INSIDE Research in the New Economy

APPLIED CLINICAL TRIALS

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➤ SURVEY

Salary and Career Development Survey

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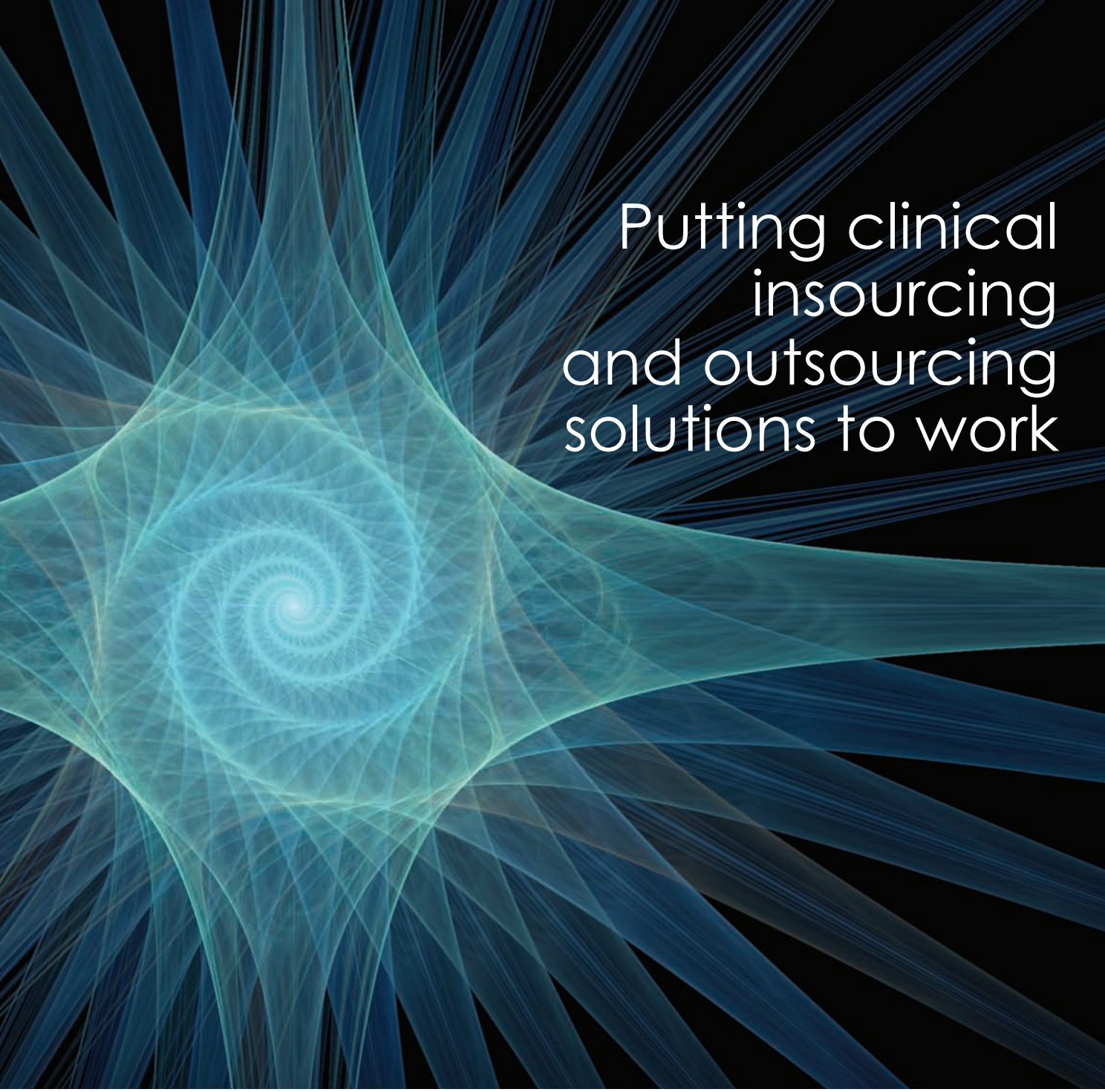

