Insights from the C-Suite:

Contract Research Organizations

CRO growth continues to outpace other sectors. Frost & Sullivan estimates that the CRO market earned revenue of $11.43 billion in 2010 and estimates that the sector will top $20.09 billion in 2017.

According to a recent Frost & Sullivan report, the U.S. CRO market bucked the trend amidst the economic downturn to post impressive growth rates of 8.5% in 2009. The slowdown in funding for early-stage projects has, no doubt, dampened the market's prospects for the next three years to four years, but this lack of funding also has restricted companies from investing in in-house clinical trials, creating opportunities for CROs. Market participants are optimistic about continued growth due to the interest shown by new sponsors, especially biotechnology and specialty pharmaceutical companies, which are demanding full services — from the preclinical to post-commercialization stages.

Despite the existence of CROs for more than two decades, the penetration rate of outsourcing, as a percentage of the total R&D spending, is less than 25%, Frost analysts say. Therefore, there is great potential for CROs to grow through just expansion.

Meanwhile, as trials continue to become increasingly complex and global, the competition for access to patients, new investigators, and fresh studies has started heating up. The gap between patient access and studies has been rising consistently over the past decade and could affect future studies. For studies that depend heavily on emerging markets, this patient access-study gap could lower productivity by lengthening the time for each trial.

According to Tufts CSDD, greater R&D productivity will flow from R&D partnerships, the concentration of internal company resources on fewer, rather than more, disease areas, and improved investigative site management, among other tactics.

WENDEL BARR

CEO


Wendel Barr

Synteract *is a privately held, full-service contract research organization dedicated to meeting the clinical research, technology, and safety needs of biotechnology, medical device, and pharmaceutical companies.*

For more information, visit synteract.com.

Today's successful CRO works to find solutions for its clients to address the challenges of ever-increasing costs, extended timelines, and the growing complexity that characterizes the current clinical research environment. Pipeline productivity is a critical issue because the cost of producing drugs continues to escalate at the same time drug sales are declining due to patent expirations. It is widely accepted that the model of drug development needs to change to more efficiently bring drugs to market, and we see opportunity for CROs to be part of the solution by working collaboratively with pharma/biotech partners throughout the drug development life cycle.

The support of a well-matched CRO partner in providing efficiencies in protocol development, site selection, and data management and reporting, resulting in timely access to actionable data, makes it possible for clients to get to decision points faster.

A recent industry report indicates that more than one third of clinical trials conducted by pharmaceutical companies are now being outsourced. As the trend toward outsourcing continues to escalate, I see continued opportunity for CROs to build trust and confidence with clients by delivering custom solutions on a consistent basis and to help accelerate development and reduce costs.

LARRY BROWNSTEIN

Executive Corporate Development

CRI Lifetree *offers a broad range of Phase I-IV services and rapid access to specific patient populations to meet the requirements of complex clinical research programs.*

For more information, visit crilifetree.com.


Larry Brownstein

The CRO industry continues to see increased demand for competitive pricing, specialized services, and the delivery of reliable results while meeting tight deadlines. But perhaps the most important opportunity/challenge facing the industry is the dramatic increase in the complexity of early-stage clinical research protocols.

We continue to see several key trends that are driving the increase in complexity: heightened safety concerns; compressed timelines; emphasis on longer sequestering and in-patient-like settings; increasing focus of patients vs. healthy volunteers; and translational and combination protocol designs.

As sponsors continue to seek ways to overcome the inherent challenges of early-phase research, they are increasingly seeking partnerships with specialized research organizations that can provide the level of specialization, sophistication, and focus that are required to achieve meaningful results.

To meet today's high-complexity challenges, CROs must provide effective and efficient solutions to complex trial needs, must efficiently recruit appropriate patients for specific therapeutic areas, and must continuously work to bridge the gap between basic science and clinical research in order to provide clean, complete and accurate data.

Although the challenge is significant, recent experience demonstrates that success in this area will help advance the industry in support of progress. In the years ahead, CROs and research service providers alike need to demonstrate access to patients and deep expertise in complex, early stage research to ensure their long-term success. At CRI Lifetree, we are committed to this initiative.

ADAM BUTLER

VP, Client Services

Bracket *is dedicated to helping pharmaceutical sponsors and CROs achieve greater certainty and accurate outcomes in their clinical trials.*

For more information, visit unitedbiosource.com, email adam.butler@bracketglobal.com, or via twitter @AdamJButler.


Adam Butler

The current landscape relies on a large number of stakeholders to successfully bring a new treatment to market. These stakeholders, who include patients, manufacturers, regulators, insurers, and payers, have a diverse set of incentives and processes. This is especially true in global markets. As the process has evolved over the years, there is an increasing number of complexities that all these stakeholders need to navigate. The most prominent recent examples include new and varying regulatory structures and the increasing importance of private and government payers.

