

*Avance Clinical Recognized for*

**2021**

**Customer Value Leadership**

Asia-Pacific Contract Research

Organization Industry

*Excellence in Best Practices*



## 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 contract research organization space.

AWARD CRITERIA	
<i>Business Impact</i>	<i>Customer Impact</i>
Financial Performance	Price/Performance Value
Customer Acquisition	Customer Purchase Experience
Operational Efficiency	Customer Ownership Experience
Growth Potential	Customer Service Experience
Human Capital	Brand Equity

### Contract Research Organization Overview

Frost & Sullivan estimates the Asia-Pacific's (APAC) clinical contract research organization (CRO) market, currently at \$6.01 billion, to reach nearly \$11.04 billion in 2026, growing at a compound annual rate of 12.2%.<sup>1</sup> The region is becoming the go-to research and development market, with China, Japan, Australia, and South Korea in the lead, accounting for 16% of the APAC clinical CRO market in 2020.<sup>2</sup>

Founded in 2009 and headquartered in Adelaide, Australia, Avance Clinical, one of the region's leading CRO's, provides clinical research services to the local and international drug development industry. Avance Clinical is a recipient of Frost & Sullivan's prestigious 2020 APAC CRO Market Leadership Award. The company has supported biotech companies with their early phase clinical trials for more than two decades. It leverages state-of-the-art technologies, a world-class Australian ecosystem that enables rapid study start-up. Avance Clinical boasts a team of more than 150 clinical trial specialists with expertise across a broad range of therapeutic areas having conducted over 200 early phase clinical trials for biotech companies over the past five years and highly knowledgeable scientific, quality assurance, quality control, and project managers with experience from over 100 global pharmaceutical and biotechnology companies to deliver high-quality services.

<sup>1</sup> Post-COVID-19 Trends Disrupt the Global Contract Research Organization (CRO) Market, (Frost & Sullivan, May 2021)

<sup>2</sup> Ibid.

Avance Clinical has grown rapidly over the past year since our last analyst review, including further expansions of clinical services across Australia and New Zealand. Its impressive repeat business rate of greater than 70% speaks to its customer value and reputation in the sector and is a key factor in the 2021 award selection.

### ***Deploying World-class Technology and an Experienced Clinical Team to Deliver High-quality Clinical Research Services in APAC***

*“By using best-in-class technologies, the company strengthens its data and compliance management processes. In addition, Avance Clinical ensures program compliance with continuously changing global regulations. Implementing the Argus platform is particularly critical for Phase II clinical trials where adverse events in patients are more common.”*

***- Supriya Lala Kundu, Best Practices Research Analyst***

Avance Clinical offers a truly agile, responsive, and adaptive approach that enables clients to rapidly move from pre-clinical through to Phases I-III. Avance Clinical's clients are biotech companies from North America, Europe, and Asia. These clients are seeking a premium CRO with the same experience and advanced technology platforms offered by the major global CROs, but with an agile and customer focused approach to clinical management in Australia and New Zealand.

The company's clinical data is accepted by all global regulatory authorities. Avance Clinical has a high level

of customer service and expertise. Its comprehensive in-house clinical research services deliver drug development expertise from pre-clinical to Phase III.

Avance Clinical's services include scientific, regulatory and medical affairs, clinical project management, trial monitoring, data management, statistical analysis, pharmacokinetics, safety and pharmacovigilance, and CDISC programming. Avance Clinical's extensive clinical trials experience includes oncology, central nervous system, cardiovascular, infectious diseases, and dermatology.

The highly experienced team of more than 150 clinical trial specialists has deep experience across more than 105 indications. The company offers best-in-class technologies from leaders such as Oracle, Medidata and Medrio enabling rapid high-quality data management that is accepted by all the major regulatory authorities globally. The Oracle Argus pharmacovigilance system is the latest addition to its state-of-the-art systems suite. The Argus Cloud, the industry's best-in-breed safety, pharmacovigilance, and regulatory compliance technology, provides a scalable and secure solution within a multi-tenant International Council for Harmonization (ICH) E2B R3 XML compliant database for Avance clients.

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Avance Clinical's experienced clinical data management team offers the highest standards of biostatistics and pharmacokinetic analysis. In addition, data management services include: data management plans and edit check specification, electronic case report form (eCRF) development and

validation using Medrio or Medidata, Clinical Data Acquisition Standards Harmonization (CDASH) conforming CRF design, electronic patient-reported outcomes (ePRO), edit check programming, and medical coding. By using streamlined capture, analysis, and reporting techniques, these services deliver high-quality data sets. As quality is its primary focus, Avance Clinical employs stringent quality assurance (QA) procedures and services.

The in-house QA team conducts external vendor audits including hospital trial sites, Phase I units, investigational product vendors, central laboratory providers. Further internal audits are performed for all trial databases, trial master files, and clinical study reports.

### ***Leveraging Regional Genetic Diversity to Cater to Rising Demand for Cell and Gene Therapies***

*“Avance Clinical uses a range of eClinical technologies such as ePro, eSource, and eConsent to support clients conduct DCTs or site-based studies. The advanced technologies heighten research data value, improve patient engagement and data collection, and provide real-time visibility on the study's progress at every step through sponsor-visible portals and ongoing status reports.”*

**- Supriya Lala Kundu, Best Practices Research Analyst**

Home to large ethnically and genetically diverse populations, the APAC region is ideal for recruiting sample populations for novel cell and gene therapy (CGT) drug trials. Furthermore, with Australia supporting large-scale genome projects and making genomic data profiles available, the region can potentially emerge as a hub for specialty clinical trials, especially in post-marketing surveillance activities.

