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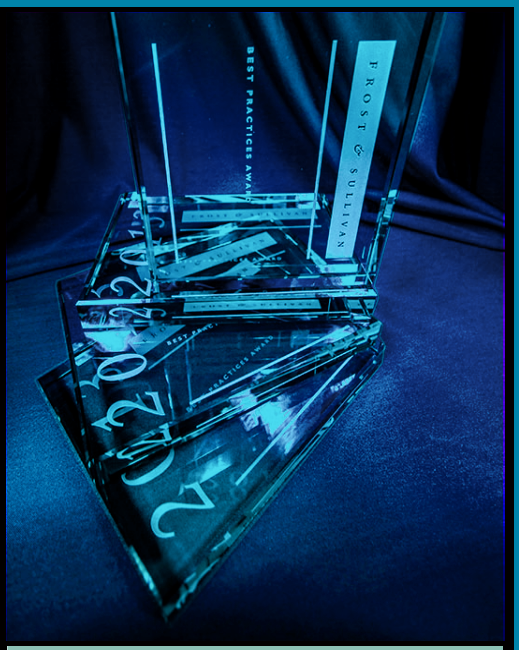
cytori

2016 North American Cell Therapeutics Technology Innovation Award



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2016 BEST PRACTICES AWARD

NORTH AMERICAN CELL THERAPEUTICS TECHNOLOGY INNOVATION AWARD

2016
BEST PRACTICES
AWARDS

Contents

Background and Company Performance

Industry Challenges

Cell therapeutics is one of the principal areas of regenerative medicine, which — after more than two decades of basic research — is considered a remarkable innovation in medical care. Regenerative medicine encompasses principles of stem cell technology and tissue engineering and combines advanced biomaterials with small molecules and biologics to either replace or regenerate human tissues and organs and restore their functions.

Beyond the treatment of acute injuries, chronic diseases, and congenital malformations, regenerative medicine opens a plethora of opportunities in therapeutics across multiple fields of research, including difficult-to-treat diseases and impaired tissues. Although still demanding more specialization on the part of both scientists and clinicians, regenerative medicine is expected to address the most serious challenges related to current medical therapies.

In March 2015, the European Commission, following a recommendation from the European Medicines Agency (EMA) Committee for Orphan Medicinal Products, issued orphan drug designation to autologous adipose-derived stromal vascular cells for the treatment of scleroderma. Beyond the advance towards commercialization, the designation allows for tracking and collecting key program data and documentation to provide valuable insights concerning the demand for and use of adipose-based cell therapy platforms.

The competitive landscape for regenerative medicine is complex. Among the key competitive strategies that industry participants adopt to effectively address challenges and stay ahead of the competition is partnering with companies from other geographies. Japanese companies look attractive due to the changes in healthcare regulatory landscape. Mergers and acquisitions also are gaining momentum to penetrate new customer niches and/or regions.

Technology Attributes

Criterion 1: Industry Impact

For more than a decade, Cytori Therapeutics has been advancing in the field of regenerative medicine. Its proprietary Cytori Cell Therapy™ platform has become the leading technology to enable the research and practice of cellular therapies that harness the potential of stem and regenerative cells from adipose tissue. Cytori was the first company to introduce a technology platform that uses cells from adipose tissue. The company is strongly positioned with a product development pipeline covering a broad spectrum of therapeutic areas including orphan and rare diseases, genitourinary disorders, orthopedics, cardiovascular disease, and acute and chronic wound care.

Cytori strengthened its global patent portfolio in Japan and Europe in 2015 and 2016. The

company now has 89 global patents — 12 of which are in Japan and 8 in Europe — and 77 pending applications globally. As a late-stage cell therapy company, Cytori has focused on the development of autologous cell therapies from adipose tissue to treat a variety of medical conditions. Its cellular therapeutics platform exploits the unique attributes of living cells derived from a patient's adipose tissue, known as Adipose-Derived Regenerative Cells (ADRCs) or Stromal Vascular Fraction (SVF) cells. Cytori Cell Therapy™ is for investigational use in the United States. Several preclinical studies and clinical trials have demonstrated the platform's capacity to promote healing by improving blood flow, modulating the immune system, and facilitating wound repair.

