Serving the CLINICAL TRIAL ECOSYSTEM

From central lab services to patient recruitment to site management to data management to staffing, clinical trial service providers are upping their game to provide best-in-class tools, products, and strategies to reduce drug development costs, increase efficiencies, and speed time to market.

With drug development costs topping $2 billion, R&D spending at an all time high, and as the global market for clinical trials continues to grow and diversify, there is increasing pressure on the industry to bring drugs, biologics, and devices to market with increased speed and greater efficiency.

Helping to drive much-needed changes in a complex system are clinical trial service providers, many of which are on the cutting-edge in terms of innovation and finding new ways to move the proverbial needle. These partnerships, if viewed as collaborative and strategic, provide sponsors with valued resources allowing them to concentrate on their own core capabilities.

According to Evaluate Pharma, pharmaceutical companies are projected to spend about $144 billion on research and development in 2016, growing to $160 billion by 2020. Many pharmaceutical companies are also choosing to allocate a greater share of development dollars to outsourced providers over internal resources. A number of factors are contributing to and will continue to drive the growth of the pharma outsourcing industry, including increased number of drugs entering early development; added pressure to evaluate potential drug candidates in a timely and cost-effective manner; and increased regulatory scrutiny from the FDA and other governing bodies.

Additionally, Evaluate Pharma analysts say, the shift of development dollars from blockbusters to niche busters — medicines for smaller, targeted populations — and continued pressure from insurance carriers to rein in drug prices, is increasing the need for pharmaceutical manufacturers to shorten product development cycles, reduce fixed costs and generate efficiencies by outsourcing a greater percentage of functions including R&D, clinical trial management, manufacturing, and analytical testing.

A Specialty Transformation

According to the analysts at Roots Analy-

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MARK ENGELHART
Chief Commercial Officer, ACM Global Central Laboratory

A CENTRAL LAB PARTNER DERIVES MULTIPLE BENEFITS

With numerous diagnostics available, test selection is never easy, but it can be simplified. By asking 'what do you need to prove?,' we can better understand the outcome that a sponsor is trying to reach and select the appropriate tests for achieving that outcome in the most efficient way possible. Sponsors that involve a central lab partner during the protocol development stage find that they're able to drive more efficiencies, avoid potential protocol amendments, and minimize costly study delays.

ENSURING DATABASE SAFETY

Central labs ultimately provide a database that serves to demonstrate the safety and efficacy of the investigated drug. The global scope of clinical trials has contributed to elevating the central lab's role in these two areas by delivering a cleaner, more robust database. Studies are increasingly bigger with more investigative sites spread across a greater number of countries. The more sites utilized, the more difficult it becomes to rely on different local labs to demonstrate that the results are all viable. Central labs eliminate that issue right from the get-go and deliver a cleaner, more robust database.

DENISE KUROWSKI
Senior VP, FSP, Advanced Clinical

BEYOND THE FAMILIAR

Familiarity often causes sponsors to routinely engage the same provider(s) for the same services. Truly maximizing the partnership, however, can mean exploring trusted suppliers' innovative solutions and expanded services. This allows solutions deployment in an atmosphere of trust and cooperation rather than with an unknown and untested supplier. Staying current on the offerings of proven supplier partners can produce synergies beyond the current relationship, maximizing both the time invested in the partner and success long term.

JASON CASARELLA
Senior VP, Business Development & Marketing, Advanced Clinical

AUTOMATING BUSINESS PROCESSES

Business process automation (BPA) software creates Web-enabled applications to automate and mirror a company's existing processes that are accessible 24/7 around the world. BPA technology allows for data to be migrated from a single source of truth versus multiple databases that may have variations of data, therefore creating timely and accurate reporting. BPA is cost-effective, timely, and user-friendly while meeting the demand to reduce costs and improve the effectiveness of our business.

