



Onera Health Recognized for

2021

Technology Innovation Leadership

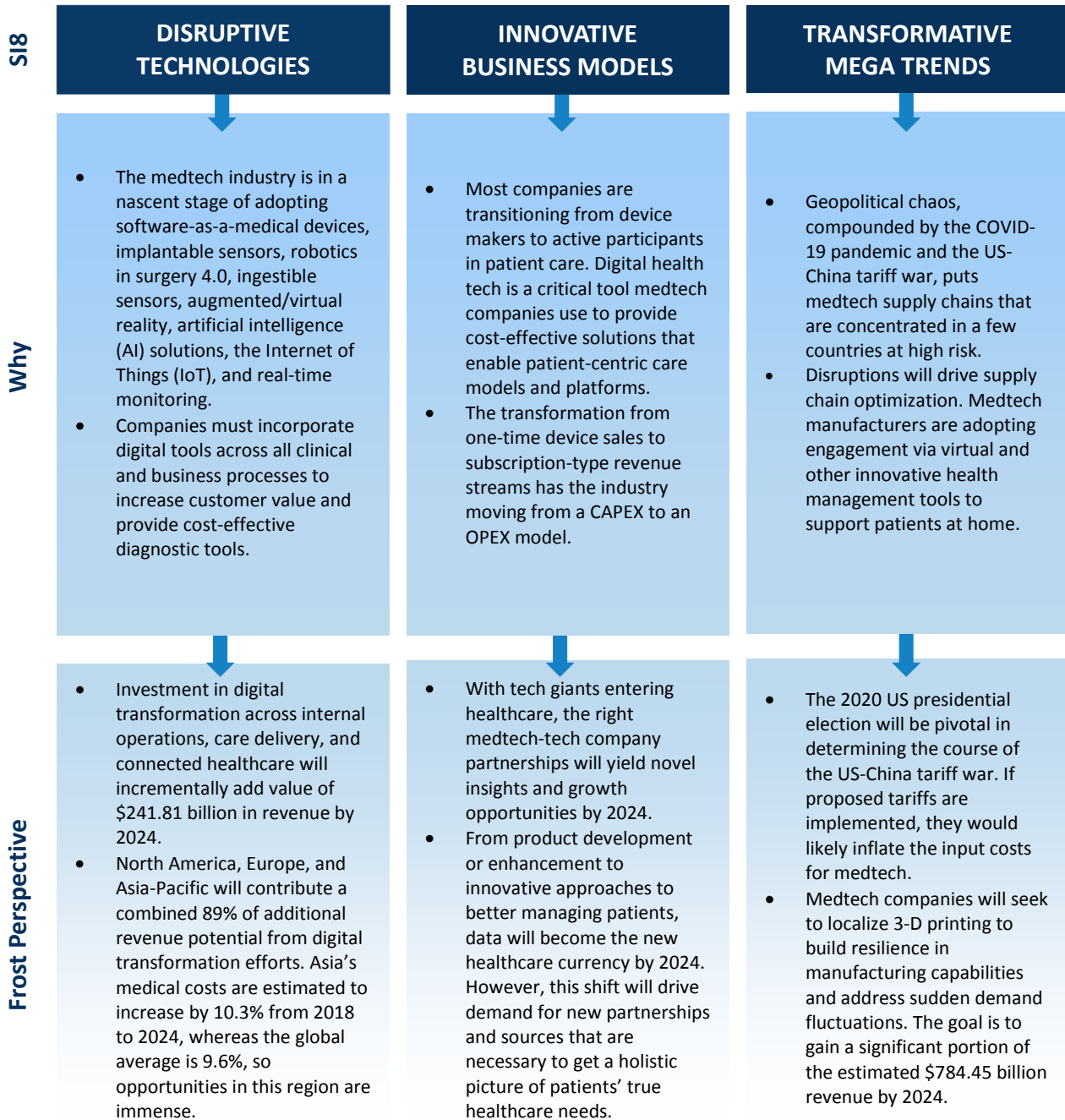
European

Sleep Diagnostics Industry

Excellence in Best Practices

Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the medtech industry: disruptive technologies, innovative business models, and transformative Mega Trends. Every company that is competing in the medtech space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan’s recognition of Onera Health is a reflection of how well it is performing against the backdrop of these imperatives.



Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Onera Health excels in many of the criteria in the sleep diagnostics space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Business Impact</i>
Commitment to Innovation	Financial Performance
Commitment to Creativity	Customer Acquisition
Stage Gate Efficiency	Operational Efficiency
Commercialization Success	Growth Potential
Application Diversity	Human Capital

Addressing Needs with Innovative Solutions

Sleep disorders cause adverse health effects, and early identification can result in improved quality of life and reduced mortality¹. One in five people suffers from a sleep disorder, with the most common being chronic insomnia, obstructive sleep apnea (OSA), restless leg syndrome, and abnormal periodic leg

“With comprehensive diagnostics/monitoring functionality, Onera Health’s medical-grade technology helps to not only identify various sleep disorders, but also enable clinicians to remotely monitor patients to optimize treatment.”

– **Srinath Venkatasubramanian, Industry Analyst, Transformational Health**

movements during sleep. Sleep disorders such as insomnia, sleep apnea, and narcolepsy can lead to severe chronic conditions, including cardiovascular diseases, stroke, and depression. Sleep apnea is characterized by the cessation of breathing during sleep. Depending on the traits of breathing events, there are three types of sleep apnea: OSA, central sleep apnea, and mixed sleep apnea. OSA, the most common type, occurs in more than 80% of sleep apnea cases. With neurological and cardiovascular morbidities, OSA is a serious medical condition that can lead to various

¹ <https://academic.oup.com/sleep/article-abstract/43/10/zsaa072/5819386>

complications such as daytime fatigue, sleepiness, hypertension, cardiovascular problems, and diabetes. However, it remains undiagnosed in most cases, even in developed countries. In terms of prevalence, 936 million and 425 million adults (aged 30 to 69 years) are estimated to have mild to severe OSA and moderate to severe OSA, respectively².

Founded in 2017 and headquartered in Silicon Valley, Onera Health is an innovative medical device company that simplifies access to sleep disorder diagnosis through its unique, compact, patch-like device which has obtained the CE mark for Medical Devices for commercialization in Europe and is currently pending regulatory approval in the United States. The company aims to democratize sleep monitoring by enabling individuals to run the test in the comfort of their home. With comprehensive diagnostics/monitoring functionality, Onera Health's medical-grade technology helps to not only identify various sleep disorders, but also enable clinicians to remotely monitor patients to optimize treatment. Frost & Sullivan commends the company's mission to advance sleep testing by making sleep diagnostics and monitoring more accessible and user-friendly with the world's first at-home medical-grade sleep diagnostic patch technology.

Commitment to Innovation and Creativity

Onera Health fills a market gap with accessible sleep diagnostics, changing the way sleep testing can be conducted. The current diagnostic technologies are cumbersome or non-comprehensive, and many individuals have limited access to sleep professionals and appropriate infrastructure to diagnose and treat sleep disorders. Polysomnography (PSG), the current gold standard in sleep testing, is expensive, ridden with technical difficulties, and only available in hospitals, sleep laboratories, or sleep clinics, making it inaccessible to most individuals and resulting in poor case detection rates; only one-fifth of sleep disorder cases are diagnosed. Respiratory polygraph, a portable alternative to PSG, does not offer comprehensive and reliable diagnosis of sleep disorders. Due to issues with affordability, accessibility, and ease-of-use, sleep diagnostic tools' penetration in the market is minimal. As such, a significant proportion of the population is unable to get tested and treated.

