

F R O S T & S U L L I V A N

FROST & SULLIVAN BEST PRACTICES AWARD

PREDICTIVE HEALTH ANALYTICS AND MONITORING
GLOBAL

Visionary Innovation Leadership
2019

FROST & SULLIVAN

2019

BEST
PRACTICES
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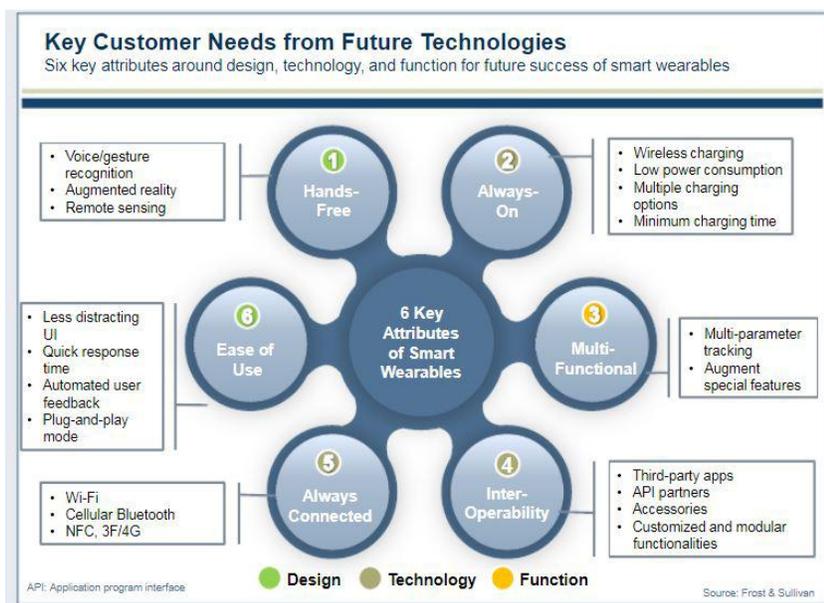
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Background and Company Performance

Industry Challenges

The incidence of lifestyle-driven chronic diseases is rapidly increasing, accounting for three-quarters of all deaths worldwide by 2020. The subsequent rising demand for services and resulting economic pressure is unsustainable for healthcare systems in the long-term. An OECD report estimates that the premature deaths of 550,000 working-age European Union (EU) citizens from chronic diseases, including heart attacks, strokes, diabetes, and cancer, cost EU economies €115 billion or 0.8% of gross domestic product annually.¹ In the US, chronic conditions are responsible for over 75% of all healthcare costs.² The annual expenditure for congestive heart failure (CHF) alone is currently around \$36 billion and expects to reach \$100 billion by 2030. Additionally, high rates of re-admission—CHF averages a 22.3% re-admission rate within 30 days of discharge—compound the already substantial costs associated with the hospitalization of Medicare beneficiaries³. With billions in reimbursement at stake, many hospitals have begun migrating toward digital tools to improve value-based operations. Consequently, health systems in both Europe and the United States (US) are moving to value-based care plans to replace traditional fee-for-service models.

Frost & Sullivan notes that digital solutions have the potential to significantly reduce the cost and clinical burden of lifestyle-driven chronic health conditions through enabling early diagnosis and prevention. Studies show that digital health intervention—e.g., remote cardiac remote monitoring solutions—among early-stage cardiovascular disease (CVD) populations can reduce relative risk by 40% and absolute risk by 7.5%, significantly decreasing CVD events, hospitalizations, and deaths.⁴ At the same time, increasing comorbidity with other health complications and disease conditions necessitate multi-parameter monitoring beyond the electrocardiogram to make cardiac care more targeted and efficient. Predictive analytics capabilities are another key area where clinicians and researchers see value in managing healthcare.



Source: Frost & Sullivan

¹ <https://www.oecd.org/eu/health-at-a-glance-europe-23056088.htm>

² <https://www.cdc.gov/chronicdisease/pdf/2009-Power-of-Prevention.pdf>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5436769/>

⁴ <https://healthmetrics.heart.org/wp-content/uploads/2017/10/Cardiovascular-Disease-A-Costly-Burden.pdf>

Despite technology playing a pivotal role in outcome-based preventive care practices, current monitoring technologies fail to address industry needs adequately. Conventional and widely-used monitoring solutions like electrodes fail to afford patients freedom of movement. Implantable technologies, while not restricting movement and, in the case of CHF, effective at identifying decompensating heart failure weeks before an event, are invasive and expensive.

