

F R O S T & S U L L I V A N

2024 COMPANY OF THE YEAR

*IN THE GLOBAL BIOTECH
CONTRACT RESEARCH
ORGANIZATION
INDUSTRY*

F R O S T & S U L L I V A N

BEST
2024 PRACTICES
AWARD

NT NOVOTECH™
Biotech's Partner at Every Phase

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. Novotech excels in many of the criteria in the biotech contract research organization space.

AWARD CRITERIA	
<i>Visionary Innovation & Performance</i>	<i>Customer Impact</i>
Addressing Unmet Needs	Price/Performance Value
Visionary Scenarios Through Mega Trends	Customer Purchase Experience
Implementation of Best Practices	Customer Ownership Experience
Leadership Focus	Customer Service Experience
Financial Performance	Brand Equity

A Market Snapshot

Despite stagnation in the pharmaceutical industry’s research & development (R&D) activities following the COVID-19 pandemic, the global pharma R&D pipeline accounts for over 21,000 molecules (as of April 2023), indicating a 5.8% increase from 2022, with more than 6,100 molecules in active development.¹ In 2023, biologics accounted for 44% of the drug development pipeline², with an anticipated surge in biologics R&D in 2024 and beyond. As a result, the biologics segment will drive the global pharmaceutical industry’s overall growth, increasing its market share from 34.1% in 2024 to 38.5% in 2028.³ The biologics market, valued at \$519.04 billion in 2024, will grow at a compound annual growth rate of 9.4% between 2022 and 2027.⁴

Moreover, small-to-mid-segment biotechnology (biotech) players (companies with less than two molecules in the pipeline) continue to drive pharmaceutical innovation, accounting for over 16% of the active global pipeline.⁵ As a result, the demand for outsourcing activities is rising globally, propelling the uptake of biotech contract research organization (CRO) services. Frost & Sullivan’s research anticipates

¹ “Growth Opportunities in Drug Discovery and Early Development Outsourcing Services,” (Frost & Sullivan, February 2024).

² “Growth Opportunities in Global Biotech Investment, 2024,” (Frost & Sullivan, April 2024).

³ “Global Pharmaceutical Industry Outlook, 2024,” (Frost & Sullivan, April 2024).

⁴ Ibid.

⁵ Ibid.

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.⁶

Despite these positive prospects, companies increasingly face multifaceted challenges, including regulatory complexities, skilled resource constraints, rapid technological innovation, and price control pressures. Similarly, companies struggle with clinical trials' lengthy timeframes, hefty costs, and patient pool diversification, recruitment, and retention requirements.

“Overall, Novotech distinguishes itself in the ever-expanding CRO market by successfully addressing the complex regulatory landscape with a deep understanding of local regulations and overcoming cultural barriers to establish itself as a truly global CRO. As a result, the company progresses closer to becoming a preferred global partner with regional leadership and localized expertise.”

- Umesh Lal
Global Research Director

Founded in 1997 and headquartered in Sydney, Australia, Novotech addresses these challenges by uniquely leveraging its early- to late-phase CRO suite of services, growing global footprint, deep industry relationships, and extensive operational infrastructure to accelerate and diversify clinical development for biotech companies. Operating across 34+ locations in Asia, Europe, and the United States (US), the company offers biotech clients access to a diverse, global patient population, including areas with faster patient recruitment.

In 2023, Frost & Sullivan recognized Novotech for its enhanced clinical data quality, improved patient experiences, and efficiencies across studies. Frost & Sullivan remains impressed with the company's continuing innovation and sustained leadership.

Novotech: Biotech's Partner at Every Phase

As a leading full-service global CRO, Novotech strategically leverages the biotech sector's growing shift towards one-stop-shop service providers. To this end, the company supports these clients with a comprehensive 360-degree approach to clinical development, covering all trial phases and therapeutic areas while customizing integrated clinical trial services to clients' specific needs.

Novotech increasingly leverages advanced technologies to enhance its clinical research capabilities, including ongoing investments in:

- **Artificial Intelligence (AI):** Through its extended partnership with Medidata, a wholly owned subsidiary of Dassault, Novotech is an early adopter of the Medidata AI Intelligent Trials solution that provides insights into high-enrolling sites and future study enrollment potential. Additionally, the company has established an AI framework, including standard operating procedures and a working group, setting standards that direct its use of AI to improve tasks such as document creation. Novotech is further exploring AI applications in regulatory compliance, including utilizing chatbots for efficient database searches and AI-driven analysis of regulatory guidelines.
- **Big Data and Advanced Analytics:** Novotech leverages big data and advanced analytics to enhance its clinical trial operations by acquiring deeper insights, identifying emerging trends, and optimizing trial design and execution to drive informed decision-making. The company consistently utilizes Real-

⁶ Frost Radar™: Asia-Pacific Contract Research Organizations, 2023 (Frost & Sullivan, December 2023).