Criterion 2: Product Impact

The major impact of Cytori's innovative technology platform is based on the use of human adipose tissue as the raw material to develop cellular therapy models. Human adipose tissue is a unique reservoir of multiple types of cells, including several involved in healing. The Cytori Cell Therapy™ platform avoids adverse effects typically associated with allogeneic cell or tissue transplantation, such as immunological rejection or disease transmission, eliminating the need for immunosuppressant drugs.

Cytori Cell Therapy™ is prepared on-site from a patient's own adipose tissue using Cytori's fully automated Celution® System device, proprietary enzymes, and sterile consumable set allowing administration of therapeutic cells to the patient either the same day of the extraction or after cryopreservation.

The Celution System family is expanding with new products and next-generation devices, single-use consumables, and related instrumentation around the regenerative medicine sphere.

Criterion 3: Scalability

Cytori's approach to cell therapy permits a distributed manufacturing approach in which the cell therapy product is prepared at or near the patient's bedside rather than relying on large scale central manufacturing. This allows for easy scalability; a center's manufacturing capacity can be doubled by simply adding a second device at very low cost compared to doubling the capacity of a conventional cell processing center (CPC). Totally committed to establish Cytori Cell Therapy™ as the first cell therapy to market for the treatment of impaired hand function in scleroderma, Cytori is undertaking important initiatives to advance clinical and translation research in the next 2 to 3 years. Its STAR trial in the United States will assess both safety and efficacy for the single administration of ECCS-50, the product candidate developed via the Cytori Cell Therapy™ platform, to scleroderma patients with affected hands and fingers. Initiated in mid-2015, the 48-week, randomized, double blind, placebo-controlled, phase III pivotal clinical trial completed enrollment in June 2016 with a total of 88 patients.

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In addition to this lead program, in late 2014, Cytori received investigational device exemption approval from the US Food and Drug Administration (FDA) for the ACT-OA knee osteoarthritis phase II study. The study is fully enrolled with 94 randomized patients.

This product has also advanced in the pipeline outside the US. Cytori in December 2015 submitted an expanded application for orphan medicinal product designation for ADRCs for the treatment of systemic scleroderma, highlighting Cytori's timely approach to obtain protocol assistance from the EMA in the advancement of its ECCS-50 development program in Europe for scleroderma, while facilitating full marketing authorization for the ECCS-50-based therapy under EMA's centralized procedure.

Also, in collaboration with the Biomedical Advanced Research Development Authority at the US Department of Health and Human Services, Cytori in 2013 began the development of a new therapy for thermal burns due to radiation.

Cytori's Celution® Systems can operate in over 50 countries within the appropriate national or regional approvals, clearances, or registrations for research and commercial customers.

Criterion 4: Visionary Innovation

Cytori's focus on use of non-cultured cells as a basis of Cytori Cell Therapy™ represented a true paradigm shift over the prevailing wisdom at the time. When Cytori began on this path it was almost universally believed that this type of cell therapy required substantial cell culture to generate a homogeneous stem cell population. Cytori believed that this process was not only unnecessary, it was actually detrimental to the safety and efficacy profile of the product in that culture-based expansion eliminated therapeutically-capable cells from the product. Over time this belief has been vindicated as several head-to-head preclinical studies have shown superiority of the non-cultured product in terms of efficacy, cost, and time-to-treatment.

