



Developing a TRUE Strategic Partnership

Industry leaders have spoken for years about the need to move beyond transactional outsourcing to more strategic partnerships. The time may finally be right for the strategic outsourcing model to take hold.

The biopharmaceutical industry is facing intense pressure within research and development to bring new drugs to the market at a time when drug development has become complex and expensive. Blockbuster patent expirations, more complex protocols, increasing R&D costs, patient recruitment issues, and more stringent regulatory and safety issues are all challenging drug developers.

As a result, pharmaceutical and biotech companies are beginning to rethink their approach to outsourcing and how best to build alliances with external service providers, according to a panel of industry leaders recently convened by the Tufts Center for the Study of Drug Development.

Our experts say they too are beginning to see a shift in the partnerships between CROs and sponsors that go beyond functional outsourcing. Sponsors are beginning to see the value in more strategic partnerships that focus on outcomes or

FACT

DRUG SPONSOR SPENDING FOR CONTRACT CLINICAL SERVICES OVER THE LAST DECADE HAS OUTPACED ANNUAL INCREASES IN GLOBAL SPENDING ON NEW DRUG DEVELOPMENT, 13.4% VS. 9.1%.

Source: Tufts CSDD

that shift risk. Biopharmaceutical companies are trying to figure out how to reduce their fixed cost structures by leveraging the cost/benefit of outsourcing or through risk sharing that comes with working with partners.

The contract research industry is evolving as well. CROs are looking at their structures and evaluating their core competencies to be able to be more accountable. CROs have developed a deeper understanding of the needs

of customers and are evaluating their own internal resourcing models and processes to support these strategic relationships.

At the same time, both sides have to address the issues that can cause partnerships to break down. In fact, 35% to 55% of R&D outsourcing sponsors are dissatisfied with projects, according to a report by Business Insights. Researchers say most R&D outsourcing failures are avoidable with careful implementation of appropriate controls and procedures.

New Ways of Working Required

1. Fundamental changes are facilitating the need for a different type of sponsor-CRO partnership.
2. Sponsors are beginning to realize the advantages of a strategic relationship with CROs.
3. Risk sharing is starting to be incorporated into contracts.

AIZE SMINK. CHILTERN. There is a change happening with CRO-sponsor partnerships. The need for change has been talked about for a long time, and now it is happening. The larger biopharmaceutical companies are taking outsourcing to a higher strategic level and are looking at how they need to do development differently and how to use CROs more fully and cost-effectively. Companies are shifting their point of view on how to use CROs more strategically. Functional outsourcing is definitely the most frequently used model, yet there are a number of companies looking at staffing businesses, or resourcing solutions. There is growing interest in strategically using these types of companies.

MARK ROSEMAN. KENDLE. Many 'strategic partnerships' are in fact still very tactical in nature. But there is in fact some movement on both sides, and there is a realization that there are many advantages to a true strategic partnership.

TIM DIETLIN. INC RESEARCH. Evidence of change is not everywhere. The evidence is in individual relationships and pockets within

“ The old development model is simply too expensive, and there is too much risk. ”

VINCE AURENTZ / Quintiles



the industry. The vast majority of sponsor-CRO relationships are still highly tactical. We need to create an economic business relationship that is mutually beneficial for both sponsor and CRO whether that is risk sharing or resource oriented or some other nontactical model.

VINCE AURENTZ. QUINTILES. The era of big pharma is changing. This fundamental change demands that biopharma companies think differently about how to develop drugs. On the other side, clinical research organiza-



“ Strategic partnerships are, in fact, still very tactical in nature. ”

MARK ROSEMAN / Kendle

Tips for Creating Strategic Partnerships

- » Be clear on what the outcomes are and what each party has to deliver for those outcomes to be successful.
- » Have a governance structure in place and a process for working through issues.
- » Harmonize the process and agree on a standard approach to how to optimize working together.
- » Pharma companies should use the CRO's knowledge about what the issues are and work on a solution that is tailored to the company.
- » CROs should be open to understanding the specific context in which they are working and be flexible to adapt their solutions.
- » Consider the people: the initial start to building a good-quality relationship is to become comfortable with the team members.
- » Have honest and frequent communications.
- » Put in place alliance managers on both sides, whose job is to make sure things work for both parties.
- » Harmonize and standardize a set of technology or e-clinical solutions.

