FROST & SULLIVAN

BEST PRACTICES AWARDS

biorasi™

2020 NORTH AMERICAN CONTRACT RESEARCH ORGANIZATION ENTREPRENEURIAL COMPANY OF THE YEAR AWARD

Contents

Background and Company Performance

Industry Challenges

With a lengthy, expensive, and failure-prone drug discovery and development process, it takes nearly a decade for a drug's commercial launch at a cost estimate of $2.6 billion.[1] Pharmaceutical clinical trials, in particular, are slow and expensive, taking nearly six to seven years, and account for approximately 50% of research and development expenditures.[2] According to Frost & Sullivan's analysis, the complexity and cost of conducting clinical trials, increasing regulatory requirements, trial failures, poor patient recruitment and retention rates, and the growing number of multi-regional and international trials are some of the current challenges in the clinical trial industry.

The problem gets compounded when it comes to life-threatening, rare diseases because of the limited pool of eligible patients. Rare diseases affect approximately 350 to 400 million people worldwide.[3] Currently, only about 5% have treatment, presenting a substantial commercial opportunity for drug sponsors to target rare and difficult-to-diagnose diseases.[4] Other than disease areas, products' growing complexity also adds to the challenges, e.g., cell and gene therapies. Additionally, as precision medicine and technology-driven therapy integrate with every aspect of healthcare delivery today, clinical trials of digital therapeutics (DTx) represent unique concerns regarding regulatory compliance, data quality, protocol optimization, logistics, and challenging-to-target patient populations.

Among these issues, patient recruitment and trial monitoring activities are the most costly and time-consuming. Nearly 80% of pharmaceutical clinical trials do not meet enrollment deadlines. Accordingly, for a given drug candidate, there is an average loss of up to $1.3 million per day. About 37% of research sites fail to meet their enrollment targets, and 10% fail even to recruit a single patient for the research. Even though more than $2 billion in annual cost accounts for just recruitment efforts and delays, success rates are low—up to 45% of study delays by six months due to patient recruitment challenges, while only 30% of patients that sign up remain for the entire length of the study.[5]

Due to recruiting issues, nearly 100% of trials require timeline extensions. Another 35% of participants are non-adherent to study protocols, which costs about $1 million per trial in lost productivity alone due to wasted clinical resources, protocol deviations, and delays. Additionally, traditional on-site management is expensive—recruitment, retention, and monitoring comprise 30% of the overall Phase II and III trial costs. Hence, these challenges make patient-centric trial designs a strategic priority for pharma sponsors.[6]

---

[1] *Influence of Artificial Intelligence on Drug Discovery and Development* (Frost & Sullivan, July 2018)
[2] *Global Pharma Clinical Trial Patient Recruitment & Monitoring IT Solutions, Forecast to 2020* (Frost & Sullivan, May 2018)
[3] *Novel Therapies for Rare and Genetic Diseases (*Frost & Sullivan, June 2018)
[4] *Ibid*
[5] *Global Pharma Clinical Trial Patient Recruitment & Monitoring IT Solutions, Forecast to 2020* (Frost & Sullivan, May 2018)
[6] *Ibid*

Pharmaceutical and biotech participants increasingly rely on contract research organizations (CRO) for cost-effective and time-efficient drug development, highlighted by the global outsourcing penetration reaching 48% in 2019, up by 18% from 2015.[7]

The global CRO market is witnessing an increased adoption of digitization such as eClinical solutions, using technology and machine learning-based platforms, to alter the global clinical trial paradigm through adaptive, virtual, and remote clinical trials. However, the growing number of clinical trials globally is generating data capture and management gaps. This evolving landscape requires innovative CRO's to develop advanced management systems to support smooth clinical trial completion.

In this scenario, vendors designing patient-centric trials with an established global patient network will accelerate recruitment, improve trial adherence, enhance patient engagement, and prevent trial failures. Hence, CROs increasing sponsor's overall drug development profitability, i.e., speed, efficiency, and success, will emerge as market leaders.