World Data (RWD) and Real-World Evidence (RWE) to design and implement Diversity Action Plans meticulously developed to ensure representative enrollment and alignment with the latest FDA guidelines (June 2024). Novotech further employs RWE to examine the historical differences in safety and efficacy across various ethnic groups, guiding the strategic selection of geographies, countries, and sites for clinical studies. This data-driven approach ensures the company's Diversity Action Plans are both informed and achievable, providing sponsors with realistic and actionable strategies. Novotech deeply values the comprehensive perspective that RWD and RWE offer on patients, populations, and disease states, thereby utilizing these data sources to shape its clinical development strategy and trial design. By harnessing these insights, the company ensures the execution of patient-centric and inclusive clinical trials, reaching a diverse and representative patient population.

- **Digital Clinical Trials:** Novotech further expanded its virtual clinical trial capabilities through its 2021 investment in ObvioHealth, a global digital clinical trials company. This partnership designates ObvioHealth as Novotech's preferred provider for virtual clinical trials, enabling it to leverage the partner's innovative platform to drive greater efficiency, flexibility, and patient-centricity in clinical trial operations. In return, Novotech positions itself as ObvioHealth's preferred CRO for hybrid and virtual trials.⁷
- **Cloud-based Software Platforms:**
 - Veeva: Novotech leverages its long-standing partnership with Veeva, a cloud-based software provider for the life sciences industry, to enhance its biotech clients' drug development programs. To this end, the company utilizes the customized Novotech Veeva Suite Ecosystem to empower its clients with streamlined procedures, improved data visibility, advanced trial planning, and predictive capabilities.⁸ Similarly, Novotech leverages the partner's Vault Study Training solution to eliminate its system silos by enabling the direct uptake of clinical operations data and documents in study training tasks. All in all, Veeva helps Novotech create a unified, dynamic, and automated platform to drive seamless, efficient, and easily accessible study training capabilities.⁹
 - Medidata: Novotech utilizes Medidata Clinical Cloud's end-to-end solutions, the industry's only unified platform dedicated to clinical research, to continue scaling clinical studies in various therapeutic areas.¹⁰

Collectively, these technological advancements are transforming the clinical research landscape, making Novotech trials more efficient and effective.

In addition to this technology focus, Novotech offers a robust bioanalytical services portfolio as a part of its central laboratory services, with four facilities across China and South Korea. Among the earliest APAC-based bioanalytical labs to use liquid chromatography-mass spectrometry (LC-MS) assays, the company employs 34 LC-MS machines and 100 personnel to process around 34,000 samples monthly. These capabilities ensure Novotech is well-equipped to support bioavailability/bioequivalence and

⁷ <https://novotech-cro.com/news/novotech-expands-virtual-clinical-trials-capabilities>, accessed July 2024.

⁸ <https://novotech-cro.com/news/dr-yooni-kim-vice-president-clinical-services-novotech-delivers-keynote-address-veeva-korea>, accessed July 2024.

⁹ <https://www.veeva.com/Client-stories/novotech-vault-study-training-eliminates-silos-drives-efficiencies/>, accessed July 2024.

¹⁰ <https://novotech-cro.com/news/novotech-and-medidata-expand-partnership-continue-advancements-clinical-research>, accessed July 2024.

pharmacokinetic/pharmacodynamic assessments, among other areas, ultimately strengthening its regional leadership.

Novotech supports biotech clients across diverse therapeutic areas, including cell and gene therapies, precision medicine, RNA-based vaccines and therapeutics, antibody-drug conjugates, microbiomes, radiopharmaceuticals, and more. Specifically, the company offers expertise in oncology CRO services, pharmacometrics services, drug development consulting, GMO Solutions, liver disease CRO services, infectious diseases and vaccines CRO services, orphan and rare disease CRO services, and clinical and regulatory strategy.

Most importantly, as part of its exclusive focus on the biotech sector, Novotech intimately understands the differences between serving larger pharmaceutical players and agile biotech companies. As a result, the company tailors its offerings across its people and systems to address its target client base's specific requirements, helping expedite research pipelines — a factor crucial to biotech companies with limited revenues and assets.

