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By extracting deep insights from clinical and digital biomarkers and other real-world data sources, digital transformation initiatives can power precision medicine, improve clinical outcomes, and optimize return on investment for pharma.

How Digital and Clinical Biomarkers Drive a Precision Medicine Strategy

October 2022

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Integrating Insights from Clinical and Digital Biomarkers

Traditional or clinical biomarkers are routinely used to diagnose and track the progression of disease and monitor the safety/efficacy of a therapy. They are frequently used as surrogate markers, which replace clinical outcomes for regulatory approvals of clinical trials. Clinical biomarkers are usually less expensive than clinical outcomes and can be measured more objectively and consistently. However, fueled by patients going remote and the acceptance of decentralized clinical trials, digital biomarkers are being rapidly adopted. Unlike clinical biomarkers, digital biomarkers are noninvasive. They can be measured passively and continuously using digital devices such as sensors, wearables, implantables, digestibles, and mobile phones and are less expensive. They can provide longitudinal, quantifiable physiological and behavioral data that can yield valuable insights in real-world settings.

The ability of digital biomarkers to capture data in a noninvasive manner is particularly valuable when dealing with patients who require long-term follow-up. The digital biomarkers market has seen double-digit growth, driven by the unique insights that digital biomarkers provide about a patient's health. More than 500 studies related to digital biomarkers are listed on **clinicaltrials.gov**, indicative of the growing use of digital biomarkers today.

The "patient sapiens" — the digitally savvy patients of today — are willing to adopt technology (and often enthusiastic about doing so). The rise in mental health issues during the pandemic and the relaxation of digital health regulations have also fueled the need to be able to remotely monitor patients' mental health and have driven the growth of digital therapeutics, which operate based on digital biomarkers. Artificial intelligence (AI) and machine learning (ML) are being used to transform the massive data influx from digital therapeutics into meaningful intelligence, driving treatment decisions. With the shift to the cloud, hyperscalers are adding the critical element of scalability and flexibility to power integrated insights.

AT A GLANCE

KEY STATS

- IDC's *AI Path Survey* (May 2021) found that more than 56% of the life sciences industry was planning on increasing its AI spend on clinical trial recruitment in 2022.
- Life sciences companies that adopted digital transformation saw a more than 50% increase in revenues, compared with the industry average of 21%, according to IDC's *Future Enterprise Resiliency and Spending Survey, Wave 5* (June 2022).

KEY TAKEAWAYS

As the focus on precision medicine and personalized care continues to scale, the ability to develop an integrated view of a patient's health profile by monitoring multiple data points that relate to clinical outcomes (including digital and clinical biomarkers) is becoming critically important.

Digital biomarkers including motion, sleep, voice, heat, subtle eye movements, photoplethysmography (PPG), and breathing can effectively monitor both physical and mental health issues. Biomarkers can be categorized into different types based on their application:

- **Diagnostic biomarkers** confirm the presence of a disease or condition of interest.
- **Susceptibility biomarkers** assess the risk of developing a disease.
- **Monitoring biomarkers** consistently monitor the status of a disease.
- **Prognostic biomarkers** identify the likelihood of a clinical event, disease recurrence, or disease progression.
- **Predictive biomarkers** identify individuals more likely to experience a favorable or unfavorable effect.
- **Pharmacodynamic/response biomarkers** assess a biological response to a drug or an environmental agent.

The ability to combine insights from both digital and clinical biomarkers, and to obtain a holistic understanding of a patient's health, holds enormous promise. The integration of multiple biomarkers reshapes trial design and fine-tunes patient recruitment, allowing one to select patients who specifically meet inclusion criteria. This integration optimizes trial outcomes and fuels a precision medicine strategy. A biomarker hub that can integrate these diverse types of biomarker data and tap into phenotypic and digital real-world data (RWD) provides powerful synergies to drive clinical trial strategy, inform clinical trial design, and drive portfolio management decisions.

