

FROST & SULLIVAN

BEST PRACTICES

AWARDS

FROST & SULLIVAN

2020 BEST PRACTICES AWARD



**2020 NORTH AMERICAN CONCUSSION/
TRAUMATIC BRAIN INJURY ASSESSMENT
TECHNOLOGY INNOVATION LEADERSHIP AWARD**

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Background and Company Performance

Industry Challenges

A concussion is a kind of brain injury resulting from a blow to the head that impacts normal brain functioning and affects memory, speech, balance, and many other functions. The United States (US) Centers for Disease Control and Prevention estimates there are more than 2.5 million emergency room visits in the US due to head injuries annually. Furthermore, there are suggestions that the actual number of concussions occurring in the US each year can potentially be up to 10 million.¹ Traumatic brain injury (TBI) is the leading cause of disability and the number one cause of death for young adults.² Automobile accidents, sport-related injuries, falls, and assaults are common TBI causes.

In neurological care, a quick reaction is obviously essential; therefore, Frost & Sullivan notes that determining and applying the best treatment pathway as quickly as possible is the key to success for neuro-management strategies. In this context, an accurate and efficient diagnosis of neurological disorders such as concussion/TBI is a vital element of care that determines a patient's health outcome. Nevertheless, Frost & Sullivan points out that there is currently a lack of a clinical gold standard in concussion diagnosis: the diagnostics tools are still subjective.

Traditionally, TBI diagnosis is symptom-based, which is inconclusive and inaccurate. At times the symptoms are not present or noticed at the time of injury and can take up to 24 hours to appear. In addition, cognitive tests used for evaluating disorientation from a concussion often require prior testing to create a basis for comparison. Another problem faced by medical professionals stems from the fact that concussions often do not show up on magnetic resonance imaging or computed tomography (CT) scans right away, delaying diagnosis and intervention. As such, Frost & Sullivan analysts recognize that there is a growing need for an objective solution to diagnose TBI rapidly, which will help avoid undiagnosed cases and expedite appropriate treatment.

Frost & Sullivan believes that while a company pioneers an innovative solution, it is crucial to build trust and gather credibility among the medical community. Therefore, it is essential to provide the healthcare community and patients clear information about the perspectives and benefits of solutions through the proven evidence from clinical and scientific researches.

¹ <https://www.globenewswire.com/news-release/2019/10/29/1936938/0/en/Ocologica-Announces-New-Category-3-CPT-Code-Created-by-American-Medical-Association.html>, accessed July 2020

² National Center for Injury Prevention and Control. Report to Congress on Mild Traumatic Brain Injury in the United States: Steps to Prevent a Serious Public Health Problem. In. Atlanta, GA: Centers for Disease Control and Prevention; 2003.

Technology Leverage and Business Impact

EyeBOX: Ground-breaking Innovation

Founded in 2013 by Dr. Uzma Samadani, MD, Ph.D., a neurosurgeon and research scientist, Oculogica is a medical device manufacturing company that leverages its innovative mindset to pioneer an algorithm-based neuro-diagnostics for brain health. Specifically, it focuses on neuro-diagnostics, brain injury, TBI, concussion, and eye-tracking.

Oculogica initially understood that there was no clinical gold standard in concussion diagnosis; and existing diagnostics have been quite subjective. To provide objectivity to concussion assessment, the company introduced EyeBOX, a breakthrough eye-tracking system diagnosing concussions and TBI.

With EyeBOX, assessment is simple, requiring a patient only to place their head on a chin and forehead rest while watching a video for less than four minutes. Notably, there are no literacy or language requirements or even an ability to follow specific directions, apart from just watching the television. The novel device uses ocular motility to detect cranial nerve function. Oculogica's proprietary technology collects and analyzes more than 100,000 data points across 67 domains of eye movement to generate an objective assessment unique to each patient.

EyeBOX Device



Source: Oculogica

In only four minutes, the proprietary algorithm generates BOX ScoreSM, indicating TBI or concussion. EyeBOX does not require baseline data or individual calibration, and a patient's intention cannot influence the results.³

The company built the solution for patients who deserve much better answers than those provided today. As such, it focuses on transparency, quality, and bringing data and objectivity to this field. Notably, EyeBOX is non-invasive; it requires no radiation exposure (such as with CT imaging). Healthcare professionals can use the solution to diagnose both children and adults, as it is an appropriate tool for people ages 5 to 67.

EyeBOX provides detailed, real-time information on TBI and concussions. As a result, it enhances the chances of rapid and precise diagnosis and a better understanding of patient outcomes. Also, with eye-tracking technology advancements, physicians are better informed to rule out traumatic brain injuries from neck injuries and various conditions, such as inner ear damage, that may mimic a concussion.

