

FROST & SULLIVAN

INOTIV

2022
CUSTOMER
VALUE
LEADER

NORTH AMERICAN
BIO-ANALYTICAL TESTING SERVICES
INDUSTRY

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. Inotiv excels in many of the criteria in the bio-analytical testing services 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

Filling the Gap in the Drug Discovery Industry

Current complexities in drug development drive academic institutes and early discovery biotechnology (biotech) start-ups to partner with contract research organizations (CROs) to expedite the development of novel therapeutics. These CROs have valuable development and disease area expertise, configuring an excellent candidate to support the transition from bench to clinic. The increased need for novel operating business models for drug discovery paves the way for testing service providers with best-in-class Good Laboratory Practices (GLP) and exceptional track records.¹

While large pharma companies ramp up their research and development (R&D) spending, small emerging biopharma companies explore private financing and partnerships that limit the impact on their outsourcing budgets. Frost & Sullivan estimates outsourcing drug development activities to exceed 60% by 2026, with drug discovery and pre-clinical development accounting for over 20% of total R&D spending between 2020 and 2026.²

Bio-analytical testing is a crucial aspect of early-to-late-stage drug development. It includes in vitro and in vivo studies such as pharmacokinetics, pharmacodynamics, bioequivalence, bioavailability, toxicokinetic, and immunogenicity testing alongside other related assessments. These activities require specialized capabilities in advanced mass spectrometry and bioassays, driving high outsourcing demand.

¹ *Global Drug Discovery and Early Development Outsourcing Growth Opportunities* (Frost & Sullivan, August 2021)

² *Post-COVID-19 Trends Disrupt the Global Contract Research Organization (CRO) Market* (Frost & Sullivan, May 2021)

“CROs must offer fit-for-purpose drug testing approaches and Quality-by-Design methodologies to facilitate sample analysis accuracy, providing their clients with boosted success rates. Inotiv uniquely leverages its bio-analytical testing expertise to cement its position in the bio-analytical testing industry.”

-Aarti Chitale
Senior Industry Analyst, Healthcare

Therefore, CROs must offer fit-for-purpose drug testing approaches and Quality-by-Design methodologies to facilitate sample analysis accuracy, providing their clients with boosted success rates. Inotiv uniquely leverages its bio-analytical testing expertise to cement its position in the bio-analytical testing industry.³

Frost & Sullivan estimates the global CRO market (non-clinical and clinical) to reach \$83.34 billion in 2026, with a compound annual growth rate of about 9.4% from 2021 to 2026. The increased outsourcing of large molecules (owing to the growing biologics pipeline)

alongside technological advances provides an opportunity for niche CROs in bio-analytical testing services.⁴

An Example to Follow

Inotiv (formerly Bioanalytical Systems – BASi) was founded in 1974. The company addresses drug and device developers’ bio-analytical, non-clinical, and clinical research needs. It operates in two business segments: contract research services and research products.

Inotiv provides a highly competitive and comprehensive R&D offering by offering a range of facilities and experienced scientists. The company stands out for its top-notch bio-analytical capabilities and enterprising acquisitions. Overall, Inotiv strives to deliver outstanding client service with a consultative and scientifically driven method.

Creating Value for Clients by Addressing Market Needs

Inotiv’s drug discovery and development approach goes beyond its extensive laboratory expertise, with client value as a strategic imperative. The company has earned a sterling reputation for supporting small and mid-sized biotech firms through its unique early-stage fit-for-purpose and fully GLP-validated methods. Unlike competitors, Inotiv builds its services in close associations with different stakeholders to evolve alongside market trends and respond suitably to clients’ needs.

For instance, the company recently expanded its protein/peptide bio-analytical capabilities with the acquisition of Protypia. It added Protypia’s quantitative tissue-based large-molecule capabilities to its mass spectrometry-based bio-analytical offerings. Inotiv’s scientists can now understand the relationship between the molecule’s target, the therapeutic modality, and effect. The result is a service that matchlessly supports the development of new biologic therapies.

In addition, Inotiv is creating a “Center of Excellence” focused on biotherapeutics to further enhance its expertise in the segment. The laboratory will address innovations in biologics while supporting biomarkers tied to small molecules as well as biotherapeutics.

³ Global Contract Research Organization (CRO) Market, Forecast to 2024 (Frost & Sullivan, November 2019)

⁴ Post-COVID-19 Trends Disrupt the Global Contract Research Organization (CRO) Market (Frost & Sullivan, May 2021)

The company's offerings cover the entire drug discovery process, assisting with regulatory requirements. Its laboratory and analytical testing expertise span in vivo, toxicology, drug metabolism and pharmacokinetics, i.e., DMPK, bio-analytical, and histopathological evaluations. Inotiv also has robust, state-of-the-art imaging capabilities for surgical models and device testing modules.

Drug Discovery Services

Inotiv depicts a rich service portfolio for in vitro and in vivo drug metabolism (absorption, distribution, metabolism, and excretion, i.e., ADME), biomarker identification, quantification, and pharmacokinetic modeling. The company creates fit-for-purpose assays using in vitro molecular and cell-based tools, addressing the specific drug action mechanism.

Bio-analytical Testing Services

Inotiv shows expertise in non-regulated discovery and regulated pre-clinical/clinical bioanalysis. Its unique approach utilizes bio-analytical platforms to enable rapid drug discovery. Furthermore, its pre-clinical bio-analytical testing process is compliant with the Food and Drug Administration (FDA), the European Medicines Evaluation Agency (EMA), and the Organization for Economic Co-operation and Development (OECD). The company provides method development and validation, in vitro and in vivo sample analysis, method transfer, drug-drug interactions, and biomarker testing/validation, among other services, as part of its service portfolio.

