FROST & SULLIVAN

BEST PRACTICES AWARDS

AVANCE CLINICAL

ASIA-PACIFIC CRO MARKET LEADERSHIP AWARD

Contents

Letter of Congratulations

I am proud to present you with this year's award for Market Leadership in the CRO industry.

Frost & Sullivan's global teams of analysts and consultants research a wide range of markets across multiple industries and regions. A core aspect of the research is to determine the leaders in each market, or, to be precise, the market share leaders. This is a rigorous exercise that involves analyzing revenue and shipments for each company, and cross-verifying this analysis through primary and secondary research, ultimately resulting in a clear determination of the market leader. As such, Frost & Sullivan is pleased to recognize Avance Clinical Pty Ltd as the Market Leader in the CRO industry.

Achieving market leadership is never an easy task, and is made even more difficult considering today's competitive intensity, customer volatility, and economic uncertainty, not to mention the difficulty of innovating in an environment of escalating challenges to intellectual property. In this context, your receipt of this award signifies an even greater accomplishment.

Frost & Sullivan recognizes that this accomplishment is the result of many employees, customers, and investors making daily choices to support your organization and contribute in a meaningful way to its future.

I enthusiastically acknowledge and celebrate these achievements, and wish you great success in the future. Frost & Sullivan is here to support you on any future endeavor.

Sincerely yours,

David Frigstad
Chairman
Frost & Sullivan

Background and Company Performance

Industry Challenges

The increasing strength of the biotechnology and pharmaceutical sectors in Asia-Pacific is creating excellent growth opportunities for contract research organizations (CROs) across the region, an indisputably important geography whose large population provides a wide pool of patients for participation in clinical trials.

The CRO industry in Asia-Pacific is segmented as follows:

1. Multinational CROs (including IQVIA, Parexel, PPD, Syneos Health, PRA, ICON, and Covance) that all have a strong presence. These companies are designed for global scale and to support large multinational Phase 3 studies primarily conducted by Big Pharma and large biotechnology companies.

2. Regional CROs including Avance Clinical, Novotech, George Clinical, CMIC, Tigermed, C&R Research. These CROs have strong geographical coverage throughout Asia-Pacific and specialize in multinational studies in the region.

From an economic standpoint, the strength of growing markets including China, Taiwan, South Korea, Singapore, Hong Kong, India, and Australia is a major driver for biotechnology and pharmaceutical companies. In addition, robust government support for clinical trials, decreased trial costs, and increasingly high-quality standards make Asia-Pacific an in-demand location for trials globally. The region has a patient population in significant need of medical care, which supports effective recruitment because these naïve patients rely on clinical trials to access new medications and treatments.

The following factors are contributing to an increasingly strong biotechnology and pharmaceutical sector, and consequently, a strong CRO sector in Asia-Pacific:

1. Asian regulatory reform, such as the CFDA reform, supports new product launches to expedite clinical trial approvals and boost the region's appeal.

2. Significant focus on building infrastructure and attracting high-quality talent support biotech sector growth. For example, GlobalData, in August 2019, reported "South Korea plans to invest over US$1.7 billion in its biotechnology and biopharmaceutical sectors over the next five years, attracting foreign investment as pharmaceutical market growth is set to rise from almost US$19.5 billion in 2018 to over US$23.2 billion by 2022."[1] Similar investments are seen in China, Taiwan, and Japan.

3. The region has strong small and large molecule manufacturing capability that effectively synergizes good manufacturing practice (GMP) standards with competitive pricing.

[1] https://www.globaldata.com/south-koreas-pharma-biotech-space-to-attract-foreign-investment-as-market-set-to-be-worth-us23-2bn-by-2022-says-globaldata/

4. The region provides access to many ethnicities for clinical trials, with Australia catering for the Caucasian population, which satisfies the ethnicity requirements for major regulators around the globe.

5. A streamlined regulatory process and financial benefits offered by the Australian government mean that Australia is the premier global location for conducting early phase research from a speed, cost, and quality perspective.

