The opportunity of *digital biomarkers*

Unlocking next-generation healthcare

Capgemini invent

Setting the context

Digital biomarkers enable technology-driven healthcare

Your heart rate is up. Your blood glucose has dropped. Your skin is sweaty. What is happening – and what should you do?

We intuitively know that **biological characteristics reveal information about our physiological state** (maybe you are out for a run). Oftentimes, we know how we should respond to help our bodies cope with the conditions (maybe it's time for an energy bar). Nowadays, we might even be tracking some digital statistics about the state of our bodies. But fitness tracking is just the tip of the iceberg when it comes to digital measurements of health.

Digital biomarkers offer powerful interpretations of a patient's digital measurements and correlated medical conditions. They capture and analyze an array of physiological, behavioral, and environmental data through sensors, wearables, and digital platforms.

While data points that provide a signature of a patient's health status are not new, what is new is the **proliferation of digital devices and advanced algorithms** that can provide novel data points that are measured in the patient's day-to-day environment. But these digital measurements are more than additional data points. Digital biomarkers support a **technology-enabled model of healthcare delivery**. The digital ecosystem that delivers these measurements empowers both individuals and their healthcare providers with dynamic, personalized insights into their health. What advantages might these insights bring? Think about spotting the onset of a disease before it arrives and rapidly evaluating the effect of treatment – both in trials and in the clinic.

We believe digital biomarkers will **deeply transform healthcare** by driving innovations in disease prevention, diagnostics, treatment, and monitoring.

Read this point of view to learn why digital biomarkers are game-changing for patients, healthcare professionals, and pharmaceutical companies.

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Biomarkers go digital

Introducing digital biomarkers

BIOMARKERS

How do you know when you are ill? How do you know what the illness is? You might have symptoms like a headache or a fever. And these symptom might be indicative of a specific medical condition. But underlying these symptoms are biological processes carried out at a molecular level through chemical reactions and interactions between molecular structures. These processes are linked together in complex ways to ensure that your body performs its necessary functions. When you are suffering from a medical condition, the underlying biological activity changes. This biological activity is measurable through characteristics known as **biological markers (biomarkers)**.

Biomarker examples

The blood is the classic trove of biomarkers. Levels of biomolecules circulating in the blood such a glucose (high levels might indicate diabetes) or cardiotrophin-1 (a molecule in heart cells whose excess supply in the blood can indicate heart dysfunction) provide a window into disease processes playing out – even before a patient experiences subjective symptoms of illness. Biomolecules in other bodily fluids (like sweat) or expressed in bodily tissues (like the liver) can also serve as biomarkers. Biomarkers can also appear as features in bioimages (such as abnormalities on a mammogram that indicate breast cancer) or mutations in genes (such as BRCA genes that are linked to cancer risk because their proper function helps repair damaged DNA). Any objective and quantifiable indicator can be a biomarker if it is linked to a biological process.

DEFINITION OF A BIOMARKER

A biomarker is an objective and quantifiable indicator of normal biological processes, disease-causing processes, or responses to medical treatment.

DIGITAL BIOMARKERS

Nowadays, we are surrounded by all types of smart devices: From smartphones, smartwatches, and fitness bands, to a proliferating selection of exotic wearables and connected devices in the form of shirts, bathmats, shoes, and so on. In the context of healthcare, devices can even be implanted (e.g., a pacemaker) or ingested by patients (e.g., gastrointestinal capsules).

These connected devices can record data on diverse health parameters, such as heart rate, walking pace, typing speed, and so on. Such **digital measurements that offer insights into biological processes are referred to as digital biomarkers.**

More specifically, digital biomarkers are digital measurements that are directly related to biological characteristics[1,2].They require a direct link between the digital signal and the biological signal to be established. Agencies such as the Food and Drug Administration (FDA)[3] lean towards this definition since it builds off the traditional definition of biomarkers as objective indicators of biological processes.

Digital biomarkers are sometimes defined more broadly. An example of this is measuring human behavior (such as the pattern of interaction with a smartphone) that is correlated to a biological characteristic (such as brain function)[4].In this example, the measurement is only indirectly related to biological characteristics.

Today, the digital biomarkers market is booming. The global market is currently valued at 1.5-1.9B USD$ with an estimated growth rate of 32-36% until 2030[5,6].

According to Human First, there are more than 1,200 market players offering digital biomarkers – with more than 1,400 types of measurement.

DEFINITION OF A DIGITAL BIOMARKER

An **objective, quantifiable measure** of **physiology and/or behavior** used as an **indicator of a biological, pathological process** or response to an exposure or an intervention that is derived from a **digital measure. EMEA**

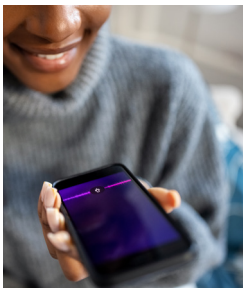
ANATOMY OF A DIGITAL BIOMARKER'S DATA

Biological data **collected digitally**, which is interpreted by **an algorithm**, and is connected to a **physiological state**.

