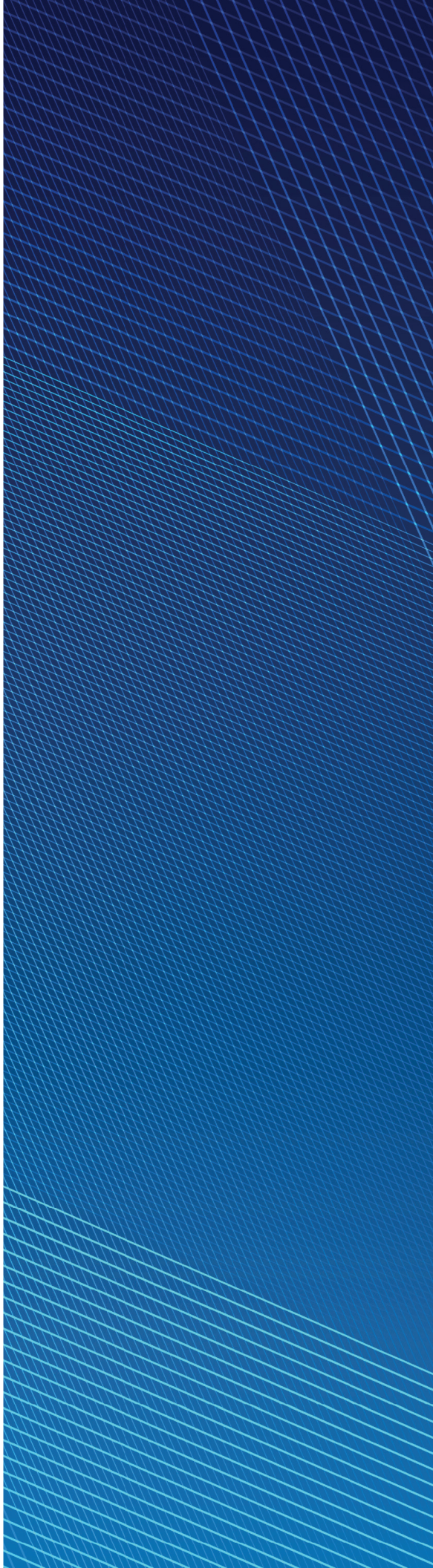
FROST & SULLIVAN

MICRONOMA RECEIVES THE 2023 TECHNOLOGY INNOVATION LEADERSHIP AWARD

Identified as best in class in the North American liquid biopsy for lung cancer 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. Micronoma excels in many of the criteria in the liquid biopsy for lung cancer space.

The Longstanding Gap in Lung Cancer Detection

Over the last several years, healthcare's outcomes and value focus gained traction as the industry rapidly becomes patient-centric. Clinical diagnostics players improve upon their instrument, assay, and informatics capabilities to meet clinical demands and expand their precision diagnostics portfolio. Still, lung cancer remains one of the most significant examples of critical unmet needs.

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

Early cancer screening and diagnostic failures annually cost 4 million lives worldwide[1]. Lung cancer accounts for 18% of cancer deaths and has one of the highest mortality rates[2]. Traditionally, clinicians detect the disease through complex tissue biopsies, often leading to adverse patient side effects. Besides, current lung cancer diagnostic tools also have a high rate of false positives, raising healthcare costs and patient discomfort.

[1] Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries (Micronoma webpage: https://www.micronoma.com/)
[2] Ibid

Survival rates for stage I lung cancer patients are as high as 82%, a 16-fold increase over patients treated in stage IV[3]. The high mortality and survival rate juxtaposition is glaringly apparent, requiring new approaches to address this critical issue. Within this context, recent liquid biopsy advancements can improve the lung cancer diagnostic pathway, providing an appropriate solution for this severe market need.

Frost & Sullivan estimates the United States (US) liquid biopsy market will reach $7 billion in 2025, with a compound annual growth rate of about 14% from 2020-2025[4]. Liquid biopsies will record rapid adoption in early cancer screening/detection, fostering innovation through precision technology. Specifically, Micronoma leverages its disruptive technology to meet patient needs. The company is well-positioned to capitalize on new growth opportunities, cementing its pioneering leadership in the liquid biopsy for lung cancer space.

Micronoma: Outside-the-box Innovation

Founded in 2019 and headquartered in San Diego, California, Micronoma is the first company to develop a minimally invasive, microbiome-driven liquid biopsy test for early cancer detection, i.e., stages I and II. By using sensitive microbiome techniques, its leaders aim to revolutionize cancer diagnosis and treatment, helping patients live longer and healthier lives.

