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BEST PRACTICES

AWARDS

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2020 BEST PRACTICES AWARD



**2020 NORTH AMERICAN CONTRACT
RESEARCH ORGANIZATION IN DERMATOLOGY
CUSTOMER VALUE LEADERSHIP AWARD**

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Background and Company Performance

Industry Challenges

Outsourcing drug discovery and development—both pre-clinical and clinical—to contract service organizations became integral to pharmaceutical (pharma) companies' cost containment strategies over the last two decades.

The contract research organization (CRO) market is a highly fragmented market with more than 1,000 participants spread across the world. Fierce competition, a shifting pharmaceutical industry toward specialty drugs and biologics, and the globalization trend in clinical trials lead to moderate growth globally. North America remains the primary contributor to the global CRO market, with the leading CROs based in the region. Frost & Sullivan estimates the North America CRO market at over \$12 billion in 2019, increasing at a compound annual growth rate of approximately 7% to reach above \$17 billion by 2024.¹

Despite the challenging dynamic landscape, an overall research and development (R&D) investment of approximately \$170 billion in 2018 toward developing innovative curative therapies, e.g., regenerative medicine, make the industry extremely attractive.² With high-quality and speed-to-market as critical success factors, CROs are offering integrated, streamlined end-to-end services, engaging potential pharma partners early in a projects' life to forge long-term relationships and compete successfully.

Furthermore, vendors in the space target diverse product lines and therapeutic areas, technology leadership, and geographic reach, to name a few, to deliver a higher value proposition to customers and create a competitive advantage in a mostly undifferentiated CRO landscape.

Customer Impact and Business Impact of Tergus Pharma

Headquartered in Durham, North Carolina, and founded in 2012, Tergus Pharma (Tergus) is a leading CRO in dermatology. The company established a functional service provider-like model to meet specialty pharma's end-to-end needs in topical drug discovery and development programs.

Keys to Success: Foundational Experience and Knowledge

Clinical testing in dermatology encompasses about 5% of the global CRO industry.³ Competitors within this segment are mainly pharma subsidiaries, often leading to conflicts of interest between projects and, usually, winding up on monies diverted to support large R&D therapeutic areas, including cardiovascular diseases, central nervous system disorders, and oncology.

A niche segment with few CRO participants, specialty pharma companies developing skin products engage multiple vendors, typically three to four, to advance topical formulations successfully, from concept to commercialization. As a result, projects are often delayed due

¹ *Global Contract Research Organization (CRO) Market, Forecast to 2024* (Frost & Sullivan, November 2019)

² *Ibid*

³ *Ibid*

to gaps in workflows, communications, and project backlogs, increasing development costs and time to market.

Vijendra Nalamothu, Ph.D., Chairman and Chief Executive Officer (CEO), leveraged over 25 years of experience across the dermatology R&D spectrum, including drug discovery, testing, and manufacturing, establishing Tergus to fill a vacuum in the industry.

The forward-focused organization began with high-quality R&D development services at the pre-clinical stage. Over time, Tergus steadily extended its capabilities and resources—such as early skin biology services and clinical supplies manufacturing—to provide end-to-end development continuity, with commercialization as the end goal.

Customer service excellence underpins its growth strategy, with agility and flexibility as pillars. Tergus pushes itself to become more than a leader in R&D, but manufacturing as well, making it an unmatched powerhouse within dermatological drug development. The company maintains this forward-thinking strategy to date, ensuring that their customers' objectives guide the development process.

Tergus gained an industry-wide reputation as a strategic partner with flexible development capabilities, experiencing rapid growth—from 50 employees in 2015 and to over 85 employees in 2020. In addition to its organic growth, the company also expands via acquisition, incorporating streamlined offerings to build on its customer value proposition and tailor development and manufacturing to customer's needs.

Today, Tergus uniquely offers comprehensive, end-to-end to pharma and biotech companies worldwide through its cGMP-compliant, state-of-the-art facility located at The Research Triangle Park, a new hub for R&D and manufacturing.

