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BEST PRACTICES

AWARDS

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2020 BEST PRACTICES AWARD



**2020 CHINESE CONTRACT
RESEARCH ORGANIZATIONS
CUSTOMER VALUE LEADERSHIP AWARD**

Contents

Background and Company Performance	3
<i>Industry Challenges</i>	3
<i>Customer Impact and Business Impact</i>	4
<i>Conclusion</i>	7
Significance of Customer Value Leadership	8
Understanding Customer Value Leadership	8
<i>Key Benchmarking Criteria</i>	9
Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices.....	10
The Intersection between 360-Degree Research and Best Practices Awards.....	11
<i>Research Methodology</i>	11
About Frost & Sullivan	11

Background and Company Performance

Industry Challenges

Frost & Sullivan estimates China's pharmaceutical (pharma) industry at \$258 billion in 2019, reaching nearly \$392 billion by 2025—the second-largest globally, with biologics' share increasing from 7% to 13% in the same period.¹ Government-led initiatives, such as the "Made in China 2025" reform (MIC 2025 Initiative), boost productivity and compel innovation, a catalyzing economic growth driver, particularly, in novel complex biologics and cell and gene therapeutics.

The country's robust pipelines (more than 700 molecules²), recently launched products, and policy changes expediting the drug review process support a budding innovator drug industry. Substantial funding into China's emerging biotechnology sector by an enthusiastic investor community - along with an increasing interest from multinational companies (MNCs) and small overseas pharma and biotechnology firms - further propel market expansion. Today, China is among the top five preferred markets for research and development (R&D) investments worldwide.³

Frost & Sullivan analysts observe how China's outsourcing industry has been positioning itself for high-growth over the last several years. The country offers a vast and highly diverse patient population base, with higher chronic disease prevalence compared to Western economies, to accelerate clinical trial timelines. Around 58% of China's 1.4 billion residents live in urban areas,⁴ allowing sponsors access to more patients in greater concentrations faster. Additionally, higher disease incidence rates, e.g., cancer and diabetes, and a relatively higher proportion of naïve patients result in smooth and rapid enrollment opportunities to sponsors, increasingly challenging as the industry moves towards precision medicine, i.e., targeting smaller population subsets. Patient-centric trials are becoming a strategic imperative for sponsors to improve drug development success rates and enhance overall profitability.

Likewise, the government's regulatory overhaul streamlined regulatory pathways and aligned studies with international quality standards, driving a surge in local outsourcing activities. Several domestic contract research organizations (CROs) and contract manufacturing organizations now collaborate with local, regional, and MNC sponsors catering to their clinical research needs. Frost & Sullivan points out that revised clinical trial policies, predictable and established pathways for new drug approval, improved intellectual property protection, and cross-border collaboration all fuel high-growth, creating a vibrant ecosystem for developing innovator molecules. Moreover, the country now accepts clinical trial data generated outside China for drug approval, paving the way for even higher outsourcing in the region.

¹ *Growth Insights on China's Pharmaceutical Industry, Forecast to 2025* (Frost & Sullivan, January 2020)

² *Ibid*

³ *Ibid*

⁴ <https://chinapower.csis.org/china-middle-class/>

Already a pharma manufacturing powerhouse in chemical drugs, China is also strengthening its capabilities as biologics become the fastest-growing segment. Frost & Sullivan projects the Asia-Pacific (APAC) CRO market at over \$7 billion in 2019, with double-digit growth through 2024, outpacing the global CRO market.⁵ Overall, APAC is emerging as the go-to-market for R&D lead by China, Japan, India, and other Southeast Asian countries. Cost reductions of up to 50% compared to the United States (US), technology and infrastructure advancements, widespread hospital networks, and 'hassle-free' CRO activities are also contributing factors propelling R&D activity in the region.⁶

Despite bullish predictions, Chinese CRO services mostly focus on domestic needs while the ongoing regulatory overhaul and local pharma and biotech companies expanding goals, e.g., Beigene, have their sights set on global markets.

