CLINICAL RESEARCH:
A Legacy of Innovation,
A Future of Transformed Medicine
Every year, members of the Association of Clinical Research Organizations (ACRO), and the 100,000 research professionals they employ, conduct more than 9,000 clinical trials in 142 countries around the world. The purpose is simple: bring life-changing medicines to market as efficiently and safely as possible, so patients can get the treatments they need.

Clinical research organizations (CROs) pursue innovation in clinical trials because a competitive industry demands it, and because it’s what patients awaiting new medicines deserve. Research sponsors choose to work with clinical research organizations because they have confidence CROs will work tirelessly to conduct safe, thorough trials on schedule and within budget.

Clinical trials today are more responsive, individualized, and effective because it’s written into the DNA of CROs to challenge the status quo. CROs are harnessing real-time data analytics and visual reporting software tools; they’re building innovative strategic partnerships, and breaking down communication barriers between trial sponsors, trial sites, patients, and even regulators.

**These process innovations help patients get access to life-saving treatments faster** and encourage continued investment in the development of medicines and rare-disease treatments around the world.

Truly optimizing the process and potential of clinical trials, however, requires more than just the commitment of CROs. Legislative and regulatory policies must be made to align with industry efforts and similarly foster innovation. Recommendations for policy improvements in the United States and European Union are included at the conclusion of this document.

9,000 CLINICAL TRIALS

142 COUNTRIES

1.4 MILLION PATIENTS

The top US states for CRO employment are North Carolina, Pennsylvania, Massachusetts, New Jersey, Texas, and California; the top European locations for CRO employment are the United Kingdom, Germany, France, and Spain.
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It takes successful clinical trials for patients around the world to get access to the life-saving medicines they need.

Pharmaceutical, biotech, and medical device companies invest billions of dollars to develop treatments and medicines, but before these reach patients, rigorous testing must take place to ensure safety and gauge how treatments perform over time. Clinical research organizations design and implement those tests.

Clinical trials are essential to the drug development process, which in and of itself is a lengthy, expensive, and complex undertaking. On average, bringing a new drug to market can take 15 years and cost as much as $1.2 billion.

The drug development process—involving discovery, pre-clinical research, clinical trials, and regulatory approval—requires collaboration among trial sponsor staff, regulators, physicians, academic researchers, and patients.

ACRO member companies contribute to all aspects of drug development with an emphasis on Phase I – IV clinical trials and related laboratory services.

Clinical research organizations have always sought to bring greater efficiency to the clinical trial process. ACRO members have been leaders in promoting common data standards throughout the clinical research industry, a collaborative practice that ensures data from various clinical trials is standardized to ease regulatory review and promote sharing among researchers for greater efficiency. Additionally, ACRO members have led in the implementation of Good Clinical Practices to prioritize patient safety and maintain trial quality throughout the clinical research process.

ACRO members have also been early adopters of new technologies and big ideas in clinical trials that have driven innovation throughout the drug development process. CROs have been quick to embrace and capitalize on the efficiencies of electronic data capture and have helped drive the globalization of clinical trials, bringing research opportunities to more patients than ever before and driving efficiency and expediency in the development of new, life-changing medicines and treatments.

Clinical trials conducted by CROs are completed on average 30 percent more quickly than those conducted by sponsoring companies or academic research organizations (AROs) in-house. This results in average time savings of somewhere between four and five months, which is an invaluable period of time for patients in need of treatments. Additionally, the ability of CROs to complete clinical trials more expeditiously translates to $120 million to $150 million in development cost savings.
Saving time and money in the clinical research process is absolutely essential both for biopharmaceutical developers and patients around the world. Among the biggest challenges confronted in clinical research are the stunningly high costs of drug discovery, tight time constraints to prepare for trials and complete trial benchmarks within budget, myriad regulatory hurdles in the U.S. and abroad, and the critical task of finding the right patients to become trial participants.

According to Tufts University, 48 percent of sites in a given trial under-enroll or fail to enroll a single patient. Delays caused by a failure in patient enrollment are costly. A study on clinical trial performance by respected industry analyst firm Gartner estimated that one day of drug development costs a sponsor $37,000 in operational costs, with opportunity costs for delayed drugs ranging from $600,000 to $8 million per day.