Source: PharmaVOICE

EXPERTS



VINCE AURENTZ. Head of Customer Solutions, Quintiles, a services company offering clinical, commercial, consulting, and capital solutions worldwide. For more information, visit quintiles.com.



TIM DIETLIN. VP of Alliance Development, INC Research, a therapeutically focused contract research organization.

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MARK A. GOLDBERG, M.D. Chief Operating Officer, Parexel International, a global services organization that provides the

right level of guidance to bring safe and effective treatments to patients sooner. For more information, visit parexel.com.



RAYMOND PANAS. Director of International Clinical Development, Sucampo Pharmaceuticals, which is

focused on the development of medicines based on prostanes. For more information, visit sucampo.com.



JULIAN REMNANT. R&D Advisory Lead Partner (Europe), Consulting, Deloitte, which offers professional services that cut across all segments of the healthcare and life-sciences industry. For more information, visit deloitte.com.



MARK ROSEMAN. Senior VP, Sales and Chief Marketing Officer, Kendle, a global clinical research organization providing a full range of early- to late-stage clinical development services. For more information, visit kendle.com.

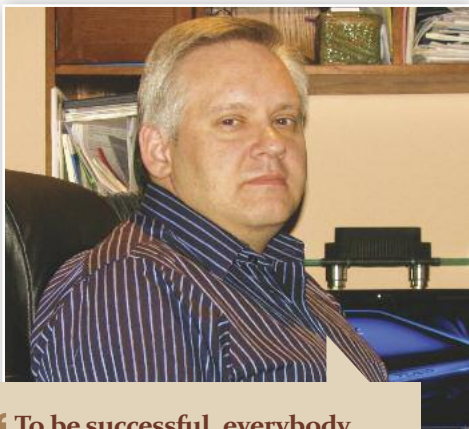


AIZE SMINK. Executive VP, Global Clinical Development, Chiltern, a global contract research organization with experience conducting Phase I to Phase IV clinical trials. For more information, visit chiltern.com.



COLIN TERRY. Executive VP, Commercial Operations, Aptuit, an integrated services company that provides drug development and drug discovery solutions. For more information, visit aptuit.com.

GENE WRIGHT. Senior VP, Clinical Development, Zalicus Inc., a company that discovers and develops novel treatments for pain and immuno-inflammatory diseases. For more information, visit zalicus.com.



“To be successful, everybody involved in the project has to be a stakeholder.”

RAYMOND PANAS
Sucampo Pharmaceuticals



“Larger companies are looking at how they can use CROs more fully and cost-effectively.”

AIZE SMINK / Chiltern

tions need to think about how they can help biopharma companies through this change. One thing that CROs can do is work proactively rather than reactively. There is really no way around changing these partnerships because pharma companies have to do something different. They cannot operate under the current model anymore; it's simply too expensive, and there is too much risk. The hurdles within drug development continue to grow; the costs and the risks are greater than the potential. The only way to align the costs and have a higher chance of success is to develop strategic partnerships and put the value on results.

FACT

AMERICA'S PHARMACEUTICAL RESEARCH AND BIOTECHNOLOGY COMPANIES INVESTED \$65.3 BILLION IN 2009 FOR R&D, AN INCREASE OF MORE THAN \$1.5 BILLION FROM 2008.

Sources: PhRMA and Burrill & Co.

JULIAN REMNANT. DELOITTE.

Companies are focusing their drug development resources where they have the most impact on value generation. Consequently, we see organizations building discovery alliances to diversify risk on the research side and forging fewer strategic partnerships with CROs to reduce cost on the development side.

CROs should be able to pool capacity across different sponsor organizations and thereby drive down the unit cost of this external capacity. The contracting model between a CRO and a pharmaceutical sponsor is moving toward remuneration based on outcomes, which is based on risk sharing.

DR. MARK GOLDBERG. PAREXEL.

More companies are coming to the conclusion that a different way of relating between sponsor and CRO has real value in terms of improving the development and commercialization process. Many of these organizations are now coming up against patent cliffs that have been on the horizon for some time. There is now an aggressive focus on costs, prioritizing pipelines, and making faster, better go/no-go decisions than ever before. This has accelerated the search for appropriate partnerships in order to lower costs and improve productivity. The ability to convert what had historically been fixed costs to variable costs — just as many other industries have done with outsourcing over the years — has proven to be an effective approach to both decreasing costs and increasing productivity. We're seeing an acceleration of interest both from larger and smaller companies to formulate these relationships in a way that creates real value.