As CROs begin to take a more prominent role in the research and development process, it's critical that they are equipped to assist in the navigation of all of these hurdles. Serving as an effective facilitator above and beyond the traditional CRO responsibilities of implementation is an exciting opportunity. Bringing stakeholders together, and helping pharmaceutical companies manage this process, is a critical challenge that we are already seeing the CRO industry embrace.

STEPHEN CUTLER, PH.D.

Group President, Clinical Research Division


Dr. Stephen Cutler

ICON *specializes in the global strategic development, management, and analysis of programs that support clinical development — from compound selection to Phase I-IV clinical studies.*

For more information, visit iconplc.com.

I believe the CRO industry has a number of important challenges that will need to be confronted over the next few years. But probably the one I am most concerned about is the conflict we face between being a service-based industry, which aspires to delight pharma customers by doing things they want us to do vs. being a more proactive, innovative and assertive provider of better, faster, and more efficient processes and solutions to the pharma industry.

We need to make the transition from organizations that reflect and imitate the conservatism and inefficiency of our pharma customers to being the acknowledged and established experts in the execution-orientated aspects of drug development. If the CRO industry continues to unimaginatively serve — and reflect — pharma rather than taking a more creative, risk-based and technology-focused approach to developing new drugs more cost-effectively and efficiently we will not realize the potential our industry currently has to dramatically grow the clinical spend that is currently outsourced. This is not an easy transition and it will take courage and conviction from leaders within both the pharma and CRO industries, and failing to make this move within the next few years will condemn CROs to being commodity providers that perpetuate inefficiencies and are stuck in yesterday's model; the Googles, IBMs, and Tatas of this world would welcome that.

ROBERT EPSTEIN, M.D.

President


Dr. Robert Epstein

United BioSource Corporation *is a global scientific and medical affairs organization in more than 25 countries across the globe dedicated to meeting the needs of life-science companies by providing real-world evidence.*

For more information, visit unitedbiosource.com.

There are many challenges for those of us supporting the biopharmaceutical industry in 2012. One of the chief issues for all of us is the recruitment and retention of top talent in the science and technology areas because the needs of the industry continue to drive continued outsourcing of expertise. As the science of drug and biologic development evolves beyond biotechnology into newer areas like biosimilars, pharmacogenomics, epigenetics, and stem cell research, very specific advanced expertise is needed within our industry to help bring these technologies to the marketplace.

Additionally, the ongoing need to recruit patients outside the United States and European Union suggests that emerging markets in particular will continue to be important geographical considerations for research in the foreseeable future. The economics of drug development necessitate us to be better, faster, and more cost-effective partners, and we will need to continually seek to harness technology to improve study precision while lowering costs. And finally, the increasingly vocal stakeholder known as the payer, and the articulation of their evidentiary requirements, is becoming a greater consideration for study design and communication of results.

Having worked in healthcare for more than 30 years, I can absolutely say that the rate of change in scientific methodology, policy, regulation technology and reimbursement is unprecedented at this moment. Our industry will need to keep pace in order to help guide those attempting to innovate in this seatide of change.

KEVIN J. GOUDREAU

VP, Commercial Development


Kevin Goudreau

DaVita Clinical Research *is committed to advancing the knowledge and practice of kidney care.*

For more information, visit davitaclinicalresearch.com.

The biggest opportunity — and challenge — facing CROs today is to become more than just the research hands of biopharma manufacturers. Instead, they must become contributing parts of the research brain of each client.

In biopharma's blockbuster days, contract research was widely commoditized. While a CRO's output had to be accurate and timely, its role and processes were relatively undifferentiated across therapeutic categories. In most cases, disease- and category-specific expertise resided largely with the manufacturer.

Today, however, the traditional mass-market approach is giving way to more specialized needs and more specialized processes. Medco's 2011 Drug Trend Report projects that roughly 40% of the approximately 150 products expected to be approved over the next few years will be specialty products. Another 17% will be either monoclonal antibodies or therapeutic proteins. To be successful, today's CRO must deliver a new level of expertise for specialty brands and across all layers of contract research. Becoming part of the client's brain is crucial.

To meet the increasing demands for sophistication and knowledge, CROs must accomplish three tasks: create a specialized identity, build a world-class team, and develop deep patient access.

Gone are the days when one CRO could provide all research to all brands. Today's biopharma manufacturer is looking for a CRO that has specialized skills in the client's therapeutic category. Each CRO must identify its specific expertise (e.g., neurologic disorders) and become the go-to provider in that category.

