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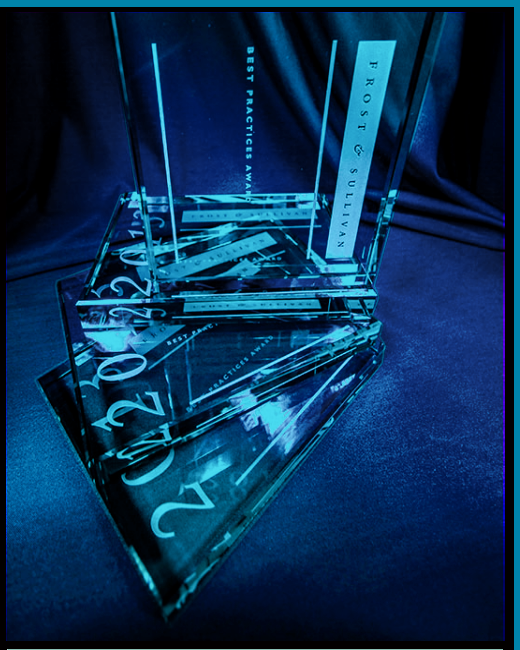
inspirata
Transforming Cancer Diagnostics

2016 North American Digital Pathology and Cancer Diagnostics Technology Innovation Award



FROST & SULLIVAN

2016 BEST PRACTICES AWARD

NORTH AMERICAN DIGITAL PHATHOLOGY AND CANCER DIAGNOSTICS TECHNOLOGY INNOVATION AWARD

2016
BEST PRACTICES
AWARDS

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Background and Company Performance

Industry Challenges

Innovations in digital imaging technologies have led to revolutionary workflow improvements in diagnostic departments within healthcare organizations over the last two decades. Similar to the advent of digital radiology in the mid-1980s, more affordable imaging systems are presently reshaping the diagnostics landscape in pathology departments aided by automated workflows that are helping to simplify the transition towards digital operations.

While digital pathology is still somewhat novel, it is catching on and is expected to expand rapidly in the U.S. once the FDA approves the use of Whole Slide Images (WSIs) by pathologists for primary diagnosis.

Whole-slide scanners are employed to digitize patients' glass pathology slides containing biopsied tissue specimens. This process is done at high resolution, typically over 160nm per pixel. Once these specimens are available digitally, image analysis can be used to reveal a vast amount of new diagnostic, therapy-related and even prognostic insights. These new possibilities have captured the attention of the clinical community, particularly in the realm of histopathologic image analysis.

On this note, digital pathology is associated with the next generation of big data, in which the morphology of diseased tissue can be used to strengthen both clinical research and improve medical treatment. In addition, digital pathology may act as the main catalyst to discover biomarkers related to molecular pathways associated with disease progression.

An added bonus in moving from an analog to a digital workflow in pathology is that it creates the synergy among radiographic imaging and the "omics" technology-based measurements, particularly proteomics and genomics, in which features extracted from images may significantly help improve the prediction of disease aggressiveness and progression, as well as help inform decisions about therapy and patient outcome.

The advantages of digital pathology for the current case load may seem clear; however, imagine scanning the millions of retrospective glass slides in order to leverage the treasure trove of data they hold? Many believe this task is insurmountable. However, transforming challenges into opportunities, especially in the area of precision medicine, such implications represent remarkable opportunities in image computing and big data analytics. Indeed, digital pathology slide images enable quantitative modeling of disease appearance, thereby promoting enhanced prognostic prediction and treatment decisions.

Emerging developments in computational image analysis tools and deep learning schemes for predictive modeling of Whole Slide Images are focused on disease detection, segmentation, feature extraction and classification. This constitutes one of the most promising opportunities in this field.

