

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

FROST & SULLIVAN BEST PRACTICES AWARD

DIRECT-TO-CONSUMER MICROBIOME TESTING  
GLOBAL

Company of the Year 2019

V I O M E

FROST & SULLIVAN

2019

BEST  
PRACTICES  
AWARD

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## Background and Company Performance

### *Industry Challenges*

The growth of the human microbiome industry parallels the growth of the genomics industry. Assessing the microbiota in the gut using next-generation sequencing (NGS) is a key advancement in the field of the human microbiome. Leveraging this assessment for specific microbial patterns in the gut to create a personalized diet plan can help with weight management, mood disorders, skin issues, digestion problems, and reduce or even eliminate chronic health conditions.

Microbiome testing leverages DNA and RNA sequencing technology. The DNA-based 16S technology and metagenomic sequencing technology are conventional ways to profile the gut microbiome and connect it to human health. However, these technologies lack the ability to provide recommendations on food and supplements that can help maintain a healthy digestive tract. In particular, the 16S technology is based on using a portion of the 16S ribosomal RNA gene to identify some bacteria. As a result, other microorganisms in the gut, such as viruses, phages, yeast, mold, and fungi, cannot be detected using this technology. However, many companies continue to use 16S sequencing because it is simple and inexpensive.

In addition, some companies are implementing a metagenomic analysis of gut samples. Metagenomic analysis has a higher resolution for identifying most microbes (except for RNA viruses and phages) than 16S. However, this technology is limited by its ability to categorize organisms by function. Another drawback of this technique is that it cannot differentiate the DNA between dead and alive microorganisms. Because of DNA's high stability, the possibility of interference from food or dead microorganisms in the patient sample could result in false positives, thus wasting the sequencing data.

Recently, RNA-based metatranscriptomic analysis has demonstrated the gut microbiome's potential as a target for personalized nutrition by overcoming the limitations of conventional techniques. Metatranscriptomic analysis offers the high-resolution (strain level) detection of all living organisms (e.g., bacteria, archaea, viruses, phages, yeast, fungi, mold, and parasites) and can analyze the activity of these organisms and their functions that have a direct impact on immunity and overall health.

### *Visionary Innovation and Performance/Customer Impact*

Founded in 2016, Bellevue-based Viome Inc has developed the Gut Intelligence™ Test, which is the most advanced gut microbiome test available in the market today and is capable of measuring both microbial activity and biochemical functions. This test is based on metatranscriptomic sequencing technology developed at the prestigious Los Alamos National Laboratory for purpose of mapping the strains and species of microorganisms that make up the unique human gut microbiome. Viome leverages this technology to examine the genes expressed by the gut microbiome and determine if the food consumed is converted into either useful nutrients or injurious toxins. The company's artificial intelligence (AI) platform, Vie, transforms the collected insights into actionable insight by delivering personalized dietary recommendations to improve the overall health and wellness of customers.

## **A True Health Companion**

Viome's Gut Intelligence Test is the only direct-to-consumer microbiome test to leverage metatranscriptomic technology to analyze the activity of microbes in the gut microbiome and then provide customers with tailor-made nutrition recommendations for healthy bodily functions. The test's mode of operation includes sequencing the RNA in a sample for quantifying and identifying the live gut microbiome in the highest resolution available. Viome's sophisticated technology provides unique functional information from the human microbiome and is the only test in the market to offer the same. Based on its high-resolution analysis, the AI platform generates many scientifically-backed recommendations for food and supplements that are required for the peak performance of each customer's metabolism. Other competing tests currently available in the market leverage 16S and metagenomic sequencing techniques that lack the ability to measure microbe functions, which is key to providing personalized diet and lifestyle recommendations.