A Scientifically Driven Client Experience

Inotiv ultimately directs all improvements to empower its clients with high-quality scientific guidance. For example, the "Center of Excellence" provides resources for better comprehending the biomarkers needed for each assessment. This wisdom is helpful to clients, especially in complex cell and gene therapy development. The facility simplifies the outsourcing of pre-clinical/clinical regulated biomarker services

and satisfies international regulatory authorities' scrutiny throughout the drug development process.

"Inotiv's essential value proposition relates to its absence of intermediaries: clients deal with resources directly assigned to their projects when they speak with study directors, program managers and analytical scientists. This distinctive and frictionless approach skips tedious steps, eases the information flow, and positions it as a partner of choice."

- Albornoz, Manuel
Best Practices Research Analyst

The company sustains and attracts its knowledgeable staff using effective retention policies. It rewards business accomplishments through discretionary incentive programs. People working at Inotiv also have individual pay-for-performance bonuses. Overall, the compensation is equitable between employees, and the company strongly focuses on career development. These decisions decrease employee turnover and explain the extraordinary growth Inotiv had in the last year, from approximately 550 to about 2,000 workers.⁵

⁵ "Inotiv Investor presentation" (Inotiv, September 2021) and "Inotiv Investor presentation" (Inotiv, February 2022).

The company also secures highly transparent communication workflows in its assessments. There is a substantial emphasis on employee training and quality standards. Moreover, end-to-end project involvement guarantees a complete understanding of the vital client engagement requirements.

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Client Service Versus Customized Service

Inotiv's combination of scientifically driven services with client-focused strategies enhances its market positioning. The company is a fitting candidate for small and mid-sized biotech firms needing drug discovery and development guidance. In addition, its unrivaled bio-analytical testing capabilities also captivate giant CROs looking for subcontracting specialized associates so that they can concentrate all efforts on clinical trial deployment.

Inotiv goes to great lengths to ensure seamless integration with its partners and standardizes this strategy as the "Proven Process," a 5-step adopted foundation to support clients until the project starts. Throughout the project, the company ensures translational validation to different regulatory authorities.

At the same time, Inotiv constantly incorporates client feedback into its strategic decisions and implementation plans. For example, it formed a department as an interface between clients, laboratory operations, and business development. The "Client Experience" department maximizes short-term growth opportunities while providing a path for future revenues. The company organized internal investments through this mechanism, implementing enhancements to client services and building program management functions to enhance communications and the overall client experience.

Achieving Financial Success

Inotiv's sterling reputation and client-centric framework have led to its coveted partner status. As of 2022, the company has sales to over 3,500 clients, from emerging biopharmaceutical firms to international pharmaceutical corporations. It demonstrates growth potential by providing industry-leading solutions in high-demand sectors.

Moreover, Inotiv is constantly involved in strategic acquisitions to boost its service line. The Protopia deal is just one of many investments targeting early drug development. In 2021, the company acquired Plato BioPharma for its drug discovery and in vivo pharmacology assets. The same year, it expanded its integrated laboratory support services and in vivo infrastructure by acquiring Gateway Pharmacology Laboratories. Before these deals, Inotiv incorporated the genetic toxicology segment of MilliporeSigma's BioReliance into its business.

Finally, the company co-located Synexa's new center at its Rockville facility, facilitating collaboration and seamless biomarker and bioanalysis workflows. It is well aligned to strengthen its biotherapeutics division by co-marketing with Synexa, with the bioanalysis/biomarker firm supporting the delivery of Inotiv's pre-clinical capabilities to its established client base.

The company's revenues increased from \$17.8 million in Q1 2021 to \$84.2 million in Q1 2022, a 370.8% growth. As opposed to 429 employees working in five locations as of Q1 2021, Inotiv expanded its workforce in leaps and bounds, employing over 2,000 people across 22 different sites by Q1 2022.⁶ Furthermore, the company plans to enhance its mass spectrometry services in the bio-analytical segment with several investments and collaborations with other CROs to outsource small molecule work.

Frost & Sullivan believes Inotiv will become a significant player in the CRO industry over the following years. Combining top-notch services, strategic growth, and a client-centric approach ensures that the company will drive the bio-analytical testing space into its next phase. Inotiv will distinguish itself for its quality service and scientific focus, capturing market share and sustaining its market position.

Conclusion

Client-centric strategies help companies safeguard leading positions, but only with an authentic approach and seamless performance. That is the case of Inotiv, which incorporates client-focused strategies and exemplifies best practice implementation.

The company builds a robust client base by evolving its services alongside market trends and providing a unique consultative drug discovery and development approach. In addition, it guarantees constant monitoring by training its staff across all functions and assuring end-to-end project involvement. Inotiv targets the early to late phase drug testing space with strategic acquisitions that increase its client value proposition and boost revenues. Furthermore, the company is entering a rapid growth phase driven by its top-notch services, intelligent strategies, and client-centric processes to enhance its market positioning. Ultimately, incorporating client feedback into its decisions and implementation plans will cement Inotiv's coveted preferred partner status.

An overall client-first approach offers immense value to existing and new clients. It solidifies the company's reputation as a key competitor in the bio-analytical testing services market and across the contract research organization industry. For its strong overall performance, Inotiv earns Frost & Sullivan's 2022 North America Customer Value Leadership Award in the bio-analytical testing services market.

⁶ Inotiv Investor presentation (Inotiv, February 2022)

What You Need to Know about the Customer Value Leadership Recognition

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

Best Practices Award Analysis

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

Business Impact

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

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

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

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

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

Customer Impact

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

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

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

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

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

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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)**