Hence wearables leveraging convergent innovations in sensors, microelectronics, and wireless platforms to perform various real-time functions such as data recording, reporting, analyses, and communication are a critical layer to the mHealth ecosystem. Frost & Sullivan classifies healthcare wearables into consumer-grade and medical-grade devices. Clinical-grade wearables require regulatory approval by national health authorities such as the US Food and Drug Administration (FDA), providing a significant barrier to both new and established market participants.⁵

Nevertheless, medical-grade wearables present the most promising product segment supporting the broader healthcare trend of value-driven and patient-centered care. Specifically, wearables providing real-time health data integration and medical-grade biometrics can improve care delivery, quality, and patient outcomes. Frost & Sullivan estimates the global clinical-grade wearables market at approximately \$2 billion in 2015, growing at a compound annual growth rate of nearly 33% from 2015 to 2020.⁶ Despite the rapid adoption and proliferation of wearables, significant issues remain around form factors and data quality, with research indicating that between 33 to 50% of customers will stop using a purchased wearable within six months.⁷ User-friendly design and affordability are critical to market success. Additionally, devices often have a high degree of variability, leading to inconsistent biometric data capture and inaccuracy.

The ability to effectively integrate biosensors, artificial intelligence (AI), and algorithms to make data capture meaningful and actionable are crucial to transforming wearables into employable digital tools. Specifically, the ability to create medical-grade signal quality is essential to spur the continued adoption of wearables for multiple use cases in the health and wellness sector. Frost & Sullivan research reveals that advanced biometrics capable of tracking and monitoring multiple disease states and physiological conditions serve as a powerful market differentiator.

Focus on the Future and Best Practices Implementation of Chronolife

Founded in 2015 and headquartered in Paris, France, Chronolife is a health technology company Committed to developing innovative mobile solutions for remote monitoring services through multi-parameter biosensing technology. The company's innovative smartwear platform provides data-driven insights through the capture of biometrics for the healthcare markets. Chronolife's technology allows for AI integration into low-bandwidth

⁵ *Wearable Technologies in Clinical and Consumer Health, Forecast to 2020: Potential for Effective Management of Chronic Diseases to Create \$30 Billion Market Opportunity* (Frost & Sullivan, March 2016)

⁶ *Wearable Technologies in Clinical and Consumer Health, Forecast to 2020: Potential for Effective Management of Chronic Diseases to Create \$30 Billion Market Opportunity* (Frost & Sullivan, March 2016)

⁷ <https://www.forbes.com/sites/reenitadas/2016/01/07/the-future-of-wearables-can-companies-avoid-the-pitfalls-threatening-healthcare-wearables/#4a18b2786630>

edge devices such as smartphones, enabling the collection of valuable data to track chronic conditions such as heart disease.

Frost & Sullivan notes the company's key differentiator is its patented Hierarchy of Event-Based Time Surfaces (HOTS algorithm). Conventional remote monitoring includes the transmission of large quantities of data to remote servers for analysis. However, typically only a small portion of the data contains information that has medical relevance. Chronolife's neuromorphic HOTS algorithm is event- versus time-based—allowing it to efficiently parse data while analyzing multiple data flows to characterize clinical events. As a result, the company does not require continuous data gathering or cloud-based large servers to conduct big data analytics. Instead, once a signal exceeds a pre-defined threshold, an event is triggered—generated targeted event data that is subsequently collected and subjected to on-site analytics that can determine the need for further intervention. Since large servers are no longer needed to support analytics, data processing can occur on small devices such as smart phones in near real time. Chronolife can subsequently alert patients in case of an oncoming event. In CHF applications, the app is designed to predict the risk of cardiac decompensation by comparing biometric measurements to a pre-determined protocol, allowing patients to avoid costly hospitalizations.



Frost & Sullivan research further reveals that current European monitoring solutions typically consist of multiple standalone medical devices to take daily readings. As a result, chronic disease patients are often overwhelmed and cease daily monitoring—compromising efficacy and health outcomes. Chronolife's end-to-end solution—an all in one single T-shirt and smartphone application—allows end users to integrate diagnostic monitoring with the activities of daily living seamlessly, a key to ensuring market success.⁸ Overall, the seamlessness of the device can help achieve better patient adherence and compliance. Specifically, the Chronolife T-shirt allows the company to integrate multiple capabilities into a single device while also providing ease-of-use. Electronic components are integrated into the Chronolife T-shirt, allowing it to be washed. The non-invasive monitoring solution empowers settings ranging from acute to ambulatory care.

