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WuXi AppTec

2020 GLOBAL
CONTRACT RESEARCH ORGANIZATION
CUSTOMER VALUE LEADERSHIP AWARD

Contents

Background and Company Performance

Industry Challenges

The pharmaceutical industry is regarded as a high-risk due to its fluctuating success rate and threats to patent protection traditionally enjoyed by novel drugs. The mean research and development (R&D) costs involved in bringing a novel drug from the laboratory to the market is estimated to be approximately $1.34 billion, with the overall probability of a drug entering clinical development being approved for commercialization pegged below 12% [1]. This is further appended by growing pricing pressure on drugs, unforeseen scenarios such as the COVID-19-pandemic, and ever-evolving reimbursement models. To curtail the massive investment costs required for R&D, and share the risk of drug discovery and development, pharmaceutical companies have actively outsourced vital components of the drug development process over the last 2 decades to specialist companies such as contract research organizations (CROs).

CROs play a critical role in the drug development process as pharmaceutical companies rely on CROs for a number of services including clinical research management, pre-clinical research, clinical trials, and pharmacovigilance. CROs, by design, offer an array of services which facilitate not only a reduction in drug development costs by enhanced operational efficiencies but access to industry expertise and a smoother entry into new markets with heterogeneous regulatory guidelines.

To become a strategic partner for the pharmaceutical industry, it is essential for CROs to cater to the different tiers of pharma sponsors, ranging from small and mid-sized biotechs to larger conglomerates, by providing a range of services from pre-clinical to pharmacovigilance and, most importantly, offering both regional specialization and global presence with access to a wide patient network.

Although clinical trials may appear straightforward to an unassuming observant, it involves customization of clinical trial designs, massive and secure data management, adherence to local regulations and protocols, and a constant need for technology upgrades to accommodate for shifts towards a digitalized ecosystem. Frost & Sullivan's analysis reveals that the largest challenges facing the clinical trial industry today are patient recruitment and retention, trial monitoring, and increasingly stringent regulatory requirements. For example, according to a study carried out by the Tufts Center for the Study of Drug Development on investigative site enrollment achievement, it was found that approximately 11% of sites in a given trial fail to enroll a single patient, 37% sites under-enroll, 39% meet their enrollment targets, and only 13% exceed their targets. Moreover, 85% of clinical trials fail to retain patients, with dropout rates exceeding 20% per treatment arm in a large number of trials. In some cases, dropout rates reach as high as 40%, leading to trial abortion. Clinical trial recruitment and retention issues can end up costing up to $37,000 per day.

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[1] Wouters OJ, et al., Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018. JAMA.2020. PMID: 32125404

Nevertheless, as CROs overcome these challenges and share drug development risk with the pharmaceutical industry, the segment is poised to grow. Frost & Sullivan estimates the global CRO market will grow from $43 billion in 2019 to more than $63 billion by 2024 at a compound annual growth rate of 8.2%[2]. While the global CRO market is set to witness steady growth, Asia-Pacific (APAC) regions such as China, India, Japan, South Korea, and Australia are fast becoming an increasingly attractive region for outsourcing R&D, preclinical, and clinical research by pharmaceutical companies due to the availability of required resources and lower investment costs in comparison to North America and the European Union. However, in terms of clinical trials management, some APAC regions pose a major challenge due to the lack of International Council for Harmonization (ICH) participation and different regulatory environments for product approvals.

Finally, and most importantly, COVID-19 has had a major impact globally on the pharmaceutical industry and its support ecosystem. Globally, almost 53.5% of clinical trials stand suspended, 14.2% terminated, and 32.3% withdrawn, with small and mid-sized companies hit the hardest. In APAC especially, many pharmaceutical support functions reached a standstill as few companies were able to quickly respond and put into action a business continuity plan. During the pandemic, CROs across the globe have faced various challenges in supporting their pharmaceutical partners (i.e., supporting the development of drug innovations targeting COVID-19 and moving from regular clinical trials to virtual clinical trials.)

Frost & Sullivan asserts that CROs which can offer business continuity to its clients during the pandemic will ultimately emerge as long-term reliable partners.