Nonetheless, opportunities presented by the large economies in Asia are countered by complexity including different cultures, regulatory requirements, local laws, currencies, and governments. Working across any region involves numerous important considerations which include financial regulation, varying legal requirements, currency rate fluctuations, and the local political landscape.

Overall, the key challenge is to understand and align with each region's unique business culture and establish good communication channels, including ways to work around language barriers. Particularly in Asia, being successful relies on a CRO having strong in-country knowledge and skills to navigate the different local environments.

Market Leadership of Avance Clinical

Avance Clinical believes that the global pharmaceutical landscape has shifted, with Asia-Pacific positioned as the powerhouse of the pharmaceutical and biotechnology industries. The shift is supported by the region's economic growth, low-cost manufacturing, and the government's reform and investment in the sector to spur clinical trial activity. With this and the increasing trend of outsourcing, CROs will continue to see significant opportunity and growth from Asia-Pacific.

Technology Leverage

Avance Clinical understands that the success of clinical program delivery is underpinned by robust systems that drive quality. In addition to utilization programs, such as SAS for statistical analysis, MedDRA and WHO-DD for coding, Phoenix WinNonlin for Pharmacokinetic and Pharmacodynamic analysis, and Medrio and Medidata for database management and CDISC, the company has invested heavily in quality systems over the past 18 months. This investment is driving quality service delivery.

Program delivery is also supported by the Flex Databases Clinical Trial Management System as well as training, compliance, and quality assurance by the eQuality Management System and eLearning Management System from MasterControl. Leveraging Australia's regulatory notification system and private Phase 1 site network to initiate Phase 1 trials within four weeks, Avance Clinical has implemented a new integrated finance system called Business Central to manage its own financial accounts, those of its clients, as well as all third-party and vendor accounts.

Avance Clinical has a full suite of best-in-class systems to deliver quality outcomes. Developing a strong understanding of the ethical requirements that enable adaptive design studies to be created, (i.e., starting with Single Ascending Dose and Multiple Ascending Dose studies and including a patient cohort), allowing biotech companies to get an early sign of efficacy and quickly track the development of new therapies.

Avance Clinical is also taking a progressive approach to developing partnerships with other CROs around the globe. It supports biotech companies with their multinational trials through these collaborations. The partnerships include CMIC (Asia) as well as C & R Research (Korea and China). The adoption of these world-class systems and investment in CRO partnerships worldwide have allowed Avance Clinical to gain a strong position as the CRO of choice for biotech companies conducting early phase clinical programs. Moreover, because Australia has managed the COVID-19 pandemic well, Avance Clinical and many of the leading sites it works with have remained open and operational throughout the crisis.

As soon as COVID-19 was declared by the World Health Organization (WHO) as a pandemic, Avance Clinical took immediate and appropriate actions to ensure the health and safety of all of its employees, contractors, visitors/clients, and study participants. The company moved quickly to pivot its business and implement any required strategies in line with its business continuity policies to ensure study activities ran as planned and to minimize disruption of approved protocols and the services provide. Telemedicine, remote assessment of patients, and greater use of electronic patient-reported outcomes (ePRO) will also reshape patient recruitment and enrolment in clinical trials. There will be more significant opportunities for access to patients who are located great distances from city-based clinical trial centers and will be more readily adopted and accepted.

Furthermore, eSource and adoption of increased remote monitoring activities have been gaining acceptance with sponsors, sites, and regulators, resulting in fewer transcription errors and faster review of data. COVID-19 has significantly accelerated the adoption of these concepts and technologies in Asia-Pacific.

Customer Purchase Experience

Avance Clinical believes the best purchase experience demands proactive communication, timely follow-up, and willingness to provide accurate, pragmatic advice to clients about their project plans. The Avance executive team is involved in all client interactions relating to the purchase of services and provides clients with both upfront and ongoing advice throughout the purchase process. The company's projections and recommendations relating to all aspects of the proposed studies undergo a thorough investigation of subject-matter literature and any competing clinical research activities, personal communication with clinical investigators in-network, and prior experience. Furthermore, the company's established collaborative relationships with third-party vendors (e.g., IMP manufacturers, central PK, and PD laboratories) place it in the best position to recommend vendors to clients based on prior good/quality service experience.