Examples of digital biomarkers and their applications

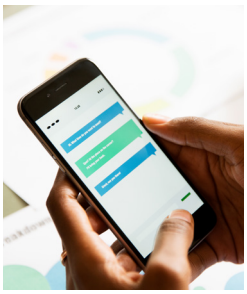
Heart rate, body temperature, and breath rate monitoring and tracking through a ring

E.g., OURA RING



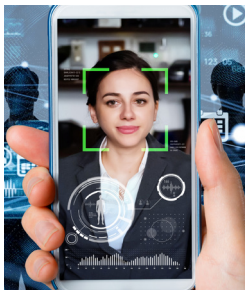
Measuring voice to track mental fitness over time

E.g., SONDE HEALTH



Measuring brain health via the energy levels of a person typing on a smartphone

E.g., NEUROKEYS



A 30-second selfie video to attain pulse, breathing rate, and more

E.g., QUANTIQ

[1] https://www.frontiersin.org/articles/10.3389/fpsyt.2021.740292/full
[2] https://www.nature.com/articles/s41746-022-00583-z
[3] https://www.ncbi.nlm.nih.gov/books/NBK326791/
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6550173/
[5] https://www.psmarketresearch.com/market-analysis/digital-biomarkers-market
[6] https://www.strategicmarketresearch.com/market-report/digital-biomarkers-market

COMPARING WITH OTHER DIGITAL ASSESSMENTS

Digital biomarkers offer a wider range of measurements than non-digital biomarkers. In addition to biological measurements, they can provide information on functional outcomes.

A biomarker is an **objective characteristic** that tracks a biological process. It is not necessarily an assessment of how an individual feels, functions, or survives (so-called, functional outcomes). As a matter of fact, **functional characteristics** are measured by (electronic) clinical outcome assessments (COA or eCOA). Digital biomarkers can capture **both concepts**[7].

Indeed, digital biomarkers may also serve as **surrogates for clinical (functional) outcomes**[8-10].To be validated as a substitute marker of a clinical endpoint, there must be a clear mechanistic or epidemiologic rationale, and well-evaluated clinical data that demonstrates that the digital biomarker predicts a specific clinical outcome. Such digital biomarkers are typically validated as surrogate endpoints for only a narrow body of cases (e.g., a specific disease setting and/or treatment regimen).

In the next chapter, we'll be looking into the technological foundations of digital biomarkers.

USES OF (DIGITAL) BIOMARKERS

Biomarkers can serve various purposes. The BEST Resource5 from the US Food and Drug Administration (FDA) identifies seven primary types of biomarkers.

- **Susceptibility/risk**: A biomarker might predict the potential for developing a medical condition in individuals without any current medical conditions.
- **Predictive**: A biomarker's presence or change might predict a patient's likely response to a specific medical intervention.
- **Diagnostic**: A biomarker might detect or confirm the presence of a disease or its subtypes.
- **Prognosis**: A biomarker might identify the likelihood of disease progression, recurrence, or a clinical event in patients with a certain medical condition.
- **Pharmacodynamic/response**: A biomarker's levels might change in response to a medical intervention and can be used to measure the intervention's biological outcome.
- **Monitoring**: A biomarker measured serially might assess the status of a disease or find evidence of exposure to particular agents.
- **Safety**: A biomarker might indicate the presence of a harmful effect of an intervention.

[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10339690/
[8] https://www.ncbi.nlm.nih.gov/books/NBK453484/
[9] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3551627/
[10] https://karger.com/dib/article/5/3/216/823092/Digital-Endpoints-Definition-Benefits-and-Current

Digital biomarkers are positioned at the junction of Clinical Outcomes Assessment (COA),* Biomarkers, and Digital Health Technology (DHT):

COA

What is measured: how patient feels, functions, or survives; must include an aspect of health meaningful to patients

How it is measured: by means of patient, clinician, observer rating. or performing a defined task

How it is validated: establishing content validity, test-retest reliability. sensitivity to change, usability

Biomarker

What is measured: normal physiology, pathology, or response to intervention

How it is measured: by means of laboratory techniques, electrophysiology methods, or imaging

How it is validated: establishing method performance characteristics and a relationship with an outcome of interest