⁸ <https://www.forbes.com/sites/reenitadas/2016/01/07/the-future-of-wearables-can-companies-avoid-the-pitfalls-threatening-healthcare-wearables/#4a18b2786630>

How It Works

The company's flagship offering, the Chronolife HOTS algorithm, leverages the company's that Ibiosensing T-shirt to integrate various sensors to monitor physiological data in near real time for heart failure patients. Key metrics include:

- Electrocardiogram (ECG)—tracking heart rate, heart rate variability, and arrhythmia
- Pulmonary impedance—to determine edema characterization,
- Thoracic and Abdominal respiration—tracking respiratory distress, respiratory rate & breathing capacity
- Skin temperature—tracking temperature variation
- Physical activity—offering fall detection, number of steps, posture indications, and intensity

Captured biometrics data transmits through BlueTooth Low Energy to the user's smartphone application for continuous data integration and analysis. The t-shirt can store data locally for up to 10 hours. Remote cloud-based servers upload patient data whenever a Wi-Fi connection is available, and the smartphone is on. Data is subsequently archived on accredited data hosting servers for easy access by patients or providers. Chronolife's companion app is compatible with a range of iOS and Android devices. Frost & Sullivan notes that Chronolife's platform technology makes it practical and straightforward for end users to use smartwear daily.

Future Focus

Staff and resource limitations force most wearables developers to either position their device as a consumer device for health and wellness or a validated, medical-grade product that can inform clinical decision making. While the manufacture of consumer devices offers a quick path to commercialization, the complex route of approving a product for medical use—e.g., meeting CE and FDA regulatory guidelines—provides long-term and sustained value for end-users. As a result, manufacturers can capture greater market share. Frost & Sullivan firmly believes that Chronolife's work to secure robust and clinically vetted solutions positions the company for a major market opportunity.

Specifically, the company is working to validate its monitoring and predictive solution as medical-grade. To that end, the company is currently embarking on a year-long European clinical trial that will consist of over 500 plus heart failure patients from across France, Denmark, Germany and Netherlands among other countries. Patients will receive the Chronolife device following a cardiac decompensation and hospital discharge. The captured data will be used to train, refine, and ultimately validate the company's HOTS algorithm. The company has recently obtained a first commercial CE mark on the multi-sensor t-shirt for European market in addition to FCC approval for USA. At present several healthcare entities are interested in testing and evaluating the technology internally for monitoring applications.

During the first semester of 2020, the company expects to obtain its class IIA and FDA approval to validate its medical-grade multi-sensor t-shirt for monitoring applications. The company believes that the Commercial CE is an excellent opportunity for Chronolife to subject the solution for validation and evaluation. Upon testing, the company expects to convert validation participants into customers.

Chronolife is initially focusing on Europe and the US for predictive heart failure applications. The company also plans to commercialize the t-shirt for other chronic cardiovascular conditions to support ageing in place and prevention programs and plan to launch its first product with consumer CE mark for test and validation before year end. Key client bases that Chronolife is targeting include pharmaceuticals, insurance companies, large system integrators, service platforms for digital health, and nursing homes. The company's innovative technology has enabled the company to raise \$11 million euros from venture capitalists to date.

While Chronolife is currently pre-commercial, the company's adaptable biosensing platform has the potential to target a plethora of use cases and applications. The company is actively exploring other applications including sudden infant death syndrome, epilepsy, and medical conditions related to sleep apnea. Frost & Sullivan notes the company is likely to be especially effective for use cases requiring the gathering of large amounts of medical data to spur therapeutic efficiency and inform risk reduction.

Conclusion

The advent of value-based care requires innovative and cost-effective chronic disease management strategies. Chronolife's innovative bio-sensing platform pairs advanced artificial intelligence with an accessible form factor to uniquely monitor and predict medical events in near real time on edge devices. With a state-of-the-art algorithm that captures multiple, medical-grade parameters, the company can generate contextualized, accurate, and relevant biometrics critical to leveraging the cost-saving and transformative potential of wearable technologies. With its strategic innovation, technical excellence, and potential to enhance health across market sectors, Chronolife earns Frost & Sullivan's 2019 Global Visionary Innovation Leadership Award in the predictive health analytics and monitoring market.