Key Use Cases for Integrating Digital and Clinical Biomarkers in Life Sciences

Patient Recruitment

Patient recruitment has always been a huge challenge for the clinical trial industry. As per the Tufts Center for the Study of Drug Development (CSDD), more than one-third of clinical trial sites under-enroll, and 11% fail to enroll a single subject. More than 80% of clinical trials are delayed by at least one month, and a third of patients drop out of clinical trials, further delaying approvals and resulting in significant revenue loss. Tufts CSDD has reported that 30% of Phase III studies fail due to enrollment challenges. In certain therapeutic areas such as oncology, the recruitment rate is as low as 3%. In the case of rare diseases, it may be difficult to find more than one patient per site. In such cases, the mining of electronic medical record (EMR) data can be used to geotarget patients, enabling one to drill down on sites with patients who have those rare or ultra-rare diseases. The use of clinical biomarker data can help zero in on the right patients, increasing accuracy and speed. For example, the detection of epidermal growth factor receptor (EGFR) gene mutations, which occur in 10–35% of patients with non-small cell lung cancer (NSCLC), can serve as a quick indicator to detect patients with this condition. In addition, precision neurology platforms are being developed that leverage cognitive and functional digital biomarkers to provide a cross-sectional and longitudinal analysis of brain health and enable the early diagnosis of Alzheimer's disease. Thus, the integration of genotype-based disease-risk stratification, neuroimaging phenotype analysis, and cognitive biomarkers can power accurate and rapid patient selection for clinical trials with neurological disorders.

Clinical Trial Design

The industry is implementing biomarker-based clinical trial design, integrating prognostic and predictive biomarkers into core clinical trial strategy. While cancer drugs are usually developed based on single gene or protein predictive biomarkers, multivariate classifiers have been used mainly as prognostic indicators for disease progression. The integration of composite lifestyle biomarkers in trial design provides valuable insights regarding patient experiences and the impact of the therapy on a patient's quality of life.

Predictive and Preventive Care

There is extensive application of digital biomarkers to monitor patient behavior and mitigate risk. For example, wearable heart monitors are used to detect heart arrhythmias, while motion sensors that assess an individual's gait are being used to predict and preempt the risk of falls in patients with Parkinson's disease and vocal and visual biomarkers are being validated to predict suicidal ideation.

Definitions

- **Clinical biomarkers:** The BEST (Biomarkers, EndpointS, and other Tools) team of the FDA-NIH Biomarker Working Group defines a biomarker as a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. This can include molecular, histologic, radiographic, or physiologic characteristics.
- **Digital biomarkers:** The FDA defines a digital biomarker as a characteristic or set of characteristics collected by digital health technologies that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions.
- **Clinical trial endpoints:** They measure the outcomes of the trial, including clinical outcomes and surrogate endpoints.
- **Clinical outcomes:** They directly measure whether trial participants feel or function better or live longer.
- **Surrogate endpoints:** A surrogate endpoint is a clinical trial endpoint used as a substitute for a direct measure of how a patient feels, functions, or survives. While surrogate endpoints may stand in for clinical outcomes, even though they are not yet validated under the FDA's Accelerated Approval Program, they do need to be validated through post-approval studies. Although all surrogate endpoints are biomarkers, not all biomarkers are useful surrogate endpoints, and only a few qualify as surrogate endpoints based on the FDA's Biomarkers Qualification Program.

Considerations

The development and qualification of biomarkers include the following key steps:

- **Analytical validation:** Whether the biomarker can provide reproducible and accurate measurements
- **Clinical validation:** The degree to which the biomarker can be used as a surrogate for clinically relevant conditions or outcomes
- **Assessment of clinical utility:** The practical use of the biomarker in real-world clinical practice

The complexity in using biomarkers lies in identifying the endpoints with clinical significance and in validating them, determining which biomarkers serve as true identifiers of a specific disease population or as indicators of the performance of a study drug. When it comes to technology-enabled measurements, one initially needs to assess their potential in real-world settings, quantify the benefits and costs of these technologies, and drive analysis to demonstrate concrete business value to fuel investment in technology. Resources need to be allocated ahead of time to run technology-inclusive study designs well before initiating pivotal studies. Study teams need to provide guidance on specific signals that are indicative of treatment response.

