’s disease to be performed by measuring the tremor using the phone’s internal accelerometer. The scientific team behind the App was able to recruit more than 7400 people for the clinical study in less than a day.

Interestingly, the main reason why patients normally fail to participate in clinical studies is mainly due to the inconveniences they face. The patient centric thinking of mPower is the first aspect to get it right. Normally, patients would need to go regularly to health care providers for continuous testing, for example once a week to the hospital to give blood, have an examination or do some tests. These hurdles cause about every third patient to stop during the clinical study. With the mPower App, patients can participate in the clinical study whenever and wherever they want.

New virtual designs of clinical studies
Digitalization offers compelling benefits with regard to reaching the patients as the mPower App cleverly proved. Patients are even willing to share their data and they do so without getting any direct benefit. The pharmaceutical sector is on its way to becoming a data science company. But digitalization on its own hardly provides the solution to the issue. Digitalization is the tool that must be combined with patient centric thinking. Pharma and MedTech companies should engage and co-develop directly with patients in order to understand why they do not want to participate in clinical studies. Together with the patients, they need to find digital solutions that are convenient.

Digitalization offers not only new designs for clinical studies but also direct access to patients. About 60% of the African population has no access to health care as most people live in rural areas, but about 80% of the same population group can be contacted via a mobile phone. Through digitalization, new population groups can be involved in virtual clinical studies.

Broad technological expertise
Once patients are involved in the development process and the business case is understood, the technological feasibility needs to be addressed as well. Medically approved wearables and mobile technology require broad technological expertise: Involving skills in medical device and sensor development, secure web connections and Artificial Intelligence as well as intuitive visualization of insights. All these developments have to be embedded within an approved quality management system in alignment with ISO 13485.

The second part of the series on changes in the pharmaceutical and medtech industry:
• Why e-health only works if backed up by strong information security (Raphael Reischuk)
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