**CLINICAL TRIALS TODAY**

ACRO members are doing their part to overcome challenges and bring about more efficient, patient-centered trials. Partnering with biopharmaceutical companies and thought leaders in the research space, CROs are finding and implementing innovative solutions to make trials more affordable and increase efficiency throughout, all to bring life-saving drugs, treatments, therapies, and medical devices to market as quickly and safely as possible. Fittingly, demand for CRO services is growing among pharmaceutical, biotech, and medical device companies.

Optimized clinical research requires collaboration. On a global scale, ACRO members are engaging regulators like the FDA and EMA and forming innovative partnerships with academic researchers, trial sponsors, patient groups, and trial sites to streamline patient recruitment, accommodate adaptive trial designs, and break down barriers to communication.

Given the scope of the patient recruitment challenge in clinical trials, ACRO members are rethinking trial recruitment and enrollment processes. In some instances where the pool of eligible global participants is particularly small and the distance between patients and clinical sites could pose a barrier to entry, ACRO members are thinking outside the box.

- **INC Research** went so far as to incorporate expertise from a travel agency to arrange accommodations for prospective patients in a global study of a rare pediatric neurological disorder.
- **PAREXEL**, another ACRO member, launched an aggressive ad and text message outreach campaign to successfully recruit participants in a 13-day time period.
- **inVentiv Health Clinical** chartered a Clinical Trial Educators Program designed to leverage the expertise of experienced professionals to coach and assist sponsors and trial sites through successful recruitment and trial administration.

“It’s a very humbling business to be in. When you experience how actual patients are benefitting from clinical trials that change their lives, it’s a wonderful thing.”

Jay Dixon, PPD
Clinical trials produce an overwhelming volume of data, with CROs delivering more than 100 million central laboratory test results and managing more than 1 million square feet of lab space around the world. Mastering data tracking and analysis at each and every clinical site, of which there are approximately 27,000, is one of the keys to reducing the overall time and cost of trials. ACRO members are on the front lines of data innovation and integration, developing solutions to make the most of the information collected over the course of a trial.

Recognizing that real-time data tracking enables risk-based monitoring and adaptive trial design, ACRO member PPD created a “protocol optimization” process to leverage trial data toward more cost-efficient and time-efficient trials. In one oncology study, the use of protocol optimization led to a savings of $1.2 million and an accelerated trial timeline. Both PPD and ACRO member ICON have also developed dynamic software solutions to track and respond to trial data in real time, allowing clinical research associates (CRAs) to monitor and optimize clinical trials as they are being conducted.

ACRO members see data integration as a gateway to personalized medicine. Dr. Nicholas Alp from ICON remarked recently that successful data integration “means helping primary data sources – from patients, from clinical operations, and from many other sources – to speak together, integrate, and aggregate.” He went on to say that integrating enormous amounts of living data from trials will enable clinical research organizations to individualize appropriate treatments for patients, given their particular health and disease state. That, he said, “will have an enormous impact on how we plan and conduct clinical trials in the future.”

With all the exciting developments in clinical trials today, there is a notable shift taking place toward personalized medicine and customization for rare diseases. PPD’s Senior Vice President of Global Quality and Compliance, Jay Dixon, says, “The changing development paradigm is making the classical clinical trial a thing of the past.”

More information on clinical trial innovations championed by ACRO members is included in the Case Studies section of this document.
THE FUTURE OF CLINICAL TRIALS

Because of innovations and partnerships that have increased the value and power of data in trials today, clinical trials in the future are likely to be smaller, faster, and involve fewer participants. All the while, patient involvement in the clinical trial process is likely to increase as INC Research Chief Operating Officer Alistair Macdonald notes.

“Patients,” he says, “are becoming much more informed…and they’re aggressively going to sites and looking for trials to be involved in.”

The push to amplify the voices of clinical trial patients throughout the industry has already begun, says Jay Dixon. “I think an area that we really need to bring in is the patient advocacy, really understanding at the end of the day, when we help a client commercialize a product, the end product is there for a patient.” Dixon and others advocate incorporating patients and patient advocacy groups into the design of clinical trials.

With more patient involvement and continued progress in the areas of data management, recruitment innovation, and strategic partnerships within the CRO industry, we expect to see the following from clinical trials in the future:

- **Individualized medicine—trials will pair the right medicine with the right patients at the right time**
  As data enables researchers to learn more about patients and drugs at the same time, future clinical trials will be focused on developing therapies that are more individualized, personalized, and targeted to the right patients, based upon their genetic makeup and other factors. Diagnostic tests developed in conjunction with drugs will help identify the individuals who are right for a specific study, and which specific treatment individual patients should receive for their common condition.

