



Parexel Recognized for

2021

Enabling Technology Leadership

Global Clinical Research

Organization Industry

Excellence in Best Practices

Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan’s recognition of Parexel is a reflection of how well it is performing against the backdrop of these imperatives.

SIB	GEOPOLITICAL CHAOS	DISRUPTIVE TECHNOLOGIES	INTERNAL CHALLENGES
Why	<ul style="list-style-type: none"> Supply chain stability, manufacturing capabilities, and residual healthcare budgets will dictate the industry’s growth trajectory despite the nondiscretionary nature of pharma products in the COVID-19 scenario. Supply chain resilience will continue to be tested as companies scramble to reallocate and ramp up manufacturing to address supply shortages and tackle government protectionism measures. COVID-19 is likely to result in a higher demand for access to remote treatment solutions and methods. 	<ul style="list-style-type: none"> The global life sciences industry has benefited from a combination of novel technologies, including artificial intelligence (AI) platforms, the Internet of medical things, and blockchain. Adoption of advanced analytics, automation, and cloud solutions results in increased productivity and better decision-making. Life sciences firms are digitizing operations to address inefficiencies and create patient-centricity and personalized value-based healthcare solutions. 	<ul style="list-style-type: none"> Fragmented channels in customer communication, lower margins, and intensifying competition challenge the life sciences industry. Companies are seeking to shift focus from existing therapeutic portfolios to COVID-19- related developments and treatments. Mergers and acquisitions are directly impacting central pharma and instrument developers by exerting cost pressures and mandating consolidation to achieve economies of scale and operational synergies.
When	<ul style="list-style-type: none"> Healthcare organizations will accelerate innovation to respond to the COVID-19 crisis while rethinking post-pandemic care delivery and financing. Government-funded COVID-19 testing initiatives will boost revenues in the next 1 to 3 years. Pharma companies will experiment with new point-of-care (POC) testing, digital supply chain tools, and patient-doctor connectivity programs based on digital platforms. The pandemic will drive new digital-tech adoption in drug discovery and testing services, and federal funding will encourage deeper product pipelines and inventory. 	<ul style="list-style-type: none"> The revenue from AI solutions used in drug discovery is expected to grow 26.3% and reach \$455 million by 2020. New technologies such as augmented reality will be incorporated into labs, processing lines, and drug manufacturing sites to increase safety, reliability, and efficiency. In addition to reinventing R&D through technology-enabled drug discovery and clinical trials, digital transformation will improve commercial and supply chain processes during the next 5 years. Significant growth opportunities await in sensor development for medical instruments and equipment management for connected labs, which will enable remote monitoring and controlling. 	<ul style="list-style-type: none"> The challenge of economically scaling-up manufacturing will remain a major impediment to advancing therapies from the lab to clinics in the short term. Big Pharma companies will decentralize and outsource the manufacturing of novel cell and gene therapies to contract development and manufacturing organizations. Companies must pursue acquisitions of digital solution targets to leverage data monetization opportunities and drive growth in precision medicine. Pharma companies must aggressively invest in improving last-mile connectivity with patients and focus on improving overall health outcomes.

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. Parexel excels in many of the criteria in the CRO space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Customer Impact</i>
Commitment to Innovation	Price/Performance Value
Commitment to Creativity	Customer Purchase Experience
Stage Gate Efficiency	Customer Ownership Experience
Commercialization Success	Customer Service Experience
Application Diversity	Brand Equity

Founded in 1982 with dual headquarters in Massachusetts and North Carolina, the United States (US), Parexel is a clinical research organization (CRO) supporting the development of innovative medicines to improve the health of patients. From clinical trials to regulatory and consulting services to commercial and market access, the company's therapeutic, technical and functional ability is underpinned by a deep conviction in the services it provides. Parexel works in a variety of business models to meet customer needs; these range from large hybrid approaches combining functional services and full-service offerings for large pharma customers to end-to-end full-spectrum support for virtual biotech customers that have no in-house capabilities in clinical development.

Leveraging a robust suite of end-to-end biopharmaceutical development services, from clinical trial designing and execution to regulatory and consulting to commercial and market access, Parexel has successfully delivered development programs in more than 100 countries. Parexel has a global employee base of approximately 18,000, and the company is the second largest CRO in the Asia/Pacific region, with a significant presence in China, Japan and India). To date, the company's market-leading capabilities enabled it to assist in developing 99% of the 200 top-selling biopharmaceuticals. Parexel was named "Best Contract Research Organization" in December 2020 by an independent panel for Informa Pharma Intelligence.