Within its specialty, each CRO must build a network of investigators and clinicians that matches or exceeds that of its clients. The team must be so strong that clients will trust the CRO to participate fully in all aspects and phases of the research plan.

Going forward, successful CROs must be able to provide clients with ready access to a deep pool of relevant patients.

JAMES OGLE

CEO


James Ogle

INC Research *is a therapeutically focused clinical research organization with a high-performance reputation for conducting global clinical development programs of the highest integrity.*

For more information, visit increasearch.com or follow at @inc_research.

The CRO industry is experiencing a significant shift away from project-specific outsourcing relationships to more multi-year strategic alliances and innovation partnerships with biopharmaceutical companies. This shift is providing opportunities for CROs to not only offer more of their input, but also to focus more deeply on the commercial and regulatory viability of compounds much earlier in the drug development life cycle.

Our experience in quickly developing and adopting game-changing advances in digital and scientific technologies enables us to play a more critical role in helping sponsor companies stay competitive.

Biopharmaceutical companies can benefit from the innovations developed by CROs to create greater efficiencies that help bring drugs to market faster. The challenge is learning to be flexible and creative in developing these alliances. CROs must keep the bar high by evolving partnership models with their customers to simultaneously take costs out of the process, while spawning innovation in clinical development.

A new breed of pharmaceutical investors entering the market poses another opportunity for CROs, especially when it comes to the funding of R&D. These investors see opportunities in the compounds and therapies that asset holders lack the resources to develop internally, which could lead them to partner with CROs and other outsourcers to develop these compounds and manage risk.

There are also significant opportunities in the area of cost management around global operations. Contract research organizations are often in the best position to track total drug development costs on behalf of pharmaceutical sponsors, as we have better resources to manage and track clinical supplies, central lab, and cold chain management logistics costs.

Pharmaceutical companies are relying on CROs to analyze and manage costs, while protecting their total drug development spend on their behalf.

DAVID UNDERWOOD

CEO and Chairman


David Underwood

Quanticate *is a global biometrics clinical research organization.*

For more information, visit quanticate.com.

With the pharmaceutical industry going through a multifaceted assault on its profitability through increased safety requirements, patent expiries, and limited pipeline there has been an increased focus on determining which activities are core and those that can be outsourced to CROs.

Most large and mid-size pharmaceutical companies have recognized the need to become leaner and more efficient in a short timeline and strategies around reducing internal headcount, using lower cost regions, and outsourcing more tasks have become key. This presents short-term opportunities for CRO and BPO companies with the capabilities and scale to be able to quickly take over entire functions from the pharmaceutical companies.

The challenge for these mega-outsourcing approaches is that the focus on reduced cost can put pressures on the profitability of CROs. The costs associated with transitioning these large initiatives, coupled with the expansion of lower cost regions, recruitment costs, the inability to fully use staff that are on-boarding, and the sometimes limited availability of talent with skills in specific regions can result in challenges that impact the desired outcomes of the partnership.

We are seeing signs that pharmaceutical companies that have changed to a low-cost, full-service strategy are recognizing the importance of CROs that provide specialist experience in particular areas and their role in keeping development quality and costs at optimal levels.

They are seeing that although a full-service outsourcing strategy based around lower cost regions, and removal of internal expertise has lower FTE hourly rates, it can be difficult and costly to manage.

We are also seeing additional opportunities, including a trend toward the centralization and standardization of study data across portfolios, to optimize outcomes and the value of the data and solutions that minimize on-site monitoring of sites.

We are therefore optimistic for the future and that there will be more opportunities for specialist CROs as the outsourcing model evolves.

JOSEF VON RICKENBACH

Chairman and CEO


Joseph von Rickenbach

Parexel International *is a global bio/pharmaceutical services organization that helps clients expedite time-to-market through development and launch services.*

For more information, visit parexel.com.

