

FROST & SULLIVAN

GINA LIFE

2022
TECHNOLOGY
INNOVATION
LEADER

ISRAELI
FEMTECH INDUSTRY

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. Gina Life excels in many of the criteria in the femtech 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

An Untenable Situation

Women's health comprises only 4% of pharma's research and development (R&D) budget. Over the last century, male bias dominated the space, resulting in poor quality of life and low survival rates for patients

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**- Dr. Tiran Rothman, Ph.D., MBA
Vice President, Head of Israel Operations**

with women-associated diseases. The most critical example is late-stage diagnoses, primarily responsible for endangering women and burdening healthcare systems. For example, 75% of women with ovarian cancer receive an accurate diagnosis when they have a mere 5% to 20% survival rate. Endometriosis diagnosis is another instance, taking between six and ten years to diagnose and, usually, only after several unnecessary invasive surgeries.¹ This grave situation suggests an enormous potential to help millions of women whose needs remain unmet.

As the healthcare industry moves towards personalized medicine and health equity, gender consideration is essential in democratizing disease diagnostics and optimizing treatments.

¹ Frost & Sullivan Interview with Gina Life, August 2022

All around the world, women play the role of physicians, families, earners, and decision-makers in their households. In the medical arena, they help eliminate the male bias, promoting the growth of the nascent femtech market. Also, start-ups are paying more attention to women's health-oriented technology solutions.²

Gina Life: A Long-Awaited Solution Designed by Women for All Women's Health

Founded in 2015, Gina Life is an admirable example of this global shift to improve women's lives forever. The femtech company focuses on early disease detection in women using Machine Learning, Artificial Intelligence (AI) and data science.

This Israel-based start-up leads a paradigm transformation in early disease detection. With its technology, Gina Life identifies crucial biomarkers for women-associated diseases by performing novel vaginal discharge analyses. The company envisions an easy-to-use test pad that captures vaginal discharge and performs biomarker analysis. Moreover, it will develop a mobile application to enhance its testing device's accuracy with AI features.

Gina Life anticipates its first product to hit shelves by 2025. The company's first product will be a simple vaginal swab taken by a physician and sent to the Gina Life lab for analysis. Later on, the company will launch a home-use test, which will resemble a normal pregnancy or COVID-19 test, a handy home solution with proprietary biomarkers letting women know when to seek further healthcare assistance and ensure early disease diagnosis and prompt treatment.

A Trailblazer's Path: Unlocking the Power of Vaginal Discharge Analysis

At Gina Life's front, Dr. Inbal Zafir-Lavie is an experienced leader and Chief Executive Officer with expertise in gene therapy, molecular immunology, and antibody engineering. In 2015, she lost her 38-year-old sister to cancer because of a late diagnosis that surprised physicians. Rather than giving up, Inbal Zafir-Lavie

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**- Manuel Albornoz,
Best Practices Research Analyst**

decided to make a lasting change in the industry, uniquely striving to address what she understood as an unbearable situation in the women's health space.

Over the last years, Gina Life refined its holistic approach to determine the best method to ensure early disease detection in women. The company realized that the early signs of several diseases, generally presumed to be found only in human blood, are also located in women's vaginal fluids. With its foundational basis in place, Gina Life started

developing a comprehensive product portfolio to bridge industry gaps.

Having experienced a tragic loss, Dr. Inbal Zafir-Lavie teamed up with Dr. Shlomit Yehudai-Reshef, founder and CSO, and they began work on an early test for ovarian cancer, becoming Gina Life's first groundbreaking solution. The proof of concept involves characterization of the biomarkers that enable early detection of ovarian cancer using Machine Learning and Artificial Intelligence. While the test will be

² *Growth Opportunities for Digital Twins in Global Healthcare* (Frost & Sullivan, May 2022)

conducted at the clinic at first, the vision is to have an intelligent at-home easy to use pad that every woman can use, which captures and analyzes vaginal discharge for several indications. This platform will be supported by an AI based app which will guide the woman how to use the pad and will analyze the results. Experts are currently testing the technology in clinical trials with excellent preliminary results. Not settling on providing a cancer-related testing device only, Gina Life started designing another innovation: a testing swab that analyzes vaginal secretions for detecting Endometriosis.

The company's scientific team ultimately intends to deliver a six-pack-test kit at an affordable cost to aid in the detection of several women's diseases. Gina Life visualizes a future in which women from around the world can purchase these tests at a local pharmacy to clear any doubts about their health. For this goal, it hires people devoted to changing people's lives. Gina Life strives to find talented experts aligned with its core mission: improving healthcare for all women, with no distinctions regarding country, skin color, or socioeconomic background. It has a strong focus on finding outside-of-the-box thinkers during the hiring process. Regarding organization, all internal meetings aim to eliminate limitations caused by hierarchical structures to boost creativity and employee comfort by allowing everyone to speak at an equal level.