Entrepreneurial Innovation and Customer Impact of Biorasi

Expertise in Difficult-to-recruit Studies with Focus on Partnership and Transparency

Founded in 2002 and headquartered in Miami, Florida, Biorasi is a full-service CRO with a comprehensive suite of services and enhanced focus and proficiency in hard-to-recruit studies across the Americas, Europe, and Asia-Pacific. The company works with pharmaceutical (pharma), biotech, and medical device firms on all the phases of drug trials, with expertise in neurology, oncology, nephrology, and complex dermatology.

Biorasi specializes in designing the right clinical strategies for a particular indication quickly and finding suitable sites and patients to participate in studies for those indications. With similar difficult-to-recruit patient dynamics, the company's enrollment expertise extends to orphan and rare diseases, and the emerging DTx domain, in which Biorasi is a leader. The company differentiates in the market through its specialized know-how in rescuing trials and solving recruitment problems.

When recruitment of study subjects is a challenge - and it most often is - Sponsors are in a precarious situation with most CROs in the industry whose billings depend primarily on time and effort. Unfortunately, time and effort can spin rapidly out of control even when the CRO partner is underperforming and not meeting enrollment and other critical study milestones. A milestone-based CRO, Biorasi sees the relationship between CRO performance and billings in an entirely different way - one that is positively, rather than negatively, correlated. To that end, it ties payment proportionally to sponsors achieving certain milestones and also provides real-time transparency and visibility in the studies' progress.

[7] *Global Contract Research Organization (CRO) Market, Forecast to 2024* (*Frost & Sullivan, November 2019*)

Unlike other CROs that hike prices due to varying study parameters, the company follows a partnership-based model, where risk sharing is the norm, and incentives help align the goals of both partners to realize successes, and failures, together. Biorasi's model is especially valuable for innovative science-driven but smaller drug and device developers who rely heavily on outsourcing partners to translate research from labs to markets and are especially sensitive to price increases and timeline delays.

Biorasi adopts a patient-centric approach to trial execution; it involves training and education that enables pharma companies to recruit difficult-to-target patient populations rapidly. It optimizes patient recruitment for rare disease research by leveraging its relationships with advocacy groups, national registries, and global site networks. Through these channels and many others, drug and device sponsors gain access to the target population, allowing the study to meet recruitment goals and timelines.

The company’s geographic approach is disease-specific, based on a particular disease’s frequency of occurrence and representation across the globe. Leveraging its partnership with data science enterprises, Biorasi can create heat maps specific illnesses, enabling it to locate patient clusters and quickly target trial recruitment efforts. Moreover, the company leverages its presence across Europe (Russia and Ukraine a particular focus for rare diseases), along with expert personnel and process efficiencies for recruiting trial participants for hard-to-recruit indications studies. The strategic location choices allow Biorasi to offer competitive pricing options to its sponsors.

The company’s prime business focus is in phases Ib and II, where protocol optimization and design are particularly challenging. Nonetheless, Biorasi works on a selection of phase III trials for specific rare and other difficult-to-recruit diseases. The company’s primary clients include the biotech and small to medium pharma players with world-class scientific acumen, but lacking the capabilities required to develop a drug from start to finish in-house. To that end, Biorasi’s partners with small and mid-size firms, providing the necessary framework, capability, scalability, and flexibility for protocol enhancement early in the process and progress the trial, thus managing complexity.

Designing Patient-centric and Technology-enabled Trial Rapidly

Beyond solving patient recruitment and engagement challenges, Biorasi addresses issues related to protocol design, clinics, and delays due to new regulations. The company's medical and scientific experts design trial protocols as per the rapidly evolving regulatory environment to support software-as-a-Medical Device (e.g. DTx) and device.

Biorasi’s clinical trial optimization programs are quick, intelligent, and integrated with company experts and technology to improve trial performance, especially in the DTx area. With limited CRO focus for trial recruitment, study protocol, and design, it supports DTx trials to receive reimbursement from payers. The company helps sponsors in validating DTx’s efficacy and legitimizing its impact. Combined with drug therapies, Biorasi aids in advancing remote monitoring, adherence, telemedicine, and disease-specific digital tools as an alternative to medication, especially in behavioral health, e.g., depression.

The company is vested in assisting DTx companies in establishing the clinical evidence and utility to support DTx's regulatory approval and reimbursements.