Onera Health's groundbreaking device is a huge step forward in terms of ease-of-use and ease-of-diagnosis. The non-invasive, compact smart device powered by artificial intelligence (AI) technology conveniently brings the gold-standard quality of a hospital diagnosis directly to a user's home. With the device's simplicity and ergonomic design, the user does not need to visit a sleep clinic and be in close contact with a healthcare professional, making the contactless procedure an infection risk-free solution. Onera Health's innovative, convenient, and reliable patch can solve the space crisis and challenges in accessing healthcare professionals as users can instantly connect to a sleep professional through its platform, which also sends data to clinicians remotely. The patch is simple to use (similar to applying a band-aid), portable, and offers a comprehensive diagnosis similar to traditional PSG, enhancing the user experience. Apart from at-home diagnostics, the patch can be used in hospitals and patient wards that have no access to a sleep clinic. To maintain its competitive advantage, the company's research and

² <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7007763/>

development team based in the Netherlands is constantly innovating the technology to improve outcomes and deliver superior clinician and patient experience.

Economic Value and Application Diversity

Onera Health's sleep diagnostic patch provides value to multiple stakeholders. It provides clinicians with access to patients who would otherwise remain undiagnosed and not seek medical therapy. By providing insights into patient health status, the patch enables specialists such as cardiologists and neurologists to understand patients better before recommending or starting a treatment, improving patient outcomes. By diagnosing the condition early and in the comfort of the user's home, the device provides value to payers through saving cost of care as potential morbidities and visits to sleep clinics or hospitals can be minimized. These benefits are aligned with the tenets of value-based care through appropriate care utilization and improvements in cost efficiency and patient outcomes.

Apart from diagnosing common sleep disorders, the patch is able to remotely monitor neurological and respiratory functions, helping patient cohorts in home care, skilled nursing facilities, and rehabilitation facilities and patients with chronic conditions or infectious diseases such as COVID-19. The respiratory and cardiovascular parameters captured by the device can benefit other specialties in healthcare. Onera Health is exploring new applications for its medical-grade technology through the device's ability to capture various cardiovascular and respiratory parameters. Frost & Sullivan applauds the company's aim to empower people to take control of their health by offering powerful next-generation tools to the medical community.

Commitment to Product Quality and Compliance to Standards

Onera Health's team consists of professionals with robust technology and industry expertise. Apart from the experienced core team, the company has illustrious medical advisors across geographies that are sensitive to market needs to support clinical validation and product improvement. Through better product design and technology to yield diagnostic accuracy on par with PSG, the company has addressed expected adoption barriers. It has built a very comprehensive dataset that minimizes variability, standardizing the diagnosis process and results to improve reliability. Onera Health's patch provides a differentiated user experience compared to traditional PSG, which has multiple barriers to adoption. Today, patients need to visit a sleep clinic or specialized hospital to use PSG for testing. Setting up PSG is cumbersome, taking over an hour for clinicians to place multiple leads on the patient's body. Clinicians also spend hours to interpret the data manually. Onera Health's patch drastically decreases the time taken to run a sleep study, from hours to minutes, and produces an instant report.

Onera Health's business model focuses on partnering with end users to offer a full-stack sleep solution, differentiating it from competitors and providing a superior value proposition to all stakeholders. Through its technology, Onera Health simplifies a study's setup and creates a sleep report with cloud-based solutions that can be integrated into physicians' workflow and electronic medical records. The device is Health Insurance Portability and Accountability Act (HIPAA)-compliant and General Data Protection Regulation (GDPR) standards. Onera Health offers at-home gold standard sleep diagnostics that cover comprehensive parameters related to cardiovascular and respiratory functions, unlike competing products that are restricted to sleep laboratories, cover only a few parameters, and diagnose

a narrow range of sleep disorders such as OSA. Onera Health's patch uses bioimpedance technology to provide accurate respiratory analysis and biopotential measurements such as electrocardiography (ECG), electroencephalography (EEG), inertial sensors to track movements, and optical sensors to measure blood parameters. The company differentiates itself by taking sleep diagnostics to the next level with its compact, user-friendly, easy-to-apply, clinical-grade device that is underpinned by technological innovations such as sensors, machine learning, system integration with patch interface, and proprietary chip technology.