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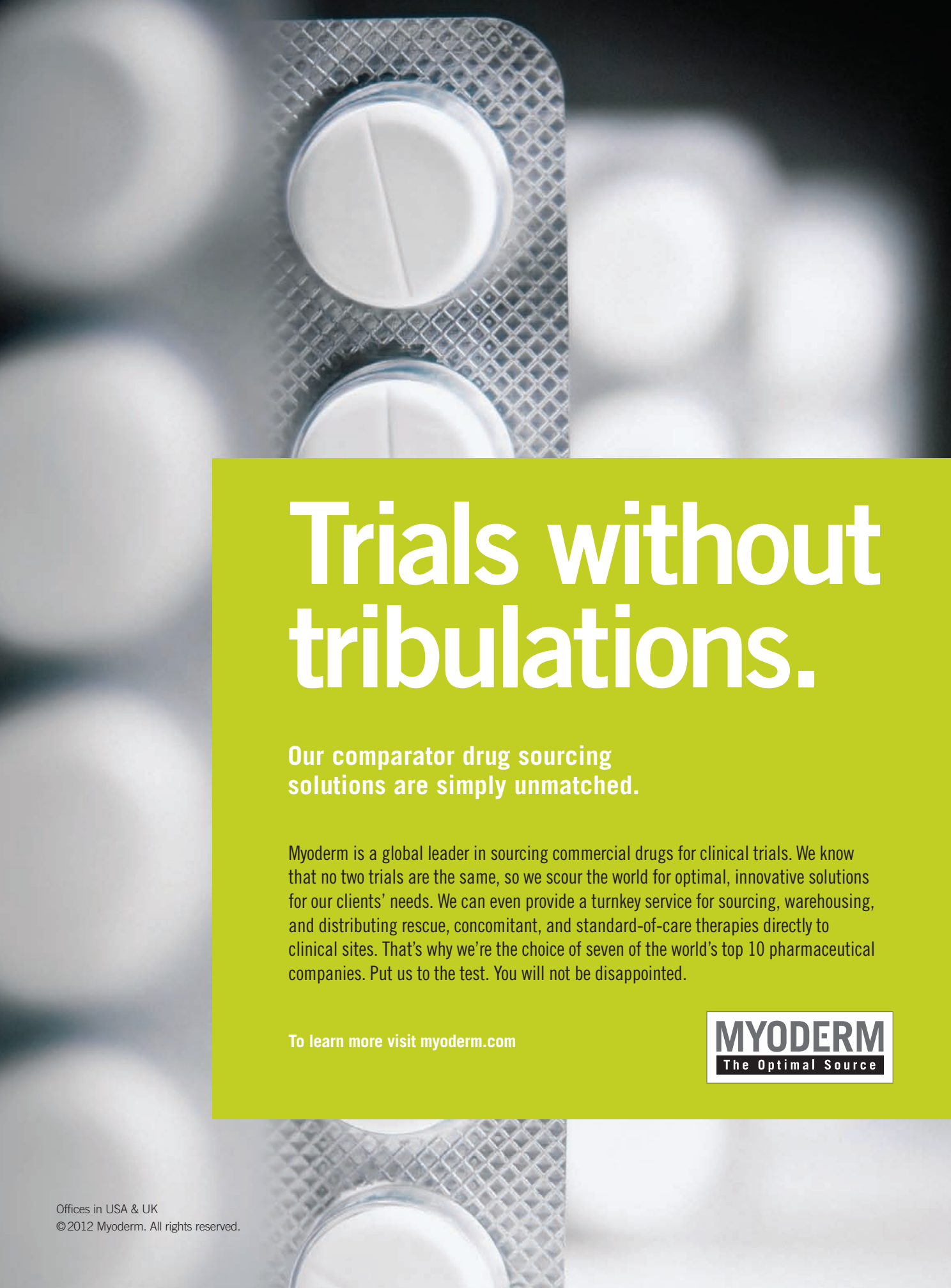

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As many as 30% of subjects in Phase III clinical studies drop out. Grueling schedules, high travel costs, and time waiting for expense reimbursement can all be factors in these fall rates. This can be problematic, delaying or even leading to the cancellation of the trial. It is crucial to keep subjects motivated, and one way is through efficient travel and expense management.