- **Patient-centric protocols**
  The process of increasing patient involvement in clinical trials is going on now and will continue into the future where patients will be involved earlier and earlier in the clinical research process. Trials will be designed to take into consideration what patients identify as being important to them and the various risk levels patients are willing to assume in the course of a trial.

- **Direct patient engagement**
  The days of physician referrals being the only point of entry for clinical trials are gone. Social media and innovative recruitment techniques will continue to empower patients to find, choose, and enroll themselves in clinical trials.

- **More standardized, turnkey investigator networks**
  Because of longstanding relationships with investigative sites, CROs already possess a detailed understanding of which sites are best qualified in various therapeutic areas, which are most effective at patient recruitment, and which can be relied upon to produce the highest quality data. In years to come, we expect to see this knowledge spread throughout the clinical trial space as it is critical to ensuring that studies start and finish on time, that patients receive proper care, and that trial results are most reliable.

“Through integrating this enormous amount of living data, we can start to do things that we can only dream of right now…”

Dr. Nicholas Alp, ICON plc
• **Accessibility for patients around the world**
  Trials are becoming more and more globalized and the means for patients to learn about trials is no longer confined to the walls of their physician’s office. Recruitment efforts will continue reaching out to patients directly and information about clinical trials and trial eligibility will hopefully be centralized and more robust in the future.

• **Responsive, flexible trial designs**
  Closer collaboration between regulators, sponsors, and CROs will make it possible for more trials to make adjustments to protocols in response to trial data and refine and improve outcomes in the midst of a trial.

Reaching this optimized state and realizing all of the potential for future clinical trials requires more than just innovation within the CRO space. CROs are refining trial processes, developing data management tools to simplify and streamline trials, and building relationships with the regulators, physicians, and trial sponsors to meet an industry need to make trials as time efficient and cost efficient as possible. That industry-led innovation will continue because that’s what trial sponsors demand and that’s what’s needed to get life-saving treatments to patients.

Industry innovation, however, can only accomplish so much. There are policies and matters under government’s purview that must be improved as well.

### POLICY RECOMMENDATIONS TO COMPLEMENT CLINICAL RESEARCH INNOVATIONS

In order to ensure that there remains an atmosphere conducive to innovation and medical research and development, and for more trials to be successful and for investments in trials to pay off, regulations for clinical trials must be clear and predictable. There also must be even more cooperation, collaboration, and communication among regulatory bodies, research sponsors, and CROs.

**United States**

About half of clinical trials take place in the United States—more than any other nation in the world. ACRO’s legislative agenda in the U.S. is focused on promoting policies that foster innovation in the medication development process and ensure that the U.S. remains a competitive venue for clinical trials.

To improve and optimize the work of clinical research organizations in the United States, we recommend:

- **Supporting the passage of S. 2715, the Compete Act**
  Permanently extending the R&D tax credit and other competitive tax policies which recognize the critical role CROs play in medical product development will foster innovation in the United States clinical trial space.

- **Advocating for the integration of electronic health records (EHRs) with the federal database of clinical trials**
  Allowing the integration of EHRs with clinicaltrials.gov, the federal government’s comprehensive database of clinical trials, will facilitate awareness of clinical trials among doctors and patients and help in the determination of which trials may be most appropriate and convenient for individual patients.

- **Updating and expanding www.ClinicalTrials.gov**
  ClinicalTrials.gov is not as helpful as it could be for patients or researchers. In fact, it’s often seen as intimidating and unclear. The site’s database of clinical trials, however, is the most robust available.
Improving the user experience at ClinicalTrials.gov, expanding the information that is included, and also allowing for EHR integration with the database will facilitate better research and empower patients with information about clinical trials for which they may be eligible.

- **Fostering better collaboration with the FDA**
  Making it explicitly clear within the development process that regulators, trial sponsors, and CROs may communicate before and during trials will improve trial outcomes, advance the adoption of adaptive trial designs, and promote a culture of innovation within the FDA itself.

- **Updating HIPAA to accommodate the realities of 21st century data exchange and usage for research purposes**
  “Big Data” has the potential to be a game-changer in medical research, transforming everything from clinical trial recruitment to the ways health outcomes are studied. For this potential to be fully realized, however, HIPAA must be modernized to allow and encourage the free exchange of electronic health data while safeguarding patient privacy.

