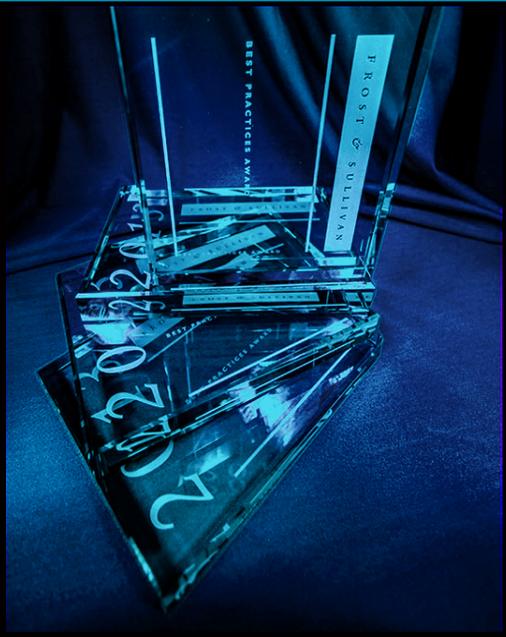


MDxHealth

2016 Global
Prostate Cancer Diagnostics
Technology Innovation Award



FROST & SULLIVAN

BEST
2016 PRACTICES
AWARD

GLOBAL PROSTATE CANCER DIAGNOSTICS
TECHNOLOGY INNOVATION AWARD

2016
BEST PRACTICES
AWARDS

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Background and Company Performance

Industry Challenges

According to the American Cancer Society, there will be over 220,000 new cases of prostate cancer diagnosed in the United States (US) this year, which leads to over 27,000 deaths. Per the National Cancer Institute, this makes prostate cancer the second leading cause of death from cancer in men in the US. Early prostate cancer identification increases the chances of success for patient survival from curative treatments. Current prostate cancer screening tests measure the presence of prostate-specific antigens (PSA). Elevated PSA levels indicate that the patient may have prostate cancer — leading doctors to recommend that men get a prostate biopsy to confirm the presence of cancer.

Frost & Sullivan points out that PSA tests are not specific to indicate prostate cancer, and therefore, a positive result can oftentimes result from other factors. According to the National Institute of Health, PSA tests can provide a false positive or negative reading based on the following factors:

- Larger than normal prostate
- Prostate infection
- Urinary tract infection
- Recent bladder or prostate tests
- Recent intercourse

Since all of these factors can lead to elevated PSA levels, many men must undergo painful biopsy procedures to determine the presence of prostate cancer. The typical prostate biopsy procedure entails the use of a thin, spring-loaded needle, alongside an ultrasound probe, which is inserted through the rectum to obtain 10 to 12 tissue samples from several sites within the prostate. These biopsy tissues are sent to a lab for histopathological analysis. Biopsy procedures are known to cause complications in many men, with approximately 15% of patients experiencing bleeding and, at times, infection, sometimes requiring hospitalization. One of the most significant challenges with this standard of care is that the standard 12-core prostate biopsy samples less than 1% of the prostate gland, leading to a high false-negative result, where one in every four men biopsied is left with undetected cancer (despite the negative histopathology result). The fear of undetected cancer leads to over 43% of these men getting repeated biopsies, to rule out cancer.

Frost & Sullivan notes that providers need a test that can more accurately identify prostate cancer to decrease the number of unnecessary repeat prostate biopsies — reducing painful and potentially harmful invasive procedures as well as the financial strain placed upon

patients. Liquid biopsy is an exciting new approach that provides another alternative to prostate biopsies and which can help support a histopathological diagnosis.

Technology Attributes and Future Business Value of MDxHealth

Maintaining its commitment to advancing molecular diagnostic tests for urological cancers, MDxHealth has continued to generate data supporting its ConfirmMDx for Prostate Cancer test, and furthermore, recently acquired a urine-based “liquid-biopsy test” they call SelectMDx for Prostate Cancer. Frost & Sullivan appreciates the fact that these two offerings can significantly reduce the number of men undergoing a biopsy procedure, eliminating unnecessary pain, infection, and cost. A positive ConfirmMDx or SelectMDx test can also indicate whether a man has an increased risk of harboring an aggressive cancer versus a non-aggressive cancer

MDxHealth’s Advanced Test Offerings

ConfirmMDx™: A More Accurate Biopsy Test

MDxHealth’s flagship offering that gave the company its recognition as a leader in prostate diagnostic techniques is an epigenetic test called ConfirmMDx for Prostate Cancer, which it launched on the US market in 2012. While prostate cancer lesions are often small, the tissue around the cancer is often affected by the tumor and can contain DNA methylation changes. MDxHealth’s ConfirmMDx test is used to analyze prostate tissue samples, previously interpreted as benign or normal, with epigenetic biomarkers to identify DNA methylation changes associated with the presence of prostate cancer. Using the residual tissue from the original biopsy, ConfirmMDx effectively expands the analysis a larger region of the prostate to rule-out the presence of cancer, thereby eliminating the need for unnecessary, costly, and painful repeat biopsies. Since 2012, MDxHealth has performed the ConfirmMDx test on approximately 35,000 patients. Based on the literature, cancer cells could be present in about 25% of the samples that pathologists previously identified as cancer-free, clearly demonstrating the medical need for the test. ConfirmMDx has a 96% negative predictive value to rule-out aggressive prostate cancer, when the test result is negative; negative results are accurate for two to three years. Medicare covers the test, eliminating any additional cost burden on patients over 65 years old. The test is currently available in the US and accounted for 85% of the company’s third quarter revenues in 2015.

