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BEST PRACTICES

AWARDS

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2020 BEST PRACTICES AWARD



**2020 NORTH AMERICAN AI-DRIVEN DIGITAL
PATHOLOGY LAB SOLUTIONS COMPETITIVE
STRATEGY INNOVATION AND LEADERSHIP AWARD**

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Background and Company Performance

Industry Challenges

The advent of precision medicine, particularly precision oncology, has created a strong demand for more accurate biomarker evaluation and more quantitative histopathologic cancer diagnosis to optimize therapeutic decisions. The most promising and essential advancement in digital pathology is tightly associated with the introduction of artificial intelligence (AI), machine learning (ML), and deep learning (DL) methodologies that empower computer models with image recognition technology. Moreover, AI-driven systems constitute a step forward in precision digital pathology by providing new methodologies and tools to deliver highly sensitive and specific diagnostics, thereby complementing or even outperforming human expert decisions.

The digitalization of microscopic images of tissue sections and biopsies is facilitating the increasing utilization of quantitative AI-driven image analysis as a clinically valuable tool to detect diseases precisely and predict patient outcomes. Consequently, innovative digital image analysis methodologies are needed that can improve therapy-response prediction and outcome prognosis. AI-based technologies offer unprecedented levels of solutions convergence capabilities, whereas cloud-based infrastructure and virtual reality/virtual experience (VR/VX) allow companies to provide solutions with a multinational presence. Even though the exact path in which digital image analysis should be implemented in the clinical setting is still challenging, AI-driven digital image analysis is exhibiting the best-suited results in terms of biomarker classification, visual interpretation, and reproducibility in cell counting.

The introduction of AI-driven solutions in digital pathology will help medical diagnostics companies advance their precision medicine solutions, thus providing accurate, time- and cost-effective treatment that will allow the medical community to address the most concerning and life-threatening conditions.

Strategy Innovation and Customer Support

Strategy Focus

Interest and competition in digital image analysis solutions for clinical applications are rising. According to Frost & Sullivan, the North American digital pathology market was valued at \$279 million in 2019 and is expected to reach \$593.2 million by 2025, at a compound annual growth rate (CAGR) of 13.4%. In addition, Frost & Sullivan emphasizes the increasing growth of the software solutions market segment, which is expected to expand at a CAGR of 19.2% between 2020 and 2025.

Roche is a leading participant in the US market and offers the key product line of VENTANA, including whole slide imaging (WSI) scanners, image analysis software, workflow management solutions, and additional training products. While the lack of system interoperability and the high cost of software licenses have traditionally been the two key barriers for the acceleration of the digital pathology software segment, Roche has faced these challenges by expanding its portfolio, based on a transformation of the pathology lab experience far beyond microscopes and glass slides. In this highly competitive sector, Roche

has taken advantage of a large intellectual property portfolio and proven ability to develop innovative solutions. These two factors of success have allowed Roche to maintain its competitive advantage.

Strategy Effectiveness

The Roche Digital Pathology division has concentrated its efforts on streamlining the workflow between laboratories and patient information. For instance, the Roche uPath enterprise software can remarkably boost the efficiency of the pathology laboratory workflow by enhancing both connectivity and automation capabilities. Consisting of a universal platform, which seamlessly integrates communication tools with intelligent, AI-driven digital image analysis tools, the Roche uPath software empowers pathologists in the assertive, quantitative, and accurate assessment of WSI.

For Roche, supporting the growth of digital pathology solutions in clinical trials is essential as well. Therapeutics-specific software application development involving image management solutions is increasing significantly, driven by about 10% of the annual increase in the slide workload. On that note, Roche has been largely focused on improving image analysis algorithms using ML/DL platforms. Although Roche's competitors have introduced web-based image management systems equipped with archiving systems, metadata fields, image viewers, and user manager tools, Roche promptly envisioned the major role of AI-driven digital image analysis in pathology labs.

Furthermore, one of Roche's competitive strategies includes ensuring that all developed and/or incorporated technology can be reused in further innovations, thus maximizing investment returns. AI-driven systems play an essential role in this process, securing a proven and established approach in one of the most promising fields of the future of medicine.