Market Validation and User Experience

Onera Health compiles feedback from multiple stakeholders to improve its technology in the pilot stage and constantly measure diagnostic clinical data, usability, and efficiency to improve its solution. The feedback is aimed at providing healthcare utilization or data efficiency to payers and clinicians and improving user experience for patients. Obtaining feedback, whether on the device, cloud infrastructure, or reporting mechanism, is part of the company's development process to continuously improve to stay relevant.

Onera Health works closely with sleep doctors and clinics integral to the business model to shorten diagnosis time, monitor patients' treatment, and improve treatment efficacy. Through the device's sensors and cloud architecture, the company generates all data streams that sleep doctors need, along with other data such as neurological, cardiovascular, and respiratory data. With machine learning and AI, the device helps to diagnose the problem more efficiently and accurately, accelerating diagnosis turnaround time and decreasing technicians' workload. The company has received favorable feedback from clinicians and patients during its trials in the United States and Europe, validating the device's post-market success.

"With machine learning and AI, Onera Health's device helps to diagnose the problem more efficiently and accurately, accelerating diagnosis turnaround time and decreasing technicians' workload."

*– Srinath Venkatasubramanian,
Industry Analyst, Transformational
Health*

Onera Health has set a new benchmark in the sleep diagnostics industry, receiving several recognitions for its breakthrough technology. The company was part of CB Insights's 2020 top 150 digital health companies, received the European Innovation Council Accelerator grant in 2020, and two Red Dot Awards for product design and innovation in 2021.

Product Launch and Customer Acquisition Strategy

With rising prevalence of metabolic and lifestyle disorders, consumers are more aware of and interested in fitness, nutrition, and well-being. This creates a huge volume growth for wellness devices, including those for sleep diagnosis, and is a massive opportunity for Onera Health. The company will test its commercial model and value proposition by launching the product initially with a select number of institutions in Europe in H2 2021 & H1 2022, and in the US in H2 2022, to ensure it fits in a clinical workflow. The company is already running clinical studies and business pilot studies in these geographies, where the device is eligible for payer coverage through existing reimbursement codes. The

company also plans to partner with telemedicine providers to expand to other geographies, capitalizing on existing reimbursement provisions. The company will partner with doctors and medical institutions to overcome accessibility issues, thereby accelerating and expanding sleep testing at home and in relevant hospital departments that do not have access to sleep diagnostics. The device is a win-win-win solution for payers, sleep physicians, and other specialists.

Onera Health's technology is set to transform sleep diagnostics treatment as the market currently lacks convenient and accessible options for people who want to be tested. Frost & Sullivan believes the company is able to fill this large unmet need across countries with its easy-to-use and accessible sleep diagnosis device.

Conclusion

One in five people suffers from a sleep disorder that can precipitate various ailments, including cardiovascular and neurological conditions. It is important to diagnose the condition early to improve cost of care and health outcomes. Onera Health's patch-like, compact device for sleep diagnosis is accessible, user-friendly, and reliable. It informs patients of their health status, provides clinicians with access to undiagnosed patient cohorts and comprehensive patient profiles, and supports payers to promote value-based care by decreasing costs. Onera Health's comprehensive evaluation and full-stack solutions, from diagnostics to treatment rationalization, differentiate it from competitors in the market.

With its strong overall performance, Onera Health earns Frost & Sullivan's 2021 Technology Innovation Leadership Award in the European sleep diagnostics industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Award recognizes the company that has introduced the best underlying technology for achieving remarkable product and customer success while driving future business value.

Best Practices Award Analysis

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

