

Digital Biomarkers

How to improve early diagnostics with the application of digital biomarkers?

1. BACKGROUND INFORMATION

Digital biomarkers (DB) are objective, quantifiable, physiological and behavioural, clinically-relevant information. While often seen as consumer-generated physiological and behavioural measures collected through connected digital tools (mainly wearables and apps), DB could be considered in a broader context - such as new ways of capturing data that before was not possible.

The use and evaluation of DB is growing rapidly with the benefits potentially three-fold. From the patients' point of view, DB could unlock hidden information able to track and accurately measure any changes and lead to ways to slow, or even prevent, disease progression. For physicians, DB could fine-tune personalised treatment by continuously monitoring DB (even in real-time). From a scientific perspective, DB holds the promise of opening new paths to a better understanding of the progression and the management of diseases.

2. OPPORTUNITY

Patients living with a condition may only see a medical professional once or twice a year and are not necessarily be able to recount their health or pin point their feelings on a particular day. DB provides the means to collect information cost-efficiently and *en masse*, helping to give a comprehensive picture of a longer period of time.

What's more, the characteristics of DB have great potential for value-based, patient-centred healthcare. Longitudinal and individual-level data collection provides the granularity and time context necessary to understand, prevent, detect, and manage disease. To date, only large cohort studies have been able to collect granular and longitudinal information, but at a high operational cost.

DB are increasingly proving their value in several areas in the medical field; such as chronic pain management, cognitive function assessment, and neurodegenerative disorders. For example, the use of DB for neurodegenerative disorders aims to overcome the limitation of the sparse collection of subjective data to inform drug development and the design of phase III trials in the presence of unreliable, physiological biomarkers. The data generated by mobile phone and wearable/implantable devices are independent from raters and virtually free from intra- and inter-rater variability. For instance, motor assessments of finger tapping have been used in clinical trials in Parkinson's disease and gait assessments have been used in clinical trials in Huntington's disease.

3. CURRENT CHALLENGES

Even though DB represent an opportunity to capture clinically meaningful, objective data in a cost-effective manner, the steps required for their identification and implementation will be met with various challenges.

First, not all health data can be easily captured, identified, validated, and translated into DB. This challenge may be particularly relevant to conditions or specialties in which objective outcomes are difficult to measure - like depression or pain.

Second, agreement on and adoption of condition-specific outcomes is neither widespread nor integrated into routine clinical care. This challenge applies to all types of outcome measurements. Thus, DB cannot be useful unless outcome measures are deemed clinically appropriate and useful.

Third, cost-benefit assessments are needed to determine the value generated by DB. Expensive, intrusive, or invasive biosensors will pose the greatest challenges.

Finally, the integration of any data stream, particularly new data streams, into clinical workflows or with other technologies poses special challenges. Current electronic health record systems, which are not designed to easily capture or report provider-recorded outcomes, are also not well positioned to accept diverse DB from diverse devices and applications.

4. POSSIBLE AREAS OF INTERVENTION

In order to address the above challenges, EIT Health is seeking proposals primarily focused on one of the four main categories, outlined below:

- ***New Digital Biomarkers***

DB could significantly help in bringing healthcare from a reactive towards a more preventive approach, as researchers will not only be able to explain diseases better, but more and more data will be available to analyse what healthy, normal states signify and to predict future health outcomes. In order to provide more information, EIT Health is looking for identification of new types of DB such as, but not limited to:

- A. Vocal biomarkers: using voice to detect diseases and conditions (for example, mood and depression. Also, it could be potentially addressed to diagnose cardiac health, pneumonia, COPD, heart attack, Parkinson's, Alzheimer's, Dementia).
- B. Thermal/Heat biomarkers: using heat/thermal to detect diseases and conditions.
- C. Ocular biomarkers: using pupil response or eye movement to detect diseases and conditions.
- D. Breathing biomarkers: using respiratory to detect diseases and conditions.

- ***New features***

There are several features involved in collecting the different types of DB. In order to full maximise the benefits of collecting DB, a number of factors need to be taken into consideration:

Which technological features could make DB collection more efficient? How can DB be fully utilised and integrated under different types of features? In this category, EIT Health is looking for new ways of collecting DB.

- ***New therapeutic areas***

There has been a broad range of data collection activity in a number of therapeutic areas including, but not limited to, cardiovascular disease, respiratory conditions, neurodegenerative conditions and diabetes. There is a clear correlation between the devices that people wear and signals they give to allow for tracking/monitoring a particular condition. EIT Health is looking for ideas to extend this pattern of using DB to connect to, monitor and collect information on conditions to other therapeutic areas.

- ***Integration/Validation Platforms***

The main challenge stopping the wider use of DB by patients and physicians is the ability to validate the information. Methodologies to compare objective measures to more traditional self-reporting measures can help increase the uptake of new technologies by researchers and clinicians. This variety provides tremendous advantages in terms of flexibility, diversity and adaptability of tools available to generate DB, but it also requires a clear strategy to translate the initial signals into a reliable, validated digital biomarker than can be used to yield meaningful scientific evidence. EIT Health is looking for the development of a standard platform that fully integrates the collection of DB.

5. WHY IS THIS A WILD CARD CHALLENGE?

The use of DB holds potential for a significant leap forward in clinical practice, but we know for a fact that various barriers exist, from regulatory to technological issues. As a well-founded, pan-European network collaborating closely with each other, EIT Health will accelerate the growth of a start-up targeting implementation of DB in standard clinical practice by providing easy access to all relevant stakeholders and potential for scale-up of the solution across European markets.