Frost & Sullivan highlights Roche's strategy effectiveness throughout the introduction of innovative digital solutions across its entire portfolio, positioning the digital pathology lab as a direct interactive experience for all participants in the value chain.

Strategy Execution

Frost & Sullivan research indicates that in the digital pathology space, the demand for digital pathology is expected to be driven by several factors, such as the rising cancer prevalence, drug discovery applications, and increasing tele-consultations. Market growth will be largely driven by the expected approval of digital pathology solutions for primary diagnosis purposes, growing focus of diagnostics labs on improving lab efficiency, increasing number of cancer cases, and lowering cost of digital pathology solutions. Furthermore, improvements in image analysis algorithms will drive the adoption of digital pathology solutions at both the clinical level and in academic research and clinical trials. In addition, the adoption of AI and ML/DL tools will help companies improve their existing solutions and gain traction from other user segments, including drug development, clinical trials, and biobanking. For instance, companies expecting to receive US Food and Drug Administration (FDA) accreditation need to conduct data validation exercises of their WSI systems for primary diagnosis. AI-driven digital image analysis may significantly assist them to achieve this goal.

Suitably, Roche's strategy execution is based on the expansion of its product portfolio through partnerships and acquisitions, while exploring new technologies for image analysis and addressing key customers' needs by optimizing their workflow integrations. Moreover, Roche is permanently making investments in research and development (R&D), such as opening virtual reality labs to serve key digital pathology market segments.

Competitive Differentiation

The key areas differentiating digital pathology companies are based on the adoption of innovative technology; the use of AI; Big Data-based image analysis; and a focus on niche areas, such as oncology, plant pathology, and forensic science.

Roche is well positioned as a pioneer in oncology therapy, resulting in the expansion of its consumer base, which is represented by companies that excel in technology innovation, cancer research, and drug discovery and development, among many others.

In tighter collaboration with its parent company, Roche Pharmaceuticals, Roche Diagnostics has increased the rate of companion diagnostics receiving FDA approval for oncology-based drugs and tests, and is now adding digital pathology solutions as an adjunctive tool to augment diagnostic confidence in scoring for these assays. To strengthen such a position, Roche is heavily investing in accurate biomarkers assessment and in the development and delivery of medical diagnostic systems, including machine and deep learning technologies to advance the development of AI-driven image analysis solutions to support clinical decision support for more personalized healthcare.

Stakeholder Integration

Digital pathology services are offered through different business models, including outright purchase, leasing, pay-per-use, and software-as-a-service (SaaS). Based on Frost & Sullivan analysis, Roche critically understands the value of the clinical laboratory within the broader healthcare ecosystem.

The Roche Healthcare Consulting division utilizes Proven Methodologies and Best Practices from the best-performing labs across the world and other leading industries to create custom solutions for our customer's most pressing issues. Frost & Sullivan commends Roche's leveraging their data analytics capabilities to gain a deep understanding of the challenges and opportunities laboratories face when standing up their digital capabilities. In addition, Roche's Best-in-Industry Expertise leveraging hundreds of years of experience, innovative tools and techniques, and metric-based actionable insights are critical to helping customers manage and motivate laboratorians' adaptation to their changing digital environment.

Customer Service Experience

Overall, Roche offers the following three main digital transformation solutions focused on pathology:

- Digital workflow and case management solutions, which streamline the typical pathology workflow and enable access to specialists through seamless virtual connections to discuss and obtain a second opinion with time-saving efficiency while allowing practices to expand worldwide.
- Image Analysis Services, which use a CE mark and US IVD-validated companion algorithm software to provide specialists with rapid, consistent, and reproducible immune-histochemistry (IHC) interpretations.
- Education Services, which expand learning possibilities with high-tech access to standardized content, including slide images and materials, by reshaping medical education and non-clinical collaborations while eliminating the risk and cost of sharing multi-headed resources.

All these services have in common a user-centric design based on an enhanced user experience, with an innovative design for rapid case sign out. In addition, the design offers customizable options based on personal preferences and one-click image analysis, thus providing speedy, fully automated analysis for specific biomarkers, safe access and automated data transfer, enhanced authentication, and database encryption.