- **People:** Novotech adopts a project manager-centric approach, carefully selecting motivated, skilled, and adaptable professionals to lead projects. These project managers take full ownership, proactively advancing client initiatives to ensure superior Client experiences.
- **Systems:** The company customizes systems around the biotech sector's needs, focusing on delivering high-quality data without the complexity of conventional approaches.

Novotech further strengthens its biotech value proposition with an unwavering commitment to its clients, particularly during challenging market conditions. For instance, during the recent funding slowdown, the company offered equity investments to deserving client projects, fostering third-party funding and bolstering client value. Similarly, Novotech embraced at-risk models, shouldering certain downsides for underperformance on clients' key objectives. This proactive approach not only enhances client trust but also fuels Novotech's continued growth amidst an adverse market climate.

Empowered with this unique perspective, cutting-edge technological capabilities, and sophisticated operational infrastructure, Novotech has successfully established itself as biotech's partner at every phase.

Transition from APAC CRO to Global Biotech Partner

Having mastered the APAC CRO market, the most complex clinical trial region globally, Novotech recently shifted its focus to geographic footprint expansion. The company implemented this strategic move in response to its existing clients' increasing demand for the company to directly manage their latter-stage projects at a global scale. To address this client, need, the company extended its presence in the US and Europe by acquiring its close alliance partners NCGS¹¹ (May 2022) and Easthorn¹² (January 2023). Similarly, Novotech acquired CBR International¹³ (January 2023), a US-based pharmaceutical consulting firm, to strengthen its regulatory services, documentation, and strategic planning capabilities. Today, the

¹¹ <https://novotech-cro.com/news/novotech-acquires-us-cro-expands-global-expertise>, accessed April 2024.

¹² <https://novotech-cro.com/news/novotech-acquires-european-cro-strengthens-global-operations>, accessed April 2024.

¹³ <https://novotech-cro.com/news/novotech-acquires-us-based-drug-development-consulting-firm-cbr-international-expands-drug>, accessed April 2024.

company maintains a robust and carefully curated on-the-ground presence in all major biotech centers worldwide.

Furthermore, Novotech significantly strengthened its senior leadership team to lead this global transition by appointing high-caliber medical executives in key roles. For instance, the company appointed Dr. Judith Ng-Cashin, an industry veteran with over 20 years of international pharmaceutical, biotech, and CRO experience, as Chief Medical Officer. Dr. Ng-Cashin will support Novotech's established global operations by directing its multi-regional later-phase strategy and ensuring the high-quality delivery of medical services.¹⁴ Similarly, the company hired Rick Farris, a seasoned clinical research and life sciences industry professional, and Dr. David Ng, an experienced biostatistics and biometrics specialist, as its North American Managing Director and Global Vice President (VP) of Biometrics and Data, respectively. Novotech intends to leverage their expansive industry experience, proven expertise, and exceptional leadership to propel its continued growth and success.¹⁵ The company's other key appointments include Dr. Ian Braithwaite as VP of Global Project Management¹⁶ and Scott Schliebner as VP and the Global Head of Drug Development Consulting (DDC) team.¹⁷

In alignment with its global expansion goals, Novotech is also reinforcing its value propositions in its core APAC markets. For example, in June 2024, the company announced the launch of a dedicated Early Phase Strategic Delivery Unit (EP SDU) with a focus on leveraging Australia and New Zealand's unique advantages for early-phase clinical development. This new unit, the first in Novotech's upcoming series of Strategic Delivery Units, provides specialized multidisciplinary expert teams and tailored processes for different types of complex clinical trials.¹⁸ Besides ensuring high-quality operational delivery in early-phase projects, the EP SDU will facilitate its biotech clients' seamless transition from early-phase work to later-phase global development. This integrated approach, which includes engagement with Novotech's world-class DDC team for comprehensive program development services, further underscores the company's dedication to providing support at every phase of clinical development, from preclinical stages to post-marketing efforts.¹⁹

Overall, Novotech distinguishes itself in the ever-expanding CRO market by successfully addressing the complex regulatory landscape with a deep understanding of local regulations and overcoming cultural barriers to establish itself as a truly global CRO. As a result, the company progresses closer to becoming a preferred global partner with regional leadership and localized expertise.

Frost & Sullivan believes Novotech is well-positioned to capitalize on new growth opportunities, cementing its position in the global CRO space.