Considering Wipro

Wipro's strengths lie in product engineering, IoT gateway and blockchain, cybersecurity, data-driven advanced analytics, and technology infrastructure services and support, complemented by its strong life science domain expertise. Founded in 1945 and headquartered in Bengaluru, India, with offices in the Americas, APAC, Africa, Europe, the Middle East, and India, Wipro has been serving the life sciences industry for 19 years. It has more than 230,000 employees and pursues a "digital first" approach, focusing on the four foundational pillars of business value generation, connected intelligence, compliance, and trust.

Wipro has its own genomics labs with next-generation sequencing (NGS), reverse transcription polymerase chain reaction (RT-PCR), viral proteomics, vaccine analysis, and target validation capabilities and is supporting customers with the development of digital biomarkers. Wipro leverages its proprietary platform for AI (Wipro Holmes) and its Data Discovery Platform (DDP), complemented by its Wipro Biomarker Hub, to integrate digital and clinical biomarker data.

Wipro's global genomic database is built through the company's partnership with 4basecare, providing direct access to TarGT Indiegene, a large tumor gene panel in APAC encompassing comprehensive tumor profiling of more than 1,500 cancer patients covering 28 different cancer types, 450 histological types, and more than 1,000 genes. Wipro leverages its platform to carry out the annotation, aggregation, and integration of variant data and identifies mutational signatures to carry out tumor gene profiling. This activity provides insight into mechanisms of disease progression while also leading to greater understanding of why certain patients do or do not respond to treatments and allowing for the analysis of heterogeneity in immune response to help target new therapeutic agents.

After the clinical biomarker profiling, Wipro taps into EMRs to carry out the geotargeting of patients, accurately identifying sites with patients who express the right clinical biomarkers/tumor profiles, thus accelerating clinical trial recruitment. Further, Wipro leverages RWD garnered through Wipro's patient portal (as well as through wearables and sensors) to identify digital biomarkers of interest and then uses scalable compute through its partnerships with hyperscalers to derive meaningful insights on disease progression and on patient experiences.

Wipro brings to the table a comprehensive set of solutions, including the Wipro genomic database, the Wipro patient portal, the Wipro Biomarker Hub, enriched RWD (publicly accessible or procured) and AI-powered insights to accurately identify patients who meet the specific inclusion criteria of a study protocol, to identify the optimal trial sites and improve clinical trial outcomes.

Challenges

Wipro does face the following market challenges, however:

- **Working with scientific experts to define the right biomarkers:** This is no easy task, and it requires a deep understanding of the disease area to pinpoint the right biomarkers that will provide objective, consistent, and measurable results. Expertise is required not only in qualifying these biomarkers but also in validating them.
- **Data integration and governance:** The integration of multimodal data brings in its own challenges as data types may vary significantly. It is essential to establish robust data governance models and delineate well-defined data flows.
- **Data security and privacy:** Cybersecurity becomes critical when dealing with extremely sensitive protected health information (PHI). Cyberattacks against the life sciences industry have been accelerating, and this calls for extreme caution. One needs to ensure compliance with regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR).
- **Orchestrating complex workflows:** There are multiple moving parts, and the complexity is high. Streamlining workflows and data flows and ensuring data integrity through the entire process will be challenging.

Conclusion

With the molecular profiling of an individual patient becoming more affordable and accessible, and with the accelerated adoption of the Internet of Medical Things (IoMT), wearables and sensors, and mobile apps, clinical trials are increasingly using both clinical and digital biomarkers to personalize care and design therapies that work for patients.

If Wipro can effectively address the challenges described in this paper, then by leveraging its Wipro Biomarker Hub, its patient portal, its global genomic tumor database, and the scalability and flexibility garnered through partnerships with hyperscalers, it can generate deep data-driven insights that can help the life sciences industry drive precision care, accelerate trial recruitment, and speed time to market.

The integration of clinical and digital biomarker data with genomic and phenomic real-world data is providing a holistic, integrated view of the patient, fueling precision medicine and scaling patient-centric care.

About the Analyst

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Dr. Nimita Limaye is a Research Vice President with IDC Health Insights and provides research-based advisory and consulting services as well as market analysis on key topics related to R&D strategy and technology in the life sciences industry. She addresses aspects such as the role of digital transformation in discovery research and eclinical ecosystems.

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