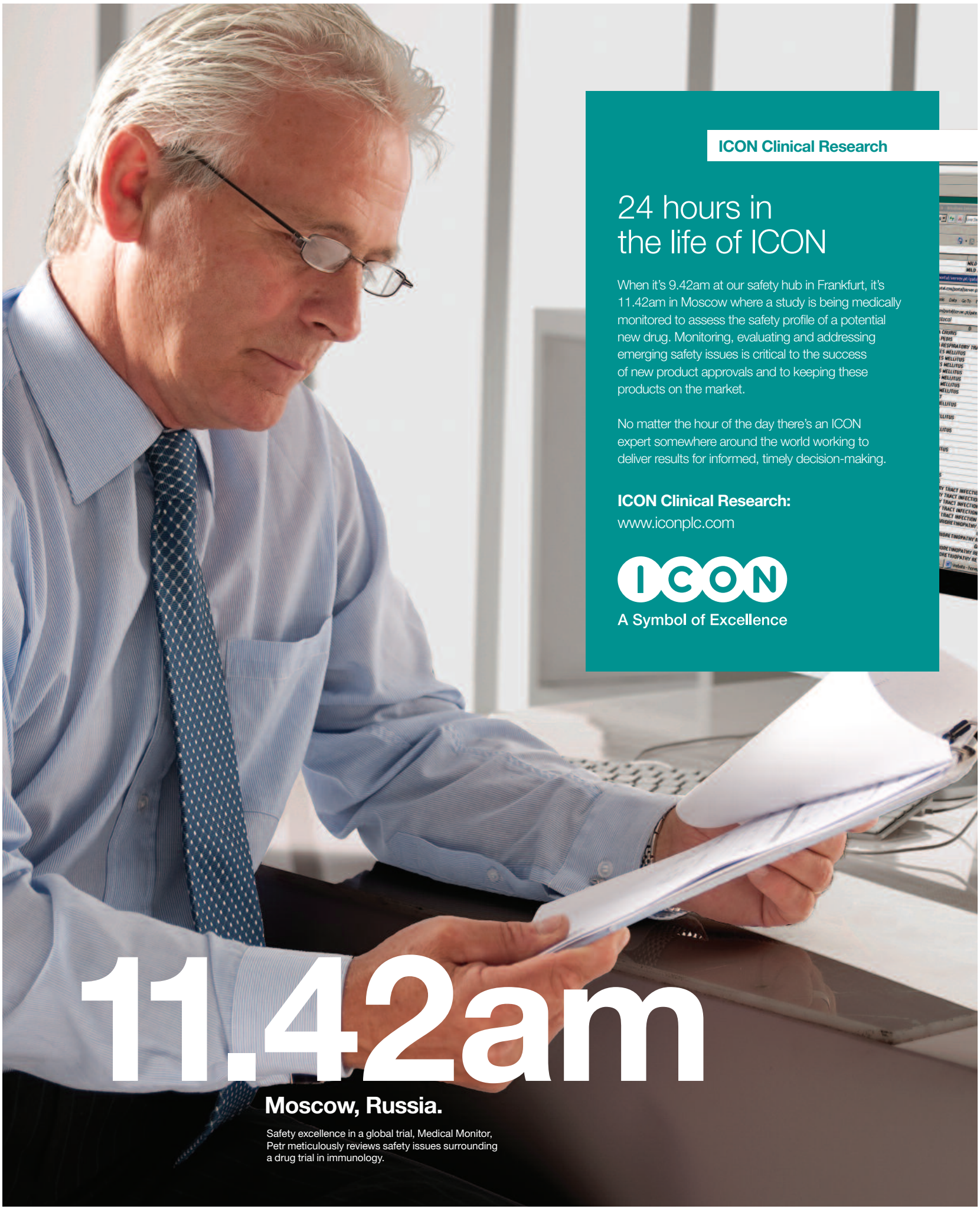
The factors driving future growth in outsourcing relate to unprecedented scientific, competitive, and financial pressures that our biopharma clients are facing today.

Many biopharmaceutical companies are focusing now more on therapies that address specific disease areas. This emerging model depends on moving a larger number of compounds through discovery and clinical development into the market. Larger numbers of compounds demand an R&D strategy focused on core competencies.

We expect that more large-scale, late-stage clinical trials will be turned over to process specialists. This scalable outsourcing has made it possible for biopharmaceutical companies to sponsor trials worldwide, without having to invest in a global clinical infrastructure of their own. Biopharmaceutical companies are increasingly launching their new products simultaneously in multiple regions worldwide as a way to speed up their overall market penetration. The result is a need for global reach and scope to effectively support worldwide clinical research.

As biopharma companies focus less on the clinical trials process, their approach to outsourcing work is becoming more strategic. Strategic partnerships are a better fit for the post-blockbuster R&D paradigm. In strategic relationships, service providers are focused on delivering expertise and capabilities to help their partners improve development effectiveness. That being said, CROs need to continue to be flexible in offering biopharma companies of all sizes a spectrum of proven operating practices and relationship models that can significantly reduce timelines and costs and streamline protocols and programs.

Another key market trend is adoption of information technology. This adoption is driven particularly by the globalization of clinical trials — their growing size and complexity, as well as the pressure for more efficient drug development. Over the past few years we've seen steady growth in demand for domain-specific IT products and services, with the result that today, most trials rely on several e-clinical technologies. PV



ICON Clinical Research

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