Digital Biomarkers

Digital biomarkers

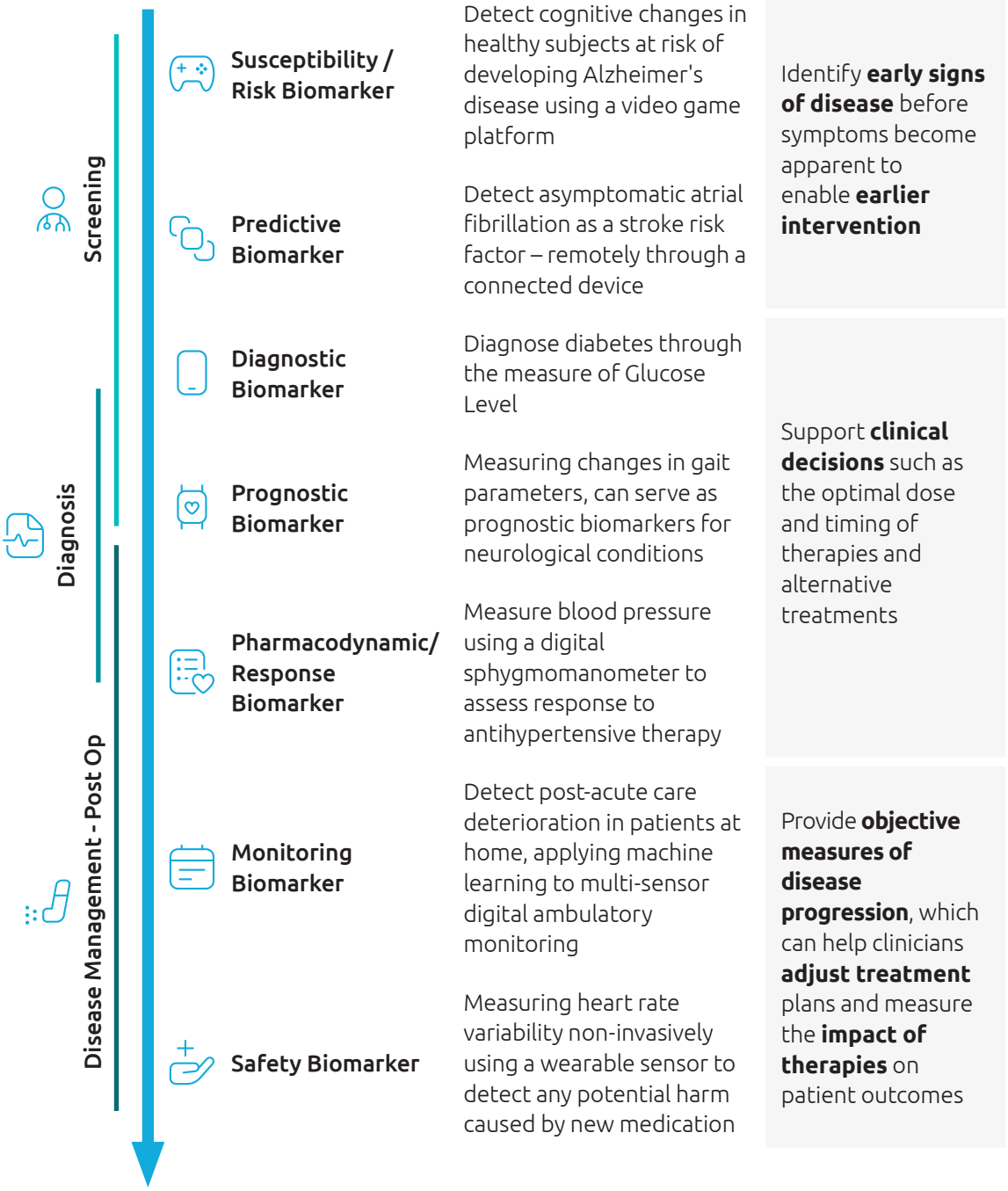
DHT-derived measure

What is measured: physiology, symptoms, function, physical activity, or response to intervention

How it is measured: objectively by means of sensors and data processing algorithms

How it is validated: establishing method performance characteristics, content validity, test-retest reliability, sensitivity to change, usability, and relationship with an outcome of interest

DIGITAL BIOMARKERS ALONG THE PATIENT CARE PATHWAY



The technology foundation

Data signals and algorithms underpin digital biomarkers

DATA COLLECTION

Digital biomarkers can provide near real-time health-related information to healthcare professionals and patients. They also give information around context, such as the time, place, and measurement conditions, which serve to enrich the biological data.

Overall, the data collected through digital devices provides a broader and more precise representation of a patient's daily status. Data collection can be active or passive; i.e., done during prompted actions or without deliberate action from the patient (with their consent).

Active data collection

Active biomarkers are captured and generated when a person **intentionally interacts with the device**; for example, eye movement tracked using a device's camera, or dexterity when doing some specific exercises. Active data collection can increase patient engagement and awareness – and collect more data points than those available during consultations.

Passive data collection

On the other hand, digital biomarkers can be collected passively by **simply wearing a device** (for example, heart rate and oxygen saturation), or **interacting with a device** (for example, stepping on a bathmat, or talking or typing on a phone). Passive collection enables the continuous monitoring of biological characteristics with little burden on the patient. Such monitoring is useful for detecting changes in health status early.

There is an acceleration of sophisticated passive digital biomarkers. Some are already available today – and others are under development and will be ready in a few years.

Outside of the mobile phones, there are various examples in the connected bathroom (e.g., bathmats (Bbalance), toilet seats), and the connected bedroom (cushions (Withings), footwear, clothing, eyewear, jewelry, and watches etc.

DATA SIGNALS

Digital devices use sensors to measure biologically relevant parameters. These bio-signals are typically processed by algorithms before being interpreted as digital biomarkers. Various sensing technologies are used to collect the bio-signals.