Innovation-driven CRO with a Patient First Culture

Parexel has grown its expertise to meet customers' varying drug development needs across various therapeutic areas. The company partners with its customers to support a spectrum of program development and execution across all phases of clinical trial, external control arms (synthetic control arms), low-intervention trials, electronic clinical outcome assessments (eCOA) and retrospective chart reviews. Parexel bolsters secondary-database analyses, pharmacovigilance programs, including risk evaluation and mitigation strategies, managed access programs, and quality-of-life research. The company conducts observational (OR)/non-interventional (NI) studies observing consistency with industry, -scientific, and operational guidelines pertaining to good pharmacoepidemiology practices, the International Society for Pharmaceutical Engineering, and the International Society for Pharmacoeconomics and Outcomes Research. Its pharmacoepidemiology and NI studies are conducted by the Parexel® Regulatory and Access team.

"Parexel designs a flexible and agile delivery model to effectively address the needs of biotech clients. A strategically focused, dedicated project team incorporates patient insights into trial planning, design, and execution."

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

Biotech Focus

Parexel designs a flexible and agile delivery model to effectively address the needs of biotech clients. A strategically focused, dedicated project team incorporates patient insights into trial planning, design, and execution. It improves trial participation rates and patient engagements, increasing patient recruitment and retention, thus driving better outcomes and trial success rates. To meet all

stakeholders' needs (regulatory, clinical, and commercial) Parexel designs real-world evidence (RWE)-focused projects to determine the best research methodology and define the most useful endpoints. The company's several expert teams are committed to various impactful medical specialties (e.g., oncology and infectious diseases) and innovative research fields (e.g., rare diseases, gene therapy, and COVID-19)

Late-phase Research Focus

Parexel has been developing and implementing novel and successful late-phase research models for 19 years. The company has unparalleled experience in building tailored partnership engagements via its Partnership Center of Excellence. With an unprecedented understanding of both late-phase research approaches and regulatory and market-access decision-making, the team's experts design and efficiently conduct several therapy programs in the advanced stages of clinical development and the post-approval setting.

Consulting services

Parexel's Regulatory & Access business is one of industries largest consulting groups with 1000 plus consultants covering 110 countries. The group includes nearly 100 former regulators and HTA assessors alongside industry luminaries providing strategies to overcome regulatory and market access hurdles. Parexel's consultants help customer understand how regulators and payers will view innovative approaches where the guidelines are still emerging including examples such as using real-world data/evidence for registration, decentralized clinical trial (DCT) data, risk based quality monitoring

approaches and for fast evolving therapy areas such as cell and gene therapies (CAGTs).

Deep Commitment to Patient-centricity

Focused on exceptional delivery and demonstrating its deep commitment to patients, Parexel continually strives to re-engineer its internal capabilities, programs, and technologies to transform scientific discoveries into innovative therapies. With a heightened focus on patient-centricity, real-world data (RWD), RWE, precision medicine, and adaptive and flexible trial design, it designed a Patient Innovation Center (PIC) and built strategic ties with technology and specialist vendors. This approach allows Parexel to adapt promptly, offering customers the best solution in a dynamic global development environment. The PIC team also explores and implements strategies to empower the patients as experts and actively involves them in the drug development process. PIC collaborates and holds discussions with global patient advisory groups, acquainting them about bottlenecks and priorities and seeking patient (and caregiver) insights to impact clinical development guidelines positively.

Parexel simplifies the patient journey to enhance patient satisfaction and compliance with study requirements. Notably relevant to DCTs, Parexel reduces unnecessary patient burden while maintaining strict patient safety oversight. For instance, its patient app provides reminders and educational material (including consent video) and ad-hoc or on-demand telemedicine, and alerts sent to sites upon patient responses within the app.

Equipped to provide home nursing facilities, Parexel assists in conducting patient assessments or procedures at the patient's home. Examples include:

- Medicinal investigation product (IMP) receipt
- Administration and reconciliation
- Urinalysis
- Symptom-led physical assessments

Recently, Parexel collaborated with Synexa Life Sciences, a biomarker and bioanalytical science expert, and Drawbridge Health, a healthcare technology company to provide a streamlined solution for remote blood sample collection and serology testing. The solution eliminates the challenges of in-person blood collection, improves accessibility for patients, and enhances the clinical trial experience for patients participating in the COVID-19 clinical trials.

Similarly, to bolster its patient-first focus, the company manages its direct-to-patient (DTP) drug shipments through the Clinical Trial Supplies & Logistics team, collaborating with local regulatory agencies to facilitate shipments per local guidelines. As the only CRO with a global capability, Parexel ensures that patients' home nurses receive IMP and clinical supplies timely and with the utmost agility and flexibility.

Developing Real-World Data Expertise to Accelerate Research Timelines

The pandemic restricted randomized clinical trials, preventing sponsors from meeting urgent patient needs. As a result, many companies adopted an RWD-driven approach to propel research seamlessly. Parexel Regulatory and Access and RWE research services support generating evidence-based insights to improve late-phase real-world studies' designs and value. The regulatory authorities are making efforts

to facilitate the clinical development and expedite review and approval process based on RWD and RWE.