¹⁴ <https://novotech-cro.com/news/novotech-appoints-dr-judith-ng-cashin-chief-medical-officer-drive-global-medical-services>, accessed July 2024.

¹⁵ <https://novotech-cro.com/news/novotech-announces-key-leadership-appointments-rick-farris-and-david-ng>, accessed July 2024.

¹⁶ <https://novotech-cro.com/news/novotech-appoints-dr-ian-braithwaite-vice-president-global-project-management-lead-world-class>, accessed July 2024.

¹⁷ <https://novotech-cro.com/news/novotech-appoints-commercial-and-clinical-life-sciences-specialist-head-global-drug>, accessed July 2024.

¹⁸ <https://novotech-cro.com/news/novotech-launches-dedicated-early-phase-unit-biotechs-leveraging-australian-and-new-zealand>, accessed July 2024.

¹⁹ Ibid.

Roadmap to Success: Client-centric, Continuous, Proactive

With its client-centric corporate philosophy, Novotech operates on the central tenet that its success depends on client satisfaction. This philosophy permeates the company's daily practices. To this end, the company stands out against its contemporaries in the global CRO space, consistently focusing on factors critical to biotech clients, including speed, quality, and flexibility.

- **Speed:** Novotech continually invests in cutting-edge technology, including piloting a range of artificial intelligence-enabled approaches, significantly expediting study timelines. In macro terms, Novotech increased the efficiency of some of its processes by a remarkable 10% to 20% in 2023, which in turn translates to increased speed for its biotech clients.²⁰
- **Quality:** Besides streamlining standard operating procedures, Novotech extensively utilizes Medidata²¹, the market's only unified platform dedicated to clinical research, to generate high-quality, reliable, and statistically sound data. Moreover, the company invests in various tools to enable its clients to directly visualize their data, which is a highly valued asset.
- **Flexibility:** The company balances speed with flexibility to accommodate biotech companies' propensity to change plans/trial designs.

Novotech enhances client value by fostering close collaboration with clients and consistently provides expert support and guidance. As part of its strategic approach, the company engages senior clinical staff,

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- Sama Suwal
Best Practices Research Analyst

country managers, and potential investigators in discussions with clients as early as possible. This proactive approach reassures sponsors that their projects will receive the dedicated attention they deserve, distinguishing Novotech from other global CROs. Additionally, Novotech secures new clients by employing an analytics-driven approach that tracks client opportunities. The company leverages a commercial analytics team to evaluate newly established biotech firms, assessing their likelihood of engaging Novotech's services based on their therapeutic focus and their existing relationships with the company. Moreover, the company employs targeted marketing initiatives, including participation in global events like BIO Europe, JPM, oncology summits, and others, to build substantial

recall value among potential clients. Recently realigning its focus to acquiring high-value clients (i.e., later phase global projects), Novotech has enjoyed considerable popularity among its US and European client base.

Case Study: Multi-National and Multi-Site Trials Case Study | Muscular Dystrophy²²

ReveraGen BioPharma Inc. (ReveraGen), a US-based clinical-stage company dedicated to tackling rare diseases such as Duchenne Muscular Dystrophy (DMD) and Becker Muscular Dystrophy, partnered with

²⁰ Frost & Sullivan interview with Novotech (April 2024)

²¹ <https://novotech-cro.com/news/novotech-partners-medidata-accelerate-clinical-research-discoveries-asia-pacific>, accessed June 2024.

²² <https://novotech-cro.com/case-studies/muscular-dystrophy-multi-national-and-multi-site-trials-case-study>, accessed June 2024.

Novotech to conduct a pivotal Phase 2b study of vamorolone, a promising DMD treatment. Despite facing pandemic-related obstacles, the partners completed the clinical trials in August 2021. The collaboration achieved significant milestones, enrolling 121 patients across 11 countries and 32 sites. Considering its seven-year partnership with Novotech as instrumental in navigating the complex drug development landscape, ReveraGen intends to further collaborate with the company to advance clinical research for new therapies for rare diseases.

“We began working with Novotech in 2017 as we needed support for the two Australian sites taking part in the phase IIa studies in DMD. Based on our very positive experience with Novotech on these two studies, we decided to contract with them for our pivotal Phase 2b study as we required continued support for the Australian sites enrolling into this study. We were extremely comfortable with this decision as Novotech had always delivered in every aspect of their contracted responsibilities. Their contribution was vital for the success of the vamorolone clinical program”.