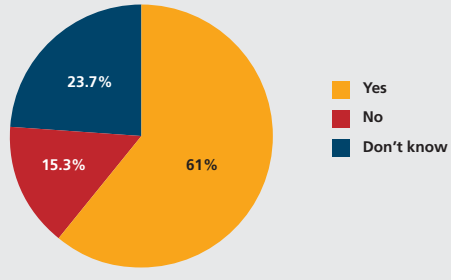
Confidentiality rules and regulations stipulated by regulatory bodies such as the FDA and EMA ensure that a sponsor cannot know specific patient information. This made the arrangements of travel and expense reimbursement for the subjects challenging. The concept was formed 10 years ago on the idea of being the middleman between the investigating site and sponsor. Subjects are given the choice to use and contact the independent, third-party travel service directly. As the service is used by choice and in conjunction with pre-approved travel and expense guidelines, institutional review boards (IRBs), independent ethics committees (IECs), or ethical review boards (ERBs) are satisfied that subjects are not being enticed to use the service.

To make sure that no sensitive information is relayed to the sponsor, codes are assigned for subjects and the study in place of personal information. Travel is then organized on their behalf. The bills go directly to the company, which can then de-identify any sensitive information and charge back to the sponsor.

Franc Jeffrey, *Managing Director, Equilibrium Travel Management*

Editor's Note: The full text of this article is available in the Noteworthy section of our home page.

Are You Currently Integrating Endpoints for Comparative Effectiveness Data into Phase II-III Research?



Source: *Applied Clinical Trials,* Clinical Trial Optimization Survey, August 2012

Comparative Effectiveness

This question was posed as part of our Clinical Trial Optimization Survey to discover if protocols were becoming more complex due to potential post-marketing information needs. With the clear trend toward collecting more patient-reported outcomes data, and adding in comparative effectiveness questions, an impact on protocols can be inferred.

NOTEWORTHY

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And the Winner Is...

Congratulations Martha Kelly, CCRC, Regulatory Coordinator for WellStar Research Institute in Marietta, GA for winning the $100 gift card drawing for participating in our salary survey. The results of the survey appear in this issue, with additional charts online.

Business Process Integration

Go to http://bit.ly/QHXtqD to watch a round-up of CBI's Sponsor/CRO Business Process Integration conference that happened last month. Topics included data sharing best practices; using visualization tools; training CROs to use internal systems; and more.

EDC Autoquery Rate

Phase I-IV data from the Medidata Insights metrics warehouse—comprising of over 2,600 studies from 65 sponsors and 16 therapeutic areas—indicates that autoquery rates (AQR) are directly proportional to data correction rates (DCR). Sites with high AQRs also have high DCRs. See more in the Data Analysis section online.

VIEW FROM WASHINGTON

Administration, Congress Face Challenges in Funding Biomedical Research, FDA Initiatives

The end of the highly acrimonious election campaign has signaled a shift by policy-makers and interest groups to focus on dealing with the so-called government "fiscal cliff:" nearly $500 billion in tax increases and spending cuts are scheduled to kick in January 1, 2013 under an authorized "sequester" process unless Congress acts quickly. With Republicans maintaining tight control over the House of Representatives but losing ground in the Senate, much depends on the ability of President Obama to engineer some kind of fix to the mounting deficit during the year-end "lame duck" Congressional session—or for the White House and Congress to agree on delay and leave major budget decisions and tax reform for next year. Whatever the strategy, the outcome promises to have a major impact on federal funding for the Food and Drug Administration, the National Institutes of Health, and government healthcare programs such as Medicare and Medicaid.