Examples of bio-signals

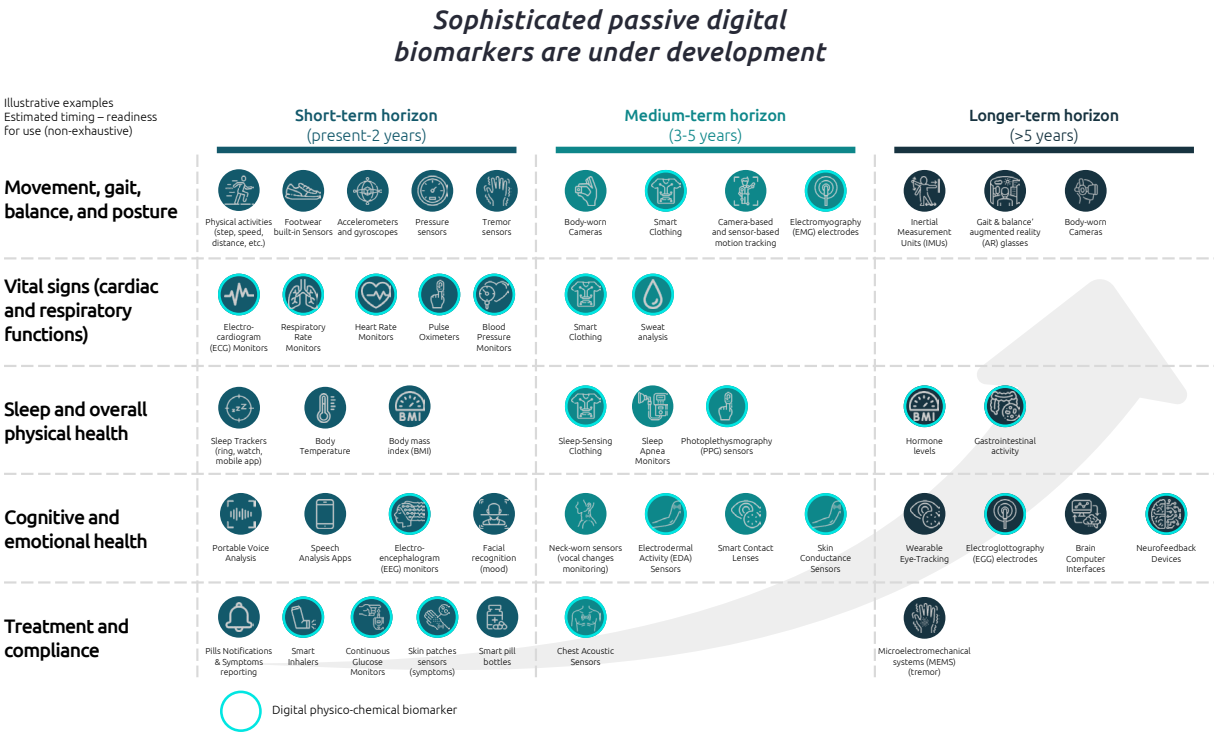
Modes of physical measurements such as light and electricity can capture relevant bio-signals.

Optical signals: Photoplethysmogram (PPG) is widely used in smartwatches and other wearable devices to monitor vital signs such as heart rate, blood pressure, blood oxygen saturation, and other physiological parameters. The signal is derived by emitting light into the skin and measuring the returned waveform pattern.

Electrochemical signals: Electrical current can be used to analyze chemical characteristics of fluid samples. For example, sweat can be analyzed for electrolytes and metabolites, which offers rich information on body hydration, osmotic balance, muscle fatigue, blood glucose levels, and so on[11].

Multi-modal signals: The bio-signals of several measuring modalities can be combined to derive a new digital biomarker. Different modalities can capture different aspects of a patient's health – and combining multiple signals can provide a more comprehensive view of a patient's health status and offer a more accurate assessment. Integrating similar bio-signals is also useful to improve the robustness and reliability of a digital biomarker.

Electrical signals: Electrical conductivity can be used to analyze the electrodermal activity of the skin. This is measured by applying a low voltage to the skin. Such actions are related to the activity of the nervous system and serve as bio-signals for stress.



Source: Capgemini analysis 2023

[11] https://www.nature.com/articles/s41378-022-00443-6

Computerized algorithms interpret sensor data

Raw data from sensors needs to be processed and interpreted. This is done through algorithms. Algorithms analyze the data to identify meaningful patterns, correlations, and associations with disease.

There are three main types of algorithms used to process bio-signals for digital biomarkers:

1. **De-noising:** Removes outliers and distortions in the data
2. **Enhancement:** Improves data quality and accuracy. For example, dealing with missing values and adjusting for factors such as age, ethnicity, and gender (bias management)
3. **Prediction layer:** Enables real-time data interpretation

Additionally, algorithms are also used to **generate bio-signals from raw data sources**. For example, computer vision algorithms can extract digital biomarkers from images and videos. Algorithms can also extract digital biomarkers for audio files, such as a patient's speech pattern. These extracted bio-signals can then be analyzed further. For example, certain speech patterns are correlated with conditions like Parkinson's disease.

In some cases, algorithms are used to **derive multi-modal digital biomarkers**. These are based on a combination of digital biomarkers and are treated as a **composites**.

VALIDATING A DIGITAL BIOMARKER

Digital biomarkers must undergo thorough study to be validated for their intended uses.

Analytical and clinical validations

There are two main aspects for establishing whether a biomarker is fit for purpose. Firstly, the method of biomarker testing must be validated to ensure that the test can replicate the measures that it is intended to analyze (**analytical validation**). Secondly, the biomarker must be validated for its ability to measure or predict a relevant clinical concept (**clinical validation**). The biological signal and the means of testing for the signal are tightly coupled with digital biomarkers. This differs from traditional biomarkers where the biological signal and the device used to measure can be seen as separate.