GENE WRIGHT. ZALICUS. We use a functional outsourcing model, and our plan right now is



“In a strategic partnership, there has to be a commitment that quality is first and foremost.”

DR. MARK GOLDBERG / Parexel

to continue with this model. We work with smaller vendors, consultants, and CROs. It has been a very positive experience. I am convinced that this is the best model for small pharmaceutical and biotechnology companies, it allows us much more flexibility in selecting which companies will be doing the work.

RAYMOND PANAS. SUCAMPO.

We do a fair amount of outsourcing, from clinical trials to data management to clinical monitoring to drug safety surveillance activities. We also do a fair amount of in-house activity from the planning process and the oversight of our clinical programs, but we don't always have the internal staff to implement large-scale programs, to monitor them, and to make them run as efficiently as we'd like. As such, we rely heavily upon the use of CROs to support our services. We've worked with one CRO for a very long time. If the relationship works, then there is a benefit to keeping that relationship because the CRO knows our company and how we work. It knows our project teams, and the CRO knows how we function. At the same time, we want them to represent Sucampo in the most positive way and that's why it's important we feel comfortable with the team members and their capabilities. We re-



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“ Sponsor-CRO partnerships are changing — relationship by relationship. ”

TIM DIETLIN / INC Research

“ The outsourcing market will be defined by three or four big players. ”

COLIN TERRY / Aptuit



“ There is a push now for remuneration based on outcomes. ”

JULIAN REMNANT / Deloitte

ally need the individual CRO team members to feel like they are part of the Sucampo team. We want projects to be very successful and the only way we can do that is make everybody involved in the project a stakeholder in what happens.

COLIN TERRY. APTUIT. The benefit of a strategic partnership is that spending is more efficient. We can create specific teams backed up by our Executive Committee so that customers have senior-level visibility and commitment as well. We have regular business reviews to make sure goals are met at a strategic level as well as project level. This is a process that can be done in detail with perhaps three or four partners but not for 150 partnerships.

ROSEMAN. KENDLE. The biggest advantage of a strategic partnership model is the familiarity gained when working with a limited number of partners. Understanding the strengths and weaknesses of partners can be helpful in a number of ways. This can help determine which programs to outsource to which partners. Most pharmaceutical groups choose to go with two to four partners, but this varies depending upon the sponsor. Working with a limited number of partners, there is the advantage of being able to develop and then track metrics around the key performance indicators and over a longer period of time.

Where Relationships Break Down

1. Differences in expectations, lack of governance, lack of trust, and management change can all lead to a breakdown.
2. A focus solely on price can lead to an unhealthy partnership.
3. CROs need to position themselves as thought leaders that can provide expertise when problems arise.

PANAS. SUCAMPO. Communication is where partnerships break down. When there is a lack of communication between the sponsor and the CRO or the CRO to the sponsor, vital information gets lost and the confidence in the team goes away. Another area where the partnership breaks down has to do with the actual contract. Change orders seem to be one of those areas that can doom a program. If every time a sponsor asks a question and is told that's a change order, then the organization starts to believe the CRO is more interested in the contract and the revenue stream than the relationship with us.

TERRY. APTUIT. People on either side of the equation often go for a short-term win. CROs too often win work by quoting a basic job and changing the scope on a regular basis and that just erodes trust on both sides.

REMNANT. DELOITTE. The most obvious reason relationships break down is differences in expectations around what the partnership is trying to achieve and a lack of proper governance structures to oversee the realization of these expectations. There has to be a shared set of outcomes that both organizations subscribe to, and these need to be articulated at a good level of detail. In terms of the governance structure, there has to be a document in place that protects both organizations' investment in the partnership. Additionally, there needs to be a change management understanding on both sides of the relationship in order to get the best results from the partnership — where the whole is greater than the sum of the parts.

ROSEMAN. KENDLE. Everybody talks about expectations and having the right set of expectations properly set. There is a lot of truth to this. But I believe the biggest break down results from a lack of trust and a failure on both sides to care about the interest of the other party. On the sponsor side, it's in the company's best interest to have strong partners, which means basing the relationship on more than price. As in other industries where the sponsor or the buyer is only focused on price, often suppliers are driven to the very brink of going under. A partnership has to allow both suppliers and sponsors to flourish.



