FROST & SULLIVAN

2024 CUSTOMER VALUE LEADER

IN THE GLOBAL BIOTECH CONTRACT RESEARCH ORGANIZATION INDUSTRY

AVANCE CLINICAL

FROST & SULLIVAN

2024 BEST PRACTICES AWARD

Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated company. Avance Clinical excels in many of the criteria in the biotech contract research organization space.

A Market Snapshot

Despite a slowdown in biologics R&D investment following the COVID-19 surge, the segment remains a significant contributor to the drug development pipeline. Specifically, small-to-mid-segment biotechnology (biotech) firms (companies with less than two molecules in the pipeline) continue to power drug innovation and advancement, accounting for over 16% of the active global pipeline.[1] The anticipated upsurge in biologics R&D investments in 2024 and beyond will further drive biotech activity.

This ongoing biotech activity, in turn, increases the demand for outsourcing activities, propelling the uptake of biotech contract research organization (CRO) services. Within this context, Frost & Sullivan's research anticipates the global CRO market, estimated at over $50 billion in 2023, will witness robust growth at 10.5% in the next three to five years.[2]

Despite these positive prospects, biotech companies face multifaceted challenges, including escalating drug development complexities, regulatory complications, skilled resource constraints, and rapid technological innovation. Companies also struggle with clinical trials' lengthy timeframes, hefty costs, and patient pool diversification, recruitment, and retention requirements. More specifically, the continuing effects of the downturn in R&D investments pressurize biotech companies to save costs and increase efficiencies. However, Frost & Sullivan's research finds that over 50% of biotechs engage with more than

[1] *"Global Pharmaceutical Industry Outlook, 2024," (Frost & Sullivan, April 2024).*
[2] *"Frost Radar™: Asia-Pacific Contract Research Organizations, 2023," (Frost & Sullivan, December 2023).*

one CRO throughout their clinical programs, leading to a less streamlined approach that increases project costs, delays, and knowledge/data transfer challenges.[3]

Within this context, it is increasingly crucial for biotech companies to select the right CRO that can deliver at every phase of their drug development programs, especially for firms aiming to meet investor milestones while navigating a constrained financial landscape. As a result, biotechs seek to partner with mid-sized, agile, and responsive CROs with a proven ability to expedite quality clinical programs.

Avance Clinical: Biotech's Ideal CRO Partner

Founded in 2009 and headquartered in Adelaide, Australia, Avance Clinical is a leading CRO facilitating top-tier clinical trials with globally recognized data for biotech firms worldwide. With an exclusive focus on the biotech sector, the company leverages over 30 years of deep clinical research experience across 120+ therapeutic indications to provide customized services catering to biotech R&D's dynamic needs. Avance Clinical possesses particularly robust expertise in Cell & Gene Therapies, Central Nervous System (CNS), Dermatology, Endocrinology, Infectious Diseases, Oncology, Ophthalmology, Rare Disease & Orphan Drug, and Respiratory & Allergy indications. Overall, the company's world-class team exceeding 330 clinical and regulatory specialists delivers high-quality clinical trials in Australia, New Zealand, Asia, and North America for international biotechs.

"Unlike larger multinational CROs, this intimate approach enables Avance Clinical to understand customer challenges closely, empowering it to deliver flexible solutions and hands-on guidance that optimally position it to match the fast-paced nature of biotech R&D. As a result, the company's agility and responsiveness make it the ideal partner for small to mid-sized biotech companies, addressing a crucial need that competitors often struggle to fulfill."

- Unmesh Lal
Global Research Director

As a full-service CRO, Avance Clinical builds on its extensive expertise across various modalities (ranging from small molecules and antibiotics to advanced cell therapies) to offer sophisticated solutions covering the entire spectrum of drug development, from preclinical stages through to Phase III studies. Hence, the company comprehensively supports biotech clients through all clinical trial stages from protocol development to site selection, patient recruitment, and data analysis, eliminating the need to engage with multiple CROs. Ultimately, this streamlined approach optimizes clinical study efficiencies, minimizes overall costs, and accelerates trial timelines.

Moreover, Avance Clinical, as a midsized entity, embeds itself deeply into its biotech customers' operations, with its scientific and regulatory consulting teams engaging with them as early as possible to optimize their trial designs and protocols. The company's flat organizational structure provides customers with direct access to leadership teams, facilitating continual collaboration throughout their drug development journeys. Unlike larger multinational CROs, this intimate approach enables Avance Clinical to understand customer challenges closely, empowering it to deliver flexible solutions and hands-on guidance that optimally position it to match the fast-paced nature of biotech R&D. As a result, the company's agility and responsiveness make it the ideal partner for small to mid-sized biotech companies, addressing a crucial need that competitors often struggle to fulfill.