SelectMDx™: A More Accurate Predictive Measure

The SelectMDx for Prostate Cancer test was designed and validated to aid in the identification of men at risk for aggressive prostate cancer. The test is indicated for men with elevated PSA test results, suggesting the risk for prostate cancer, at which point many physicians recommend the patient undergo a biopsy. Since PSA screening measures a protein level within the blood, it can be elevated due to a variety of factors - including benign prostate hyperplasia or even an infection. The urine-based SelectMDx test assesses prostate cancer specific mRNA biomarkers, to differentiate men at risk who may benefit

from an initial prostate biopsy. Urologists collect a urine sample from their patient and send it to MDxHealth's laboratories to perform the SelectMDx test. Within seven days, urologists receive the test result, which provides the likelihood of detecting prostate cancer upon biopsy as well as the risk for high-grade or low-grade cancer. Urologists can use this information to make a more informed decision whether or not to perform a prostate biopsy. The SelectMDx test is currently available for use in Europe as a laboratory service offering in the Netherlands, Luxemburg, and Belgium; and will also be available in CE-marked reagent kits in early 2016. In the US, MDxHealth will offer SelectMDx as a laboratory developed test in early 2016. The test costs about \$500 and does not have broad reimbursement established yet, but MDxHealth is projecting that the test will be covered in the near future.

MDxHealth's Commitment to Meeting Urologists' Needs

MDxHealth understands the need for fast turnaround time to meet its customers' needs. The company uses FedEx shipment, ensuring overnight shipment of samples to the laboratory. In addition, MDxHealth chose to base its headquarters in California, utilizing the time difference to ensure efficient delivery; the company sometimes receives samples the same day they are shipped. The company has a 37 member sales force, allowing it to raise awareness of the advantages of molecular testing and helping to expand its market share.

MDxHealth is very keen on educating urologists and spreading knowledge about the use of its tests. The company attended 60 tradeshows in 2015 to disseminate knowledge to the industry. The company is expanding its screening offerings into other urological applications as well, and created the AssureMDx™ for Bladder Cancer confirmation. The test is currently undergoing clinical validation trials, and MDxHealth expects to release the test into the market by the end of 2016. As such, with a strong pipeline of products targeting different urological cancers, MDxHealth truly creates a paradigm shift in the cancer diagnostics market.

MDxHealth's Rapid Market Growth

MDxHealth's commitment to meeting its customers' needs has led it to experience rapid growth. For the first nine months in 2015 the company reports commercial revenue growth of 44% to \$11.9 million compared to \$8.3 million in the same period of 2014. Additionally, its test sales rose 48% in 2015 compared to the corresponding period in 2014. MDxHealth acquired NovioGendix in September of 2015, giving the company access to a validated, non-invasive liquid biopsy test - SelectMDx. NovioGenedix's laboratory in the Netherlands is the base of the SelectMDx's launch and expansion into Europe. Finally, MDxHealth announced its recent partnership with SouthGenetics, Inc. that will allow MDxHealth to expand its market share and offer the ConfirmMDx test in both Central and South America.

Conclusion

Currently accepted prostate cancer screening methods are inaccurate, resulting in only about a third of prostate biopsies showing a positive identification of cancer. Prostate biopsies are painful, expensive, and have risks of infection. Furthermore, prostate biopsy screening only tests less than 1% of the prostate, resulting in undetected cancer and leading to painful, and sometimes unnecessary, repeat biopsies.

To provide a more accurate identification of cancer to reduce unnecessary biopsies, MDxHealth developed its ConfirmMDx and SelectMDx tests. The SelectMDx test provides a more accurate determination of whether a biopsy is needed, and ConfirmMDx is a more in-depth tissue analysis test that allows urologists to ensure result accuracy. These test's advancements have led MDxHealth to experience rapid growth in the market and pioneer innovative prostate screening technologies.

With its commitment to technological innovation reduces unnecessary prostate biopsies, MDxHealth earns the 2016 Frost & Sullivan Global Technology Innovation Award.

Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market, and upon maintaining a long-term commitment to innovation. At its core, technology innovation or any other type of innovation can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. This spark can result from a successful partnership, a productive in-house innovation group, or the mind of a single individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.

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 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 winner 	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 may 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

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 almost 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 31 offices on six continents. To join our Growth Partnership, please visit <http://www.frost.com>.