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SOUND BITES FROM THE FIELD ▶

PharmaVOICE asked industry suppliers to address what needs to happen for the CRO/sponsor partnership to be a success and what other players in the drug development process have to do to ensure successful partnerships.

EDWARD J. BRENNAN, M.D., is President and CEO, IndiPharm Inc., a clinical research organization (CRO) providing the full range of clinical trial services. For more information, visit indipharm.com.

“As more studies move offshore, such as to Asia, it is essential that the CRO/sponsor partnership has robust and open communications, a complete and intimate understanding and respect from a cultural standpoint, and an expert understanding of the regulatory landscapes both locally and globally. Not only must CROs possess operational excellence and a strong cultural understanding in the countries where they operate, but there must be direct lines of communication, ideally in the same time zone as the sponsor. Sponsors need to be in touch with their data continuously and it is up to the CRO to make certain even the most distant countries are connected real time. Bringing seamless communications together with strong operations and in-country expertise helps ensure a successful partnership.”



GRAHAM BUNN is VP, Partnerships and Alliances, Medidata Solutions, a global provider of SaaS-based clinical development solutions. For more information, visit mdsol.com.

“There are many players involved in the drug development process alongside CROs and sponsors, and a theme worth exploring is moving away from today’s typical tactical customer-vendor relationship. A new model of a more strategic partner-centric relationship would enable organizations to break down the operational and organizational silos in traditional, tactical outsourcing. Technology can have a significant and, to date underutilized, role to play in facilitating this shift.

With the potential for an increasing volume of more strategically oriented business going through the CRO outsourcing channel, the role of clinical technology providers may be set to change. It is still imperative that providers continue to deliver technology that enables the industry to create innovative, game-changing solutions. But this alone will not be enough. Along with great technical functionality there is an increasing need for solutions that also provide teamwork tools that enable the sponsor and the CRO to together deliver added value, innovation, and improved healthcare.”



KRISTAN GALLITANO is VP of Data Management Solutions at eClinical Solutions, a division of Eliassen Group, and a clinical data management consulting firm. For more information, visit eclinicalsol.com.

“For sponsors, the truly valued CROs are the ones that go beyond just serving as tactical arms and legs to help conduct trials; they also understand the strategic goal of the data being collected. By supporting sponsors’ short- and long-term clinical development plans and offering specialty expertise — whether it be in a therapeutic area, data management, clinical technology, etc. — CROs will become a valued resource and a natural extension of a sponsor’s clinical development team.

Sponsors are going to continue to rely on a growing number of vendors to support different areas of the clinical development process — from EDC to IVRS to central labs to drug packaging. While the lines between CROs and technology vendors continue to become blurred, both need to be one step ahead of the sponsor when it comes to not just implementing technology solutions, but adjusting the SOPs/workflow around those solutions. Each vendor needs to understand the make up of each individual project team and agree on who will be responsible for oversight of each vendor and the impact that shared responsibilities have on the trial. In addition, similar to CRO/sponsor partnerships, CROs and vendors need to establish trust to ensure that they are working together toward a successful clinical trial, not just one piece of the trial.”



RANDY KEHRMEYER is President of Kforce Clinical Research, a professional staffing and solutions firm. For more information, visit kforce.com.

“For a sponsor partnership with an FSP or CRO to be successful, the relationship should be embedded within the sponsor organization. When this occurs, the partner can be truly aligned with the sponsor’s goals, enabling it to contribute to, participate in, and evolve with the sponsor’s progress over time. With this strategic alignment, communications are more effective and efficiencies are increased through consistent processes and greater connectivity of common platforms. The most successful partnerships involve selecting a provider that is best

in class by function. This is not about being a jack of all trades. Sponsors should search for partners with unique capabilities within specific functional areas that will provide them with the benefit of niche expertise based on years of proven experience. This higher level of expertise positions niche providers to be more consultative and strategic in the relationship to deliver greater value to their sponsor partners.”



JF MARIER, PH.D., is VP and Lead Scientist, at Pharsight, a Certara company, a provider of software products and scientific consulting services to facilitate improved productivity and strategic decision making in drug development. For more information, visit pharsight.com.