Additionally, the company hosts advisory boards with clinical key opinion leaders to receive clinical guidance for database selection activities. As the ability to access and leverage real-world data is core to Parexel's business strategy, it has an extensive global database research experience spanning more than a century. An expert team comprises the company's Scientific Data Organization and is responsible for aggregating the data into the database. Accessing data and applying it to business processes, Big Data technology capabilities, and RWD investigation analytics allow Parexel to generate valuable insights to resolve queries related to care access, practice patterns, pricing, and reimbursement. Its four-pronged RWD strategy encompasses employing business processes, services, technologies, and resources for secondary data exploration techniques to enhance late phase study delivery within the RWE generation context.

In 2020, the company executed a study to ascertain the operational flexibility to incorporate RWD in a clinical trial to accelerate and enhance research. The study establishes the ease of using disparate data types and the feasibility of protecting patient privacy when connecting record-level data from multiple systems, supporting scientific inference through proper data collection.

Parexel published a model describing an applicable RWD framework for sponsors to map, gather, consolidate, and analyze while ascertaining complete patient privacy. In another initiative, it innovated by developing Synthetic Control Arm studies leveraging RWD (instead of the conventional control), especially significant for rare disease trials and pandemics restricting data collection from typical controls. The comparator-cohort study design establishes RWD's role in quickening trials, completed nine months earlier than the traditional Phase II trial design.

Coronavirus Response Strategy

Proactively responding to the coronavirus (COVID-19) pandemic, Parexel activated its business continuity plans, setting up a committee with cross-functional leaders focused on project continuity, training needs, and risk mitigations. The committee rapidly implemented a knowledge management framework, implementing a central site and communication framework to collate, validate, communicate, train, and advice on regulations and guidance related to COVID-19. The company also pivoted remote-based monitoring strategies through the pandemic to support project continuity. Parexel's "Jump Start" initiative provided a structured, risk-based, data-driven approach to enable teams to re-start clinical trials disrupted by COVID-19 while ensuring safety for patients, site personnel, and employees. To allow clients to provide insights into the pandemic's impact on clinical trials to regulatory authorities, the company deployed a COVID-19 database to track study-related insights and reporting on multi-center, multi-country COVID-19 implications on projects.

Moreover, Parexel developed an integrated, RWE research platform powered by Microsoft cloud technology to collect and analyze data retrieved from patients and providers. The platform provides patients and physicians a single source to rapidly access pooled, real-time data and analyses on the COVID-19 illness and insights on COVID-19 therapies, either under development or in use. The platform then enables physicians to make optimal individualized treatment decisions and identify promising treatments quickly.

In addition to launching its first innovative integrated research platform that included remote monitoring visits and DCTs, the company commenced a significant and increasing number of COVID-19 projects, including COVID-related therapies and treatments. Frost & Sullivan appreciates Parexel leveraging its experience from assisting in several COVID-19 projects to reapply the learning to subsequent studies and accelerate research start-up timelines, significantly shortening them from months to days, thereby benefitting patients, customers and employees.

Data-driven Risk-based Monitoring, Machine Learning, Decentralized Clinical Trials, and Secured Data Sharing

Parexel's Quality by Design principles deliver a fit-for-purpose risk-based monitoring strategy based on commercial, regulatory, medical and scientific, and operational considerations. The company applies its risk assessment capabilities, data surveillance and operational support, and integrated systems to identify and quantify risk early, taking proactive actions throughout a trial's lifecycle. Hence, Parexel limits site burden by enabling early mitigation actions and remediation support before issues escalate into rescue mode.

The company's data-driven risk-based monitoring technique combines adaptive site management methods such as Source Data Review and reduced Source Data Verification, defining risk indicators, and interventional triggers with the centralized review of data surveillance. Further, the innovative built-in data-driven monitoring and data surveillance dashboard allows a holistic and targeted assessment. Frost & Sullivan concurs that Parexel's monitoring techniques help sponsors make data-driven decisions across the project lifecycle. Also, it leads to resource optimization, improving research data integrity and credibility, predicting the outcome, providing intuitive insights into site performance, and calculating and measuring risks.

Other technology initiatives include the company's precision medicine team acquiring pharmacology modeling and analytics firm Model Answers to lower risk and produce better-informed trial designs.

“Leading in the CRO market in its continued focus to use RWD and RWE, the company accelerates research through targeted site and patient recruitment strategies, ensuring patient access to studies.”