Furthermore, Frost & Sullivan commends Roche's essential focus on the attributes of speed and performance. From an end-user perspective, this fact means the faster load time of cases and high resolution images for analysis, with an easily scalable and customizable multi-site installation. Similarly, Roche's digital pathology solutions enable a fully integrated digital environment via connection with the Laboratory Information System to enable a streamlined laboratory workflow.

Conclusion

The transition to digital pathology is raising the standard of precision medicine, based on the results of digital pathology laboratories. Pathologists' demand for access to seamless integrated connections and innovative solutions that help them enhance diagnostic confidence and efficiency is evolving faster than supply capability. Accordingly, leading digital pathology developers are in the race to position the best-suited digital pathology image solutions within the market.

Focused on digital pathology, Roche understands the dynamics of healthcare organizations at all levels, from organizational structures and processes to efficient pathology laboratory workflows. Roche's visionary innovation route is leading the transformation of the digital pathology space. By introducing AI-driven solutions, along with its supportive digital transformation solutions, digital workflow solutions, image analysis, and education services, Roche is embracing a new form to empower the medical community with accurate, precise, personalized solutions, based on the most streamlined solutions available in the market. This vision intensifies clinical confidence and raises the standard of patient care in each single innovation. AI-driven innovative solutions come with more digitization and autonomy, which are two of the principal elements expected to play the most critical role in the present and future practice of medicine.

With its strong overall performance, Roche has earned Frost & Sullivan's 2020 Competitive Strategy Innovation and Leadership Award in the North American AI-driven digital pathology lab solutions industry.

Significance of Competitive Strategy Innovation and Leadership

Any successful approach to achieving top-line growth must take into account what competitors are and are not doing; meet customer demand with a comprehensive, value-driven product or service portfolio; and establish a brand that resonates deeply with customers and stands apart from other providers. Companies must succeed in these 3 areas—brand, demand, and positioning—to achieve best-practice levels in competitive strategy.



Understanding Competitive Strategy Innovation and Leadership

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

Key Benchmarking Criteria

For the Competitive Strategy Innovation and Leadership Award, Frost & Sullivan analysts independently evaluated Strategy Innovation and Customer Impact according to the criteria identified below.

Strategy Innovation

- Criterion 1: Strategy Effectiveness
- Criterion 2: Strategy Execution
- Criterion 3: Competitive Differentiation
- Criterion 4: Executive Team Alignment
- Criterion 5: Stakeholder Integration

Customer Impact

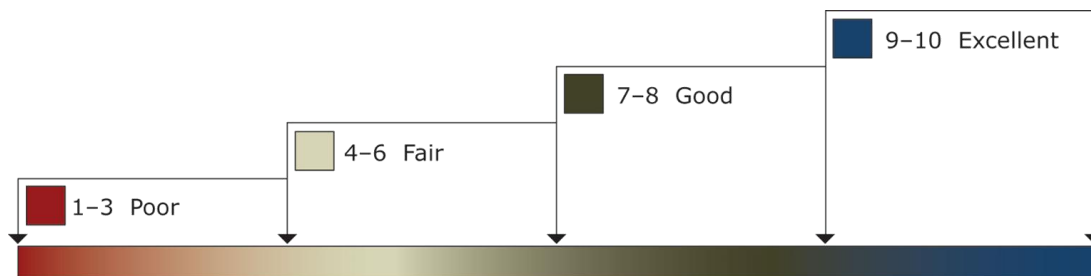
- Criterion 1: Price/Performance Value
- Criterion 2: Customer Purchase Experience
- Criterion 3: Customer Ownership Experience
- Criterion 4: Customer Service Experience
- Criterion 5: Brand Equity

Best Practices Award Analysis for Roche

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 Strategy Innovation 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>			
Competitive Strategy Innovation and Leadership	Strategy Innovation	Customer Impact	Average Rating
Roche	9.8	9.8	9.8
Competitor 1	6.4	4.8	6.1
Competitor 2	5.8	5.0	5.4

Strategy Innovation

Criterion 1: Strategy Effectiveness

Requirement: Strategy effectively balances short-term performance needs with long-term aspirations and vision for the company.

Criterion 2: Strategy Execution

Requirement: Adoption of best-in-class processes supports the efficient and consistent implementation of business strategy.

Criterion 3: Competitive Differentiation

Requirement: Unique competitive advantages with regard to solution or product are clearly articulated and well accepted in the industry.