[3] *"Avance Clinical — The CRO Partner of Choice for US Biotechs", (Frost & Sullivan, 2024).*

For instance, one of Avance Clinical's most compelling value propositions is its in-house regulatory team that seamlessly integrates into its biotech clients' clinical and project delivery operations to minimize delays and costly errors (decreasing the trial startup timeline by up to 50% and reducing costs by up to 30%[4]). The company's regulatory experts provide strategic counsel on study design, regulatory compliance, and protocol development. Additionally, Avance Clinical draws on the team's expertise across various study stages, multiple geographies, and regulatory jurisdictions to support customers' adaptability to rapidly evolving regulatory landscapes.

Moreover, as biotech companies extend their drug development to later-phase, multi-regional programs, Avance Clinical's global regulatory team, with regional and local proficiency, ensures compliance with stringent standards set by regulatory bodies. Overall, the company's in-house regulatory expertise plays a pivotal role in assisting biotech companies in achieving a 'clinic ready' status and offers a 'global ready' roadmap for later phases, effectively transitioning biotech products through the clinical development journey and towards marketing authorization.

Market-led Innovation Driving Differentiation

Avance Clinical utilizes state-of-the-art technology and robust infrastructure to streamline its biotech clients' trial operations and data management. To this end, the company maintains partnerships with leading technology providers to ensure access to cutting-edge tools and systems for efficient trial conduct. For instance, Avance Clinical supports post-market surveillance through its Oracle Argus pharmacovigilance system, its cutting-edge solution suite for clinical trial management systems. Similarly, the company works closely with other eClinical solution vendors, including Medidata (3DS) and Medrio, to support capabilities around eConsent, electronic patient-reported outcomes, eSource, and electronic data capture.

In addition to facilitating a company-wide application of industry-standard technologies, Avance Clinical's Technology and Innovations team continually identifies and reviews the latest technology solutions, including machine learning and artificial intelligence (AI) applications, to support global systems integrations. For instance, in February 2024, the company announced a strategic partnership with Ryght, the California-based generative AI (GenAI) innovator for the life science industry, to bring GenAI technologies to its clinical research networks. This collaboration allows the company to access Ryght's sophisticated GenAI platform, which utilizes various large language models fine-tuned for the biotech sector to process live data streams and complex data, optimizing clinical workflows and boosting operational efficiency.[5]

Moreover, Avance Clinical continues to form partnerships with technology companies that offer innovative solutions designed to accelerate the delivery of high-quality, globally accepted data to its biotech clients. For instance, in November 2023, Avance Clinical extended its capabilities in the Asia-Pacific (APAC) market by signing a strategic technology Memorandum of Understanding (MOU) with leading

[4] *"Unlocking Biotech Success: The Advantages of CROS with In-House Scientific & Regulatory Expertise," (Frost & Sullivan, 2024).*

[5] https://www.avancecro.com/news/avance-clinical-and-ryght-partner-to-bring-novel-genai-technologies-to-clinical-research-networks/, accessed July 2024.

Korean decentralized clinical trials and eClinical technology company JNPMEDI Inc.[6] The partner's Maven Clinical Cloud offers a one-stop-shop solution that supports patient participation while delivering efficiencies to study sites, sponsors, and CROs.

Over and above, Avance Clinical's ongoing incorporation of advanced technology-enabled solutions and its inherent scientific expertise empower biotech companies to adequately address the sector's increasing drug development complexities.

GlobalReady: Driving Transition to Global CRO

An established APAC market leader, Avance Clinical's globalization strategy extends its presence into new geographies, through organic expansions and partnerships, to better serve its biotech customers' growing global needs. To this end, the company continues to spread its footprint across the United States (US) and Asia while strengthening its CRO partnerships in Europe. In June 2023, Avance Clinical inaugurated its new North American headquarters in North Carolina.[7] This presence allows the company to offer clients a seamless drug development journey from Australia to the US, all under the guidance of the same CRO. Similarly, Avance Clinical expanded its Asian presence by formally opening new clinical operations in Seoul, South Korea, in May 2024.[8]

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- Sama Suwal
Best Practices Research Analyst

Similarly, in May 2024, Avance Clinical signed a non-exclusive MOU with Julius Clinical, the Netherlands-based full-service therapeutically specialized CRO with extensive site relationships across Europe. This partnership enables the company to leverage its partner's CNS, cardiometabolic, and rare diseases specialization to expand its regional capabilities.[9] Additionally, Avance Clinical continues to invest strategically in building strong relationships with clinical sites capable of conducting Phase I to IV clinical trials, forming an expansive network of over 2,000 high-quality, trusted clinical trial sites across Australia, New Zealand, the US, Canada, and Europe. This network includes a diverse range of clinical sites, from small rural clinics and dedicated research facilities to large academic and non-academic healthcare systems. This variety empowers Avance Clinical to deploy the optimal site strategy for each client, ensuring geographic diversity and a wide patient population.