Strategy Innovation and Customer Impact of WuXi AppTec

Unlocking the APAC CRO Market, Solidifying Role as a Global Partner
In 2000, WuXi AppTec first began its operations in the city of Shanghai under the name WuXi PharmaTech. In 2008, WuXi PharmaTech acquired US-based AppTec Laboratory Services and rebranded itself as WuXi AppTec to facilitate early-stage innovations and clinical research for the pharmaceutical industry across the globe. Today, the global company offers end-to-end services in R&D and manufacturing that enable companies in the pharmaceutical, biotech, and medical device industries to advance discoveries and deliver innovative treatments to patients.

With over 4,100 active customers worldwide, WuXi AppTec is continuously investing to build new capabilities and increase its capacities through a global network of 29 sites. In China alone, the company recently opened two new campuses in the cities of Nantong and Chengdu, reinforcing its leadership position in the APAC CRO industry.

WuXi AppTec's clinical trial capabilities are deeply entrenched in both Chinese domestic market and international markets that can support clinical trial operations regionally and globally with plan to invest and expand clinical research capabilities abroad. The company

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[2] Post-pandemic Growth Opportunity in the Global Contract Research Organization (CRO) Market (Frost & Sullivan, August 2020)

has strived to identify populations with the greatest clinical trial potential while also advancing trials that incorporate local best practices and expertise. WuXi AppTec has worked hard to promote ICH and good clinical practice (GCP) guidelines across APAC to enhance both trial quality and operation cohesion.

Likewise, the expansion of the company's laboratory testing division facility in New Jersey and increasing discovery biology service capabilities in San Diego, California, spurs the company's growing global relevance. Such a widespread global presence allows client companies to maintain project timelines, despite the pandemic, by transferring the workload from one site to another.

An Innovation-driven Company with a Keen Customer-centric Approach

Frost & Sullivan has witnessed that corporate success is often the result of a company's clearly defined vision. WuXi AppTec's customer-centric approach results from its clearly defined vision of putting customers first.

WuXi AppTec's customer service approach differentiates itself from competitors by placing a great emphasis on understanding the different needs of its individual customers and curating customized packages accordingly. By offering client-specific and feature-integrated service offerings or bundles versus a comprehensive package which may not be relevant to customer needs, the company provides superior value.

For example, the roll-out of a series of technology and service innovations in the area of DNA-encoded libraries and the availability of custom-designed solution packages such as DELlight and DELopen are great examples highlighting WuXi AppTec's drive to continuously expand the capabilities of its open-access service platform. The company aims to address the needs of different customer groups while ensuring that all clients benefit from its new cutting-edge technology at reduced cost.

WuXi AppTec's customized packages offer customers agile solutions and expedient testing and turnaround of their experiments and scientific hypotheses through access to the company's advanced technologies at different cost structures. The company has also custom-built systems and processes within several business functions to improve real-time project tracking. As a result, WuXi AppTec allows its global customer base to monitor the status of their compounds and experiments using an online interface.

Frost & Sullivan notes the company continually strives to exceed client needs and expectations by increasing its global capabilities, improving efficiency, and enhancing customer engagement through the adoption of digital technologies. Moreover, the company strengthens its technology and capability platform across multiple fronts while providing new standalone and integrated services that adhere to the company's exclusive vision of "follow the molecules". The motto defines the company's approach wherein it supports customers during the early R&D and preclinical development stage with expertise to build a trusted and long-term partnership. Finally, the company's US and APAC-based offices support around-the-clock engagement and services for its global customers.

Supporting the Development of Next-generation Innovations such as Cell and Gene Therapies

As the healthcare paradigm shifts in favour of curative-yet-complex therapies (e.g., cell and gene therapies), the accompanying development challenges are growing multi-fold. Additionally, most of the innovation in cell and gene therapies (CGT) is being spearheaded by small and mid-sized companies which lean heavily on competent partners like WuXi AppTec. While its competitors have solely focused on clinical research solutions, WuXi AppTec has progressed to become one of the early pioneers in developing capabilities that serve customers in the fast-growing CGT segment.

In the United States, WuXi AppTec has expanded its presence in eight cities, operating notably in cell and gene therapy services in Philadelphia site. The company is also building capabilities in oligonucleotide and peptide discovery, synthesis, and good manufacturing practice (GMP)-scale manufacturing. In China, WuXi AppTec has established a new site dedicated to the development of advanced therapy CDMO services.