Uniquely Addressing Needs with Unmatched Scalability

Vaginal discharge has long been taboo in the medical community to the point that it is underestimated by many physicians. Gina Life's dedicated work indicates that it is full of valuable biomarkers: from cancerous tumor growths in the ovaries to Endometriosis. The company plans to uncover unique biomarker profiles for women-specific pathologies by analyzing this excellent clinical and biological information source.

While Gina Life focuses on creating self-serve home-based tests, physicians can leverage these tools to ease their workload and assist patients with their healthcare. Healthcare systems can utilize the products to reduce employee and hospital efforts, supporting doctors with a device that lets them diagnose female patients faster and better.

The company's technology potential is immense. For instance, ovarian cancer is the seventh most common cancer among women. In 2018, it was responsible for 4.4% of total cancer-related mortality among women.³ Thus, the World Health Organization recommended preventive measures, health education, and early detection. These critical situations conform to the gap that Gina Life is filling with its solutions.

Building Trust through a Women-Centric Approach and Close Relationships

Gina Life works closely with a gynecology group in the United States (US), composed of physicians who regularly deal with women-associated diseases such as ovarian cancer. Their feedback is crucial to developing the solution and providing professional insights into how to design the implementation strategy in hospitals and clinics. Besides, by engaging early with potential healthcare customers, the company reduces future marketing efforts.

Gina Life strives to maintain accessibility with its investors and, most of all, with women. To this extent, it musters several 24/7 contact channels, responding to inquiries and providing transparency. It also intends

³ *Ovarian cancer in the world: epidemiology and risk factors (National Library of Medicine, 2019)*

to cement an educational approach to early testing with its women-centered corporate philosophy.

Through its future mobile application, Gina Life plans to provide a feedback mechanism for women to rate the product's ease of use. However, the application's most crucial feature relates to teaching its users how to proceed after the test results and understanding the meaning of the diagnosis.

Lastly, constant meetings with future customers characterize the company's launching roadmap, establishing ongoing trust in its solution's potential, and paving the way for long-lasting relationships.

A Promising Outlook for 2023 and Beyond

Groundbreaking solutions often face problems when approaching regulatory entities. For example, US Food and Drug Administration (FDA) approval requires extensive supportive data, only obtained through lengthy, expensive clinical trials in the early development stages. In the case of Gina Life, the ovarian cancer test is the closest product to market. By seizing the absence of competing solutions for ovarian cancer, the company intelligently premeditated the regulatory strategy for its entire portfolio:

Currently, Gina Life is initiating US-based clinical trials to get proof-of-concept data. When completed, the start-up will approach the Centers for Medicare and Medicaid Services (CMS) to get to market. As a result, its test will start generating revenue as a support tool while collecting millions of data points, strengthening its FDA approval proposal. Its subsequent products and indications will claim evidence-based support and evolve into diagnostic products without executing massive global clinical trials.⁴

In three years, the company projects to produce test kits to start operating. In the meantime, it frequently attends conferences to discuss the data. Gina Life plans to set up webinars close to launching to maintain transparency. Its educational approach will also secure easy access to related information, encompassing the company's journey.

Above and beyond, Gina Life completed its seeding rounds,⁵ and has leaders from Israel and the US bringing excitement and attention to its technology. Ultimately, vaginal discharge analysis will considerably improve women's health, promoting further growth while generating sustained revenues.

⁴ Frost & Sullivan Interview with Gina Life, August 2022

⁵ Ibid.

Conclusion

Market stakeholders in the femtech industry see the demand to leverage high-impact solutions to address women's urgent needs in the healthcare space. Without many options available, groundbreaking innovations become a critical success factor. Using artificial intelligence (AI) and novel vaginal discharge analysis, Gina Life's technology delivers early detection of some of the women's deadliest diseases. It rectifies the male bias while providing a product that accelerates and democratizes diagnosis, thus decreasing hospital burden and women's suffering.

The company stands out from its competitors based on its commitment to innovation and creativity. Its core mission to improve women's healthcare with no distinctions of country, skin color, or socioeconomic background is only surpassed by its ability to create far-reaching, impactful solutions.

By discovering a valuable source of biomarkers in vaginal discharge, Gina Life is in a solid position to find unique biomarker profiles for specific women's pathologies.

Ultimately, the ovarian cancer test acts as a launching pad for Gina Life's vaginal discharge analysis-based product development, generating revenues and supporting its road to success. It resembles the successful design of the COVID-19 test, with a women-centric approach and very promising results in clinical trials. Moreover, the company pairs its cutting-edge technology with customer-centric values while engaging with clinics, hospitals, and physicians. Despite its start-up status, Gina Life is already earning a solid reputation in the market.

With its strong overall performance, Gina Life earns Frost & Sullivan's 2022 Israeli Technology Innovation Leadership Award in the femtech industry.

What You Need to Know about the Technology Innovation Leadership Recognition

Frost & Sullivan's Technology Innovation Leadership 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