BRIAN SCHAECHTER
VP, Clinical Trial Division
Artcraft Health

sis, over the last few years, a structural transformation in the primary CRO business model to a more strategic approach has revolutionized R&D outsourcing. Newer players providing specific capabilities in the R&D value chain have witnessed a gradual acceptance. In its research, Research and Markets has identified more 200 specialty CROs from among more than 1,000 CROs based on their specific capabilities and the range of services they provide. These specialty CROs collectively cater to the multitude of research services required by drug developers.

Furthermore, the United States with about 115 specialty CROs, has emerged as the primary hub of specialty CROs; this is followed by Europe with about 60 CROs. India and China, where CROs offer a relatively higher cost optimized service portfolio, are emerging as new destinations; the level of activity, however, has been fairly limited so far.

Roots Analysis also found that though the broader contract research market is highly consolidated and dominated by a handful of bigger CROs, the market within the specialty CRO segment is highly fragmented. This is unlikely to change as biotech companies will continue to prefer outsourcing specific requirements of the clinical trials instead of outsourcing the entire clinical trial program to an individual CRO.

Analysts say they expect the overall market of specialty CROs to more than double in the coming decade, growing at a CAGR of 8.6%. Specific areas of growth are likely to be driven by novel services and upcoming technologies resulting in cost optimization and improved outputs.

Some of the niche opportunity areas/approaches include health economics and outcomes research (HEOR), adaptive trial designs, and eClinical solutions. Specifically, these areas typify a growing unmet need and represent untapped areas making outsourcing an attractive option. PV

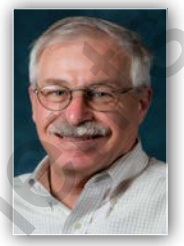
Editor's Note: Throughout this issue, nearly 100 thought leaders from all aspects of the clinical arena provide their insights on the future of clinical trials and drug development, and don't forget to check out exclusive bonus content at pharmavoice.com.

IDENTIFYING ROLES AND RESPONSIBILITIES

The key to knocking down the barriers that limit a true partnership is to clearly identify roles, responsibilities, goals, and accountability. Once these items are clearly identified the team can begin to move toward a common goal of development of the program. Ultimately, it's the sponsors that need to drive the process and the program while holding their vendors accountable to all deliverables and never forgetting that behind every new therapy is a patient, caregiver, or family.

STREAMLINING COMMUNICATIONS

The best technologies for enhancing the outsourcing model are tools that ease communication, save time, and ultimately save money for all parties. Streamlining communication from the contracting process to final delivery has a huge impact on timelines. Partners need to have 24-hour access to workflow processes and be able to view the disposition of projects at their convenience. This allows for clients to access the partner's team's work and comment 24/7.



JEFF KINELL
CEO, Bracket

ALIGNING INCENTIVES

When sponsors and service providers aren't aligned with the same incentives, the risk of trouble increases. For a successful partnership, it's key to make sure everyone has the same goal.

SCOTT GRAY
CEO, Clincierge

CLEAR AND OPEN COMMUNICATIONS

Open and clear communications is the No. 1 driver of success, both between CROs and sponsors as well as between those groups, trial sites, and patients. A major challenge to achieving this is the long contracts and timelines required for many clinical trials;

PhRMA R&D

According to PhRMA, member companies invested an estimated $58.8 billion in research and development in 2015, up 10.3% from 2014. In the United States, the biopharmaceutical industry is a driver of economic growth and global competitiveness, and it is the most research-intensive sector of the U.S. economy, investing on average six times more in R&D as a percentage of sales than all other manufacturing industries. The sector also accounted for an estimated 17% of all U.S. business R&D spending, the largest share of R&D spending by U.S. businesses. Overall, PhRMA member companies alone represented the majority of all biopharmaceutical R&D spending in the United States.

"Investing more than half a trillion dollars in R&D since 2000, our member companies remain tireless in their commitment to driving innovation and delivering greater value than ever before," says Stephen Ubl, president and CEO of PhRMA. "It is through this increased R&D that the U.S. biopharmaceutical industry continues to lead the world in the development of new medicines to address unmet medical needs of patients."