Technology Attributes

Criterion 1: Industry Impact

Whole Slide Imaging (WSI) systems are presently considered as high-risk, Class III devices by the U.S. Food and Drug Administration (FDA). This classification, however, is believed to be unnecessarily burdensome for those associated with digital pathology. Foreseeing the huge scope of digital pathology in cancer diagnostics, and owing to a collaborative effort between Digital Pathology Association (DPA) and the FDA, both organizations are reviewing clearance applications related to digital pathology systems so as to introduce a more appropriate regulatory approval route. As a result, digital pathology would be reclassified for primary diagnosis from the high-risk Class III category to the medium-risk Class II category through the de novo process.

Promptly realizing the benefits of applying digital pathology technology in cancer diagnostics and the revolutionary transformation that it can offer, Inspirata® has pioneered a digital pathology workflow solution that helps to automate the previously analog practice. Inspirata has developed an innovative approach to the market, established strategic partnerships with WSI scanning partners and created a strong brand for itself that position it to significantly tap into the opportunities owing to FDA's decision to reclassify WSI systems.

The cumulative effect of these changes has brought about holistic transformation of a 100-year-old workflow, empowered by technologies that enable an automated information workflow based on digital imaging of glass pathology slides. Such procedural improvements benefit all stakeholders in the value chain, including patients who will be able to receive their diagnosis faster and with far greater actionable insights; the clinical team, who will be able to provide more informed decisions related to treatment protocols and outcomes; WSI scanner manufacturers who will be able to invest in advancing their imaging technologies; and researchers, who will be able to study large-scale image-anchored libraries and analyze the evolution of specific populations and patient stratifications for further discovery.

Inspirata's digital pathology solutions automate the entire pathology workflow as a managed service, including providing the resources and equipment to scan the heathcare institution's retrospective and prospective case load. The company aims to reduce both time and cost of diagnosis by optimizing the workflow through the use of the digital images and leveraging its integrated Digital Pathology Cockpit and novel image analysis algorithms as well as prognostic and predictive assays to improve diagnostic accuracy. Once an institution has a digital pathology workflow, it can generate new revenue streams by providing consultation services both inside and outside its network, locally and globally. Additionally, Inspirata plans to stimulate innovation-driven product development through a large-scale cancer information database that can be used for research and educational activities as well as clinical endeavors.

Conducting research on the North American digital pathology market, Frost & Sullivan identified Inspirata as a leading influencer in the practice of pathology, delivering leading-edge solutions by using next-generation tools and technologies to accelerate cancer diagnostics, prognostics, monitoring, treatment and surveillance.

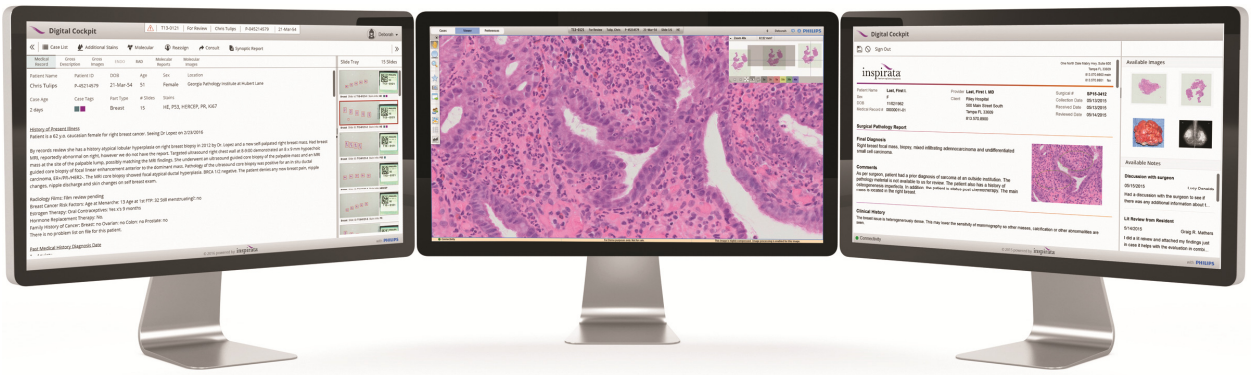
Criterion 2: Product Impact

Based on ongoing discussions between the DPA and FDA, key areas of safety and efficacy associated with the digital pathology technology have been recognized. This is expected to provide the special controls needed to ensure the safety and effectiveness of WSI systems classified under the new regulatory pathway. The most relevant factors identified rely on testing data sets, technical performance and clinical studies, analytic considerations, human factors revisions, care giver training, labeling, post-market surveillance, as well as ongoing safety and effectiveness programs to introduce variation and/or updates in WSI-based product design.