Furthermore, the company's approach to service budget proposals is flexible and aims to provide clients with cost-effective options that maximize return on investment. The company believes in a balanced approach in which budgetary spend during early phase clinical trials reflects the high risk usually associated with this phase of product development.

The company's sustainability approach is based on the organizational culture and is continually fostered and cultivated. Avance Clinical staff members are mentored and trained to adopt a proactive, solution-oriented, client-centric mentality. The company believes that the purchase experience is not restricted to the point of purchase but constitutes a continuum that spans the pre-purchase interactions as well as the ongoing service execution, mindful of the client's ongoing satisfaction with the services provided.

Price/Performance Value

The pricing offered by Avance Clinical to prospective clients never compromises quality while tailoring service offerings to fit the purpose and the objectives of each trial the company manages. All costs are based on a thorough review of the services required and robust feasibility assessments. The Avance Clinical strategy offers customers robust service and data that will stand up to the scrutiny of any auditor or regulatory agency.

In preparing cost proposals for clients, the company utilizes data from the previous experiences in conducting Phase 1 and 2 trials, data collected from sites, TrialTrove benchmark data for recruitment statistics, and discussions with key opinion leaders. The company combines all of the data and assesses it to arrive at the appropriate price point for the study. The data collected during the cost proposal phase allows the company to provide clients with an accurate picture of the overall cost for completion of the trials.

Avance Clinical is a specialist in delivering high-quality Phase 1 and Phase 2 clinical trials. The company provides an integrated full-service CRO, offered explicitly in taking advantage of Australia's world-class ecosystem for early phase research conducted by biotech companies. The company has become the right partner to biotech clients by providing profound scientific advice and expertly operationalizing the initial phase clinical programs.

Growth Strategy Excellence

Avance Clinical has positioned itself as a global leader in early phase clinical trials by developing innovative strategies and approaches to initial phase development. It helps global biotech companies set up clinic and achieve proof of concept faster with a data package that stands up to the scrutiny of global regulators. The company is well reputed for proven support of the biotech industry by providing scientific and regulatory expertise to help develop the best strategy to achieve clinical trial outcomes in the most time-efficient manner.

Avance uses a hybrid strategy, which includes a mix of private hospitals and large public hospitals that facilitate both rapid start-up and access to large patient populations. For example, for Phase 1/2 oncology studies, the company recommends utilization of a private central ethics committee to open the survey at 3 to 4 sites, enabling fast start and progression through the first dose-escalation component of the study design while at the same time pursuing approval in 3 to 4 (or more depending on the size of the study) at public hospital centers, making these available for the later part of the escalation and the expansion cohorts. Further, the increase of site numbers can be achieved either exclusively in Australia or through an expansion of the study to sites in the United States, Europe, and Asia.

Avance Clinical supports overseas clients that do not have an established presence in Australia. It acts as the local sponsor to ensure clients can use clinical conduct facilities at dedicated Phase 1 sites, hospitals, and patient clinics to access Australian populations for trials. Through extensive connections, Avance Clinical can align clients with vendors to provide necessary services required to conduct their experiments (e.g., pharmacy depots, ECG analysis providers, specialized laboratories for clinical sample testing, imaging centers, and storage facilities).

Frost & Sullivan recognizes that digital technologies are being and will continue to be implemented and adopted with an increase in remote monitoring activities (e.g., eConsenting, eSource) and decentralized services for virtual trials. As such, Avance Clinical is at the forefront of embracing new technologies that can increase the speed and efficiency of clinical data collection by utilizing eSource, ePRO, and eConsent procedures and working with sites to test and adopt these technologies, which will be the way of the future. Moreover, Avance Clinical has strategically partnered with software providers such as Medrio to develop cutting-edge solutions suited to early phase development. With a focus on the entire Asia-Pacific region, Avance Clinical has positioned itself to provide not only Asian population trials but also the necessary Caucasian patient population as required by regulators' ethnicity guidelines.