Long-term R&D investments made by the biopharmaceutical industry have led to more medicines in clinical development than ever before, more than 7,000 medicines globally. From 2000 to 2015, more than 550 new medicines were approved by the FDA, including a record 56 new medicines in 2015. Given just 12% of medicines in clinical trials ever make it to patients, Mr. Ubl says it is critical we have pragmatic, pro-innovation policies to sustain the long-term investments needed to develop tomorrow's cures.

Source: PhRMA

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study team turnover is definitely a complicating factor.

COMMON OBJECTIVES

Customers and suppliers need to agree on common objectives. There should be well-defined goals and strategy, and communications between parties should be open and frequent. A motivated customer champion and well-documented milestones that are clearly communicated along the way will also help to ensure success.

JOSEPH SGHERZA
President, ClinicalRM

TALENT AT HAND

Sponsors should take note of the talent available at their disposal and the willingness of CROs to meet their needs. CROs can tap a robust and top scientific talent pipeline ranging from notable KOLs from academia and government institutions, such as NIH, USAMRIID, and DoD to name a few. These experts can offer guidance, expertise, and collaboration on a number of activities such as concept and protocol development, pipeline management, and advisory boards. By using the extensive talent pool and global network of a CRO, sponsors can enjoy a greater level of synergy and thus a deeper level of partnership.

A WORLD PERSPECTIVE

Continuous communication and meeting the customized needs of each partnership are key to a successful partnership. These ingredients are particularly important when clinical research is being conducted in remote areas around the world where the needs are critical and evaluating priorities and goals are vital steps toward developing a mutually beneficial partnership. Having launched clinical sites in West Africa and Latin America for ID outbreaks of Ebola and Zika, having a global infrastructure group that can focus on delivering operational feasibility and improving the overall infrastructure at clinical sites can aid in both optimal partnering and flexible solutions.

BRANDON EVANS
Clintrax Global CEO
Clintrax Global, a WIRB-Copernicus Group (WCG) subsidiary

BRINGING VALUE

Sponsors and CROs both recognize that they must broaden their development relationship to include more highly specialized partners. We bring added value to the sponsor/CRO partnership by helping to negotiate contracts, budgets, and payments with investigator sites. Because we focus solely on optimizing clinical trial negotiations, we are able to deliver greater efficiency and better results than our sponsor and CRO clients could achieve alone.

THREE KEYS TO A SUCCESSFUL PARTNERSHIP

The three most important factors in the creation of a successful outsourcing partnership are communication, transparency, and the development of a strategic plan. Establishing a clear, concise plan at the outset of a trial that outlines roles and responsibilities — as well as communication and escalation pathways — facilitates the organized flow of information to all parties throughout the life of the study.

ELISA CASCADE
President, DrugDev Data Solutions

INGREDIENTS FOR SUCCESS

While we are always looking to improve on our recipe for a successful outsourcing relationship, our experience in working across pharmaceutical companies suggests the primary ingredient is customer delight, with a dash of quality, honesty, and responsiveness thrown in for added flavor.

BRETT KLEGER
Chief Commercial Officer, DrugDev Data Solutions

TECH STANDARDS

Game-changing technologies to enhance the traditional outsourcing model all share two common components. First, they are based on a proven best practice process, and are simply using technology to make it more efficient and available to the marketplace. Second, they foster collaboration among all stakeholders to a study — sponsors, CROs, sites, vendors, patients, etc. Technologies that foster standards, collaborations, and are transparent are the key to success.

RAMITA TANDON
Executive VP Commercialization and Outcomes, ICON

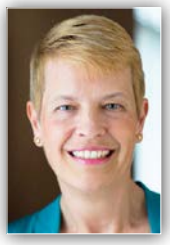
MOVING BEYOND TRANSACTIONAL ENGAGEMENTS

For postmarketing programs, the major cost drivers are commoditized services often priced and operated for narrow, transactional engagements. We tend to see major efficiency gains when a strategic CRO-sponsor partnership is focused on three strategies: first, highly efficient technologies to mine and generate real-world evidence; second, an operational model to drive patient and payer insights into early development and ensure innovation aligns with commercial viability; and, third, novel patient-centric approaches to studies that maximize relevancy and productivity.