Aligned to this approach, Inspirata developed a flexible and scalable platform that streamlines the complexities of multiple points of contact between systems. The company's Enterprise Service Bus (ESB) connects seamlessly with institution-maintained integration engines or directly to its existing systems. HL7-compliant, Inspirata's ESB facilitates the sharing of data between systems through a meaningful reduction in the number of export and import end points. Systems that the ESB can communicate with include anatomic pathology laboratory information system (APLIS), electronic medical records (EMR), radiology application data (RAD), grossing and endoscopy imaging systems (ENDO), as well as molecular and omics technology systems, among others.

PathologyNEXT® constitutes Inspirata's overall approach to transforming the pathology workflow from analog to digital. It comprises round-the-clock high-volume, high-speed slide scanning services and the integrated Digital Pathology Cockpit used by pathologists for image viewing, image sharing, annotation, image analysis and reporting. Featuring decision support and image analysis tools and predictive assays along with big data analytics solutions, Inspirata offers the most complete digital pathology solution in the market today.

Inspirata's Digital Pathology Cockpit is a specially designed desktop system with either

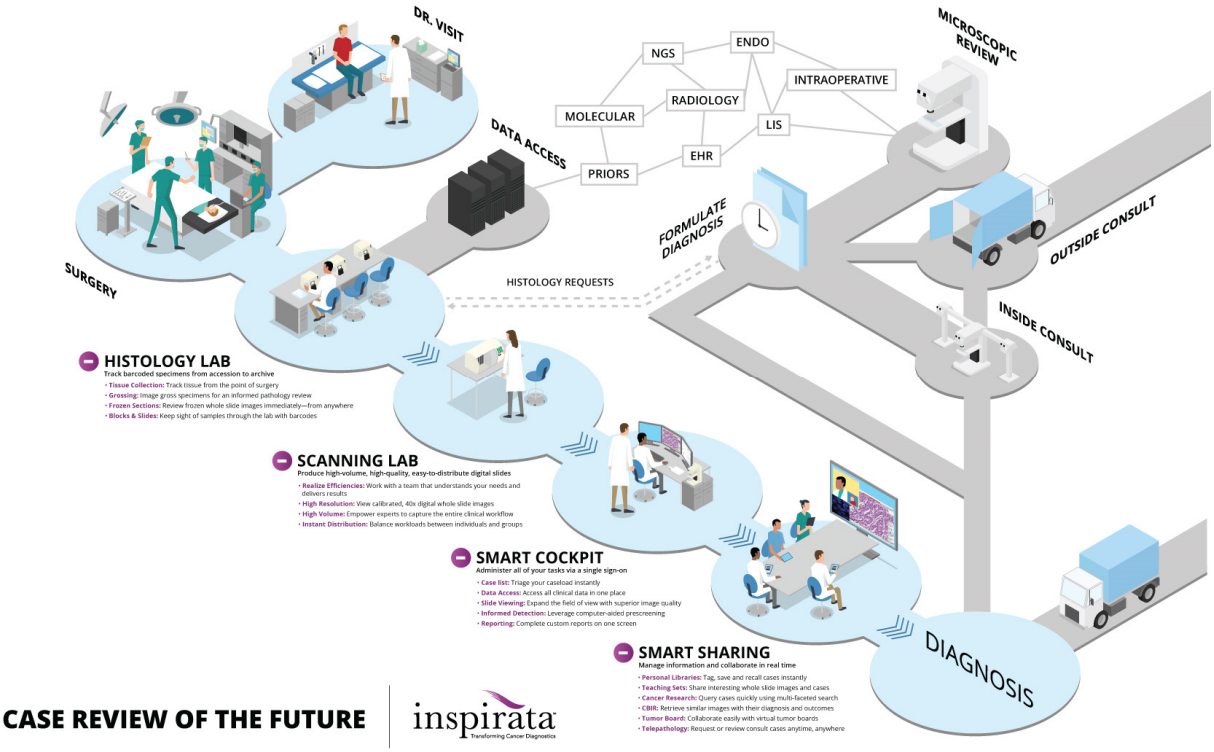


two- or three-monitor configurations that provide single sign-on access to the relevant patient's history, clinical notes and other diagnostic imaging modalities. The cockpit enables pathologists to review cases much more comprehensively and efficiently than just using the traditional microscope.

Criterion 3: Scalability

Offering a very unique business model, Inspirata is providing a far-reaching, long-term digital pathology workflow solution at the Ohio State University Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (OSUCCC-James) and the Department of Pathology of The Ohio State University Wexner Medical Center in Columbus, Ohio. This comprehensive deployment is the first of its kind in the U.S., with the aim to digitize, analyze and archive millions