“A trend for many sponsors in clinical development is the use of multiple partners to run clinical studies, collect patient data, and perform biostatistical and pharmacokinetic/pharmacodynamic (PK/PD) analysis. One challenge resulting from this network of partners is the management and oversight of complex PK/PD studies that lack standardization. Web-based technologies that securely store clinical study data should increasingly be used to serve as a central on-demand hub to tie global team members together.

Using PK/PD repositories, studies can be exported in CDISC format for regulatory submission. These repositories ensure that study data, analysis, and models are stored in a secure transaction-ready state for due-diligence, out-licensing, and M&A activity. This is important for small and specialty biotech/pharma sponsors that need to add value to their portfolios. Using PK/PD repositories can also simplify the many data management tasks required to create pooled, multi-study analyses and prepare pharmacometric models, which FDA increasingly expects sponsors to have in place early in development.”



MICHAEL SOENEN is President and CEO, ClearTrial, a provider of clinical trial operations (CTO) software. For more information, visit cleartrial.com.

“There needs to be transparency on both sides. There also needs to be visibility around how project work will be performed, the effort required, and fair profit. All of which breeds the trust that is the cornerstone to any successful partnership.”

DIETLIN. INC RESEARCH. Sponsor-CRO partnerships break down because too few sponsors view CROs as a resource to drive true economic benefit. And CROs don't do a good job of positioning themselves in this way to their customers. Sponsors largely view CROs only as an operational resource to help them execute operational activities so they don't have to carry the fixed cost. This type of relationship lends itself to both sides managing on cost and to very detailed activity grids. Strategic partnerships don't just don't fall out of the sky. They are created over time, and trust and transparency are built up over time. We have a greater chance of being successful and creating that trust and transparency if we begin the relationship from that footing rather than a footing of highly tactical micromanagement on both sides. CROs need to do a better job of sharing thoughts and ideas with sponsors and being thought leaders for clients rather than being in a constant sell mode. If CROs are viewed as thought leaders and strategic thinkers and can have those conversations at senior levels, the work will come. If a sponsor thinks of a CRO as a resource that can help them increase the value of an asset or the value of the company, then I think the relationship changes. We've established a risk-sharing program that incentivizes both parties and we think this economic value is a benefit; partnerships like these can impact stock prices of public companies as well as the valuation of private companies.

SMINK. CHILTERN. Pharma companies and CROs are still inward focused and need to look for true cooperation beyond their own companies. In a strategic outsourcing model, this focus would change by moving to a partnership view that is applicable on numerous levels.

PANAS. SUCAMPO. It's important that we can trust the CRO and trust the information it is presenting to us is accurate, and that we are working as a team. When it comes to issues or concerns, it's always helpful if the CRO provides proposed solutions, which we can either approve or modify as appropriate.

GOLDBERG. PAREXEL. The keys to delivering

and ensuring that partnerships don't break down is focusing on quality and ensuring that CROs bring best practices to the table. There has to be a total commitment by the CRO that quality is first and foremost. It can't be sacrificed. There also has to be a philosophy of working together over the long term. Both parties have to be committed to continuous improvement, learning together, and taking those learnings to create a better partnership.

Making Partnerships Successful

1. Sponsors need an outsourcing strategy that goes beyond procurement.
2. CROs have to have a deeper understanding of the needs of customers, making it easy for sponsors to do business with them.
3. Both CROs and sponsors need to look at processes to make sure they are constructed in a way that makes working together as efficient as possible, taking advantage of technology and other tools that are available.

TERRY. APTUIT. Companies need an outsourcing strategy and a structure to manage the partnership. The most successful partnerships are those when a senior level person on the sponsor side is tasked with overseeing the relationship. It is strange that R&D services are being procured in the same way that chairs or pens are purchased. Companies need to reduce their focus on price and look at the value of the whole partnership. Procurement people generally spend far too much time on price discussions than on value discussions. Most R&D professionals probably significantly underestimate what it costs to do drug development in their own organization because so many of the support costs are not visible for quality, project management, IT, and finance.

REMNANT. DELOITTE. Partnership is a ubiquitous term and, therefore, is open to a huge amount of interpretation. A partnership requires distilling down what each party means by partnership and being open and honest.

AURENTZ. QUINTILES. There has to be a much deeper understanding in the case of CROs about what customers are looking for, what's critical to them, and identifying options where they can make the decision. We have to make it easier for customers to do business with us and that hasn't always been the case. Some of this is predicated on a model that has had a lot of steps put on top of processes over time. We have to get back to the basics.