Health policy was a key point of dispute during this past year's political contest, marked by promises of better coverage and warnings of soaring costs by both candidates. The Obama victory ended prospects for wholesale repeal of the Affordable Care Act (ACA) and spurred the Department of Health and Human Services to forge ahead with new rules and policies for establishing insurance exchanges, defining benefits, and expanding Medicaid. Those initiatives require action by the states, which have been reluctant to commit to new programs during a period of political uncertainty, but now face important go/no-go decisions. House Republicans will continue to challenge specific requirements of the health reform program, but key provisions for pharmaceutical companies, such as rebates on drugs for seniors in the Part D coverage gap and authorization for biosimilars, are unlikely to change.

Most important for the development of new drugs and medical products is the promise that Obamacare will provide coverage to some 30 million previously uninsured Americans and, consequently, significantly expand the US market for innovative medical treatments. Although all sides acknowledge the imperative of reducing both public and private outlays for US healthcare, important therapies that can document value for patients are likely to gain coverage from plans and payers.

That said, drug prices and reimbursement are a prime target of cost-cutters, particularly related to outlays for federal government health programs and Medicare drug plans. House Democrats have pressed for added rebates on drugs purchased by Part D plans for low-income "dual eligible" seniors, which could total more than $100 million over 10 years, and policy-makers are considering a range of options for reducing federal spending on prescription drugs and high-cost biologics.

Executives at biopharmaceutical companies are well aware that these tax and spending proposals will shape investment in medical innovation, but also are involved in a campaign by the business community to orchestrate significant reforms in corporate taxation to make US firms more competitive in the global economy. The difficult trade-off for industry leaders is that efforts to avoid looming tax increases and gain fiscal reform would require broad budget cuts that curb government reimbursement for medical products and squeeze resources at federal agencies.

NIH, FDA challenges

The Obama victory offers a degree of stability for FDA, NIH, and federal health programs. It avoids a wholesale change in executive branch leadership, although many top administration officials are likely to move on.

Yet, budget cuts would undermine R&D and regulatory initiatives. FDA could face delays in implementing the FDA Safety & Innovation Act (FDASIA) and its provisions to accelerate approval of new breakthrough therapies and much-needed treatments for infectious diseases and rare conditions. An 8.2% reduction in the FDA budget, as proposed under the budget sequester process, would reduce FDA's 2013 budget by $320 million and prompt the agency to lay off about 1000 employees, according to consultant Steven Grossman. Even without such a severe drop in funding, Grossman fears that the FDA budget will remain vulnerable to pressures to reduce federal spending for some years to come.

Parexel CEO Josef von Rickenbach says he's more worried about funding for NIH than for FDA, which he considers "such a public agency that the administration can't really unfund it without serious consequences." But NIH, von Rickenbach notes, "provides vital support for discovery that is important for small biotech companies." Severe budget reductions could jeopardize its recently expanded translational research programs that promise to spur innovation to fill depleted new drug pipelines.

—Jill Wechsler

INDUSTRY TRENDS

Clinical Research in the New Economy

Since the 2008 financial crisis knocked the global macroeconomic environment off of its feet, clinical research organizations in biopharmaceutical and medical device enterprises faced significant challenges as they entered into a new operational realm. Investors have scrutinized biopharmaceutical and medical device enterprises to operate more efficiently, strategically, and cost effectively in the new economy. Moreover, increasing global competition from generics and a glut of expiring patents have forced many biopharmaceutical and medical device companies to rethink their operational strategies.

Large biopharmaceutical enterprises have divested from existing R&D models, and have paid top dollar to acquire other companies that offered diversified medical product portfolios in their pipelines. For example, in 2009 Pfizer acquired Wyeth for $68 billion, Merck acquired Schering-Plough for $47 billion, and Roche acquired Genentech for $47 billion. In addition, these companies pursued acquisitions in an attempt to mold into the new economic model, which requires cost efficiency, scalability and medical product portfolio diversification on the bottom line, and geographic expansion on the top line. As a result of changes in strategic directions and acquisitions, the biopharmaceutical industry made job cuts in order to consolidate operations. From 2008 to 2010, the pharmaceutical industry laid off over 157,000 employees. While the number of laid off R&D personnel is not confirmed, it is estimated that approximately 8,200 R&D personnel were laid off around that time period, http://onforb.es/UCWZFK.