of retrospective and prospective pathology slides. The principal purpose of this transformative engagement is to establish an end-to-end digital pathology workflow and achieve a deeper understanding of cancer progression associated with treatment protocols and patient outcomes. Most importantly, the technology provided by Inspirata features WSI systems in combination with Inspirata's integrated Digital Pathology Cockpits along with visualization software and image analysis automation, as well as its big data analytics capabilities.

Under this agreement, Inspirata has operationalized the cost of what would otherwise have been a cost-prohibitive capital expense, especially prior to the FDA approving the use of digital images for primary diagnosis. The engagement includes an array of vendors that Inspirata has partnered with to include the full spectrum of scanning devices, software and digital services required to underpin a fully automated end-to-end pathology workflow solution. As the project lead, Inspirata is providing the skilled staffing needed to manage the entire implementation and ongoing workflow support needed to digitize the institution's retrospective and prospective glass pathology slides.



The shift from analog-based pathology information to digital-based pathology information provides Inspirata's customers with digital access to a plethora of previously unmined data, while simplifying the pathology workflow and strengthening long-term relationships with local and regional partners to undertake both quality assurance and telepathology initiatives.

Criterion 4: Visionary Innovation

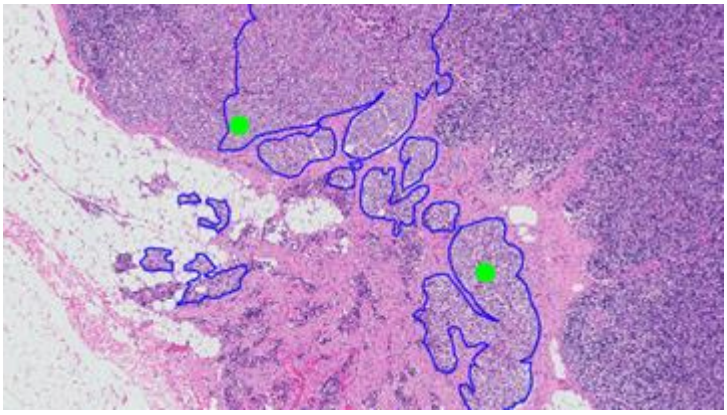
According to the World Health Organization (WHO), global estimations of new cancer cases diagnosed in 2012 have reached 14 million, which is expected to rise to 22 million annually within the next two decades. In the US alone, 1.6 million new cases of cancer were diagnosed in 2015. Nevertheless, these numbers could be dramatically reduced with appropriate early diagnosis. Inspirata is strongly committed to contributing to precision medicine, particularly in cancer diagnostics, through advancements in digital pathology.