Significance of Visionary Innovation Leadership

A Visionary Innovation Leadership position enables a market participant to deliver highly competitive products and solutions that transform the way individuals and businesses perform their daily activities. Such products and solutions set new, long-lasting trends in how technologies are deployed and consumed by businesses and end users. Most important, they deliver unique and differentiated benefits that can greatly improve business performance as well as individuals' work and personal lives. These improvements are measured by customer demand, brand strength, and competitive positioning.



Understanding Visionary Innovation Leadership

Visionary Innovation is the ability to innovate today in the light of perceived changes and opportunities that will arise from Mega Trends in the future. It is the ability to scout and detect unmet (and as yet undefined) needs and proactively address them with disruptive solutions that cater to new and unique customers, lifestyles, technologies, and markets. At the heart of visionary innovation is a deep understanding of the implications and global ramifications of Mega Trends, leading to correct identification and ultimate capture of niche and white-space market opportunities in the future.

Key Benchmarking Criteria

For the Visionary Innovation Leadership Award, Frost & Sullivan analysts independently evaluated 2 key factors—Focus on the Future and Best Practices Implementation—according to the criteria identified below.

Focus on the Future

Criterion 1: Focus on Unmet Needs

Requirement: Implementing a robust process to discover customers' unmet or underserved needs and create the products or solutions to address them effectively.

Criterion 2: Visionary Scenarios through Mega Trends

Requirement: Incorporating long-range, macro-level scenarios into the innovation strategy, thereby enabling first-to-market growth opportunity solutions

Criterion 3: Growth Pipeline

Requirement: Best-in-class process to identify and prioritize growth opportunities leveraging both internal and external sources.

Criterion 4: Blue Ocean Strategy

Requirement: Strategic focus on creating a leadership position in a potentially uncontested market space, manifested by stiff barriers to entry for competitors.

Criterion 5: Growth Performance

Requirement: Growth success linked tangibly to new growth opportunities identified through visionary innovation.

Best Practices Implementation

Criterion 1: Vision Alignment

Requirement: The executive team is aligned with the organization's mission, vision, strategy, and execution.

Criterion 2: Process Design

Requirement: Processes support the efficient and consistent implementation of tactics designed to implement the strategy.

Criterion 3: Operational Efficiency

Requirement: Staff performs assigned tasks seamlessly, quickly, and to a high quality standard.

Criterion 4: Technological Sophistication

Requirements: Systems enable companywide transparency, communication, and efficiency.

Criterion 5: Company Culture

Requirement: The executive team sets the standard for commitment to customers, quality, and staff, which translates directly into front-line performance excellence.

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 Monitor, target, and screen	Identify Award recipient candidates from around the globe	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies 	Pipeline of candidates who potentially meet all best-practice criteria
2 Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates 	Matrix positioning of all candidates' performance relative to one another
3 Invite thought leadership in best practices	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps 	Detailed profiles of all ranked candidates
4 Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> • Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles 	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> • Share findings • Strengthen cases for candidate eligibility • Prioritize candidates 	Refined list of prioritized Award candidates
6 Conduct global industry review	Build consensus on Award candidates' eligibility	<ul style="list-style-type: none"> • Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates 	Final list of eligible Award candidates, representing success stories worldwide
7 Perform quality check	Develop official Award consideration materials	<ul style="list-style-type: none"> • Perform final performance benchmarking activities • Write nominations • Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8 Reconnect with panel of industry experts	Finalize the selection of the best-practice Award recipient	<ul style="list-style-type: none"> • Review analysis with panel • Build consensus • Select recipient 	Decision on which company performs best against all best-practice criteria
9 Communicate recognition	Inform Award recipient of Award recognition	<ul style="list-style-type: none"> • Present Award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance 	Announcement of Award and plan for how recipient can use the Award to enhance the brand
10 Take strategic action	Upon licensing, company is able to share Award news with stakeholders and customers	<ul style="list-style-type: none"> • Coordinate media outreach • Design a marketing plan • Assess Award's role in future strategic planning 	Widespread awareness of recipient's Award status among investors, media personnel, and employees

The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan's 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.



About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best-in-class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.