Digital biomarkers: reinventing patient monitoring and care

By Polina Zayakina and Urs Wiedemann

In recent years, the pharmaceutical industry and academic community have increasingly acknowledged the limitations of traditional clinical measures, tests and scores to assess the disease status across manifold disease areas. The consensus is clear: there is a pressing need for more accurate and sensitive measurement tools.

Challenges with traditional outcome measurements

After searching for liquid biomarkers that promise to predict disease outcomes, the focus is shifting now to improved clinical outcome measures. Existing traditional tests face three primary challenges: they are usually non-continuous, often subjective and not sensitive enough to detect subtle changes in a patient's well-being.

Take, for instance, the 6-minute walk test (6MWT) used for patients with respiratory, cardiac or neurological conditions. This test is typically conducted during a patient's visit with the physician, usually every six months. While the test provides a snapshot of the patient's condition on that specific day, it fails to capture the patient's health status over the preceding six months.

In the case of neurological conditions like myasthenia gravis (MG), characterised by strongly fluctuating symptomatology, patients are usually assessed using either patient-reported outcomes (PRO) or healthcare professional-reported outcomes (HRO). However, these patients often feel that physicians underestimate their disease severity. Likewise, physicians are challenged to comprehensively assess a patient's status when seeing the patient only every six to 12 months.

Similarly, in multiple sclerosis (MS), the expanded disability status scale (EDSS) may not adequately detect early disease progression or subtle changes in patient disability, limiting its short-term utility, especially in the early stages of the disease.

The promise of digital biomarkers

Digital biomarker tools offer the promise of solving many of these challenges posed by traditional measurements.

While the concept is not entirely new, the initial wave of digital tools – mainly consisting of tests and games based on patient input – suffered from low adherence, as patients lost interest after several months without perceiving clear benefits.

We are now witnessing the emergence of a second wave of digital biomarker tools. These tools leverage lessons learned from previous failures and utilise advanced wearables, such as smartwatches and sensor-embedded devices, to collect data passively. Patients only need to consistently wear these devices, which can discreetly integrate into daily life without the stigma of a medical device. Advances in AI and big data analytics further enhance the ability to interpret the vast amount of data collected.

Neurokeys: passive monitoring of brain function through keyboard dynamics

An innovative example is Neurokeys, developed by the Amsterdam-based company Neurocast, a digital biomarker solution that passively collects data on keyboard dynamics to assess brain function. Analysing typing patterns on smartphones provides valuable insights into neurological conditions such as MS, Alzheimer's disease and depression, allowing to diagnose disease early on or detect subtle changes in disease progression.

AI-enabled insoles: advanced monitoring for neuromuscular disorders

Another unconventional way to capture characteristics of gait and walking function in patients with neuromuscular disorders (NMD) is AI-enabled insoles. The insoles incorporate sensors that utilise advanced AI to analyse mobility patterns and provide continuous, objective insights into NMD progression. This technology is particularly promising for conditions like muscular dystrophy and amyotrophic lateral sclerosis (ALS), offering a more nuanced assessment of disease with the potential of a more personalised treatment approach.

The Watch-PD study: utilising Apple Watch for advancing Parkinson's disease research

Utilising more widely available wearable technology, such as the Apple Watch, the Watch-PD study aims to monitor and potentially predict the progression of Parkinson's disease (PD). This study collects continuous data on movement and physiological parameters from the Apple Watch. It highlights the feasibility of using consumer-grade wearable technology to detect subtle changes in motor symptoms associated with PD. The data collected enables the development of algorithms that predict disease progression to optimise treatment strategies.

Unlocking the full potential: tailoring digital biomarkers to individual needs

These examples represent only a tiny selection from a steadily growing universe of digital biomarker solutions. They hold significant promise for pharmaceutical companies, healthcare providers and healthcare systems alike, by addressing the limitations of traditional measurements in both clinical trials and routine clinical care. They offer continuous, objective and sensitive metrics that can comprehensively characterise the disease state and capture subtle changes in patient health, thereby improving disease management and therapeutic outcomes.

However, to fully realise their potential, it is crucial to tailor digital biomarker solutions to the specific needs of each disease indication. The requirements vary significantly from one condition to another, necessitating an indication-specific and potentially a personalised approach to implementation.

By understanding and defining the unique needs of each indication, stakeholders can maximise the value of digital biomarkers, ultimately enhancing patient care and our understanding of disease evolution. The future of patient monitoring and disease management lies in the strategic integration of these advanced digital tools, paving the way for a new era of precision medicine.

References are available on request.

Polina Zayakina is Senior Consultant and **Urs Wiedemann** is Managing Partner, both at stradoo