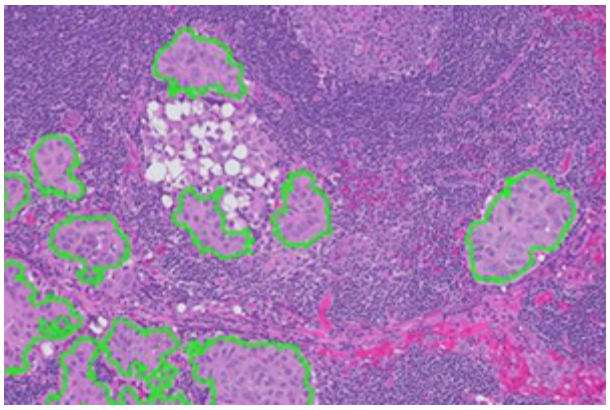
In parallel, the consequences of the FDA reclassification process around WSI systems affords impressive advantages for the healthcare industry. The possibility to establish a less stringent pathway is expected to draw new biomedical devices manufacturers to the

digital pathology space, consequently intensifying competition and boosting innovation-driven technology developments. According to Frost & Sullivan, these advances are also expected to drive the scanner technology evolution, which would potentially propel the development of higher imaging quality and performance. Encompassing these developments, next-generation software tools are expected to exhibit steep growth in the market. Together with its partners, Inspirata is positioned to embrace this opportunity and be the leading company in the U.S. to advance digital pathology adoption.

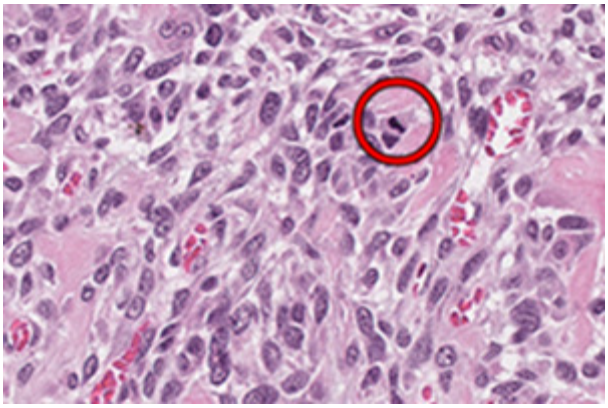
Criterion 5: Application Diversity

The application of digital pathology solutions is transitioning from glass slides to digital images. Inspirata offers a complete set of digital pathology algorithms that can be run on the image features of the digitized histology slide, thereby generating a substantial amount of actionable data. By synergistically combining its rich expertise in image analytics, big data and biotechnology, Inspirata's solutions allow for the extraction and quantification of relevant image-based information, hence creating the base for detection, diagnosis, prognostic and theragnostic algorithms and assays. This information is crucial for pathologists and biomedical companies navigating cancer diagnostics and therapeutics development.





Inspirata's suite of digital pathology algorithms is used to detect and highlight unusual cell structures and other morphological abnormalities in a pre-screening process known as Informed Detection. This application serves to triage the case list and assist the pathologist to quickly identify potential malignancies.



Another of Inspirata's image analysis algorithms falls into the Directed Review toolkit. Called MitoSĒK™, it enables the pathologies to highlight a single feature and then allow the algorithm to find all similar features in the same image, thereby eliminating the need for a time-consuming manual identification and counting processes. Another similar algorithm, histoSĒK™, illustrates spatial colocation of tumor focus while dismissing background stroma, thus providing a cost and time-efficient tool to pathologists attempting to identify tumor areas.

Criterion 6: Financial Performance

In July 2016, the National Cancer Institute (NCI) awarded a $3.3 million 5-year academic-industry grant to Inspirata and Case Western Reserve University (CWRU) for a breast cancer risk assessment assay. The work will be focused on the development and validation of a digital pathology image-based breast cancer predictor assay. Contrary to the expensive and time-consuming genomic tests currently used to identify the best course of treatment for breast cancer patients, Inspirata and CWRU are leveraging information available within cell morphology, including texture, shape and structure of glands and nuclei, to design an assay capable of determining which early-stage ER+ breast cancer patients are candidates for hormone therapy without adjuvant chemotherapy.