- **Supporting the 21st Century Cures initiative launched by the House Energy & Commerce Committee**
  Federal laws and regulations must keep pace with the innovation and improvements taking place in the clinical trial space. Policy reform can advance improvements in discovery, solutions in treatment development, and more timely delivery of innovative treatments so patients can benefit.

**European Union (EU)**

With nearly 30 percent of all clinical trials taking place in the EU, it is critical to ensure regulatory structures and research quality standards are in place to support the advancement of clinical research and protect patients across Europe.

To improve and optimize the research environment in Europe, we recommend:

- **Fully implementing the Clinical Trials Regulation**
  Full implementation of the Clinical Trials Regulation throughout Europe will bring clarity and efficiency to the regulations governing contract research. It will also ensure a competitive and robust research ecosystem for medicinal discovery.

- **Adopting suitable data protection and privacy standards**
  Robust standards will respect patients’ privacy rights while also enabling the responsible exchange and use of health information for specific research purposes.

- **Approving policies that encourage clinical research and innovation**
  Competitive regulatory, tax, and business policies will encourage responsible experimentation and innovation in Europe’s clinical trials.

- **Clarifying regulations to identify which party or parties in the research process bear responsibility for compliance**
  Some current regulations are unclear about which party is responsible for ensuring compliance with regulatory obligations in clinical trials.
Every day, clinical research professionals are thinking of new ways to improve the clinical trial process. By advocating for patient-centered, responsive medical research on a global scale, ACRO members are helping advance policies that encourage innovation in pharmaceutical, biologic, and medical device development.

**Technology today is driving innovation in how CROs collect, aggregate, and analyze data.** In fact, data is empowering the drive toward truly individualized medicine. It enables CROs to track and respond to risks and other issues in real time, making the trial process more nimble and responsive. And it facilitates adaptive trial designs, which make it possible for trials to arrive at the heart of the matter faster—whether a medicine or treatment will actually work for patients.

ACRO and its member companies will continue to disrupt the status quo and strengthen relationships with policy makers, regulatory bodies, and government officials worldwide to ensure the advancement of safe, high-quality clinical trials. ACRO will also work to promote tax, trade, and business policies that prioritize innovation—because that is part of the CRO identity. **Innovation is in its very fabric.**
Case 1 – Progress Requires Partnerships: Collaborative Innovation Helps Fast Track Rare Condition Study

Location of Case: USA
Company Featured: Covance
Innovation Example: Collaborative Innovation

A pharmaceutical company in the Midwest needed help developing two monoclonal antibody therapies for occlusive crisis rare hematological disorder, a condition which impacts more than 100,000 Americans.

The company turned to ACRO member Covance to develop and conduct its IND-enabling program, which included a range of nonclinical safety assessment studies—such as four-week toxicology studies, tissue cross reactivity studies, and the associated analytical chemistry necessary to prove the drug’s safety and green-light it for administration to trial patients.

Program Management and Phase I trial experts were brought in at the ground floor by Covance to collaborate, discuss regulatory strategy, and set the terms for the pharmaceutical company’s trial. Covance’s bold step of involving its clinical team during preclinical data review led to a seamless transition into trial Phase I, where preclinical molecule learnings were incorporated thoroughly into the trial’s clinical and post-IND development strategies.

Such end-to-end collaborative innovation enabled Covance’s pharmaceutical client to reach its first critical milestone between three and six months earlier than expected, saving them money and nearly halving the typical development time of 12 months.

The occlusive crisis rare hematological disorder treatment compound, now in Phase II clinical trials, was recently licensed by a large pharmaceutical development partner for commercialization. Because of the efficiency and speed accomplished through the collaborative development process, these life-changing therapies are on a much faster track to reach patients.

Case 2 - Innovation in Trial Recruitment Speeds the Clinical Trial Process

Location of Case: EU
Company Featured: PAREXEL
Innovation Example: Innovation in Trial Recruitment

A client new to early phase research, on a tight budget, and operating within strict time constraints, turned to ACRO member PAREXEL and its Berlin-based Early Phase Clinical Unit for guidance about clinical study processes, trial recruitment, and data quality.
PAREXEL's EPCU team provided the client a three-day workshop designed to illuminate clinical trial processes and explain what makes each phase distinct. In addition, they supplied scientific advice for study design and created an aggressive communication and recruitment plan to identify trial participants. PAREXEL's innovative recruitment plan, specifically, helped drive the client’s Phase I trial for treatment of an inflammatory disorder forward.

PAREXEL formulated a creative recruitment strategy to reach a large pool of potential trial participants in non-traditional ways—through ads in public transit systems and text message alerts.