The company's accreditation as a gene technology CRO under the Office of the Gene Technology Regulator (OGTR) has allowed it to expand into clinical trials for vaccines and GMO therapies.

### ***Employing eClinical Technologies to Maximize Data-driven Decisions, Provide Real-time Visibility, and Support Decentralized Trials***

The COVID-19 pandemic highlighted the need to increase patient access and diversity, reduce study footprint, alleviate patient participation burden, and accelerate timelines to conduct decentralized clinical trials (DCTs).

Adopting eClinical solutions, remote monitoring platforms and devices, home health services, and direct-to-patient drug distribution networks have expanded because of swift regulatory guidelines issued worldwide to address patient safety during the pandemic.

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The company partners with eClinical solution providers such as Medrio and Medidata to access regulatory-compliant and patient-centric technologies to hasten study start-up and ensure uninterrupted data flow. The company is working with sponsors to deliver early phase clinical trials for COVID-19 treatment and vaccines. Avance Clinical completed Phase I trial recruitment using Atossa's

proprietary drug candidate AT-301. Administered by nasal spray for COVID-19 therapy, the potential drug is for at-home use during home quarantine to prevent disease progression.

Increased digital technologies and telemedicine facilitates patient enrolment by providing access to patients from remote regions, fostering patient diversity and collecting data in real-life settings. It also drives seamless connectivity with the global client base and fast-tracks investments across several operations to advance flexible trial environments. Avance Clinical's eSource allows direct source data capture on-site, provides customized forms and in-built editing with instant query generation options, ongoing remote monitoring, and data review.

eConsent includes patient sign-off and investigator confirmation, and video and animation. ePRO and eConsent have email communication and all-device compatibility. Fully integrated with Medrio EDC, eSource, eConsent, and ePRO allow immediate data visibility for sponsor review. According to Yvonne Lungershausen, Avance Clinical's Chief Executive Officer, DCTs are fast becoming the new norm, "This is an incredible opportunity for the drug development sector as well as the diverse and remote patient populations that will now have access to clinical trials."

Apart from eClinical solutions, the company launched a dedicated scientific and regulatory affairs service ClinicReady, to cater to the high demand for pre-clinical study management and scientific and regulator advice. In addition, Avance Clinical rapidly deployed strategies for business continuity during the pandemic, ensuring the health and safety of its employees, clients, and trial participants, limiting disruptions, and sustaining study activities. The company invested in best practices and procedures to enable staff to access site data and private networks remotely through the information technology department's coordination.

### ***Reinforcing Positioning in the APAC Region through Innovative Growth Strategies***

Avance Clinical takes a progressive approach to develop partnership relationships with global CROs to enhance the traditional working model, resulting in greater value sharing, support, and access to expertise. For example, the company collaborates with European CRO Cromos Pharma to provide scalable clinical solutions to biotech clients. This collaboration offers clients quick pre-IND early phase study support at an economical cost due to access to patient populations in Central/Eastern Europe for Phase II/III studies. As a result, the company continuously increases its client base, both from the US and Asia.

Avance Clinical gains opportunities to expand its reach globally by leveraging the Australian government's clinical trial incentives of up to 43.5% in cash refunds for trials conducted in the country. Nearly 80% of its clients utilize the tax incentives and also benefit from the country's exchange rate upside. Furthermore, with the global recognition of successfully managing and controlling COVID-19, the company encountered a surge in proposals and study awards, leading to increased staff hiring to operationalize heightened workloads. With a trusted reputation of delivering matchless services to global clients, Avance Clinical emerges as the Australian CRO partner of choice. It continues to consolidate its industry-leading positioning to provide matchless early and late phase clinical trial programs.

## Conclusion

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Avance Clinical offers a nimble, responsive, and adaptive approach with comprehensive services suite for the early and late phases of drug development in a cost-efficient manner. Proficiency in clinical project management, clinical trial monitoring, drug safety reporting, and regulatory expertise allow Avance Clinical to meet clinical trial milestones readily. The company implements advanced technologies to automate and create workflow efficiencies across all clinical development stages.

In addition, Avance Clinical enables biotech clients to access high-quality data quickly through streamlined data capture, analysis, and reporting techniques. The company employs eClinical technologies, telemedicine, and remote monitoring to conduct decentralized trials and drive patient participation outside typical clinical settings. By implementing digital tools, Avance Clinical helps to improve patient retention and trial diversity and provides clients real-time visibility on the study's progress.

By leveraging Australia's streamlined regulatory environment, stable health systems, and well-managed pandemic strategy, Avance Clinical reinforces its position as a world-class contract research organization enabling seamless trial continuity.

With its strong overall performance, Avance Clinical earns Frost & Sullivan's Asia-Pacific 2021 Customer Value Leadership Award in the contract research organization industry.

## What You Need to Know about the Customer Value Leadership Recognition

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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

## About Frost & Sullivan

Frost & Sullivan is the Growth Pipeline Company™. We power our clients to a future shaped by growth. Our Growth Pipeline as a Service™ provides the CEO and the CEO's growth team with a continuous and rigorous platform of growth opportunities, ensuring long-term success. To achieve positive outcomes, our team leverages over 60 years of experience, coaching organizations of all types and sizes across 6 continents with our proven best practices. To power your Growth Pipeline future, visit Frost & Sullivan at <http://www.frost.com>.

## The Growth Pipeline Engine™

Frost & Sullivan's proprietary model to systematically create on-going growth opportunities and strategies for our clients is fuelled by the Innovation Generator™. [Learn more.](#)

### 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 six 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)