An unfortunate crux of the outcome of the financial crisis is that remaining staff supported lost resources from job cuts, as labor productivity rose on an annualized rate from 0.6%, 2.9%, and 3.1% from 2008 to 2010, respectively. Others left their organizations to seek further opportunities; in a recent poll, 43% of clinical operations respondents indicated that they left their roles because of too many organizational changes, and 29% needed more challenges in their roles, http://linkd.in/TRoxkk. Complications associated with staff turnover involve the loss of intangible value that is affiliated with the process. A research study discovered that staff turnover, particularly in the services sector, results in the cost of over 150% to 200% of a staff's annual salary, http://bit.ly/QGoIUD, and 500% of a staff's annual salary for highly skilled professionals, http://slidesha.re/fdbe5c. To elaborate, since the nature of clinical trials is highly dynamic, there is a heavy dependence on human skills, which involves specific areas of study expertise, strategic decision-making capabilities, GCP knowledge, and clinical trial business process experience, which attribute toward the cost impact of staff turnover.

While the clinical trial industry relies heavily on human skills, clinical trial technologies and federal regulations have been changing to address industry challenges. Many cloud-based and IT solutions are emerging; these solutions integrate data from a variety of sources and offer enhanced insights and data visualization capabilities in one place. Furthermore, FDA's new guidance on risk-based and centralized monitoring enables clinical trial organizations to practice novel and efficient monitoring methods. The guidance encourages centralized monitors to undergo statistical training, http://1.usa.gov/PU60rc.

With drastic changes in biopharmaceutical and medical device strategic initiatives, reform in federal regulations, and the introduction of novel IT systems, clinical trial personnel need to be prepared to fit into the new clinical trial model.

Changing technologies

In the early-mid 2000s, there was a boom in clinical-IT systems and data collection solutions. While these tools offered management some insights, they were not as effective and comprehensive as today's IT solutions. Today's clinical-IT solutions not only integrate data from multiple sources, but offer breakthrough and customizable visualizations, real-time data, and cost efficient resolutions in order to assist clinical teams with decision-making. Many enterprises are releasing system-based to cloud-based clinical-IT solutions.

Some biopharmaceutical companies have gone as far as fully leveraging IT solutions to implement virtual clinical trials. Pfizer, for instance, conducted the first fully virtual clinical trial "REMOTE" in collaboration with the FDA, where patients were consented electronically, medical products were sent directly to patients' homes, and patients were to conduct virtual doctor visits. This breakthrough trial design and platform seemed to have worked except for lagging subject recruitment activities, which depended on social media, http://bit.ly/SVnNeU. While subject recruitment was deemed unsuccessful by some, Pfizer indicated that they will use this model in future trials.

Albeit clinical-IT innovation is exciting, clinical trial personnel are not yet equipped with the appropriate

skills to analyze and comprehend IT offerings. In sponsor outsourcing, for instance, data visualization and insight misinterpretation can led to suboptimal decisions. As interviews with a clinical project manager indicated, their group misunderstood a data visualization, which identified enrollment under performance at several sites, and the group, subsequently, spent a significant amount of resources on unnecessary activities. The visualization merely suggested that the site was lagging in subject enrollment, and proper interpretation would have led to enriched decision-making.

Strategy reform

With changes in clinical trial analytical technologies and the need to find efficient and cost-effective operating models (as they relate to scalability), come opportunities to outsource many of the clinical trial functions that were previously internalized, such as site payments, data management, biostatistics, PK/PD, and regulatory document/records management functions. From 2009 to 2011, outsourcing expenditures to CROs increased by 6.6%, and in-house R&D expenses associated with internalized clinical operations reduced from 74% to 62% from 2010-2011, http://bit.ly/TIZm5f; this trend is likely to continue in the future. Moreover, some sponsors have formed long-term strategic partnerships with CROs and have integrated their business intelligence/IT capabilities in order to enhance productivity; Roche, for instance, partnered with Quintiles, which recently launched the Infosario platform that offers data integration and visualization solutions. Also, Pfizer formed a strategic partnership with ICON to amplify innovation and reduce operational costs.