The Berlin EPCU’s recruitment innovations resulted in 138 healthy volunteers being enrolled within a 13-day period and helped reduce the overall time for the post-clinical services (last subject, last visit to clinical study report) by eight weeks.

Case 3 - Clinical Trial Costs Reduced Through Innovative Partnerships and a Revised Trial Design

Location of Case: Global
Company Featured: PPD
Innovation Example: Innovative Trial Design, Collaborative Innovation, Innovative Partnerships

Global contract research organization and ACRO member PPD is currently collaborating with an international group of key opinion leaders, the United States FDA, and Berry Consultants to design a Phase II screening trial for novel treatments (including novel-novel combinations) in a metastatic solid tumor.

This “next generation” I-SPY design will test therapies from multiple sponsors in a single study. The design includes a shared control arm, tests first- and second-line treatment as well as the impact of sequencing of treatments, and explores anti-tumor activity by biomarker subsets.

At a recent meeting with the FDA, no major challenges to the design of the trial were raised. A reduction in the number of patients exposed to ineffective standard therapy and a 30 percent or greater decrease in per patient trial costs are among the benefits of this collaborative trial design.

Case 4 - Innovative Partnerships Put Cardiovascular Treatment Trial One Year Ahead of Schedule

Location of Case: USA
Company Featured: Covance
Innovation Example: Innovative Partnerships/Collaborative Innovation

ACRO member Covance partnered closely with its trial sponsor and a top academic research organization (ARO) to conduct a 10,000+ patient mega-trial of a drug designed to minimize cardiovascular risks for patients. The forward-thinking partnership accelerated trial completion, ensured the inclusion of the right patients—those who would most benefit from a new therapy—and safeguarded those patients’ wellbeing.

The partner ARO had a comprehensive understanding of the physician and patient needs present in this trial and used its voice to advocate on their behalf throughout the trial. Covance applied insights from the partner ARO to inform trial design and protocols, minimizing the burden on patients.

Average Number of Clinical Trial Participants:
- Phase I - 26 participants
- Phase II - 92 participants
- Phase III - 399 participants
- Phase IV - 772 participants
Covance’s clinical operations expertise and its collaborative partnership with the ARO and trial sponsor led to its complex trial, conducted with more than 10,000 patients, beginning three months ahead of schedule, with the last patient starting treatment 12 months ahead of schedule. Completing benchmarks close to one year ahead of schedule helps make it more likely for the cardiovascular treatment studied in this trial to get to market faster for the patients who need it.

**Case 5 - CRO-Championed Innovation Leads to Early Completion for Global Study of Rare Pediatric Condition**

**Location of Case: Global**  
**Company Featured: INC Research**  
**Innovation Example: Collaborative Innovation/Innovative Partnerships/Logistics**

ACRO member INC Research was contracted to manage a global trial for a rare pediatric neurological disorder. The condition being studied was so rare, in fact, that finding enough eligible trial participants—ages seven to 17—in a less than 12-month enrollment period posed a tremendous challenge for INC Research and its trial sponsor. In addition, since individuals who met the study’s strict criteria were located around the world, the trial would have to be conducted at more than 130 sites in 15 countries across North America, Eastern and Western Europe, and Latin America.

Making the trial goals even harder to reach, a protocol amendment was issued after many Institutional Review Board and Ethics Committee submissions had been made from sites around the globe. Immediately, INC Research had to identify which sites needed to submit again for IRB review and how this would play into trial timeline and enrollment end dates.

Completing trials on time and within budget requires innovative teamwork, especially where rare conditions are concerned and when protocol amendments go into effect. Examples of innovative partnerships can be found throughout this INC Research study.

INC Research conducted aggressive start-up and recruitment programs for this particular trial in tandem. Identifying potential participants and connecting them to test sites was critical. To do so in limited time, INC Research partnered with a travel agency to arrange travel and accommodation for subjects. Removing logistical barriers for participants made the trial much more attractive to those living more than 50 miles from a participating site.

**INC’s Database Review Campaign** was involved in trial recruitment to identify potential high-quality participants. INC maintained close engagement with trial sites in the recruitment process and beyond, providing sites with weekly status updates and keeping them engaged through a variety of motivational activities. Every time a site screened or recruited a subject, they were thanked by handwritten card, personal phone call, or an appreciative message.