Biorasi first builds its trial management system, Talos™, to facilitate tracking and drive participation. A focus on the clinic, an understanding of the trial site, and a set of type-relationships personalize the experience for the trial managers involved in recruitment at the sites and serve as the key components that drive study participation and success. Biorasi has rescued several trials with failed project milestones due to recruitment issues, for example completing enrollment within just three months in a program that was delayed due to lack of enrollment for several years.

By implementing Talos™, the company ensures the clinical trials are entirely technologically-enabled for high-quality data capture. Personnel expertise and a deep understanding of the Big Data accumulated from the clinical trials conducted underpin its data science capabilities. Biorasi's highly proficient data science specialists perform robust real-time analysis to progress the study ahead. The team's ability to decipher and interpret the data meaningfully enables it to collaborate closely with the medical writing team for due diligence, and FDA submission.

Frost & Sullivan appreciates how Biorasi applies a combination of know-how, self-motivation, and technology to pinpoint areas of opportunity and track project progress.

Growth Ahead

Biorasi engages early with its clients to develop long-term customer relationships (although it prefers to call them "partners"). By adding value in the first research study, the company progresses to other trial stages, thus, generating recurring business. Additionally, Biorasi will continue to support clinical trial recruitment in core therapeutic areas, i.e., neurology, nephrology, complex dermatology, oncology, with a particular focus on DTx as part of its growth strategy.

Furthermore, in response to the COVID-19 pandemic, the company is leveraging its deep clinical trial expertise to assist in recovery management and strategy design for COVID-19-related research, discovery, and innovation. To that end, Biorasi announced initiating its first US-based COVID-19 clinical trial in May 2020; the company is focusing on therapeutics for lung injuries resulting from COVID-19 virus exposure. Additionally, in June 2020, the company will launch its second COVID-19 study in Russia and Ukraine for prophylactic treatment targeted to prevent onset and severity of illness in healthcare workers. Due to the risk that COVID-19 presents to monitoring staff and the burden of the disease on the sites, many trials are being delayed because CROs cannot keep up operationally without remote-based processes in place. Here, Biorasi executes a completely remote-based trial setting to include virtual site selection visits, site initiation visits, and remote monitoring, promoting its decentralization strategy and establishing processes and operational efficiencies during the crisis.

Frost & Sullivan projects high-growth in the DTx segment driven mainly by COVID-19. The United States' DTx market revenue will increase from $293 million in 2019 to $580 million in 2023, representing a 17% compound annual growth rate.[8] As only a handful of CROs focus on DTx, the company gets a first-mover advantage with a substantial commercial opportunity. Beyond DTx, Biorasi's flexibility, transparency, and milestone-based pricing demonstrate the value of its commitment to customers. By positioning its expertise and focus in some of the industry's highest growth areas, namely oncology and neurology, which stand out as the two highest grown therapeutic areas in research, Biorasi establishes itself as an emerging leader in the CRO market.

Conclusion

Adequate patient enrollment for hard-to-recruit studies, such as a rare disease, presents unique challenges owing to limited disease representation and occurrence. As the clinical trial is the most costly and time-consuming step in the drug discovery and development value chain, delays in meeting enrollment targets have significant cost implications for pharmaceutical companies. Other bottlenecks include operational complexities, high failure rates, and regulatory pressures.

Biorasi is a full-service, milestone-based, contract research organization with a patient-centric approach to drive patient recruitment for rare diseases, hard-to-recruit indications, i.e., precision medicine, and clinical trial rescue. Its expertise in neurology, nephrology, dermatology, and oncology and international relationships with global site networks allows the company to access the global target populations and enroll participants rapidly, providing sponsors' real-time visibility in their studies' progress.

Powered by its proprietary Talos™ trial management system, Biorasi advances technology-enabled protocol optimization programs, improving clinical trial performance and success rates. Furthermore, as an expert in digital therapeutic trials, the company enables clinical validation, regulatory approval, and payer reimbursement.

For its strong overall performance and fresh viewpoint on the future of the clinical research industry, Biorasi earns Frost & Sullivan's 2020 North America Entrepreneurial Company of the Year Award in the contract research organization market.

8 *US Digital Therapeutics Market, Forecast to 2023* (*Frost & Sullivan, May 2018*)

Significance of Entrepreneurial Leadership

Ultimately, growth in any organization depends on customers purchasing from a company and then making the decision to return time and again. In a sense, then, everything is truly about the customer. Making customers happy is the cornerstone of any successful long-term innovation or growth strategy. To achieve the dual goals of customer engagement and growth, an organization must be best in class in 3 key areas: understanding demand, nurturing the brand, and differentiating from competition.