SUPPORTING CONNECTIVITY

As sponsors adapt their organizations to the

value-driven healthcare environment, CROs must support new connectivity between disciplines, particularly the silos of clinical and commercial groups. We must channel new real-world data sources, from EMRs to wearables, into patient and payer-centric insights that augment early R&D decisions about optimal target indications, opportunities to improve care management, product feature profiles that align to potentially non-obvious patient populations, and viable protocol designs or recruitment strategies.



JUDY SWILLEY, PH.D.
Executive VP and General Manager Global Clinical Operations and Alliance Management, INC Research

TOTAL TRANSPARENCY

A fundamental first step is building trust at all levels of the relationship, which starts with total transparency in all discussions from day zero. Clearly defining overall strategy, roles and goals and agreeing to revisit them as the partnership evolves are also key, along with having visibility into product portfolios so that resources can be allocated effectively. Successful partnerships have engaged, visible executive leadership from both organizations as well as effective governance and criteria for measuring success.

KEVIN DUFFY
Global VP, Life Sciences Vertical, Kelly Outsourcing and Consulting Group

A STRATEGIC COMMITMENT

In its purest sense, partnering is the strategic establishment of systematic maintenance and proactive enhancement of close, mutually beneficial, long-term business relationships. Partnering should be seen as a strategic commitment between two independent companies that transcend the realm of purchasing and requires a supportive corporate philosophy. To be effective, the partners need to execute it in an organized fashion, based on continuous improvements that either partner may initiate. Often times, how the two entities truly define a partnership gets in the way of progress. If not crafted as a win-win model, both operationally as well as financially, to include a balanced risk profile, the establishment of a true development partnership is doomed for failure.

IMPLEMENTING ESOURCE SMARTLY

Some may say there are too many technologies in play right now at the CRO, at the sponsor, and particularly at the site level. The varied training that comes with each solution has become cumbersome, the technologies are often incompatible with established systems, and the proposed tools are sometimes viewed as complex and in the end, do not deliver on the promise of ease-of-use and a streamlined process. eSource solutions are here to stay and will continue to proliferate through the drug development process; the key is to ensure the installation and implementation of the select technologies makes sense for the study at hand.

APRIL MULRONEY
Managing Director, Payments, Medidata Solutions

MORE TRIAL VISIBILITY

As outsourcing becomes more prominent, sponsors are requiring greater trial visibility and operational efficiency from their CRO partners. However, existing technology solutions offer limited opportunities for collaboration, making it difficult for CROs to meet sponsor expectations. For example, site payments, a transactional function performed by CROs, is a critical activity that could be improved with streamlined, connected technology that offers real-time data for accurate cost calculations, proper oversight and accountability, and financial tracking.

ADDRESSING FINANCIAL PAIN POINTS

CROs manage the site payments process for more than 80% of all studies globally. Different technologies have been developed to enhance clinical payments for CROs and sponsors, but most don't address all the pain points. By pulling data from cloud-based EDC systems, payments technology can accurately calculate and automatically disburse payments to sites in real time. This technology is accelerating the payment process and fostering stronger relationships among sponsors, CROs and sites, enabling them to focus less on financial administration, and more on bringing new treatments to market.

TODD MEYERS
VP, Business Development and Marketing, Medpace

TRUST AND OVERSIGHT

Trust and sponsor oversight of the CRO are two barriers to becoming true development partners. Sponsors continue to use a duplicative management structure in the oversight of the CRO partnership, at times, causing a roadblock to CRO decision making in overall study/program development and timelines. As a result, formalizing a development partnership must be somewhat fluid at the outset. Time at the beginning of the partnership must be carved out to collaboratively build a partnership charter containing a mission statement, having common goals and principles, wrapped around agreed outcomes — metrics — and governed by both parties.