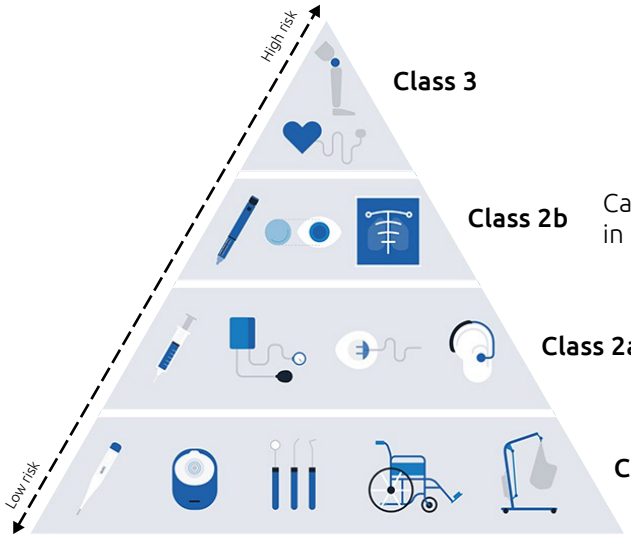
Aspects such as the **quality of data** collected by the device and the **operation of the algorithm** must also be validated.

Digital biomarkers as medical devices

A digital biomarker is considered a medical device **when it is used in a medical context to diagnose, treat, or prevent disease**.

As such, digital biomarkers must undergo a **regulatory assessment**. Medical devices are approved for use under different classes depending on the risk they present to the patient's health. Digital biomarkers can be classified between **Class I with measurement function to** in the EU. The FDA defines similar **Class IIb** classes of medical devices and has an additional classification for software as a medical device (SaMD) when the algorithm is used for medical purposes – but is not part of the device's hardware. The software aspect of digital biomarkers may also fall under the risk-based assessment of the EU's proposed AI Act if relevant algorithms are used.

Digital biomarkers are classified from Class 1 to 2b in Europe



Can cause serious deterioration in a person's health or surgery

Intended to provide information used to make decisions for therapeutic or diagnostic purposes

Intended to provide information used for patient monitoring and carry very little patient risk

TECHNOLOGY ECOSYSTEM

As the use of digital biomarkers increases, each patient will benefit from multiple types of measurements linked to different devices. These measurements will offer a broader view of a patient's health status and will create more actionable information for both patients and healthcare professionals.

This will also offer patients and HCPs new ways to communicate around common and interpretable health data.

However, different issues will need to be solved. One of these is around systems and data interoperability. There will need to be software **interoperability** between HCP / hospital and patient devices – and between the various digital biomarkers.
Another issue will be linked with how the data is used, owned, and aggregated with the **patient's consent**. New ways of collecting data through federated learning are currently being investigated.

A third issue will be around aggregation of digital biomarkers. Indeed, insights from several digital biomarkers will need to be presented in a consolidated manner – and perhaps even processed further to reveal additional insights captured in the interaction of bio-signals.

In the next chapter, we continue our digital biomarkers journey and explain why they are real gamechangers.

Digital Biomarkers are game changers

Biomarkers can bring benefits to patients, HCP, payers, and pharmaceutical companies

Digital biomarkers hold a very strong promise that speaks to all stakeholders of the healthcare ecosystem – from patients, to HCP, payers, providers, and Life Sciences companies.

THE BENEFITS OF DIGITAL BIOMARKERS FOR PATIENTS AND HEALTHCARE PROFESSIONALS, AND PAYERS AND PROVIDERS

Digital biomarkers offer three main benefits over conventional biomarkers, which position them as gamechangers for healthcare: Improving the patient journey, reducing healthcare costs, and saving care team time.

Improve the patient journey

Digital biomarkers collect biologically relevant measurements of patients in their **daily environments**. These measurements are typically **non-invasive**. Patients can therefore receive **continuous feedback** and support, such as alerts or reminders for medication adherence, physical activity, or other health-related behaviors. This also makes patients more engaged to actively participate in their own healthcare.

In a nutshell, digital biomarkers can simplify the patient journey by offering less invasive measures, always having measurements handy, avoiding unnecessary travels to the doctor's office, and receiving better holistic care (including psychological and physical care).

Helping the care team save time

The data provided by digital biomarkers can enable healthcare professionals to **monitor patients remotely**. As the information is collected directly from individual patients, the process of gathering this data is **more efficient** and can provide a **better and unbiased view** of the patient's health status. It also helps physicians allocate their time more effectively to patients with the most pressing needs and acute problems. The data also enables HCPs better follow up and personalize treatments – and ultimately improve the quality of care.

Reduce healthcare costs

Digital biomarkers can continuously monitor an individual's physiological parameters. Analysis of these measurements can provide **early signs** of health issues – and the ability to deliver **proactive interventions and preventive measures**. Detecting disease early normally means that it is easier and cheaper to treat. Digital biomarkers can also enable more **effective treatments** with better patient outcomes because they are tailored to individual needs based on data from digital biomarkers.