Customer Service Experience

High-quality output delivered on time and within budget are the primary drivers ensuring good customer service experience in the management and facilitation of clinical research. The ability to deliver on set outcomes rests heavily on Avance’s ability to attract and retain high-caliber, experienced staff that enable delivery of these goals. Avance staff and culture are key to its success, and the company considers its staff is its greatest asset.

Avance’s dedicated staff reflects its reputable culture and team stability, which lends itself to the high-quality service provided to clients by the following methods:

1. The company is committed to working in a flexible manner and will ensure staff makes itself available for real-time interactions, irrespective of the international time zones.

2. The company is committed to keeping abreast of new technologies to facilitate faster and gather more accurate clinical trial data. It has implemented new systems to ensure that clients are kept up to date with the progress of their studies, including the use of an electronic Trial Master File and a Clinical Trial Management System. These systems improve the customer service experience because they allow real-time access to trial progress data and collection of essential trial documentation.

3. The company is committed to ensuring its staff are kept up to date with the latest trends in drug development and therapy regimens by attending and presenting at local and international trade events (e.g., Drug Information Association and International Conferences) as well as specialist therapeutic area conferences such as ASCO.

4. The company is committed to ensuring staff are trained if they require specific therapeutic area expertise for a particular customer.

All of these initiatives and service offerings allow Avance Clinical to deliver an excellent customer service experience. Frost & Sullivan commends Advance Clinical for fostering highly-qualified, well-trained, experienced, and dedicated professionals committed to meeting each client's requirements in the CRO segment.

Brand Strength

Avance Clinical has been strategically investing in people and systems to become the CRO of choice for biotechnology companies conducting early phase clinical programs. Specialized in conducting studies from first-in-human Phase 1 to proof of concept Phase 2 trials, Avance Clinical stands out for delivering capabilities in this area, which no other competing CRO is able to offer.

Frost & Sullivan is impressed that Avance Clinical is the only CRO in APAC to have developed a fully integrated in-house team and best-in-class systems for early phase clinical trials that offers comprehensive services and solutions.

a) **A new Scientific and Medical Affairs department led by the newly created position of Chief Scientific Officer**: The Scientific and Medical Affairs department supports clients with expert scientific and clinical program development advice. It helps in engaging with clients at a deep scientific level and not just from a transactional clinical trial management perspective. This approach enables Avance Clinical to become an integrated part of each biotech client's team to deliver support from the early development phase through to the end of phase.

b) **Medical writing**: Avance Clinical has invested in medical writing services, which are part of the Scientific and Medical Affairs team. The company now has strong expertise in the design, development, and writing of protocol, investigator brochures, and clinical studies.

c) **Clinical data management**: The continued growth of its data management capabilities includes in-house eCRF development utilizing both the Medrio and Medidata platforms. The Avance clinical data management teams can program an eCRF and database in-house using these platforms.

d) **New digital models**: Piloting eSource documents and eConsent approaches for Phase 1 sites allows for efficient monitoring processes, including remote monitoring.

e) **CDISC**: Development of in-house CDISC capabilities includes the addition of senior, experienced staff dedicated to the programming of Analysis Data Model (ADaM) dataset and metadata standards. ADaM defines a dataset and metadata standard that supports efficient generation, replication, and review of clinical trial statistical analyses, and traceability among analysis results, analysis data, and data represented in the study data tabulation model (SDTM). ADaM is one of the required standards for data submission to both the FDA (United States) and PMDA (Japan). While other companies might claim to have these capabilities in place, Avance Clinical has made a significant investment in this area to ensure that all data generated meets the expected regulatory standards. The company provides full data traceability and track value level metadata so that the deliverables are ready for clients.

f) **Biostatisticians and pharmacokineticists**: The company has established an in-house and dedicated team of Biostatisticians and pharmacokineticists, which is the most highly qualified team in Australia and potentially in the Asia-Pacific region. This team is essential for early phase capabilities for clients; it provides expert analysis of the pharmacokinetic profile of the client's drug candidate.

g) **Implementation of an electronic trial master file and clinical trial management system**: The integrated system allows international clients to have increased visibility into the progress of the study, which is particularly useful for international clients to quickly, efficiently, and in accordance with their time line, review the data status.