While outsourcing has its advantages, the concept presents new challenges for sponsor personnel; outsourcing requires employees to be equipped with advanced skills and capabilities to perform their roles, such as centralized monitoring. Moreover, sponsors have embraced the outsourcing model as well.

Unfortunately many disasters have occurred with the outsourcing model and subsequent reversals to insource due to a lack of advanced employee skill sets. In an interview with a clinical program manager, they mentioned clinical trial quality was unmanageable with its outsourcing model, and that the group resorted to re-insourcing activities, which included site monitoring, resulting in higher costs, duplicative efforts, and lower productivity. This example demonstrates that suddenly changing strategies from outsourcing to insourcing without redesigning outsourced organizational structures to support re-internalization exhibits ruining effects on business productivity and financial sustainability. For sponsors, one of the most important facets in implementing the outsourcing model is to ensure that personnel are properly equipped with skills to operate within this model, including analyzing and interpreting data and overseeing outsourced activities via risk-based and centralized monitoring practices.

New role of clinical operations

Though the outsourcing model is not right for every company, as more enterprises start adopting the model, sponsor clinical operations personnel will need to hold necessary skill sets in order to efficiently oversee and manage CRO clinical trial activities. The new sponsor role is not to conduct day-to-day clinical trial responsibilities, but to be more accountable by making business decisions and enhancing quality management through efficient oversight. Further, with the increasing availability of insights and data visualization solutions, clinical trial personnel will not only need to exhibit clinical research expertise, but also demonstrate statistical, mathematical, business and financial expertise, and strategic decision-making capabilities in order to analyze data, interpret visualizations, and make optimal business decisions to efficiently resolve their dynamic clinical trial situations, accordingly.

While the FDA released detailed guidance on risk-based monitoring, many clinical operations personnel have expressed confusion as to how they are to conduct risk-based monitoring assessments. Part of that bewilderment includes a lack of familiarity with qualitative and quantitative risk assessment techniques. In addition, despite the availability of data integration capabilities, many sponsor IT systems require personnel to perform manual data integrations in order to obtain customized visualizations that fit unprecedented situations. By equipping employees with the appropriate skill sets, clinical operations personnel could fully leverage the benefits of the outsourcing model.

Summary

Clinical trials have entered into a new realm. With scrutinizing investor expectations, the amelioration of IT-system capabilities, the introduction of the outsourcing model, globalization, and changing FDA regulations on risk-based and centralized monitoring, existing clinical personnel need to be equipped with business operational/analytical skill sets, and new recruits must exhibit not only clinical, but analytical/statistical capabilities in order to successfully operate in newly-transformed organizational structures that focus on productivity, scalability, and cost savings.

—Moe Alsumidaie, President and Chief Scientific Officer, Annex Management

GLOBAL NEWS

DIA EuroMeeting Gets Set for 25th Anniversary

The Drug Information Association (DIA) is preparing to celebrate 25 years of training and education provision at its annual EuroMeeting.

The focus of the special anniversary congress, to be held in Amsterdam March 4-6, 2013, will be on better public health protection, greater transparency of processes and the rational use of medicinal products.

The 110 sessions will be divided into pharmacovigilance and regulatory affairs for products and devices, R&D, clinical trials, and other topics. The main presentations will cover implementation of the new pharmacovigilance legislative framework, as well as health technology assessment and the patient's perspective.

"By 2013, the new pharmacovigilance directive will have been in place for almost a year. What still needs to be done or improved upon, and most importantly, are we getting what was initially expected? These are some of the key areas that the professionals attending the meeting will be able to learn about and debate," noted co-chairs Beatriz Vicén Banzo and Peter Bachman, PhD.

"Other important topics to be covered include the falsified medicines directive, the information to patients (what is the status?), the role played by scientific societies as experts, and considerations of an aging population and the potential impact on hospitalizations," they stated.

More than 3,000 people from 50 countries are likely to attend, and there will be over 200 exhibitors. Speakers will come from the European Medicines Agency, the European Commission, the FDA, and other regulatory agencies, and patient organizations will be actively involved.