FINDING COMMON GROUND

One of the keys to a partnership relationship

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establishing common objectives for the study, including definitive scope of services and shared decision-making authorities for projects within the partnership. Invest the time in joint planning at the outset to fully understand team roles and responsibilities. Define and develop the necessary documentation around the partnering agreement and develop contingency planning for the group. Collaborating early in the process will pay off as projects begin study start up under the formalized strategic partnering agreement.

JEFF BEELER

VP, Product Innovation, Merge, an IBM Company, eClinical Division

AN EQUAL VOICE

An outsourcing partnership must be exactly that, a partnership. While many sponsors are looking to use a CRO as an extension of the company, they miss the mark if they choose a company and not a partner. Both entities must be engaged fully, and understand the risks as well as the rewards. True partners will have an equal voice to recommend strategy, patient engagement, and operational procedures throughout the clinical trial process.

REDUCING MANUAL OPPS

Any technology that can remove or reduce the need to perform manual tasks will be beneficial. For instance, direct data feeds from EDC into CTMS or a TMF will help alleviate duplication of effort and cut timelines. Using signal-driven source data verification (SDV) to drive monitoring — as opposed to a time schedule — will also be key to data quality and safety for subjects. Clinical operations can begin to look at data in a smarter, more focused way when risk-based monitoring drives SDV.

MATTHEW SMITH

Senior VP, Global Commercial Operations, SynteractHCR, San Diego

STAYING ON TRACK

Good communications are key. Having members from both the CRO and the sponsor on the project management team, with consistent update calls, really goes a long way in keeping everyone focused on the progress, challenges, and solutions — helping to ensure the trial stays on track.

STAY ABREAST OF TECHNOLOGY

There are a number of technologies that support clinical trial outsourcing, from EDC solutions to CTMS and eCTD. We are continually upgrading our systems and training our staff on the newest versions of feasibility tools, adaptive design software, pharmacovigilance systems, and interactive response technologies, among others.

ROXANNE TAVAKKOL

VP, Regulatory and Scientific Services, TKL Research

OVERCOMING IND APPLICATION PROCESS CHALLENGES

One of the biggest challenges is the integration of data from preclinical studies and drug manufacturing development into final product specifications. There must be an understanding of how these two disparate types of data fit together in support of the initial Phase I clinical trials. An IND needs to tell a complete story; it is critical to craft an over-arching regulatory strategy to ensure IND approval and rapid advance into Phase II.

U.S. VERSUS EU IND APPLICATIONS

An EU application is study-specific. An IND is an active application that is updated with new information from the areas of preclinical research, manufacturing information, and clinical efficacy and safety data from ongoing and completed clinical trials. Each IND typically covers one indication and one formulation of a drug product. Sponsors are strongly encouraged to schedule a pre-IND meeting with the FDA to discuss the content of the IND and discuss future plans.