- Supriya Lala, Best Practices Research Analyst

Similarly, Parexel's purchase of the Natural Language Processing (NLP) technology assets of Roam Analytics, Inc., a healthcare software company aims to bolster Parexel's commitment to leveraging Artificial Intelligence (AI) and Machine Learning (ML) to propel new innovations across drug development and life sciences and improve Parexel's Pharmacovigilance and RWD capabilities through NLP technology application. The company applies ML in safety surveillance, leveraging NLP to accelerate data review and identify potential safety events for

remediation. This approach led to a significant reduction in processing time with zero errors in the most recent six-month period.

Parexel's third primary focus includes DCT services that offers sites with greater study opportunities, wider access to diverse patient populations in their region, and lowered dropout rates due to remote patient engagement options. The company is advancing 130+ DCTs along with 200+ remote patient engagement strategies incorporated into trials (e.g., patient recruitment and retention platforms, e-

visits/video dosing regimens, and patient insight projects). Parexel leverages its in-house expertise, best-in-breed technologies, and patient and caregiver insights to design bespoke strategies for both fully virtual and hybrid approaches to DCT.

Finally, to enable a holistic, longitudinal view of disease progression, Parexel recently collaborated with Datavant to leverage unique Patient Keys. These encrypted identifiers securely de-identified and linked healthcare datasets at the patient level, replacing private patient information with an encrypted, irreversible “token.” The technology connects electronic medical records claims and diagnostics data with next-generation sources such as genomics, socioeconomic factors, and wearable device and behavioral data to limit secured data sharing challenges — vital for progressing clinical development.

Industry-leading Capabilities to Position as a Partner-of-choice CRO

Parexel’s competencies and capabilities align to achieve better outcomes for sponsors and patients, thus granting differentiated quality, attention, and service levels in the CRO market. The company is expanding its strategic partnerships to leverage expertise for COVID-19, accelerate patient recruitment, and grow site partnerships focusing on the Asia-Pacific region

Parexel’s Biotech division supports emerging companies with dedicated resources and curated services, creating a significant service demand increasing annually. With a cross-functional team focused on CAGTs, Parexel supported 200+ CAGT projects over the past five years. Leading in the CRO market in its continued focus to use RWD and RWE, the company accelerates research through targeted site and patient recruitment strategies, ensuring patient access to studies.

Moreover, Parexel’s functional service provider service (FSP) helps sponsors manage workforce needs across their clinical portfolios cost-effectively. Parexel FSP focuses on high performance through a focus on global reach, scale and expertise across seven service verticals, including clinical operations, data management and programming, among other specialty functional areas .High retention rates (88%) and customer satisfaction (4.75/5) support a track record of performance.

The innovation-centric company continues to focus on organic and inorganic growth by developing internal capabilities and identifying potential strategic collaborations and acquisition opportunities. These unique capabilities have earned Parexel several industry recognitions, demonstrating its superior industry position and emerge as a partner-of-choice in the CRO market.

Conclusion

Among the industry-leading clinical research organizations (CROs), Parexel streamlines clients' clinical development programs, enabling them to navigate complex, competitive, regulatory, and reimbursement-related challenges seamlessly. The company provides extensive capabilities with a breadth of coverage, including resourcing approaches under its functional service provider offering, first-in-human studies via its early phase clinical units, and through pivotal studies to real-world data (RWD), commercialization support, expert consultancy for mergers and acquisition, and regulatory and market access strategy leadership via Parexel Regulatory and Access, instrumental in meeting its customers' advanced and dynamic needs.

Parexel operates innovation centers in many areas, most notably its Patient Innovation Center. The company makes trials highly accessible to patients, improving investigators' subject inclusion and diversity, participation rates, and patient recruitment and retention, leading to high success rates with a market-differentiating patient focus in addition to implementing decentralized trials for customers. Parexel leverages its continually evolving capabilities dedicated to RWD and real-world evidence-based solutions for expediting clinical trials, positioning it as one of the most experienced CROs in the industry for synthetic cohort designs and RWD-based solutions to improve customer outcomes. Additionally, by applying data-driven risk-based monitoring approaches, the company identifies and quantifies risks early to take proactive actions throughout a trial's lifecycle.

For its strong overall performance and a heightened focus on technology, innovation, and patient-centricity, Parexel earns Frost & Sullivan's Global 2021 Enabling Technology Leadership Award in the clinical research organization industry.

What You Need to Know about the Enabling Technology Leadership Recognition

Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

Technology Leverage

Commitment to Innovation: Continuous emerging technology adoption and creation enables new product development and enhances product performance

Commitment to Creativity: Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

Stage Gate Efficiency: Technology adoption enhances the stage gate process for launching new products and solutions

Commercialization Success: Company displays a proven track record of taking new technologies to market with a high success rate

Application Diversity: Company develops and/or integrates technology that serves multiple applications and multiple environments

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