Source: John Lewis Marshall

After almost 10 years of refurbishment and modernization, the completely renovated Rijksmuseum is due to re-open on April 13, 2013.

The opening session will include a panel discussion on "Public/Private Partnerships: Working Together in the Interest of Patients." Other sessions that are likely to prove popular include those about the latest scientific issues from the European Medicines Agency, GCP hot topics, Japanese regulations, and the new regulations in clinical trials in Turkey.

One of the pre-conference tutorials will concentrate on analysis of safety data from clinical trials, and is designed to provide a basic understanding of the underlying methodology and the current guidelines on safety data. Aspects related to the planning of clinical trials, as well as the problems and pitfalls encountered during the analysis of safety data, will be presented. Some case studies will also be discussed.

Walking city

"Amsterdam is the ultimate 'small big city' and combines all the advantages of a cosmopolitan capital with a compact, easy-to-navigate size which translates into less time spent commuting and more time enjoying what the city has to offer," pointed out Vicén, head of the public affairs and technical department at Bayer Spain, and Bachman, chair of the Coordination Group for Mutual Recognition and Decentralised Procedures. "The city has a rich cultural heritage and 2013 is a year to celebrate important events there."

In addition to the 400-year anniversary of the Canal Ring, next year will see the re-opening of the renovated Rijksmuseum, the 125th anniversary of the Concertgebouw (concert hall) and the Royal Concertgebouw Orchestra, the 225th anniversary of Felix Meritis conference and event center, and the 175th anniversary of Artis Royal Zoo.

The Rijksmuseum will not be fully open during the EuroMeeting itself, but between now and its re-opening on April 13, 2013, the masterpieces of the Dutch Golden Age will be on view in the Philips Wing. From April onward, the Rijksmuseum will be the first major national museum in the world to be open to the public 365 days a year. For more information on the DIA EuroMeeting go to bit.ly/SGL9WS.

—Philip Ward

TRAINING

The GXP Training Guidelines: Raising Standards Through Competence-Based Training

Many industries have training standards such as the automotive sector, the renewable energy industry, and specialist areas such as forklift truck driving. In the field of clinical research, guidelines and regulations such as the ICH Harmonized Tripartite Guideline—Guideline for Good Clinical Practice E6(R1) make very general references to training. "Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s)" (ICH GCP principle 2.8). However there is currently no set of standards for how individuals acquire the ability to perform satisfactorily and demonstrate the required levels of competence.

In response, the International Academy of Clinical Research (IAoCR) set up a taskforce to produce GXP training guidelines. The aim of these guidelines is to share best training practices for anyone involved in the training and development of clinical research professionals. The guidelines are designed for use in any organization no matter what size, both in the non-commercial and commercial sectors.

The guidelines cover the key steps in developing competent individuals, starting with creating a competency framework, through to the assessment of learning and its documentation. The overriding theme of the guidelines is how to use various learning interventions to achieve learner competence. Having competent individuals is vital in clinical research for protecting the rights and well-being of patients and securing verifiable and accurate data. A further benefit is that new treatments for patients can be developed without unnecessary delays or costs due to errors and rework because of incompetence.

Source: Getty Images

The guidelines were designed to share best training practices for anyone involved in the training and development of clinical research professionals.

By using the guidelines, organizations can demonstrate a real investment in their people, which leads to other advantages such as increased staff retention and a sound basis for promotions and succession planning.

The taskforce that created the guidelines was made up of five clinical research professionals from various backgrounds and organizations, and represented Europe, the Americas, and the Indian sub-continent. After some additional input from the IAoCR, the first draft of the guidelines was circulated for consultation to approximately 40 organizations worldwide involved in clinical research and included universities and not-for-profit professional bodies. Following refinement from this initial consultation, a second round of opinion was sought from over 200 individuals working in all sectors of the international clinical research community. The guidelines were finalized and released in mid-November.

The content of the guidelines covers how to:

- Define competencies for job roles
- Conduct a learning needs analysis
- Select trainers
- Design and deliver learning interventions
- Assess the effectiveness of the interventions
- Gather learners' feedback
- Manage the documentation

In addition, there is a set of appendices containing examples, templates, and a reading list for those who want a more in-depth coverage of any of the topics.