Viome's platform adapts the recommendations to each customer's changing gut ecosystem, offering the option to retest and examine his or her gut microbiome regularly. In this way, the customer is always fine-tuning their gut microbiome, maximizing his/her vitality and lifespan. Viome has crossed more than 100,000 customers over the last two years and is currently the fastest growing microbiome testing company in the industry. Viome quadrupled its quarter-over-quarter volume in the first three quarters of 2019, and its Gut Intelligence Test is now available in France, the Netherlands, Belgium, the United Kingdom, Germany, Canada, Australia, and the United States. Going forward, Viome plans to expand quickly into other countries, such as Singapore, Malaysia, Thailand, India, United Arab Emirates (UAE), and South Africa.

## **Making It Simple, Affordable, and Effective for Customers**

Viome's Gut Intelligence Test can be ordered online directly from the company's website or from online marketplaces, such as Amazon. After the customer orders Viome's non-invasive, easy-to-use, and portable home kit, the collected samples can be returned in a postage-paid box. With Viome's advance scientific data analysis, a thorough understanding of the gut microbiome is obtained at the functional level. Based on all of this unique information, the AI platform then creates scientific-based recommendations for specific food and supplements that can optimize the gut's performance. Detailed explanatory dietary recommendations are then delivered to the app on the customer's mobile device or available on their web dashboard. The test's total run time takes between two and four weeks, whereas other similar offerings in the market take about four to six weeks and do not provide in-depth information in terms of microbiome pathway activity and customized dietary recommendations.

Customers are notified of result availability by email and by mobile app, and the information includes an explanation on how the recommendations were derived, thus addressing any doubts the customer may have. Viome has significantly reduced the cost of its test from \$399 per test to \$149 per test, making it much more affordable. The company continues to reduce the cost of their Gut Intelligence Test in order to achieve its mission of eradicating chronic diseases through microbiome testing that provides personalized diet and lifestyle recommendations.

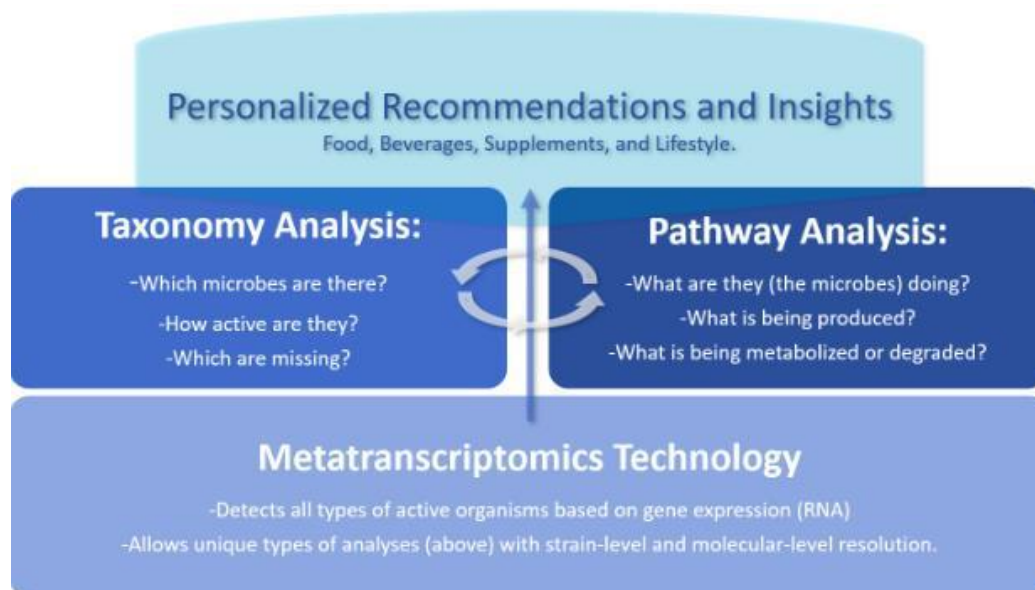
Viome is constantly expanding its database and research findings based on conducted analyses so that customers can benefit from access to updated information as part of Viome's service. Furthermore, after receiving their initial results and following recommendations for 90 days, customers can retest as often as they like in order to see what's changed in their gut microbiome throughout the year.