Avance Clinical has committed to attending and presenting at local and international trade events (e.g., BioJapan in 2019 and a Government Trade mission to Korea) as part of its increased branding in Asia. It has engaged a media partner in 2020 to release press throughout the world, including Asia-Pacific; this includes press releases translated into Chinese and Korean, which has led to increased interest in the Avance Clinical business in these countries. Also, the company offers translated versions of its website in Chinese, Japanese, and Korean, again confirming its commitment to expansion across Asia.

Avance Clinical believes Asia-Pacific will remain a major growth area, playing an increasingly important part in the drug development plans of all major manufacturers due

to the enormous potential market size. Further regulatory reforms in the region have a significant part in driving more clinical research into the area.

Conclusion

Amidst the opportunity-rich Asia-Pacific CRO market, Avance Clinical has demonstrated excellent patient access for inclusion in trials. The company offers unmatched comprehensive services and technologies, such as clinical project management, clinical trial monitoring, and drug safety reporting. This industry leader supports the biotech industry by providing scientific and regulatory expertise to help clients develop the best strategies to achieve their clinical trial outcomes in the most time-efficient manner. Also, Avance supports overseas clients that do not have a presence in Australia, acting as the local sponsor to ensure the availability of clinical trial solutions. Avance Clinical has a high rate of repeat business at 74%, which reflects its impressive success in providing a high degree of customer satisfaction.

With its strong overall performance, Avance Clinical Pty Ltd has achieved a leadership position in the CRO market with a share of 34.6% in Asia-Pacific and revenue averaging a 50% increase YoY. Frost & Sullivan is proud to recognize the 2020 Asia-Pacific Market Leadership Award to Avance Clinical in the CMO market.

Significance of Market Leadership

Ultimately, growth in any organization depends on customers purchasing from a company, and then making the decision to return time and again. Loyal customers become brand advocates, brand advocates recruit new customers, and the company grows, and then attains market leadership. To achieve and maintain market leadership, an organization must strive to be best in class in 3 key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Market Leadership

Driving demand, strengthening the brand, and differentiating from the competition all play critical roles in a company's path to market leadership. This three-fold focus, however, is only the beginning of the journey and must be complemented by an equally rigorous focus on the customer experience. Organizations that demonstrate best practices, therefore, commit to the customer at each stage of the buying cycle and continue to nurture the relationship once the customer has made a purchase. In this way, they build a loyal, ever-growing customer base and methodically add to their market share.

Key Performance Criteria

For the Market Leadership Award, Frost & Sullivan Analysts focused on specific criteria to determine the areas of performance excellence that led to the company's leadership position. The criteria include (although are not limited to) the following:

Criterion	Requirement
Growth Strategy Excellence	There is a demonstrated ability to consistently identify, prioritize, and pursue emerging growth opportunities.
Implementation Excellence	Processes support the efficient and consistent implementation of tactics designed to support the strategy.
Brand Strength	The brand is respected, recognized, and remembered.
Product Quality	The product or service receives high marks for performance, functionality, and reliability at every stage of the life cycle.
Product Differentiation	The product or service has carved out a market niche, whether based on price, quality, or uniqueness of offering (or some combination of the three) that another company cannot easily duplicate.
Technology Leverage	There is a commitment to incorporating leading-edge technologies into product offerings for greater product performance and value.
Price/Performance Value	Products or services offer the best value for the price, compared to similar offerings in the market.
Customer Purchase Experience	Customers feel they are buying the optimal solution that addresses both their unique needs and their unique constraints.
Customer Ownership Experience	Customers are proud to 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 of high quality.

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 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.

Copyright