ANNETTE STEMHAGEN, DRPH, FISPE

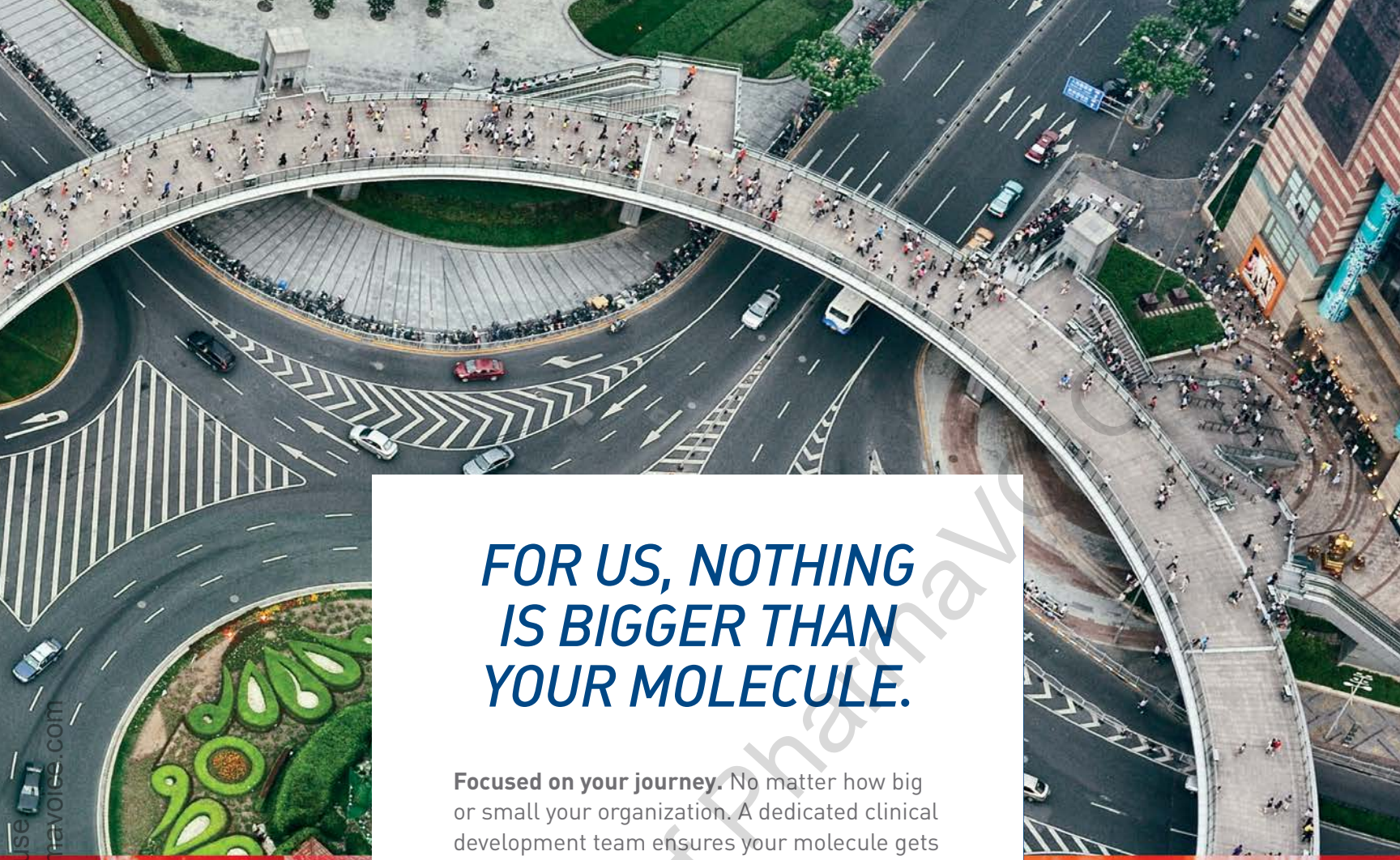
Senior VP, Safety, Epidemiology, Registries, & Risk Management, United BioSource Corporation (UBC)

REAL-WORLD VALUE

In a recent industry survey, pharma leaders cited lack of internal expertise as a factor in preventing them from applying real-world evidence to their R&D. Filling in these gaps of expertise is often crucial to development and marketing success. A service provider that knows how to collect and apply real world observations can bring great value. And, trust — while not built overnight — makes for a solid partnership that ultimately improves patients' lives.

DATA PROBES

Providers with tools that effectively improve access to and analysis of real world data will always play an important role in outsourcing partnerships. Real-time access to pharmacy and medical claims data provides insights to pharma into the safety and effectiveness of their products. But it's not enough to provide volumes of data, pharma companies need to probe the data for insights into product safety, burden of illness, and impact of new treatments in a highly organized, even visual, presentation.



FOR US, NOTHING IS BIGGER THAN YOUR MOLECULE.

Focused on your journey. No matter how big or small your organization. A dedicated clinical development team ensures your molecule gets the full attention it deserves, bringing in our eClinical solutions and consulting experts at just the right times. Find out more about our integrated approach that reduces risk and improves predictability. Watch our video at **proof.PAREXEL.com/crs**

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