### Exhibiting Technology Leadership with Pathway Analysis and Machine Learning

Viome's Gut Intelligence Test does not examine for metabolites or chemicals but rather assesses the full range of microbial functions and activities based on the RNA gene expression information obtained through the metatranscriptomic technology. Insights and recommendations are based on two types of analyses: pathway analysis and machine learning. Figure 1 provides an overview of the pathway analysis process flow, which includes both taxonomy and functional pathway perspectives. These pathways are the basis of scores shown to customers to provide insight into biological functions such as inflammation, metabolism, and digestion, and are also used for personalizing insights and recommendations.

#### Figure 1: Viome's Gut Intelligence Test Scoring Process Flow

Viome's AI platform also uses machine-learning to predict the glucose response of an individual to a range of foods, based on their gut microbiome and other biological factors. Viome's AI system was trained from data collected in a systematic clinical study which enrolled 550 subjects who tracked their blood glucose continuously for 14 days while eating a range of meals (approximately 30,000 meals were recorded).



Source: [www.viome.com](http://www.viome.com)

### Focusing on Certified Labs and Data Safety

As the only company to offer clinical laboratory improvement amendments (CLIA)-certified RNA sequencing technology, Viome proudly uses only CLIA-certified labs in the United

States for its testing. To attain CLIA certification, a lab must meet certain quality standards to ensure the accuracy and reliability of the results from Viome's microbiome test.

Furthermore, Viome offers confidential data and results by categorically dividing each user's personally identifiable information (PII) and protected health information (PHI) into two separate databases. In addition, Viome uses multiple layers of encryption and access protection by not providing the customer's information or results to employers or health insurance companies. Viome is compliant with EU General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA).

### **Delivering Faster and Continuous Results**

Viome is the first microbiome testing company to create an advanced AI algorithm called "Vie" to offer customized dietary recommendations based on high-resolution gut microbiome data using a massive and continuously growing database of information. Vie sorts through large volumes of data to find correlations among microorganisms, their functions, and any health issues an individual might face.

Vie is embedded in Viome's app. Personalized dietary recommendations are the culmination of all data points that have been analyzed, cross-checked, and reanalyzed through Vie. In contrast, competitors in this space lack the availability of such in-depth data and an AI algorithm to connect the collected data points from microbiome testing to determine personalized dietary recommendations.

### **Beyond the Gut—the Future of Viome's Metatranscriptomic Analysis**

Viome's technology aims to empower consumers to take control of their own health and change the healthcare industry by preventing chronic diseases through accurate dietary recommendations. The company's long-term mission is to facilitate a world without Alzheimer's, Parkinson's, autoimmune diseases, and more. In addition to providing successful testing options for the gut microbiome, Viome envisions using the metatranscriptomic analysis technology to examine other organs, with its next in-line testing to be based on blood transcriptome.

### *Conclusion*

In the era of value-based care, offering preventive solutions that can improve consumers' health and wellness is critical in the healthcare industry.

Frost & Sullivan applauds Viome's commitment to improving the health and wellness of its customers through personalized dietary recommendations by leveraging its pioneering microbiome testing technology. As a trusted innovator, the company is unique in this space based on its approach to human health and wellness through personalized diet recommendations that are backed by robust metatranscriptomic sequencing technology and an AI-based analysis platform. At a continuously reducing retail price and with increasing insights, Viome's Gut Intelligence Test provides complete value to customers through an in-depth gut microbiome profiling to determine personalized dietary recommendations.

With its strong overall performance, visionary leadership, and consistent commitment to benefit customers through high-quality microbiome testing services, Viome has earned Frost & Sullivan's 2019 Company of the Year Award in the global direct-to-consumer microbiome testing industry.

## Significance of Company of the Year

To receive the Company of the Year Award (i.e., to be recognized as a leader not only in your industry, but among non-industry peers) requires a company to demonstrate excellence in growth, innovation, and leadership. This excellence typically translates into superior performance in three key areas—demand generation, brand development, and competitive positioning—that serve as the foundation of a company’s future success and prepare it to deliver on the 2 factors that define the Company of the Year Award: Visionary Innovation and Performance, and Customer Impact).