As a result of these efforts, the company's unique GlobalReady model supports biotechs from their early pre-clinical stage through to later phases across the globe, leveraging the right site relationships to deliver access to the optimal patient populations. The GlobalReady program enables seamless transition and

[6] https://www.avancecro.com/news/avance-clinical-strengthens-asia-pacific-network-with-digital-technology-company-jnpmedi-inc/, accessed July 2024.
[7] https://www.avancecro.com/news/avance-clinical-opens-new-north-american-headquarters/, accessed July 2024.
[8] https://www.avancecro.com/news/avance-clinical-expands-further-into-apac-with-new-clinical-operations-in-south-korea-seoul-office-announced-at-bio-korea-2024/, accessed July 2024.
[9] https://www.avancecro.com/news/avance-clinical-expands-specialist-cns-cardiometabolic-and-rare-diseases-cro-services-in-europe-with-julius-clinical/, accessed July 2024.

coordination between regions, allowing biotechs to utilize its expertise across various markets. For instance, for biotech clients embarking on early-phase studies in Australia and New Zealand, GlobalReady ensures a smooth transition into the US market to continue their clinical development programs. Currently, Avance Clinical serves more than 100 biotech clients as part of its GlobalReady program.

Moreover, Avance Clinical's strong site network facilitates quick feasibility evaluations and rapid progression through start-up activities, allowing for expedited patient recruitment. This efficiency, in turn, translates to shorter overall timelines for the company's biotech clients, ensuring faster and more effective clinical trials, including accelerated study start-up durations of five to six weeks.[10]

A Customer-centric Approach Driving Unmatched Client Experiences

Avance Clinical works closely with customers throughout the pre- and post-purchase journey, providing unwavering support and guidance to help them achieve their desired clinical outcomes. From the initial engagement to the final project delivery, the company remains dedicated to understanding its customers' specific needs and objectives, ensuring a tailored approach to its services. Furthermore, Avance Clinical prioritizes open and transparent communication with its biotech clients to foster a collaborative environment that ensures alignment and success throughout clinical trials. Collectively, these efforts enable the company to build long-lasting customer relationships.

Moreover, Avance Clinical distinguishes itself from other CROs by adopting a unique approach to project management where each project receives individual oversight to prioritize budgeted time allocations. This approach allows project managers to focus fully on clients, address challenges, facilitate knowledge sharing, and provide the necessary guidance for success.

Avance Clinical's customer-centric approach drives exceptionally high customer satisfaction rates, with the company reporting an impressive 70% customer retention rate. Having completed more than 500 studies with over 18,000 participants in the past five years, the company's customer base spans diverse geographical regions, including APAC, the US, Canada, Europe, and New Zealand. Currently, Avance Clinical manages around 165 studies, with approximately 50% of the trials in Phases II and III.[11]

"Avance Clinical provides a strong case for why biotech companies should stay away from the big CRO's for as long as they're pipeline activities allow. They have departments, but they're not siloed. They have systems, but they're not overengineered. They have management but they give the feel of a horizontal team merging with our horizontal team, causing most of my CRO lessons learned for the last 20 years to be….not applicable. They just get the job done."

- Matthijs Schoots, Head of Strategic Planning at Uvax Bio[12]

Case Study: **Tetherex Pharmaceuticals Inc**[13]

Tetherex Pharmaceuticals Inc (Tetherex), a privately held clinical-stage biopharmaceutical company developing a single-cycle adenoviral vector COVID-19 vaccine, leveraged Avance Clinical's services to

[10] https://www.avancecro.com/cro/globalready/, accessed July 2024.
[11] Ibid.
[12] https://www.linkedin.com/posts/avance-clinical_avance-clinical-at-world-vaccine-congress-activity-7181048463055286274-wnRM/, accessed July 2024.
[13] https://www.avancecro.com/case-studies/clinicready-success-story/, accessed July 2024.

expedite the regulatory approval process for their exciting vaccine candidate's First-in-Human trial. Originally intending to administer their vaccine through both intranasal and intramuscular routes, Tetherex faced a significant 60-day delay in clinical study start-up due to the licensing requirements for internasal administration.

Within this context, Avance Clinical worked closely with Tetherex to amend their protocol design to initially focus on the intramuscular route, allowing for a faster start with a less stringent license. This agile and staggered approach showcases the company's ability to help biotechs overcome regulatory challenges to expedite and optimize clinical trials. In 2021, Avance Clinical delivered the first patient dosing for Tetherex's Phase I vaccine clinical trial, signifying an important milestone in its commitment to delivering the best client outcomes.

"The Avance team demonstrated flexibility and a solution-oriented attitude in working with us towards obtaining rapid ethics approval. thereby facilitating trial initiation in a timely and efficient manner."