One of the competing genomic solutions is capable of identifying the 50% ER+ breast cancer patients supposed to do not benefit from chemotherapy. Nevertheless, the cost of this genetic test reaches $4,000 per patient, and it must be carried out in a specialized facility. In addition, only a small region of the tissue can be tested, and results are delivered after 10-14 days.

The Inspirata and CWRU process, on the contrary, provides results in minutes, is significantly cheaper than the genomic test and the analysis can be performed anywhere in the world that the digital image of the tissue sample can be shared. Definitely, the introduction of this technology in the market and the validation of these efforts through this academic-industry partnership grant is expected to boost cancer imaging research and digital pathology application.

Criterion 7: Customer Acquisition

Frost & Sullivan emphasizes that Inspirata's digital pathology strategy, which enables a digital workflow that, apart from making the processes more efficient than before, also positions customers ahead of the digital pathology technology adoption curve once regulatory conditions enable the use of digital images in primary diagnostics.

Inspirata's Solution-as-a-Service (SaaS) delivery model is reshaping the North American healthcare sector by transforming the pathology workflow. The transition from a capital expenditure (CapEx) model toward an operational expenditure (OpEx) all but removes the financial barrier to adoption. Bundling digital pathology hardware, software and the associated infrastructure makes this a complete solution. Other features include full integration to APLIS, EMR, image analysis algorithms, pathology reporting and scan lab resources to complete the scanning process from glass slides to digital images.

Criterion 8: Technology Licensing

Inspirata is helping its customers stay ahead of the digital pathology adoption curve through its unique business model and by providing a fully managed Solution-as-a-Service. Inspirata's customized, state-of-the-art solution aims to simplify interoperability and enhance the quotient of scalability, reliability and redundancy. Furthermore, Inspirata employs a defense of depth strategy for data security, providing layered protection at multiple stages.

Under this SaaS framework, cancer centers are able to address the growing demand for more accurate cancer diagnostic services, especially in the precision medicine sphere. Inspirata's revolutionary approach accelerates digital pathology technology adoption, while enhancing productivity, reducing costs, and creating new revenue streams through second opinions, consultations and telepathology.

Remarkably, Inspirata takes on most of the financial risk by making upfront capital investment in the hardware and specialized equipment, infrastructure and software development. Integration services and staffing are also provided by Inspirata.

Criterion 9: Brand Loyalty

Inspirata has revolutionized the North American industry with a set of services supporting its technology solutions. Technology deployment, technical assistance as well as equipment and software maintenance services are part of the service package provided by Inspirata through its partners. Inspirata also engages in sponsored research opportunities at its client sites. Importantly, at the end of an Inspirata engagement, customers own the technology assets and are able to either hire the personnel or renew the contract with Inspirata to continue the managed services model.

Criterion 10: Human Capital

Inspirata's culture is structured around each employee's alignment to the company's vision and the understanding of the vital role each of them has. Inspirata's primary focus areas are cancer diagnostics and informatics-driven advancements, innovative outsourcing models, and agile and passionate work strategies.

Inspirata's leaders are committed to tapping into the advancements in scientific discovery to bring about relevant changes in medical practice. Transformational thinking about precision medicine demands multidisciplinary expertise, embracing clinical specialties, scientific research, informatics and big data analytics solutions. Frost & Sullivan sees in Inspirata an unrivaled participant in such a confluence of disciplines and skills.

Conclusion

Headquartered in Tampa, Florida, Inspirata delivers cancer diagnostics solutions through a complete set of digital pathology technologies that enable the digitization, automation and interoperability of the entire pathology workflow using a unique Solution-as-a-Service delivery model. The integrated Digital Pathology Cockpit and comprehensive suite of algorithms are central to Inspirata's solution. In addition to workflow optimization, is the extraction of relevant image-based information from digitized histology tissue specimens to gain deeper insights about cancer, its progression and its treatment. This is done to assist pathologists with more accurate information to facilitate more rapid cancer disease detection and more targeted therapeutic recommendations.