In 2020, the company presented groundbreaking research showing that all cancers have a unique microbial community detectable in human blood, establishing a new class of non-human cancer biomarkers. Starting with lung cancer, the company's Oncobiota™ laboratory-developed test (LDT) provides a diagnostic option for clinicians and their patients. It eliminates costly and unnecessary tissue biopsies by accurately predicting if a lung nodule is malignant using blood samples, even in the early disease stages.

Needs-based Technology Adoption Framework

Micronoma recognized the challenges in its three target audiences besides the patients: clinicians, regulatory agencies, and insurance companies.

On the clinician's side, they are used to liquid biopsies being a secondary diagnosis method. The standard of tissue biopsies results in lung collapse 10% of the time and requires redoing the extraction 30% to 40% of the time[5]. Moving liquid biopsies to the beginning of the process might help with quicker and more accurate detection while justifying invasive tissue biopsies only when worthwhile. The company has the solution for this objective, with an easy and minimally invasive blood test that defines whether a nodule is benign or malignant.

[3] Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries (Micronoma webpage: https://www.micronoma.com/)
[4] *United States Liquid Biopsy Growth Opportunities* (Frost & Sullivan, February 2022)
[5] Frost & Sullivan Interview with Micronoma (Frost & Sullivan, February 2023)

As regulatory entities are reluctant to rapidly accept microbiome practices in healthcare, Micronoma sustained its technology development with accurate data on cancer tissues and blood microbiomes. This data gathering resulted in the FDA granting the Oncobiota™ LDT with a Breakthrough Device Designation in January 2023. Hence, by expediting the approval process of the Oncobiota™ LDT, the FDA testaments to Micronoma's ability to save lives in the challenging Lung Cancer Detection landscape. Finally, it engaged with US insurance payers, addressing their need for reduced clinical procedure costs by avoiding unnecessary costly tissue biopsies.

Technology Sparked by a Commitment to Excellence

Micronoma created its solution by gathering solid market research and robust regulatory guidance, offering an innovative technological advancement that competitors cannot easily replicate. For example, although the Centers for Medicare & Medicaid Services (CMS) cover LDTs regulations through the Clinical Laboratory Improvement Amendments (CLIA) regulations, Micronoma undertook in parallel Food and Drug Administration (FDA)-approval measures to drive clinician confidence and rock-solid distinction. As a result, the LDT has an FDA Breakthrough Device Designation for its lung carcinoma detection solution (OncobiotaLUNG), ensuring continued guidance and prioritized reviews from the agency for its upcoming clinical trial and concomitant pre-market approval processes[6].

The company collaborates with key opinion leaders in the field of microbiome and oncology as demonstrated by their recent publication with the University of California San Diego and the Weizmann Institute of Science in Israel to systematically profile fungal and other microbe communities in 35 types of cancer, thus increasing the precision of its Oncobiota platform[7].

Furthermore, Micronoma is building a proprietary database of fungi and microbes in cancer to maintain its innovative edge, adding more than 10,000 patient samples within public and private cohorts[8].

The Oncobiota Platform: A Ramp for New Solutions

Micronoma's research and development (R&D) team uniquely drives business innovation and academic research. The company fosters genuine R&D by combining academy and industry experts, creating valuable solutions that can quickly translate into saving more lives.

The microbiome-driven technology allows the company to launch additional solutions for the healthcare industry. Aside from lung cancer, the Oncobiota platform can provide a broader advantage in early-stage cancer detection. Its most substantial capability is categorizing nodules as benign or malignant through simple blood draws, even at the early stage of the disease. Micronoma will soon extend its approach to pancreatic, ovarian, and liver cancer, which share many of the same problems as lung cancer[9]. In addition, the company is already working on colorectal and breast cancer detection[10].

[6] Micronoma Receives FDA Breakthrough Device Designation for OncobiotaLUNG, A Novel Liquid Biopsy Assay for Lung Carcinoma Detection (Micronoma press release, January 2023)
[7] Ibid
[8] Guest CEO blog from Sandrine Miller-Montgomery: Precision or Personalized Medicine – Is it Tomato or Tomahto? (Micronoma blog, January 2023)
[9] Frost & Sullivan Interview with Micronoma (Frost & Sullivan, February 2023)
[10] Ibid

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Moreover, in the event of metastasis, Micronoma's microbiome technology could potentially identify the origin of the migrating cancer cells and assist in determining the proper course of therapy. It could also save failed clinical trials by performing microbiome analysis on stored samples, unlocking new insights into the sub-population response to the tested treatment. Overall, the potential of cancer microbiome research is infinite and can only be taken further from this starting point.