This innovative approach also created a platform with the potential to provide therapeutically-active cells for an array of disease and injury states. Following the orphan drug designation for Cytori Cell Therapy™ in the treatment of impaired hand function in scleroderma in April 2015, Cytori promptly set the basis for the commercialization of its pipeline in Europe starting with a Managed Access Program (MAP) as a prelude to anticipated European Marketing Authorization for the product. In July 2015, a late stage clinical trial of Cytori Cell Therapy™ was started in stress urinary incontinence (SUI) trial following radical prostatectomy for prostate cancer. Cytori Cell Therapy™ is also in use in Japan for osteoarthritis under Japan's 'Act on the Safety of Regenerative Medicine' enacted in late 2014. This has been instrumental in enabling the company to go a step beyond its North American competitors.

Criterion 5: Application Diversity

Cytori's goal is to deliver single and definitive treatments that eliminate the need for frequent re-treatments and the shipment of cells to off-site facilities. This process innovation involves the harvest of cells in the hospital and on-site processing to ensure a more convenient delivery of medicine. Cytori has established stringent safety protocols in the use of ADRCs in its pre-clinical and clinical studies.

Cytori's pipeline comprises ECCS-50 for scleroderma associated hand dysfunction; ECCO-50 for knee osteoarthritis; ECCI-50 for urinary incontinence; DCCT-10 for cutaneous radiation and thermal injury; all of them tested in pre-clinical and/or clinical trials conducted in the United States, Europe, and/or Japan.

Criterion 6: Financial Performance

Numerous companies have started to penetrate the cell therapeutics market by developing culture media and reagents for regenerative medicine, to then advance in the development of cell-based medicines using somatic stem cells. One of their main goals is the development of cell-based medicines using stem cells. In the long term, the impact of stem cell-based therapies is expected to significantly drive the market and advance the acceptance of stem cell therapeutics worldwide.

Development of regenerative medicine's practical use and market diffusion is expected to accelerate the course of business — especially focused on stem cells — in the next 2 years.

Regulatory uncertainties have declined significantly in the North American market, allowing great transparency for Cytori's strategic business development. This has facilitated both research and commercialization relationships, with a foundation of solid clinical data consciously compiled and generated for global visibility and transparency.

Cytori is commercializing Cytori Cell and Tissue Banking platform to hospitals, clinics, tissue banks, and stem cell banking companies, involving a network of distributors and direct sales representatives across North America, Europe, Japan, and China. Cytori has designed three configurations for specific regional bases: cell banking, cell and adipose tissue banking, and adipose tissue banking. Cytori is in charge of manufacturing and sourcing the necessary equipment for its operations, including cryopreservation chambers, cooling and thawing devices, cell banking protocols, and the proprietary software and database application.

Criterion 7: Customer Acquisition

Cytori has extended its commercialization branches outside the United States, to Western Europe, the Middle East, Asia-Pacific (especially Japan and China), and Latin America. Principal products include consumables and reagents related to the Cytori Cell Therapy™ platform; sales to hospitals, clinics, and researchers are through direct representatives,

distributors, and partners.

Its customers include Bimini Technologies LLC, which in 2013 it granted a global exclusive license to use Cytori's devices and consumable products for hair applications. Through this agreement, Cytori also embraces the needs of the aesthetics cash-pay market segment. Bimini's wholly owned subsidiary, Kerastem, is conducting an FDA-approved phase II clinical trial in the United States for applying Kerastem's solution to treat female and male pattern baldness. Kerastem Hair Therapy is CE approved for use in patients with alopecia in Europe and Japan.

Cytori granted Lorem Vascular an exclusive license in all fields of use (excepting hair applications subject to the Bimini agreement) of Cytori's products for sale in China, Hong Kong, Malaysia, Singapore, and Australia.

Cytori also manufactures its own products at its headquarters in San Diego, CA, and in Wales, United Kingdom. Cytori's manufacturing facilities are periodically inspected by regulatory authorities and distribution partners and complies with FDA Quality System Regulation and equivalent requirements of state and non-US regulatory authorities, such as a notified body in Europe.