Understanding Entrepreneurial Leadership

Demand forecasting, branding, and differentiation underpin an entrepreneurial company's journey toward forming deep relationships with customers and permanently altering the market with their actions. Entrepreneurial Innovation and Customer Impact are the cornerstones of this award, as discussed further in the next section.

Key Benchmarking Criteria

For the Entrepreneurial Company of the Year Award, Frost & Sullivan analysts independently evaluated Entrepreneurial Innovation and Customer Impact according to the criteria identified below.

Entrepreneurial Innovation

Criterion 1: Market Disruption

Requirement: Innovative solutions that have genuine potential to disrupt the market, obsoleting current solutions and shaking up competition

Criterion 2: Competitive Differentiation

Requirement: Deep understanding of both current and emerging competition to create and communicate strong competitive differentiators in the market

Criterion 3: Market Gaps

Requirement: A clear understanding of customers' desired outcomes, the products that currently help them achieve those outcomes, and where key gaps may exist

Criterion 4: Blue Ocean Strategy

Requirement: Strategic focus on creating a leadership position in a potentially "uncontested" market space, manifested by stiff barriers to entry for competitors

Criterion 5: Passionate Persistence

Requirement: A deep belief in the "rightness" of an idea and a commitment to pursuing it despite seemingly insurmountable obstacles

Customer Impact

Criterion 1: Price/Performance Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market.

Criterion 2: Customer Purchase Experience

Requirement: Customers feel they are buying the most optimal solution that addresses both their unique needs and their unique constraints.

Criterion 3: Customer Ownership Experience

Requirement: Customers are proud to own the company's product or service and have a positive experience throughout the life of the product or service.

Criterion 4: Customer Service Experience

Requirement: Customer service is accessible, fast, stress-free, and of high quality.

Criterion 5: Brand Equity

Requirement: Customers have a positive view of the brand and exhibit high brand loyalty.

Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

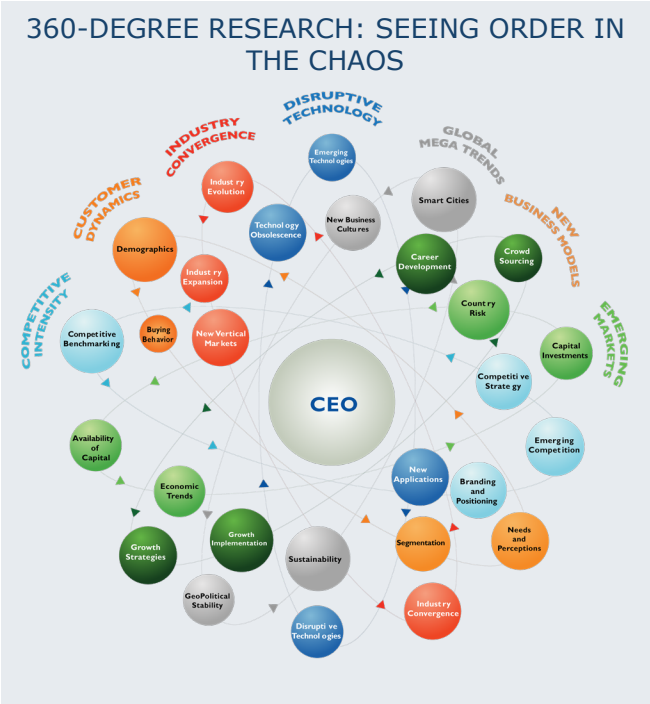
Frost & Sullivan analysts follow a 10-step process to evaluate Award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

STEP		OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify Award recipient candidates from around the globe	• Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies	Pipeline of candidates who potentially meet all best-practice 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-practice 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-practice 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-practice 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-practice Award recipient	• Review analysis with panel • Build consensus • Select recipient	Decision on which company performs best against all best-practice 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 future 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 our 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, leading to 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.



About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to 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 practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages more than 50 years of experience in partnering with Global 1000 companies, emerging businesses, and the investment community from 45 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.