INC Research collaborated closely with its trial sponsor at all points in the study to achieve immediate buy-in from every single participating site team. Weekly meetings were held with the sponsor’s legal department, and the sponsor even attended all site initiation visits, many of which were carried out by the sponsor’s Medical Monitor. Sponsor involvement at the onset of the trial helped physician investigators quickly resolve any concerns about trial protocols and procedures and establish a connection with the study team’s executive management.

Because of INC’s early involvement and collaboration with sites, the trial sponsor, and travel agencies, quality subjects were identified early. First Site Initiated, First Subject Screened, First Subject Enrolled, and First Subject Completed metrics all beat projections. Screening and enrollment beat expectations by six weeks and the trial completed successfully ahead of schedule.
Case 6 - Adaptive Trial Design Cuts Costs for Cancer Study by More Than $1 Million

Location of Case: USA
Company Featured: PPD
Innovation Example: Innovative Trial Design (Adaptive), Optimizing Trial Design for Each Unique Trial and Set of Objectives

ACRO member PPD applied its Protocol Optimization service to a client’s Phase III study of a first-line treatment for an adult solid tumor. Protocol Optimization leverages PPD’s medical and regulatory expertise, access to a variety of data sources, and the application of novel analysis tools to evaluate and optimize trial designs for clients throughout the course of a trial. Recognizing that each trial and each set of trial objectives are unique and may require highly customized designs, PPD uses Protocol Optimization to implement adaptive trial designs in real time.

As the Protocol Optimization process was applied in this cancer trial, study assessments not demonstrably linked to study objectives were removed and the trial design was adapted to include a run-in dose finding stage and an earlier interim analysis than originally proposed.

The adaptive trial design, made possible through Protocol Optimization, led to a savings of $1.2 million and an accelerated timeline for establishing a go/no go decision in this particular cancer trial.

Case 7 - Innovative Partnerships Breed Success in Clinical Trials: Clinical Trial Educators Program

Location of Case: USA
Company Featured: inVentiv Health Clinical
Innovation Example: Innovative Partnerships, Innovation in Patient Recruitment, Collaborative Innovation

A company developing an injectable urology treatment was in trouble. Six months into its Phase III recruitment period, the company had enrolled fewer than 100 of the 1,200 patients needed to complete its study. The company turned to ACRO member inVentiv Health Clinical for help. inVentiv Health Clinical’s Clinical Trial Educators (CTEs) program saved the company’s trial by helping to enroll more than 1,100 patients in less than 12 months.

inVentiv Health Clinical’s team of Clinical Trial Educators, many of whom are nurses with disease-specific experience, visited the 60 U.S. trial sites and performed diagnostic analyses to determine why each was struggling to enroll participants. Based on the site visits, the CTE team lead recommended an overall strategy and even site-specific actions to turn things around and drive enrollment.

Over the course of the enrollment period, the CTEs shared best practices with each other, applied them to other sites, and updated the trial sponsor in weekly conference calls. CTEs additionally supported trial sites in the following ways:

- CTEs re-educated site staff on the study protocol.
- CTEs served as morale boosters, keeping the trial top-of-mind and motivating sites.
- CTEs provided advice and assistance in recruiting, including supporting community outreach at patient fairs and advocacy groups.
- CTEs monitored progress and reviewed metrics with each site.
CTEs play a helping role to trial sites as hand-holders, champions, and advisors. According to inVentiv Health Clinical, “As peers, [CTEs are] able to build a relationship with study personnel that pays dividends.”

In this particular trial, the sponsor company’s Director of Clinical Operations said, “The CTE team was integral to the success of our study.”

Case 8 - Innovations in Data Management and Strategic Partnerships Achieve Cost-Savings for Biopharmaceutical Trial Sponsor

Location of Case: Global
Company Featured: inVentiv Health Clinical
Innovation Example: Innovation in Data Management (data optimizing software), Innovative Partnerships

A global biopharmaceutical company wanted to improve the way it managed clinical trial data and consolidate its data management activities. To efficiently enhance its data processes and activities, the sponsor turned to inVentiv Health’s Clinical segment for help.

Through a strategic partnership, the sponsor—a long-term inVentiv Health Clinical client—sought to:

- **Reduce fixed costs**
  Similar to other organizations in the biopharmaceutical industry, the sponsor needed to reduce costs, particularly fixed costs such as those related to data management.

- **Move to a deliverables-based model**
  A deliverables-based model, in which the sponsor would pay vendors only for the actual cost of deliverables, was needed to help the sponsor keep spending to budgeted levels.