WuXi AppTec's range of service offerings to support the development of cell and gene therapies includes:

1) *Process development and manufacturing services for CGT*, including chimeric antigen receptor T cells and tumor-infiltrating lymphocyte therapies involving adeno-associated viral and lentiviral vectors. WuXi AppTec's advanced CGT technology platforms enable clients to reach GMP and first-in-human trials more quickly while also ensuring continuous process improvement.

2) *Integrated testing and analytical development services*, including assay development and testing, which represent one of the major constraints in CGT development.

3) *CGT manufacturing support.* WuXi AppTec possesses multiple modular facilities which are flexible for capacity increments and can support CGT manufacturing. Expert manufacturing services from early clinical development to post-commercialization are provided. By offering clients the combined services of a CRO and a contract manufacturing organization (CMO), WuXi AppTec provides a one-stop solution for CGT development, clinical trials, and commercial manufacturing.

4) *Client access to major markets.* With process development, manufacturing, and testing facilities in both the United States and China, the company can offer clients access to all major markets, including APAC. Although the company currently does not have a dedicated CGT facility in Europe, it nevertheless manufactures both allogeneic and autologous products for Europe-based customers from its Philadelphia site, further highlighting the quality of its service.

Staying Ahead of the Curve to Counter Pandemic-related Challenges

The COVID-19 pandemic has had a seismic effect across the globe both on the pharmaceutical industry and its ecosystem. WuXi AppTec has demonstrated exceptional leadership qualities through its immediate response to the outbreak. By leveraging the strength of its global site network, the company quickly implemented a business continuity plan to mitigate and minimize the risks associated with unexpected work interruptions. Throughout this challenging period, WuXi AppTec has maintained close communication with its global customer base and helped push their R&D projects forward. At the same time, the company has adapted best practices to safeguard employees' health and well-being.

WuXi AppTec has displayed exceptional maturity, strategic innovation, and leadership in its efforts to tackle COVID-19. The company's innumerable efforts include the building of new scientific capabilities (e.g., developing a set of in vitro biology assays against various novel drug targets of COVID-19 at record speed, efficiently delivering preclinical testing packages for potential COVID-19 treatment under massive time pressure), thus significantly contributing to an international industry alliance against COVID-19.

With multiple on-site clinical trials on hold due to the pandemic, WuXi AppTec immediately responded by working with regulatory officials, healthcare professionals, and advisors to plan and execute new guidelines on remote monitoring and virtual trials through its subsidiary, WuXi Clinical.

WuXi SMO, another subsidiary of WuXi AppTec, provides best in class clinical trial site management services that covers 140 cities and 900 hospitals across China with 3,000+ local clinical staff, the company represents the industry's highest geographic coverage.

As communications and information technology evolve and become increasingly sophisticated, pharmaceutical companies may increasingly opt for virtual trials in the future due to advantages such as efficiency and reduced costs. WuXi AppTec is perfectly positioned to capitalize on such opportunities and meet customer requirements.

Strong Capabilities that Translate to Sound Financial Performance even during a Pandemic

Despite many companies across the globe quickly and adequately adapting to the COVID-19 pandemic to ensure the continuity of business operations, most enterprises' revenue fell as a direct effect. But, unlike many of its competitors, WuXi AppTec recorded a 29.4% year-on-year (YoY) revenue growth to RMB 4,044 million in Q2 2020 up from 15.1% YoY revenue growth in Q1 2020. Frost & Sullivan assesses that the company's financial performance is a testimony to the strength of WuXi AppTec's capabilities and the success of its quick response.

The revenue growth stems from the addition of approximately 600 new customers during the pandemic, bringing the company's overall active customer count to more than 4,000. A combination of robust demand, an increase in capacity utilization, and efficient operations ensured robust revenue growth. However, Frost & Sullivan believes the successful financial performance of the company is attributed to its company's unique strategy, vision, and business model—as summed up in in its "Follow the Customer/Follow

the Project/Follow the Molecule" motto. Specifically, the motto focuses on providing best-in-class services and expertise to customers to build long-term partnerships, thereby securing more business opportunities across the different stages of the drug development process.