With its strong overall performance, Inspirata has earned Frost & Sullivan's 2016 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. That spark can result from a successful partnership, a productive in-house innovation group, or the mind of a singular 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.

Key Benchmarking Criteria

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

Technology Attributes

- Criterion 1: Industry Impact
- Criterion 2: Product Impact
- Criterion 3: Scalability
- Criterion 4: Visionary Innovation
- Criterion 5: Application Diversity

Future Business Value

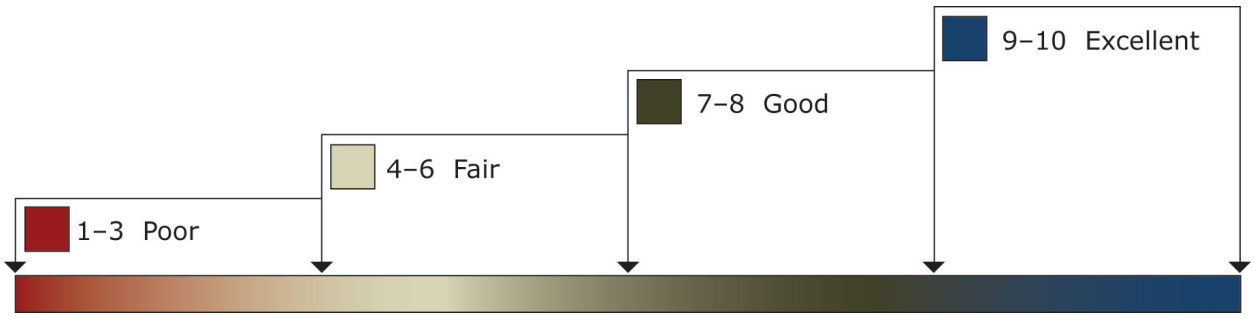
- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Technology Licensing
- Criterion 4: Brand Loyalty
- Criterion 5: Human Capital

Best Practice Award Analysis for Inspirata

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 our 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 is organized by Technology Attributes and Future Business Value (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria 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, we have chosen to refer to the other key players as Competitor 2 and Competitor 3.

DECISION SUPPORT SCORECARD FOR TECHNOLOGY INNOVATION AWARD

Measurement of 1–10 (1 = poor; 10 = excellent)			
Technology Innovation	Technology Attributes	Future Business Value	**Average Rating**
Inspirata	**9.8**	**9.8**	**9.8**
Competitor 2	4.6	3.8	4.2
Competitor 3	4.2	3.6	3.9

Technology Attributes

Criterion 1: Industry Impact

Requirement: Technology enables the pursuit of groundbreaking new ideas, contributing to the betterment of the entire industry

Criterion 2: Product Impact

Requirement: Specific technology helps enhance features and functionality of the entire product line for the company

Criterion 3: Scalability

Requirement: Technology is scalable, enabling new generations of products over time, with increasing levels of quality and functionality

Criterion 4: Visionary Innovation

Requirement: Specific new technology represents true innovation based on a deep understanding of future needs and applications

Criterion 5: Application Diversity

Requirement: New technology serves multiple products, multiple applications, and multiple user environments

Future Business Value

Criterion 1: Financial Performance

Requirement: High potential for strong financial performance in terms of revenues, operating margins and other relevant financial metrics

Criterion 2: Customer Acquisition

Requirement: Specific technology enables acquisition of new customers, even as it enhances value to current customers

Criterion 3: Technology Licensing

Requirement: New technology displays great potential to be licensed across many sectors and applications, thereby driving incremental revenue streams