- **More efficiently manage data from clinical trials**
  The company believed that improving clinical data management process efficiencies would help expedite data delivery and enable more adaptive trial designs.

- **Avoid disruptions to the portfolio**
  To avoid any disruptions to the sponsor’s portfolio, the sponsor needed a trusted partner with the right expertise and a well thought out plan for a seamless transition.

- **Maintain high standards**
  More than anything else, the sponsor wanted to ensure excellence in its standards for clinical data management.

By overseeing all trial-level clinical data management work, inVentiv Health Clinical freed up the sponsor company’s internal study team to focus on therapeutic and compound-level work, as well as other core competencies and business objectives.

The partnership with the inVentiv Health Clinical helped the biopharmaceutical sponsor **obtain expected ROI of 94 percent and a 14-month payback**. Pleased with the results, the company awarded inVentiv Health Clinical its global supplier of excellence award.
Case 9 - Clinical Trial Innovations Expedite Recruitment,Prioritize Communication, and Streamline Logistics for a Global COPD Trial

Location of Case: Global
Company Featured: PAREXEL
Innovation Example: – Innovation in Trial Recruitment, Innovation in Communication, Innovation in Streamlining Logistics

Patient recruitment, extensive equipment requirements, and consistent data quality were major challenges for global Phase II and Phase III Chronic Obstructive Pulmonary Disease (COPD) trials managed by ACRO member PAREXEL.

More than 200 other COPD trials were underway at the same time, competing with PAREXEL’s studies for sites and patients. PAREXEL took an integrated approach to overcoming trial challenges and was able to achieve recruitment goals, database lock, and study completion substantially ahead of schedule—Phase III recruitment, in particular, wrapped 2.5 months early. The overall COPD project finished 10 percent under budget, and based on study performance and results, its sponsor was able to submit regulatory filings months ahead of schedule.

Below are details of the innovative recruitment methods, communication strategies, and logistical coordination successfully employed by PAREXEL in these global COPD trials:

• **Innovation in Recruitment** – Given the competitive environment to recruit patients for these particular COPD trials, PAREXEL roughly doubled the number of trial sites to be used for qualification visits and planned for an additional 25 percent more backup sites. All site initiation visits in a country were scheduled carefully to conclude within 30 days of the first visit in that country. As a result, recruitment for both of the studies was completed well ahead of schedule.

• **Innovative Communication** – Achieving cost efficiencies across multiple studies requires ongoing communication between the sponsor, trial sites, and service providers to exchange best practices and implement adaptive trial designs.

In addition to expanding the number of sites needed for initial participant recruitment, PAREXEL launched a communications program between project leaders, functional leaders, and clinical research associates (CRAs) to identify which recruitment approaches worked best, re-use and adapt study documents, and share information through each step of the trial process.

PAREXEL implemented a preemptive Corrective Action/Preventative Action program to identify potential issues at sites early and proactively address them before they could develop into problems that could impact trial deadlines or jeopardize study results.

PAREXEL used its integrated eClinical technology platform to provide transparency with respect to data collected. A client interface was built in PAREXEL’s IMPACT® CTMS to share real-time data with the sponsor, allowing them to track trial results, progress, and trends.

• **Logistical Innovation** – COPD trials involve Spirometry. Because the consistency of data from Spirometry testing depends a great deal on the quality of equipment used and the skill of the equipment operator, PAREXEL provided Spirometry equipment to every trial site, implemented an extensive training program for site personnel, and developed detailed testing procedures to ensure consistent, high-quality results throughout both COPD studies.

PAREXEL supplied and coordinated delivery of key study equipment as well. Equipment was gathered by PAREXEL and packaged into a single shipment for each site. This approach accelerated implementation of the technology needed to conduct the study and saved each site approximately two weeks in waiting time.
Case 10 – Bringing Treatments to Market Through CRO-Supported Commercial Infrastructure

Location of Case: USA
Company Featured: Quintiles
Innovation Example: Innovative Partnerships, Innovation in Commercializing Treatments

An EU-based biotech company – with both clinical and commercial operations in Europe and in Asia – needed to establish the commercial infrastructure necessary to support its new in-licensing strategy and bring products to market in the United States. To mitigate risk and avoid the full expense of building a commercial arm from the ground up, the company turned to ACRO member Quintiles for a partnership solution.