Its suppliers include Roche Diagnostics for Celase and Intravase reagents that are used to digest patients' autologous adipose tissue. The agreement runs through December 2020, with a potential 5-year renewal period.

Criterion 8: Technology Licensing

Cytori's success strongly depends on its intellectual property portfolio, which comprises the Celution® Systems and the Cytori Cell Therapy™ platform. By taking the necessary precautions to operate without infringing on the proprietary rights of third parties, Cytori leverages patents, trade secrets, copyrights, trademark laws, and confidentiality, licensing, distribution, and supply agreements to consolidate and protect its proprietary rights.

Cytori has the exclusive worldwide license of the Regents of the University of California's rights to a portfolio related to isolated adipose-derived stem cells.

Criterion 9: Brand Loyalty

Stem cell research is booming, and competition is intensifying. Legislation varies strongly by region. The reimbursement process for regenerative medicine is not yet well established, and there is lack of insight on the cost-effectiveness of treatments to guarantee routine commissioning. As a result, Cytori faces increased competition from pharmaceutical, biopharmaceutical, medical device, and biotechnology companies, as well as academic institutions, research centers, and governmental agencies worldwide. Most industry branding initiatives are related to sourcing adult stem and regenerative cells from

a broad spectrum of tissues, including bone marrow, placental tissue, umbilical cord and peripheral blood, and skeletal muscle.

As more companies enter the cell therapy field, Cytori is forced to compete across multiple areas. Most of its brand loyalty strategies, including technology licensing agreements and manufacturing and distribution collaborations, attempt to address concerns about equity and capital, clinical trial sites and enrollment, corporate partnerships, commercial market share, and skilled and experienced workers.

Criterion 10: Human Capital

Cytori encourages its employees to be a part of every milestone. Among its 80 full-time employees, 60% — 9 in manufacturing and 39 in research and development — are devoted to technological innovation. Six employees are in sales and marketing, and 26 are in management, finance, and administration, while independent contractors support specific operations. Cytori is fostering real-world feedback through its growing global network of researchers, life scientists, and clinicians with the aim of establishing an open dialogue about cell therapeutics research and development. Its talented, creative, results-driven culture fosters an exciting work environment that emphasizes the achievement of extraordinary milestones.

Conclusion

Cytori is devoted to the development of cellular therapeutics in the field of regenerative medicine. Its Cytori Cell Therapy™ platform exploits the unique attributes of ARDCs for repair and healing. With a strong intellectual property portfolio of 89 patents, a broad spectrum of pre-clinical and clinical trials, and an extensive network of distribution and commercialization partners, Cytori has become a global leader in the cell therapeutics market.

With its strong overall performance, Cytori Therapeutics, Inc. 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.

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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

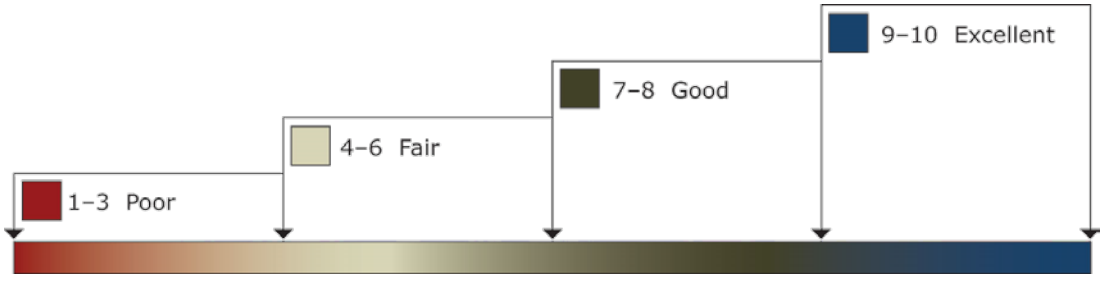
Criterion 1: Financial Performance
Criterion 2: Customer Acquisition
Criterion 3: Technology Licensing
Criterion 4: Brand Loyalty
Criterion 5: Human Capital