Micronoma's founders foster a company culture based on two core values: tenacity and ingenuity. These principles cement its talented workforce, which brings together different backgrounds in the molecular biology, computer science, and commercialization fields to create innovative solutions. Since its launch, the company has partnered with many recognized academic institutions and non-profit entities like the University of California San Francisco, the University of New South Wales, and NYU Langone[11].

Strong Relationships Leading to Adoption Opportunities

With its customer-led strategy, Micronoma will consistently bring to market best-in-class solutions. Through connecting with the clinical community, the company developed close bonds with clinicians who will promote the LDT and function as early adopters. Securing early adopters, gaining FDA clearance, and obtaining medical reimbursement are the steps that will ensure success and significantly increase adoption. Additionally, Micronoma aims to include LDT in medical guidelines within the next ten years. In the meantime, the company's team invites key opinion leaders and early adopters to conferences to share the fascinating science and performances of the microbiome-driven liquid biopsy[12].

The Ph.D. scientists at the company enthusiastically discuss their most recent viewpoints on the cancer microbiome, diagnostic advancements, and news from the healthcare sector to further engage with clinicians. For example, during the novel track at the Cell conference "Hallmarks of Cancer," two Micronoma founders (Professor Rob Knight as the keynote speaker and Greg Sepich-Poore) presented the latest data on lung cancer.

Through various web channels, the company's team provides awareness of this novel science to interested clinicians seeking Micronoma's expert feedback on the microbiome, the cancer microbiome, cancer diagnostics, market forecast for early detection, or lung cancer detection. This approach focuses on increasing awareness and combines with the company's cutting-edge advantage in the field, generating attention in what could be a challenging-to-take-over position.

[11] Research partners (Micronoma webpage: https://www.micronoma.com/micronoma-team/#sab)
[12] Frost & Sullivan Interview with Micronoma (Frost & Sullivan, February 2023)

While evolving from a technology standpoint, Micronoma never loses sight of its clinician and patient-centered perspective. Its brand maintains its academic presence while meeting market-specific needs. Given today's landscape, Frost & Sullivan believes the company is in a prime position to increase its market share in this highly competitive industry.

Conclusion

The performance of the technology is a critical success factor for the liquid biopsy industry. Yet, with many options available, market stakeholders need to leverage the most appropriate and best technology-based solutions to optimize their market impact. With its microbiome-driven liquid biopsy, the Oncobiota laboratory-developed test (LDT), Micronoma offers cutting-edge early cancer diagnosis with unique high sensitivity and specificity. Therefore, the company effectively provides clinicians with improved diagnosis services, delivering outcomes that save both costs and lives.

Micronoma stands out from competitors based on its commitment to innovation, creativity, and commercialization success. Since its founding, the company has collaborated with several academic institutions and non-profit organizations, driving interest in the medical care, patient, regulator, and clinician sectors. The Oncobiota LDT reveals the infinite potential of microbiome markers in tissue and liquid biopsies. It has multiple uses in research and commercial applications and uniquely exhibits exceptional efficacy across various cancer types.

With its strong overall performance, Micronoma earns Frost & Sullivan's 2023 North American Technology Innovation Leadership Award in the liquid biopsy for lung cancer market.

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

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
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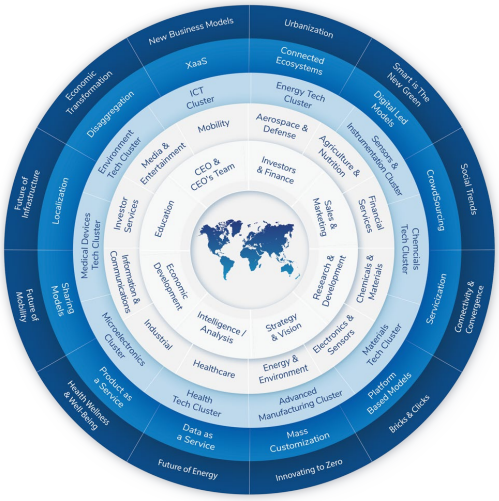
Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)