Minimizing the severity of a disease reduces hospitalization and monitoring costs and cuts down patient time in hospital. RDS, a digital biomarker company, is providing follow up kits to hospitals so that patients can be discharged earlier and still be fully monitored from home.

Digital biomarkers can benefits patients, HCP, and payers

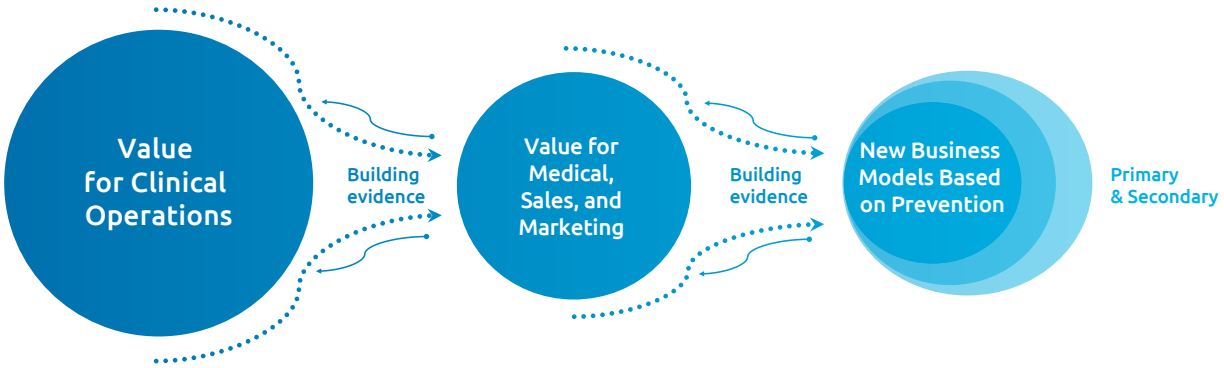
Improving the patient journey	Helping care teams save time	Reducing healthcare costs
• Less invasive measures • Easy to use • Cost and travel avoidance to the point of care • Better holistic care including psychological and physical care	• More efficient data collection • Remote monitoring • Monitoring by exception	• Preventive actions / avoiding worsening and acute events • Decrease total hospital and re-admission costs • Enable home care • Decrease overall costs of chronic diseases

THE PROMISE OF DIGITAL BIOMARKERS FOR PHARMA

Digital biomarkers also hold promise in creating value for pharmaceutical companies. We consider three levers of value creation for pharmaceutical companies, spanning short and long-term growth perspectives:

- Help clinical trials become faster and more precise
- Deliver more personalized patient treatments and experiences by offering more real-world data
- Support proactive prevention measures

Digital biomarkers hold promise in creating value for pharmaceutical companies



TIME HORIZON	Short-term	Mid-term	Longer-term
Value creation levers	• Better patient recruitment and lower drop-off • Optimized trial design and resources • Earlier decision on clinical trials (early termination and improved attrition) • More data on relevant patient stratification • Faster submission time	• Collection of RWE data (medical) • Beyond the pill: Personalized treatment experience and monitoring • DTX • Early patient diagnosis • Improved adherence	• Personalized prevention program for chronic diseases, oncology, or others with a link to lifestyle habits
	→ Cost reduction & speed to market	→ Additional revenues	→ New revenue streams

Value in clinical trials

The use of digital biomarkers can **increase precision** and **reduce the cost of clinical trials**, thereby speeding up the time to market of medicines and improving the return on investment for pharmaceutical companies.

Improved data collection precision
Incomplete data results in 30% of participants being excluded from clinical trials. The use of digital biomarkers enables easier gathering of data and makes for a better patient experience. This is both because digital biomarkers can gather biometric data passively from a network of connected devices – and because they provide real-time and instant alerts to address issues promptly.

In addition, digital biomarkers offer objective measures compared to (electronic) clinical outcome assessments, where patients may forget to provide feedback or distort their responses. It is also more accurate to use digital biomarkers over time than testing patients at different specific intervals (e.g., early in the morning or at the end of the day).

Reduced trial cost and improved access
The cost of clinical trials can be reduced by remotely tracking patients (in decentralized clinical trials or hybrid trials). Digital biomarkers enable the delivery of individualized care remotely and the ability to send health data directly to doctors and researchers. They also help reach a diverse set of patients who are located further away from the investigator sites – or who do not have the time or the means to travel.

EXAMPLE: DIGITAL BIOMARKERS IN PARKINSON'S DISEASE TRIAL

Parkinson's Disease (PD) is a progressive neurological disorder. Clinical trials for PD require a physical assessment of the disability and in-person patient visits. Attending these examinations can be a major obstacle for patients.

Emerging opportunities for the use of digital biomarker PD trials include utilizing wearable sensors and movement-related digital biomarkers. These digital biomarkers help provide real-time monitoring and the quantification of mobility outside the clinic, which can lead to quicker and more accurate understanding of disease progression.

Ongoing clinical studies are outlining the need for novel digital outcome measurements that can diagnose PD earlier. For example, in 2022, Koneksa[12] partnered with Aural Analytics to support clinical trials using speech measures to develop a variety of digital biomarkers for PD in collaboration with Northwestern University and the Michael J. Fox Foundation.