Criterion 4: Executive Team Alignment

Requirement: The executive team is aligned with the organization’s mission, vision, strategy, and execution.

Criterion 5: Stakeholder Integration

Requirement: Strategy reflects the needs or circumstances of all industry stakeholders, including competitors, customers, investors, and employees.

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

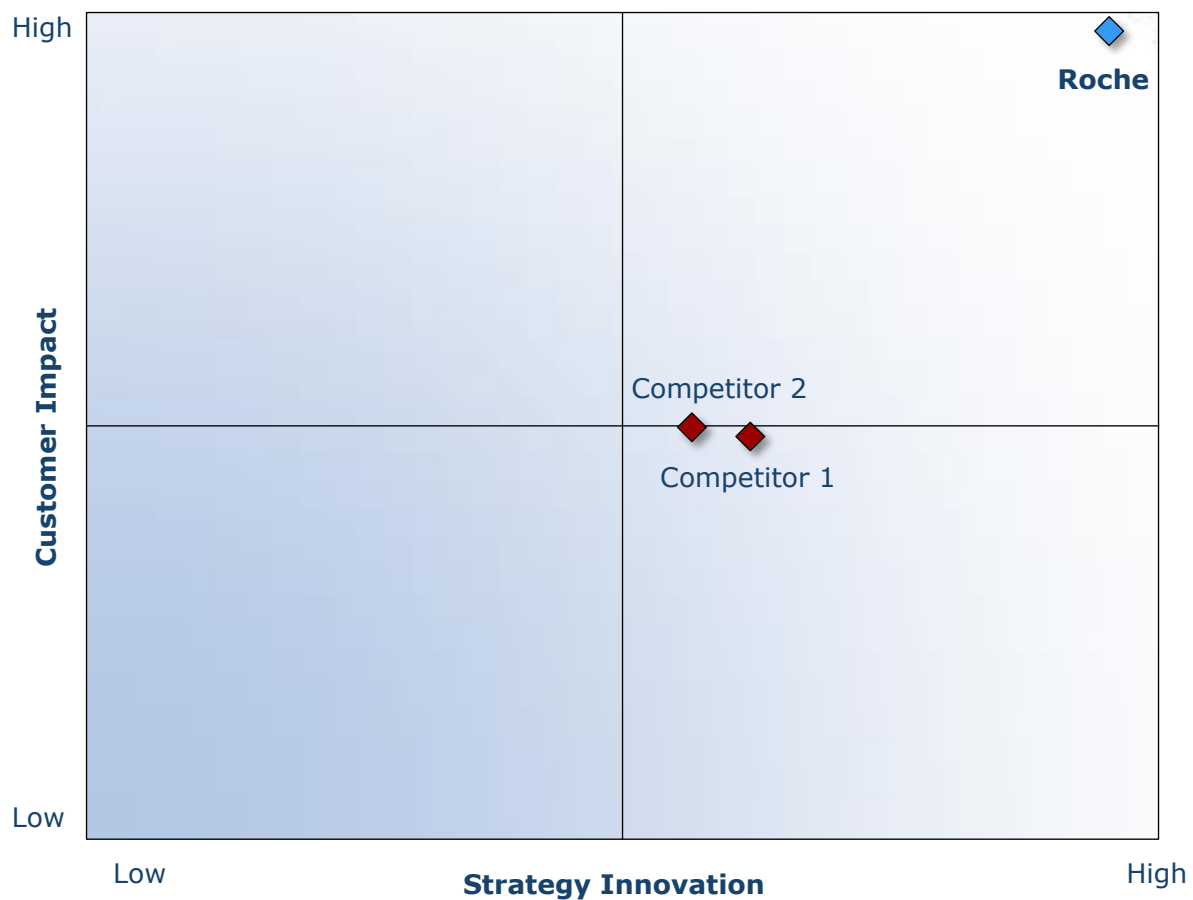
Requirement: Customer service is accessible, fast, stress-free, and of high quality.

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 practices 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 world	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging industries • Scan multiple regions 	Pipeline of candidates that potentially meet all best practices 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 practices 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 practices 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 practices 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 practices 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 practices criteria
9 Communicate recognition	Inform award recipient of 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 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 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.



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>.