Conclusion

The contract research organization market faces significant challenges, including patient recruitment and retention, newer protocols that lean towards telemedicine, and virtual trials with significant cost implications for pharmaceutical companies. WuXi AppTec offers clients an unmatched breadth of experience and end-to-end expertise in APAC, propelling innovation of its global partners, while also serving as a valued collaborator. Additionally, WuXi AppTec is expanding its industry-leading services rapidly to a global scale, with particular strong growth in CDMO for small molecules, peptides and oligonucleotides, as well as for cell and gene therapies, one of the most complex areas of drug development. As COVID-19 continues to pose a risk to ongoing clinical trials and new trials' initiation, the company's laudable response to the pandemic ensures business continuity for its partners by adopting virtual trial protocols and shifting workloads between sites.

For its strategic innovation, technical excellence, exceptional value proposition, and strong overall performance, WuXi AppTec earns Frost & Sullivan's 2020 Customer Value Leadership Award in the global contract research organization industry.

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 Award Analysis for WuXi AppTec

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

9–10 Excellent

7–8 Good

4–6 Fair

1–3 Poor
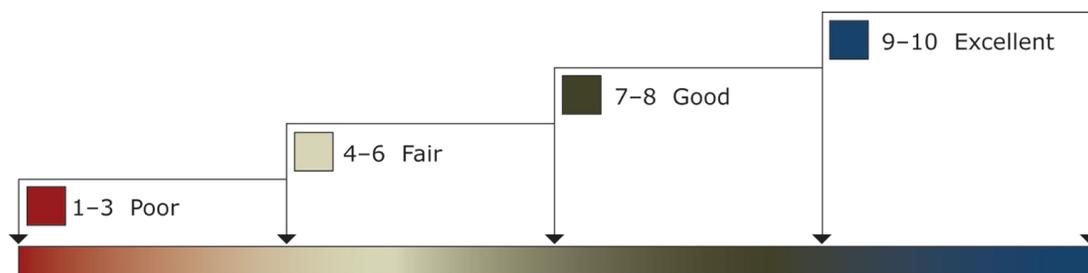
The Decision Support Scorecard considers Customer Impact and Business Impact (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criterion are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity 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.

Measurement of 1–10 (1 = poor; 10 = excellent)			
Customer Value Leadership	Customer Impact	Business Impact	**Average Rating**
WuXi AppTec	**9**	**9**	**9**
Competitor 1	9	8	8.5
Competitor 2	8	9	8.5

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.

Business Impact

Criterion 1: Financial Performance
Requirement: Overall financial performance is strong in terms of revenue, revenue growth, operating margin, and other key financial metrics.

Criterion 2: Customer Acquisition
Requirement: Customer-facing processes support the efficient and consistent acquisition of new customers, even as it enhances retention of current customers.

Criterion 3: Operational Efficiency
Requirement: Staff is able to perform assigned tasks productively, quickly, and to a high quality standard.

Criterion 4: Growth Potential
Requirements: Customer focus strengthens brand, reinforces customer loyalty, and enhances growth potential.

 "We Accelerate Growth"

Criterion 5: Human Capital

Requirement: Company culture is characterized by a strong commitment to quality and customers, which in turn enhances employee morale and retention.