[12] https://rockhealth.com/insights/the-emerging-influence-of-digital-biomarkers-on-healthcare/

Value across medical sales and marketing

Pharmaceutical companies can create additional revenue streams by delivering personalized treatment and patient monitoring through early diagnostics, digital therapies, and the collection of real-word data.

Easy disease diagnosis
Digital biomarkers can add value to diagnostics through early disease detection and by reducing misdiagnosis. Early detection of disease means better targeting of additional patients for early diagnosis – and adding value through early initiation of treatment.

Personalized treatment
Digital biomarkers are inherently personalized, as they are collected by individuals. By analyzing this data, clinicians can identify changes in a patient's health and the adherence to a particular therapy.

Digital biomarkers can be used for predictive insights regarding a patient's disease trajectory and defining and improving patient quality of life[13,14].

Patient engagement within treatment
Patient involvement in treating and reporting their condition is essential for improved clinical outcomes, and digital biomarkers are uniquely positioned to facilitate this.

They enhance patient engagement by providing continuous access to personalized health data, which can also be shared with healthcare teams to analyze, interpret, and improve treatment outcomes[15].

Collection of real-world data
Digital Biomarkers are non-invasive and enable the collection of population-level health data over time, while also providing continuous insight into individuals' health[16,17].

This information can in turn equip the medical team with insights and give them some additional data points to further engage with medical stakeholders and health authorities.

Digital biomarkers could potentially define specific characteristics of the population that could benefit from investigational drugs. This data could then be used to inform clinical pathways for drug development.

New business models based on prevention

Although further away from their traditional drug models, pharmaceutical companies could consider new business models **around proactive prevention** and offer new services to payers. Digital biomarkers would enable new revenue streams around personalized prevention programs for chronic diseases, neurodegenerative diseases, or cancers.

Primary prevention
The value of digital biomarkers would be realized in **primary prevention**, including measures that prevent the onset of illness before the disease process begins and symptoms of disease present themselves (e.g., identifying early pre-diabetes patients with a risk for developing type-2 diabetes).

Secondary prevention
Digital biomarkers could also be used for **secondary prevention** to stop patients from experiencing an escalation in their disease.

[13] https://medcitynews.com/2023/06/digital-biomarkers-the-key-to-delivering-on-the-promise-of-personalized-medicine/
[14] https://www.frontiersin.org/articles/10.3389/fdgth.2020.614670/full
[15] https://www.oxfordglobal.co.uk/resources/patient-engagement-in-biomarker-development/
[16] https://rockhealth.com/insights/the-emerging-influence-of-digital-biomarkers-on-healthcare/
[17] https://karger.com/dib/article/3/2/92/99753/Traditional-and-Digital-Biomarkers-Two-Worlds

HOW CAN WE ACCELERATE THE PROCESS? WHAT CHALLENGES MUST BE OVERCOME TO UNLOCK FULL IMPACT?

For digital biomarker markers to make an impact, they need to be created by manufacturers, used by healthcare professionals, accepted by patients, and validated by regulatory authorities. The challenges need to be considered from the perspective of each stakeholder to make the adoption of digital biomarkers successful.

Pharmaceutical companies

To realize the potential of digital biomarkers, pharmaceutical companies need to define a **clear portfolio strategy** that sets out where they will invest their efforts. Their strategy could be based on a therapeutic area, or whether to pursue a disease-agnostic or disease-specific digital biomarker. This strategy needs to **demonstrate the financial impact** of the investment and may require **collaboration with startups**, in which case, the economic model for collaboration and ownership of intellectual property must be established.

Pharmaceutical companies also must overcome the **complexity of validating** digital biomarkers. There are technical complexities that come with the **magnitude of data** that must be managed – and the technical **integration between connected devices, apps, and back-end platforms**. Finally, they will require **organizational change and new capabilities** within their companies.

Healthcare professionals

For healthcare professionals to adopt digital biomarkers, the solution must be **simple to use** throughout the treatment protocol. It must be easy to enroll patients, and easy to monitor all the relevant parameters and cover all the treatment steps. The usage of digital biomarkers must be embedded in their daily workflow.