- **Jesse Damsker, PhD Chief Operating Officer, ReveraGen²³**

Interestingly, several regional clients are replacing their existing CROs for ongoing studies with Novotech, validating the company’s superior capabilities. For instance, in 2023, Novotech significantly turned around a struggling oncology program for a biotech sponsor in China suffering setbacks in their US Phase I study by leveraging its diverse capabilities and global strategic approach. The company successfully provided crucial support to the client, implementing a Multi-Regional Clinical Trial strategy across the APAC region to gather essential data for Phase II planning. Novotech’s interventions streamlined timelines (resulting in 40-day savings for the sponsor), ensured successful recruitment in key regions, and uncovered crucial insights for securing local regulatory approval, leading to substantial milestones. This successful partnership demonstrates Novotech’s ability to empower biotech clients to overcome clinical trial challenges by uniquely delivering strategic collaborations and global perspectives.²⁴

Novotech’s differentiated operating model, Client-first approach, and close relationships position it as a partner of choice in the global CRO market.

Elevating Client Satisfaction Drives Growth

Novotech incorporates client feedback into its strategic decisions and implementation plans to maximize short-term growth opportunities while providing a path to future revenues. The company gathers this feedback from multiple channels. Firstly, Novotech conducts regular electronic surveys at various critical points of the client journey, requesting feedback on the different functions across the organization. Similarly, senior executives meet with clients regularly (e.g., at conferences) to gather client feedback. Finally, Novotech implements suitable oversight mechanisms to track and ensure client satisfaction on a day-to-day basis.

²³ Ibid.

²⁴ <https://novotech-cro.com/case-studies/expert-consulting-and-multi-regional-clinical-trial-mrct-strategy-rescues-oncology>, accessed June 2024.

These initiatives support Novotech's efforts to consistently deliver exceptional client satisfaction at every project phase to ensure clients continue their relationship throughout their clinical development journeys. As a result, the company reports an impressive Net Promoter Score of 4.2/5.²⁵

Novotech's exclusive focus on small- to mid-segment biotech companies, continual integration of cutting-edge technology, and client-first approach continue to drive strong financial performance. In 2023, the company generated over \$300 million in annual revenue, a 25% increase from 2022. Similarly, Novotech's backlog grew at around 25%, with an expected net new business growth at 30%+.²⁶

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

Conclusion

As a leading full-service contract research organization (CRO), Novotech capitalizes on the biotechnology (biotech) sector's growing shift towards one-stop-shop service providers, partnering with biotech companies to accelerate the development of advanced and novel therapeutics. To this end, the company leverages its comprehensive suite of early- to late-phase CRO services, expansive global footprint, strong industry relationships, and robust operational infrastructure to expedite and diversify clinical development. Moreover, Novotech distinguishes itself by successfully addressing the CRO space's complex regulatory landscape to establish itself as a truly global CRO, marking its transition from an Asia-Pacific leader to the preferred international partner.

Furthermore, Novotech stands out in the global CRO market by consistently prioritizing and delivering on factors critical to biotech clients, such as speed, quality, and flexibility. This client-first approach not only ensures exceptional client experiences but reinforces Novotech's reputation in the market, offering substantial value to existing and new clients. As a result, the company remains a trusted partner, earning a reputation for offering the overall best in the biotech CRO market.

With its strong overall performance, Novotech earns Frost & Sullivan's 2024 Global Company of the Year Award in the biotech contract research organization industry.

To learn more about the organization please connect here – www.novotech-cro.com

²⁵ Frost & Sullivan interview with Novotech (April 2024)

²⁶ Ibid.

What You Need to Know about the Company of the Year Recognition

Frost & Sullivan's Company of the Year Award is its top honor and recognizes the market participant that exemplifies visionary innovation, market-leading performance, and unmatched customer care.

Best Practices Award Analysis

For the Company of the Year Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Visionary Innovation & Performance

Addressing Unmet Needs: Customers' unmet or under-served needs are unearthed and addressed by a robust solution development process

Visionary Scenarios Through Mega Trends:

Long-range, macro-level scenarios are incorporated into the innovation strategy through the use of Mega Trends, thereby enabling first-to-market solutions and new growth opportunities

Leadership Focus: Company focuses on building a leadership position in core markets and on creating stiff barriers to entry for new competitors

Best Practices Implementation: Best-in-class implementation is characterized by processes, tools, or activities that generate a consistent and repeatable level of success

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

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 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)**