- Dr. Russell Rother, President and Chief Operating Officer at Tetherex Pharmaceuticals[14]

Serving as a testament to the company's high client satisfaction rate, Avance Clinical acquires many of its customers through word-of-mouth accolades, fueled by its exceptional operational strategies, customer-centric design, and technological performance. Over the years, the company has built a strong industry presence and a track record of delivering successful outcomes through word-of-mouth referrals and positive client experiences. Additionally, Avance Clinical actively engages in industry conferences, events, and networking opportunities to showcase its capabilities and forge connections with potential customers.

Positioned for Growth

Avance Clinical's customer-first approach, cutting-edge technology, regulatory expertise, and growing global presence continue to drive strong financial performance. In the financial year (FY) 2024, the company registered a health growth rate of 27% and expanded its employee base by 125 people. For FY 2025, the company strives toward a 30% revenue growth and 50% earnings before interest, taxes, and amortization targets. Similarly, Avance Clinical will continue its global expansion efforts, with the US and APAC (Japan, Korea, Singapore, Taiwan, India, and Malaysia) as the primary target markets in the near term and Europe in the mid to long term.

Overall, the company's impressive growth momentum and trajectory are a testament to its customer-centric approach, revolutionary capabilities, and exceptional operational strategies, earning its client's trust and loyalty and enabling it to capture more market share.

[14] Ibid.

Conclusion

Customer-centric strategies help companies safeguard leading positions in markets, but only if the approach is authentic and the implementation is seamless. Avance Clinical incorporates customer-focused strategies and exemplifies best practice implementation.

An established and expanding global contract research organization, Avance Clinical boasts a proven track record of providing biotech customers with the necessary services for the timely and cost-effective execution of clinical trials. The company's customer focus, agility, and responsiveness position it as the ideal contract research organization partner for biotech customers. Moreover, Avance Clinical's globalization strategy, continual scientific collaboration, unmatched regulatory expertise, and personalization capabilities set it apart from its contemporaries. The company's overall customer-first approach offers immense value to existing and new customers and solidifies Avance Clinical's reputation in the market.

With its strong overall performance, Avance Clinical earns Frost & Sullivan's 2024 Global Customer Value Leadership Award in the biotech contract research organization industry.

What You Need to Know about the Customer Value Leadership Recognition

Frost & Sullivan's Customer Value Leadership Award recognizes the company that offers products or services customers find superior for the overall price, performance, and quality.

Best Practices Award Analysis

For the Customer Value Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Business Impact

Financial Performance: Strong overall financial performance is achieved in terms of revenues, revenue growth, operating margin, and other key financial metrics

Customer Acquisition: Customer-facing processes support efficient and consistent new customer acquisition while enhancing customer retention

Operational Efficiency: Company staff performs assigned tasks productively, quickly, and to a high-quality standard

Growth Potential: Growth is fostered by a strong customer focus that strengthens the brand and reinforces customer loyalty

Human Capital: Commitment to quality and to customers characterize the company culture, which in turn enhances employee morale and retention

Customer Impact

Price/Performance Value: Products or services provide the best value for the price compared to similar market offerings

Customer Purchase Experience: Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

Customer Ownership Experience: Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

Customer Service Experience: Customer service is accessible, fast, stress-free, and high quality

Brand Equity: Customers perceive the brand positively and exhibit high brand loyalty

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The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create ongoing growth opportunities and strategies for our clients is fuelled by the Innovation Generator™.
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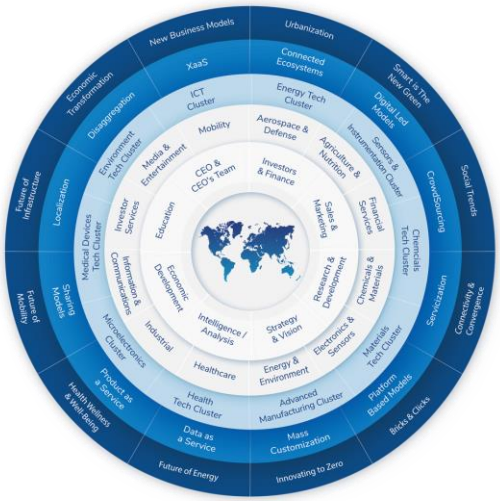
Key Impacts:

- **Growth Pipeline:** *Continuous Flow of Growth Opportunities*
- **Growth Strategies:** *Proven Best Practices*
- **Innovation Culture:** *Optimized Customer Experience*
- **ROI & Margin:** *Implementation Excellence*
- **Transformational Growth:** *Industry Leadership*

The Innovation Generator™

Our 6 analytical perspectives are crucial in capturing the broadest range of innovative growth opportunities, most of which occur at the points of these perspectives.



Analytical Perspectives:

- Mega Trend (MT)
- Business Model (BM)
- Technology (TE)
- Industries (IN)
- Customer (CU)
- Geographies (GE)