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.
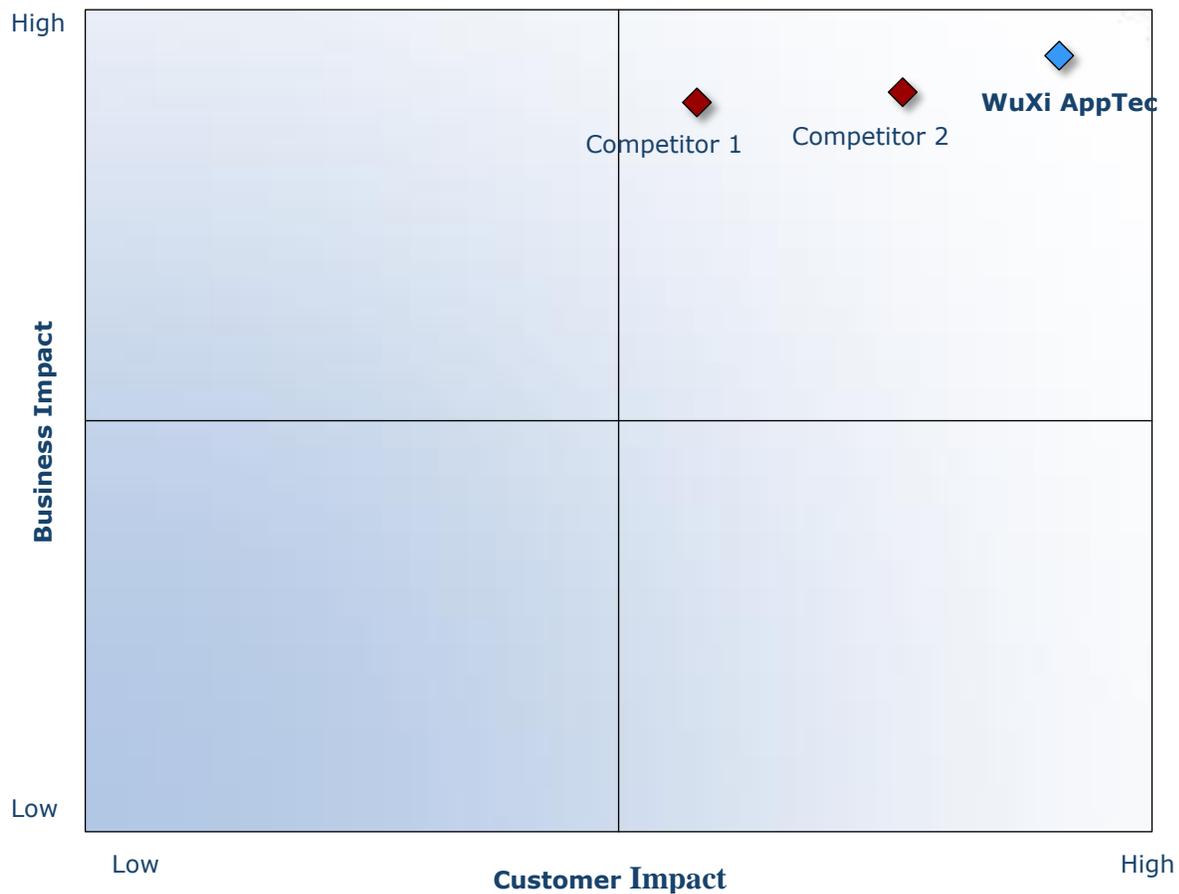
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

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	• 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	• Interview thought leaders and industry practitioners • Assess candidates' fit with best practices 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	• 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	• 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	• 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 practices award recipient	• 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 award recognition	• 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	• 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.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS
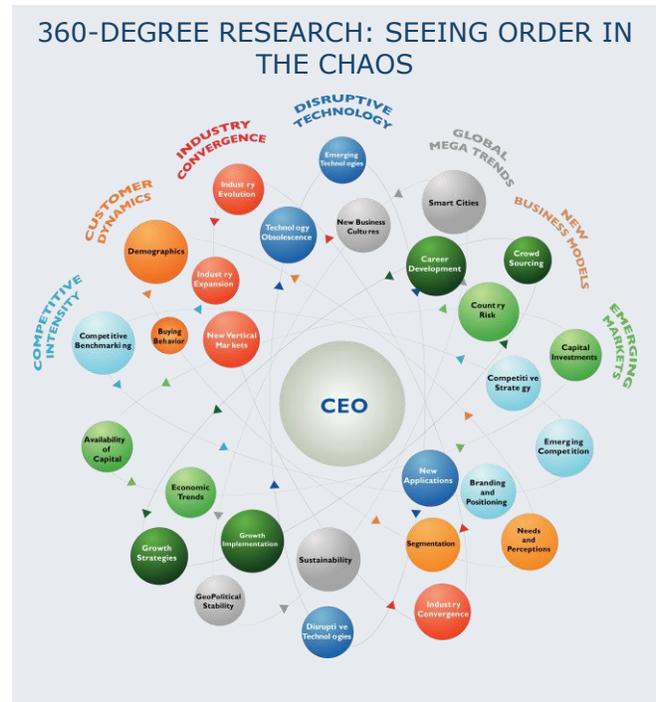
About Frost & Sullivan

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.