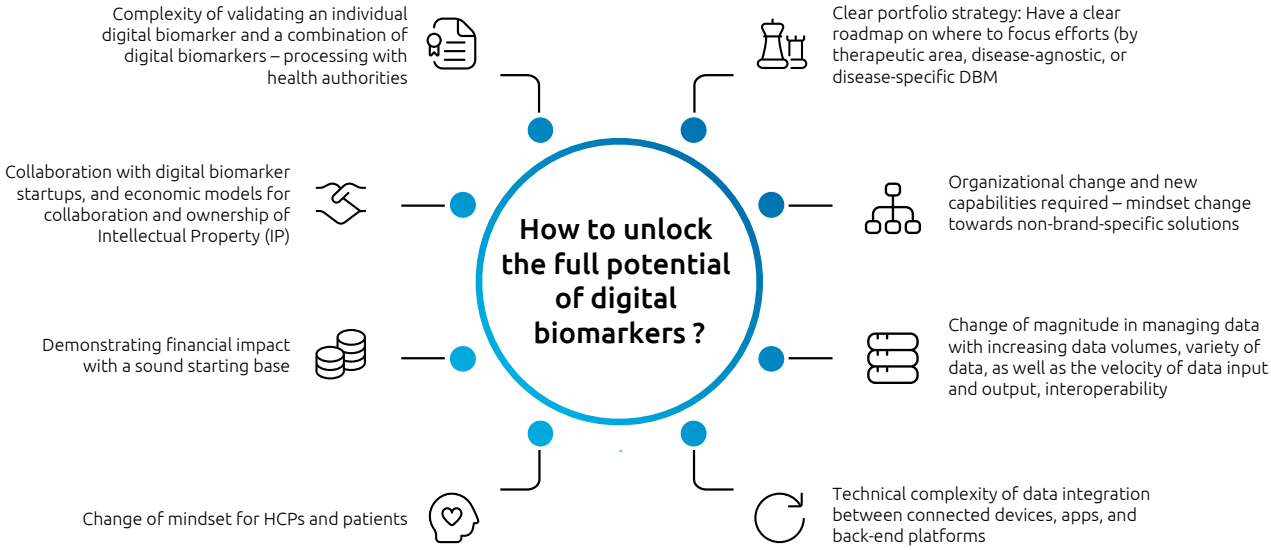
Patients

For patients to adopt digital biomarkers, they need **to experience the added value** of using the solution, such as better care and more personalized treatment. Patients also need to **have the right motivation to continue using the digital biomarker**. In this sense, passive and minimally invasive digital biomarkers could be a starting point for patient adoption.

Health authorities

Finally, the authorities need to be wholly supportive of digital biomarkers. This means validating them as end-points for clinical trials and as measures for treatment and diagnosis. In non-clinical cases, they have an important role to play in the potential reimbursement of digital biomarkers. The winds of change are starting to turn, and we see some positive dynamics with the FDA, EMEA, and within European countries (e.g., DIGA in Germany).

Challenges in scaling up digital biomarkers for pharma companies



The way forward

Developing tomorrow's digital biomarkers today

Digital biomarkers hold great potential for improved healthcare. They offer patients the promise of being more informed about their health. This shifts healthcare to a proactive stance – where treatment can be offered in a preventative manner outside of hospitals. Digital biomarkers will also change the interaction between patients and healthcare professionals. They provide the potential for a more comprehensive and real-time overview of a patient's health status, which aids healthcare professionals in monitoring patients remotely and providing more personalized care.

Digital biomarkers exist in a complex ecosystem. The implementation of digital biomarker technology will drive change in organizational processes, the clinical care pathway, and clinical trials. However, the **commercial success of digital biomarkers will largely be driven by patients**. Patients need to experience the added value of the technology. They must experience better care when they use digital biomarkers. At the same time, healthcare professionals must feel enabled by digital biomarkers. To be successful, digital biomarkers must reduce complexity for healthcare professionals and improve patient health outcomes. They must be simple to use throughout the treatment protocol and cover all treatment steps.

To bring this promise to life, pharmaceutical companies must develop functional digital biomarkers. Pharmaceutical companies must define the value digital biomarkers can offer them in terms of cost savings, as well as additional and new revenue streams. Digital biomarkers offer the promise of making clinical trials more efficient. Personalized treatment and proactive prevention are new revenue streams for pharmaceutical companies to explore.

To accelerate digital biomarker development, pharmaceutical companies must first get the technology right. This means linking digital measurements to disease through an algorithm. Patients typically present with a wide spectrum of symptoms. Aggregating measurements to make data speak in a medically meaningful way requires good data collection, mastery of algorithms, and system interoperability. Having the right technology also means designing user-centric products that meet the needs of patients and healthcare professionals. All these elements must be coordinated.

So, what promise can digital biomarkers offer your company? Do you want to know how to start your digital biomarker transformation?

Contact us below to get started.

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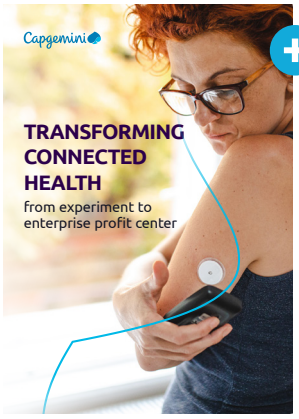

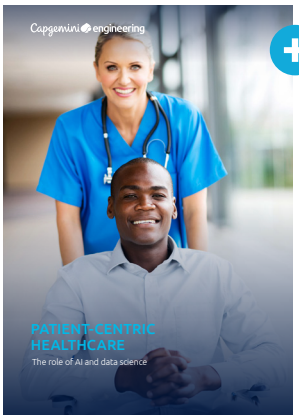

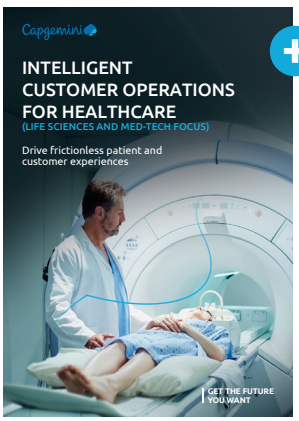

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SPECIAL THANKS

The authors would like to thank Salma Benchekroun, James Blakemore, Vincent Mittoux, Barnabé Lecouteux, and Rim Laarif for their precious contributions.

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