Best Practice Award Analysis for Cytori

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**
Cytori	**9.8**	**9.8**	**9.8**
Competitor 2	6.3	5.7	6.0
Competitor 3	4.0	3.6	3.8

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

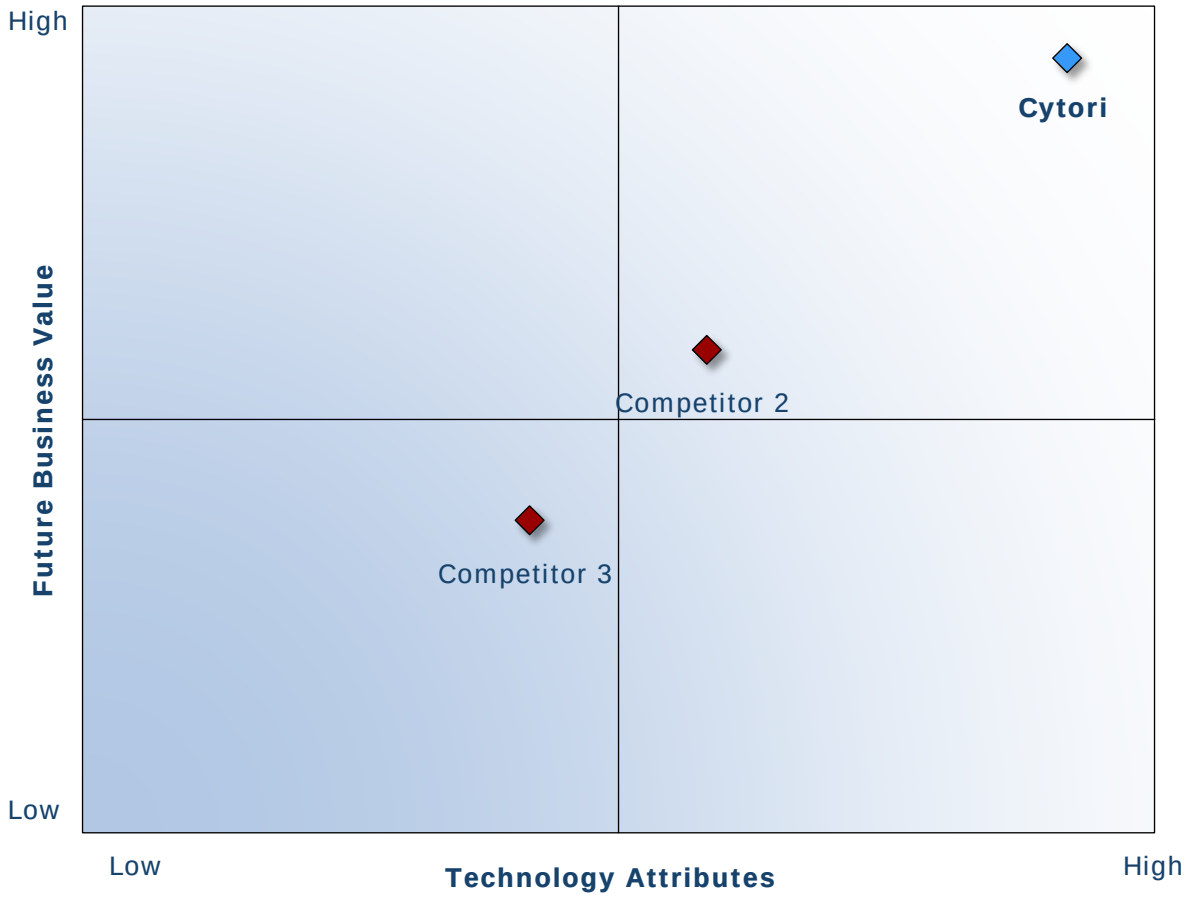
Criterion 5: Human Capital

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
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

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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.