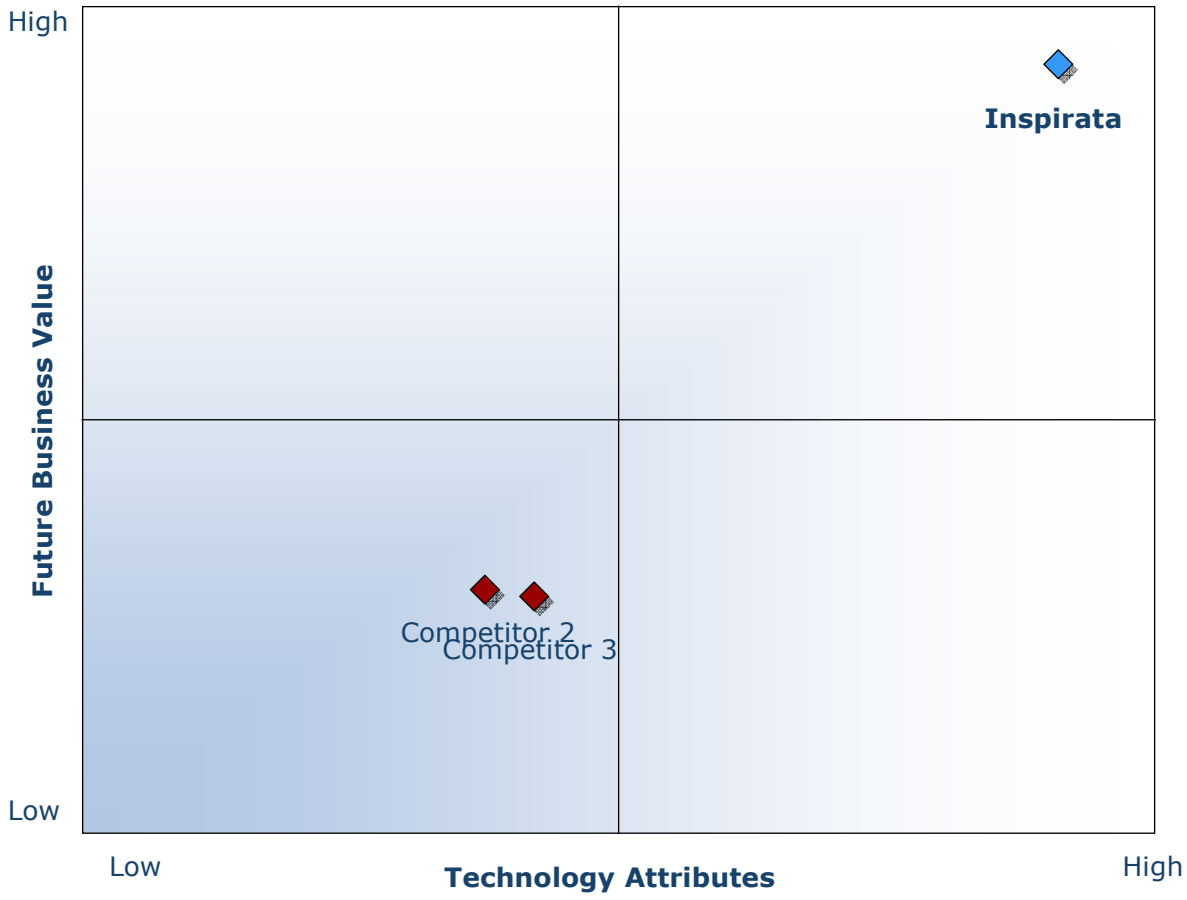
Criterion 4: Brand Loyalty
Requirement: New technology enhances the company's brand, creating and/or nurturing brand loyalty

Criterion 5: Human Capital
Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention

Decision Support Matrix

Once all companies have been evaluated according to the Decision Support Scorecard, analysts can 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.

DECISION SUPPORT MATRIX FOR TECHNOLOGY INNOVATION AWARD



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.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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

	STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
10	**Take strategic action**	Upon licensing, company may share award news with stakeholders and customers	• 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.