Quintiles put its market, regulatory, and drug safety expertise to work on behalf of the biotech company and developed a U.S. commercial arm – run by Quintiles but reflecting the look and feel of the partner company – complete with an 18-person team dedicated to managing all medical, commercial, and trade activities associated with bringing two of the partner company’s products to market domestically.

In the year after Quintiles began operating the biotech company’s U.S. commercial arm, year-over-year sales for two separate products grew by more than 10 percent, exceeding the client’s expectations.

Case 11 - Making the Most of Data: Adopting eClinical Systems Allows CROs to Visually Track Safety Data in Real-Time

Location of Case: USA
Company Featured: ICON
Innovation Example: Innovation in Data Tracking and Management, Innovation in Trial Design, Adjudication

As clinical trials have expanded in size and duration to improve risk management and patient safety, the task of preparing and analyzing data from clinical trials has become more complex. It’s more important than ever, though, to find a way to sort, track, and interpret data as efficiently as possible, since that’s what’s required to heighten productivity and get treatments to patients faster.

The confluence of growing volumes of clinical data with the heightened need for analytical speed and an industry-wide mandate for greater efficiency is driving the development of better technology solutions. ACRO member ICON is providing two such solutions through its ICONIK and MIRA software platforms.

A company faced with the task of monitoring outcomes for 9,340 patients in more than 30 countries used ICONIK software, and its innovative data visualization tools, to track lab data in real time and automate processes for managing case adjudication. The web-based ICONIK system helped the company manage, visualize, analyze, and report on the 25-30 lab variables being monitored in the outcomes of its study.

On the choice to rely on real-time data tracking software, the company’s project director remarked, “It was obvious that we could not do a proper job of monitoring the battery of lab parameters in such a broad post-marketing trial using a largely manual, paper-based process. With each of the 9,340 patients in the study having eight to fifteen scheduled medical visits and multiple lab parameters measured per visit, the volume of information would explode very quickly. It would become impossible to make sense of it all without the aid of interactive analytical tools.”

The use of advanced data analytic software in clinical trials leads to greater trial efficiency, real-time data analysis, and stronger protocol and regulatory compliance. ICON’s dynamic data reporting tools are changing companies’
approaches to trial surveillance. A Medical Director who recently used ICON’s software commented: “With it, you can get involved in a discussion that inspires a scientific line of inquiry and then instantly have the answers. I can challenge the data, looking at combinations of lab parameters and searching for trends in a way that I could never do if I had to wait three weeks for a statistician to produce a graph for me. It matches the way I think about data.”

Case 12 - Adaptive Trial Designs Maximize Trial Efficiency

Location of Case: EU, 9 countries
Company Featured: PPD
Innovation Example: Innovation in Trial Design (Adaptive), Collaborative Innovation (with EMA)

ACRO member PPD was faced with the challenge to design a cost-effective trial to monitor the long-term safety profile and signal of a client’s drug. The client’s original study design included a randomized trial that would enroll 1,000 patients at 100 sites in three separate regions (12 countries). The client had limited funding for the study and asked PPD to propose an alternative scenario.

After reviewing data, PPD recommended a single-arm observational study with fewer countries, sites, and patients. The revised study design sought to maximize efficiency throughout the trial and ultimately lowered trial costs by 60 percent.

PPD’s revised trial design did the following:

- Decreased trial scope from three regions and 12 countries to one region and nine countries
- Reduced trial sites from 200 to 100
- Reduced enrollment to 500 patients as opposed to 1,000
- Reduced volume of case report forms from 30 to 20 pages per patient
- Reduced interim monitoring visits per site from 640 to 154

PPD successfully made the case to the European Medicines Agency (EMA) that sufficient comparator data had already been collected in Phase III of the trial, thus ensuring adequate safety monitoring to protect patients.

PPD’s strategic contribution and trial redesign helped close the strategy and financial gap of executing a client’s post-marketing commitment.

These cases showcase just a few of the many ways ACRO members are innovating throughout the clinical trial process in order to get new treatments to patients faster. Their work is powering 21st Century clinical research.
ABOUT ACRO

The Association of Clinical Research Organizations (ACRO) represents companies that provide a variety of specialized services that support the development of new pharmaceuticals, biologics, and medical devices. The Association provides an active voice for the CRO industry globally. Through its member companies, ACRO helps improve the quality, efficiency and safety of biomedical research. ACRO member companies employ more than 100,000 professionals worldwide and research in 142 countries. For more information, please visit www.acrohealth.org. Twitter @acrohealth. YouTube @ACROHealthChannel. Facebook. RebelMouse.