As with the broader 'one-stop-shop' global trend, Frost & Sullivan believes that CROs with integrated, seamless, and flexible R&D services will emerge as leaders in China, and those also bringing synchronicity with international standards will further the journey into the global landscape, capturing market share along the way.

Customer Impact and Business Impact

Established in 2004, Hangzhou-based Tigermed serves nearly 1,900 customers, from emerging local, regional, and pharma and biotech firms to MNCs, e.g., AstraZeneca and Merck. The company employs over 5,200 skilled professionals at more than 130 locations worldwide—mainly throughout APAC, e.g., China, Korea, India, and Australia, as well as the US, Switzerland, and Romania—strategically distributed to service and support sponsors with local expertise as well as global clinical development programs.

The Path to Success: Continuous Improvement

"Our (Tigermed's) success is due to the high market demand from clients, particularly in China, as well as the continuous, high-quality delivery by the Tigermed team."

—Mr. Wen Chen, Senior Advisor for Strategic and Business Development, Tigermed

Tigermed's core business is in supporting innovation, i.e., drugs not approved anywhere else in the world, in sync with the country's "China New" policies and ensuring regulatory changes to increase its market presence. Since its inception, the company steadily added a range of functional solutions over the years, building a comprehensive service portfolio, expanding its expertise, and strengthening its capacity and leadership as a "true" full-service CRO.

Today, Tigermed's clinical trial services include regulatory affairs, biometrics, clinical operations and data management, and post-marketing studies. Value-added clinical services include imaging, pharmacovigilance, and central laboratory services; offerings

⁵ *Global Contract Research Organization (CRO) Market, Forecast to 2024* (Frost & Sullivan, November 2019)

⁶ *Ibid*

also extend into the preclinical stage, supporting drug metabolism and pharmacokinetics and toxicity studies.

At the Top of Its Game: Sustainable Leadership

"A top US-based global pharma is the main customer for our data services for the last 10 years. Per their feedback, they continue to work with us as a strategic partner because we consistently deliver on time and with accuracy, outperforming all of the other competitors working with them in biometrics space."

—Mr. Wen Chen

Frost & Sullivan appreciates the way that Tigermed's extensive expertise, advanced technologies, and large-scale coverage in China facilitate efficient, fast, high-quality drug development to address unmet medical needs, thus attracting both foreign customers as well as local emerging biotech companies. The company properly leverages its unique hospital network across the country to ensure balanced studies. While frequently engaging around 20 sites, Tigermed's largest clinical trial involved managing simultaneously 255 to 275 locations around the country—an impressive feat in resources and coordination management and capability by any standard.

The company notes managing over 2,000 clinical trials and participating in more than 130 innovative drug projects, bringing several of China's first novel molecules and much-needed therapeutics to market with quality, efficiency, and record-breaking speed. For instance, Tigermed participated in developing the first domestically-produced Chidamide—peripheral T-cell lymphoma; biosimilar-rituximab injection—non-Hodgkin lymphoma and chronic lymphocytic leukemia; GANOVO—hepatitis C; and an epidermal growth factor receptor (EGFR) inhibitor—non-small cell lung carcinoma, an alternative to TAGRISSO®.

The company anticipates approval by the National Medical Products Administration (NMPA)—known as China Food and Drug Administration (CFDA) until 2018—for its third-generation EGFR inhibitors, taking just 20 months to complete, from first inhuman to the last patient. Its previous EGFR inhibitor got CFDA approval with, at the time considered, a supersonic development timeline of 5 to 6 years.

Tigermed shows robust growth throughout its 15-year history. More importantly, it boasts a strong reputation in delivering high-quality, cost-efficient, flexible, and timely services consistently, which leads to its preferred strategic vendor status. Tigermed company achieved total revenues of ¥ 2.8 billion in 2019, growing 21.8% in a year.⁷

⁷ <https://tigermedgrp.com/tigermed-releases-2019-annual-report-with-solid-financial-results/>

Actions Speak Louder

"We are here to serve the unmet clinical needs."