DIETLIN. INC RESEARCH. No two of our alliance relationships are the same. They all have similar components but the deal or the structure is tailored for every situation. In some we have a discounting structure that escalates as the sponsor does more work with us and that drives the economic incentive. In others, we have a value-based delivery model where there is an incentive for both companies to meet specific milestones and there are penalties to the CRO if they aren't met. There are different ways to incentivize and share risk. From an operating standpoint, we've changed our own internal resourcing models and processes to support these relationships.

GOLDBERG. PAREXEL. We made a huge investment in an initiative called LEAP, which stands for Leveraging Expertise And Process. We took a look in the mirror and asked what does our organization need to be to meet the needs of our partners going forward. We recognized a while ago that the industry was making a transition from what was historically an activities-based relationship between the sponsor and the CRO to one that is increasingly outcomes based. In doing that, we had to take more ownership and accountability and provide more leadership. We also redefined our roles and responsibilities, reset our competency models, and evaluated our people against those new competencies models to ensure that we have the right organization to deliver on these partnerships. ^{PV}



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Challenges for *Creating* Strategic Partnerships

The outsourcing model that has evolved over time has become very complex, leading to micromanagement on both sides of the partnership. This complex model has created many connections between sponsors and service providers, but in this environment connectivity can be lost.

There are more than 2,900 medicines in clinical trials or awaiting review by the Food and Drug Administration in the United States, compared with 2,400 in 2005, according to the Pharmaceutical Research and Manufacturers of America.

With growing pipelines and pressure on internal development, pharmaceutical companies have turned to contract research organizations for development capacity. And while our experts say strategic relationships with providers can maximize value there are challenges for creating such partnerships.

“Over time, we’ve tried to apply processes on top of processes and what we have now is a very complex model,” says Vince Aurentz, head of customer solutions at Quintiles. “It should be simple to align objectives for the service provider and the company paying for that service. But if one were to look through a basic contract, the alignment based on the value that the customer is looking for is not there.”

He says this is because both sides have a lot of administration processes, which makes it very

difficult to get back to that core element of what a CRO is asked to perform.

Tim Dietlin, VP of alliance development at INC Research, says both CROs and pharma sponsors are operating too much at an operational level.

“This is a generalization of course, but for the most part, senior-level individuals at the sponsor need to be involved when deciding how to engage with a CRO, especially from the standpoint of the value that’s being created versus just the dollars being spent, and that may change their approach,” he says. “The strategic relationships need to be sold and managed at a much more senior level within both organizations so the conversation is different.”

Gene Wright, senior VP, clinical development at Zalicus, says his company has a virtual development group where they outsource the conduct of many aspects of clinical studies. But Zalicus uses a functional outsourcing approach.

“We do not outsource all of our activities to one or two large CROs,” he says. “Instead, we work with smaller suppliers, consultants, and CROs to handle different aspects of the project.

For instance we work with one company for biostatistics and data management, we use another for medical writing, and we work with another for our regulatory needs.”

Dr. Wright says the company plans to continue with this model.

“A strategic partnership entails a long-term commitment, which could get complicated if there was a need to change CROs, for example,” he says. “There should be a provision in the contract regarding performance metrics.”

Colin Terry, executive VP, commercial operations, at Aptuit, says having a single partner is less risky than having lots of providers. “People talk about having too many eggs in one basket,” he says. “But that is the wrong way to look at it. Companies need to start to think about creating stronger but fewer partnerships.” **PV**

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GENE WRIGHT. Senior VP, Clinical Development, Zalicus Inc., a biopharma company that discovers and develops novel treatments for patients suffering from pain and immuno-inflammatory diseases. For more information, visit zalicus.com.

Rising Trial Complexity Continues to Vex Drug Developers

Growing clinical trial complexity continues to challenge the ability of pharmaceutical and biotechnology companies to contain the ever-rising cost of developing new drugs, according to a study recently completed by the Tufts Center for the Study of Drug Development.

The study found that the median number of procedures per clinical trial increased by 49% between 2000 and 2003 and 2004 and 2007, while the total effort required to complete those procedures grew by 54%.

Source: Tufts Center for the Study of Drug Development. For more information, visit csdd.tufts.edu.

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