Customer-centric, Dermatology Laser-focused

Customer satisfaction and service flexibility shape Tergus' growth and investment strategies. Traditionally, the few participants in the space either excel in R&D or manufacturing. Tergus Pharma is the largest CRO for dermatology in the United States. Its industry-leading, domain-specific expertise is well-recognized worldwide. Nonetheless, the company's unwavering commitment to meeting customer needs led it to re-evaluate its services and expand into commercial manufacturing.

In June 2019, Tergus announced its partnership with Great Point Partners to raise capital, bringing it one step closer to its next transformation. One month later, the company purchased a 100,000 square foot facility near its headquarters. Tergus is currently redesigning the space, building on existing clinical supplies manufacturing capabilities, to establish the largest dermatology-related integrated R&D and production center in the United States. The company expects to open this new commercial manufacturing facility in the fourth quarter of 2020.

On its evolving journey, Tergus projects becoming the leading contract development and manufacturing organization in dermatology across the world within the next three to five years, offering sponsors a more significant competitive advantage in their road to market.

Sustained Leadership and Long-term Growth Strategy

Tergus works with customers along business verticals, i.e., generics and novel drugs, driven mainly by large pharma, specialty pharma and biotech startups. With very little year-over-year (YoY) predictability, the company's product and service diversification support strong growth regardless of changes in the industry, e.g., COVID-19 pandemic. Furthermore, Tergus' resource optimization and operational style, i.e., aspirational, family-oriented business and collaborative, customer-centric engagements, attract and retain both talented, skilled, and vested professionals as well as customers. For instance, the company invested in digital tools and new workflows, swiftly responding to the pandemic's potential consequences.

"Despite the pandemic, customers have ongoing clinical trials with urgent needs. Users must have access to drugs. COVID-19 is not going to hamper development efforts. Employees can work safely without lapses in R&D or manufacturing."

—Vijendra Nalamothu, CEO, Tergus

Also, Tergus uses predictive analytics to ensure international supply procurement proactively for the clinical supplies needed, safeguarding participant's health well-being while adhering to clinical trial timelines.

The company reports having at least 35% repeat customers, an impressive feat in a niche market. It also has a broad customer and project base, resulting in stable, continued, YoY growth. Tergus average annual engagements consist of about 27 end-to-end projects and a total of 60 to 65 projects, including smaller functional-specific and partial tasks, e.g., clinical supply manufacturing and in vitro permeation studies.

Conclusion

With the contract research organization (CRO) dermatology segment constituting only 5% of the global market,⁴ specialty pharmaceutical (pharma) companies advancing topical drugs through research and development (R&D) must rely on multiple CROs at different stages to complete testing.

Tergus Pharma (Tergus) provides full CRO services for therapeutics in dermatology. The company continually builds on technical, professional, and structural capabilities to meet customers' performance needs, gaining a sterling worldwide reputation along the way. Additionally, Tergus' customer-centric flexible and tailored services deliver a real partner-level engagement, regardless of project size. Always forward-focused on customer's goals and commercialization needs, the company invested in an over 100,000 square foot facility for its transition towards a full-fledged contract development and manufacturing organization. Tergus is positioning well to provide unmatched services to specialty pharma, spanning through clinical R&D to commercial manufacturing, strengthening its leadership as an outsourcing contract services provider in dermatology.

With its strong overall performance, Tergus Pharma earns Frost & Sullivan's 2020 North America Customer Value Leadership Award in the CRO market for dermatology.

⁴ *Global Contract Research Organization (CRO) Market, Forecast to 2024* (Frost & Sullivan, November 2019)

Significance of Customer Value Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. Satisfying customers is the cornerstone of any successful growth strategy. To achieve this, an organization must be best in class in 3 key areas: understanding demand, nurturing the brand, and differentiating from the competition.



Understanding Customer Value Leadership

Customer Value Leadership is defined and measured by 2 macro-level categories: Customer Impact and Business Impact. These two sides work together to make customers feel valued and confident in their products' quality and performance. This dual satisfaction translates into repeat purchases and a lifetime of customer value.

Key Benchmarking Criteria

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

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

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 analysts 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 participants and for identifying those performing at best-in-class levels.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS



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>.