—Mr. Wen Chen

Frost & Sullivan feels that Tigermed's response to the COVID-19 pandemic truly exemplifies its commitment to service, social responsibility, and patients, accelerating potentially life-saving therapies to market. All of the company's employees are working from home since late January 2020 to prevent the outbreak from expanding further. However, Tigermed responded with determination to the Human Genetic Resources Administration of China (HGRAC) call-to-action, becoming involved in clinical trials without prior contract negotiations, or even expecting compensation for its efforts. Likewise, the medical community, nearly 20,000 healthcare professionals across the country, joined the battle against the disease without conditions.

An investigator site contacted the company to conduct a super-fast trial at a grander scale and more efficiently than routine requests. Tigermed's Wuhan-based team fragmented as the outbreak coincided with the Lunar New Year holiday in China, and many members did not return due to travel restrictions and the lockout. The company assembled an internal team from colleagues across the country, outside the affected Wuhan and the Hubei province, in three days and created several new drug development records in its history as well as in China, including a one-day R&D allowance by the HGRAC and same day Institutional Review Board approval. By the time the drug arrived in Beijing and reached the site, the clinical research already had the authorization to initiate.

Tigermed has the setup in place for most employees to work remotely and, notably, seamlessly. The company prepared for such a situation years in advance; rolling out data collection, drug randomization, and pharmacovigilance systems into its processes. Its agile and quick response showcases Tigermed's robust systems and infrastructure, adapting to such an urgent need and accelerating technology implementation in its execution.

Coming Next: Expanding Geographic Footprint

Tigermed's continuous improvement cycle, alongside customer needs and market trends, is leading its next evolution. The company's strategy for long-term sustained growth is addressing China-based customers' needs first. With most of them seeking to go overseas, Tigermed is expanding its operations to a larger geographical scale. At the same time, international biotechs are looking for an alternative to the leading global CROs as their needs are very different from those of MNCs.

R&D globalization became evident to Tigermed's leadership from the beginning, steadily building its expertise and service portfolio to align with a more complex global clinical trial and regulatory landscape. As it further explores building its advanced technology within organizations, the company is positioning to establishing a global working environment with the add-on of the China and APAC experience and including incorporating talent from outside China.

With a proven track record of taking drugs to market, regulatory compliance on par with international standards, and service excellence, Tigermed continues to grow. Frost & Sullivan anticipates the company's patient-centric and partner-focused framework will keep the company as the front-runner in the China CRO market in the coming years.

Conclusion

China's pharmaceutical (pharma) industry will reach approximately \$392 billion by 2025, making it the second-largest in the world.⁸ The country's outsourcing industry is positioning itself for exceptional growth. A vast and highly diverse patient population base combined with recent governmental overhauls in regulations and policies, aligning with international quality standards and streamlining processes substantially, foster an innovation-driven environment attracting local and foreign emerging pharma and biotech companies as well as multinational firms.

Tigermed offers full clinical developmental services to approximately 1,900 customers. In its 16-year history, Tigermed has garnered a reputation for innovation with commitment, quality, and cost-efficiency as its banners. Having managed over 2,000 clinical trials and participated in over 130 innovative drug projects, the company helped bring many of China's first novel molecules and therapeutics to market quickly and effectively. Frost & Sullivan analysts firmly believe that Tigermed's comprehensive service portfolio, expertise, and robust systems and infrastructure cement its status as a strategic partner for the pharmaceutical industry for years to come.

Its stellar track record, expertise, and commitment to service and social responsibility earn Tigermed the 2020 Frost & Sullivan Customer Value Leadership Award.

⁸ *Growth Insights on China's Pharmaceutical Industry, Forecast to 2025* (Frost & Sullivan, January 2020)

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 both 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