Deep Focus on Providing Value and High Quality

Since EyeBOX is an innovative solution, Oculogica sees the importance of building trust and gaining credibility among the medical community, and communicating its apparent benefits, and ensuring high-quality outcomes. Frost & Sullivan observes how the company is also creating awareness about its solutions by leveraging its research focus to enhance

³ <http://www.oculogica.com/the-science-2/>, accessed July 2020

its brand recognition. Oculogica actively participates in clinical trials and does fundamental researches. Over the last few years, numerous research studies and publications have validated its concussion assessment approach. Since the launch of the EyeBOX, the company has initiated studies to assess its applicability in concussion management and treatment while exploring its potential utility in the diagnosis of other neurological conditions, such as elevated intracranial pressure.

Oculogica looks to differentiate its device from conventional solutions while adhering to strict reliability and quality US Food and Drug Administration (FDA) standards and adapting to growing market demands for innovation. Notably, the company received the FDA De Novo authorization for EyeBOX. Specifically, the De Novo pathway is exclusively for novel medical devices that are low to moderate risk. Today, EyeBOX is the only solution cleared by the FDA to detect the presence of a concussion.

The FDA granted EyeBOX De Novo status based on Oculogica's pivotal DETECT study that enrolled 282 patients at six independent clinics in the US. The EyeBOX results of patients with a suspected head injury were compared with a concussion clinical reference standard. The study demonstrated EyeBOX's high sensitivity to the presence of a concussion - as well as its ability to provide objective information in the evaluation of patients with a suspected concussion.⁴

The company maintains exceptionally high clinical standards, as it did not put EyeBOX on the market prior to FDA authorization. Many other competitors state they have FDA approval for their product; however, their product's FDA authorization is not for concussion assessments (but other applications). Unlike competitors, Oculogica is committed to the highest standards on that front, all the while extremely careful about its clinical trials. The company adheres to all FDA rules, and it is transparent about its compliance. Oculogica's approach nicely aligns with its mission statement: to place patients before process and science before marketing. The company is transparent about the product's performance and continuously improving and driving its accessibility.

Oculogica has excellent traction with various applications and partners, such as orthopedic surgery clinics, sport medicine clinics, and emergency medicine clinics. The company also plans to expand further by leveraging its growth potential outside of the US. Recently, it placed an EyeBOX unit in one of the leading orthopedic hospitals in the US. In addition, Oculogica has successfully applied for a CPT Code with the American Medical Association: eye movement analysis test without spatial calibration, allowing clinicians to appropriately report the services related exclusively to the Oculogica EyeBOX exam.⁵

Frost & Sullivan appreciates how Oculogica's technology changes the clinical approach for concussion assessment while providing speed and accuracy to concussion diagnosis. The company continues its vital growth and continually works on further innovations. Frost & Sullivan's research analysts believe that a company mindful of both industry and customer challenges is well-positioned to achieve a strong market presence. Through exceptional

⁴ <https://www.globenewswire.com/news-release/2019/10/29/1936938/0/en/Oculogica-Announces-New-Category-3-CPT-Code-Created-by-American-Medical-Association.html>, accessed July 2020

⁵ Ibid.

product value and commitment to innovation, Oculogica holds the potential to revolutionize the space, with the EyeBOX exam becoming the gold standard for concussion diagnosis.

Conclusion

Following a brain injury, swelling occurs that can lead to a concussion. Today, there is a lack of a rapid diagnostic tool for concussion and traumatic brain injuries.

Properly responding to these challenges, Oculogica leverages its innovative mindset - while ensuring transparency and quality - and brings data and objectivity to this field. The company introduced its groundbreaking EyeBOX device, basing the technology on research relating cranial nerve functions to eye movements, not subjective patient symptoms. Frost & Sullivan points out that the device's unique offering comes from the fact that it is a baseline-free, objective, personalized, and short test (taking less than four minutes), and available for multiple levels of education, language fluency, and age. Furthermore, EyeBOX is the only solution authorized by the FDA to detect the presence of a concussion.

With its commitment to innovation and unrivaled value, Oculogica earns the 2020 Frost & Sullivan Technology Innovation Leadership Award.

Significance of Technology Innovation Leadership

Technology-rich companies with strong commercialization strategies benefit from the increased demand for high-quality, technologically-innovative products. Those products help shape the brand, leading to a strong, differentiated market position.



Understanding Technology Innovation Leadership

Technology Innovation Leadership recognizes companies that lead the development and successful introduction of high-tech solutions to customers' most pressing needs, altering the industry or business landscape in the process. These companies shape the future of technology and its uses. Ultimately, success is measured by the degree to which a technology is leveraged and the impact that technology has on growing the business.

Key Benchmarking Criteria

For the Technology Innovation Leadership Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Leverage and Business Impact—according to the criteria identified below.

Technology Leverage

- Criterion 1: Commitment to Innovation
- Criterion 2: Commitment to Creativity
- Criterion 3: Technology Incubation
- Criterion 4: Commercialization Success
- Criterion 5: Application Diversity

Business Impact

- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Operational Efficiency
- Criterion 4: Growth Potential
- Criterion 5: Human Capital

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"> • Announce 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>.