## Understanding Company of the Year

Driving demand, brand strength, and competitive differentiation all play critical roles in delivering unique value to customers. This three-fold focus, however, must ideally be complemented by an equally rigorous focus on Visionary Innovation and Performance to enhance Customer Impact.

## Key Benchmarking Criteria

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated each factor according to the criteria identified below.

### Visionary Innovation and Performance

- Criterion 1: Addressing Unmet Needs
- Criterion 2: Visionary Scenarios through Mega Trends
- Criterion 3: Implementation of Best Practices
- Criterion 4: Blue Ocean Strategy
- Criterion 5: Financial Performance

### Customer Impact

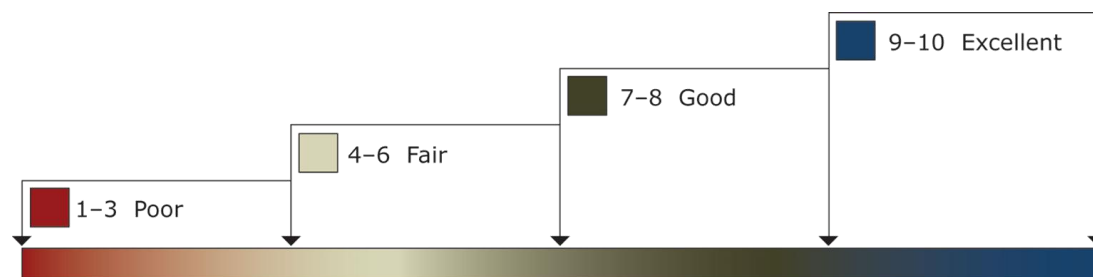
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

## Best Practices Award Analysis for Viome

### Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows research and consulting teams to objectively analyze performance according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation. Ratings guidelines are illustrated below.

#### RATINGS GUIDELINES



The Decision Support Scorecard considers Visionary Innovation and Performance and Customer Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which confirms that small changes to the ratings for a specific criterion do not lead to a significant change in the overall relative rankings of the companies.



The results of this analysis are shown below. To remain unbiased and to protect the interests of all organizations reviewed, Frost & Sullivan has chosen to refer to the other key participants as Competitor 1 and Competitor 2.

<i>Measurement of 1-10 (1 = poor; 10 = excellent)</i>			
<b>Company of the Year</b>	Visionary Innovation & Performance	Customer Impact	<b>Average Rating</b>
Viome	<b>9</b>	<b>9</b>	<b>9</b>
Competitor 1	7	6	6.5
Competitor 2	7	6	6.5

### *Visionary Innovation & Performance*

**Criterion 1: Addressing Unmet Needs**

Requirement: Implementing a robust process to continuously unearth customers’ unmet or underserved needs, and creating 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: Implementation of Best Practices**

Requirement: Best-in-class strategy implementation characterized by processes, tools, or activities that generate a consistent and repeatable level of success.

**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: Financial Performance**

Requirement: Strong overall business performance in terms of revenue, revenue growth, operating margin, and other key financial metrics.

### *Customer Impact*

**Criterion 1: Price/Performance Value**

Requirement: Products or services offer the best value for the price compared to similar offerings in the market.

**Criterion 2: Customer Purchase Experience**

Requirement: Customers feel they are buying the optimal solution that addresses both their unique needs and their unique constraints.

**Criterion 3: Customer Ownership Experience**

Requirement: Customers are proud to own the company’s product or service and have a positive experience throughout the life of the product or service.

**Criterion 4: Customer Service Experience**

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

**Criterion 5: Brand Equity**

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

*Decision Support Matrix*

Once all companies have been evaluated according to the Decision Support Scorecard, analysts then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.



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

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

### 360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



## About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, helps clients 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 practices models to drive the generation, evaluation, and implementation of powerful growth strategies. Frost & Sullivan leverages nearly 60 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on 6 continents. To join Frost & Sullivan's Growth Partnership, visit <http://www.frost.com>.