Initial reaction has been very positive. The hope is to see universal take-up of the guidelines in developing competent individuals for the benefit of clinical research worldwide.

—Martin Robinson, PhD, Principal Director, International Academy of Clinical Research Ltd

TRAINING

The Case for Universal GCP Education

As commonly defined, Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design and conduct of clinical trials involving humans. The primary objectives of GCP are to protect the safety, rights, and welfare of subjects, and to ensure the credibility of trial data and resulting reports. The need for ethical standards in clinical practice came about in response to instances of data fraud and other scientific misconduct, and as a result of numerous examples of violations of human rights in research such as those committed in the Tuskegee syphilis study where subjects were never told they had syphilis and were never treated for it.

The Food and Drug Administration has had GCP regulations in place since the 1970s and these were expanded in 1997 with the addition of E6 GCP to the Federal Register. E6 GCP states that individuals performing clinical research must be qualified by training and experience (21 CFR 312.53: Selecting Investigators and Monitors; ICH E6 5.18.2: Monitoring; ICH E6 5.5.1: Trial Management Data Handling, Record Keeping), although specific standards of GCP training are not referenced.

Pharmaceutical companies initially responded to E6 GCP by placing more emphasis on implementing GCP training for investigator sites. Basic training was (and is) offered at investigator meetings, but it often includes nothing more than a high-level overview and, because it is often time constrained, it may not include all of the critical elements. There is typically no knowledge check or completion documentation at the end of these sessions, so it may not qualify as GCP certification.

As the need for improved GCP training was recognized, many pharmaceutical companies developed intensive, instructor-led, in-house courses for their clinical operations staff. Although many of these courses included practical application exercises, there was often no knowledge check, so the value was greatly diminished. This is also a costly method of instruction for companies if decentralized staff members are expected to attend in person. For this reason, many companies progressed to web-based programs or other methods of training for both investigational and operational staff. In addition to in-house or web-based instruction, sponsor companies and CROs may use an independent GCP training consultant to implement company-specific GCP training or may send staff to a clinical research, professional society, or commercial training course. Some companies offer only a slide review followed by a knowledge check to document their training.

Current GCP expectations are that principals investigators and subinvestigators are trained in GCP and that this training is documented and tracked. It is expected that sponsors' clinical operations staff members are also trained in GCP, but there are varying requirements for refresher courses, documentation, and tracking. Regulatory agencies may have a reasonable expectation that clinical staff members are GCP-qualified, but currently there is no guidance that specifically defines what topics GCP training should include.

Typically, courses available from professional societies include topics such as the history of GCP, sponsor and investigator responsibilities, informed consent, good documentation practices, safety, essential documents, audits, and inspections. This training is often static and may not cover current issues related to evolving technology, security/confidentiality, corrective and preventative actions (CAPA) and recent agency warning letters. Additionally, there is no defined time frame for refresher training, which can be a valuable component of actually delivering GCP. Ideally, refresher training would provide updates from practical audit and inspection experience such as warning letters as well as new regulations and regulatory guidance.

There are many challenges involved with effective GCP training, not the least of which are adverse effects on sponsor/staff relationships that can occur when staff members are required to complete different GCP courses for multiple sponsors. With time frames for start-up decreasing, ensuring completion of GCP training can be a factor that delays the start of the study.

If GCP training is to keep pace with the ever-changing regulatory environment, a method of standardizing its implementation must be developed that can answer questions such as these:

- Is it acceptable to just offer a GCP course once at the time of onboarding or must refreshers be required?
- Who is responsible for documenting the training and what is the appropriate amount of documentation needed?
- Is it enough to provide a completion date or should participants be tested?
- If they are tested, what is the passing threshold?
- Who is the appropriate audience for GCP training? Should study

continued on page 15

continued from page 14

coordinators, medical writers, data management staff, and people fulfilling other roles involved with clinical trials also be trained?

To solve the inconsistencies in GCP training, a centralized group representing global regulatory agencies and clinical research associations should be charged with designing and implementing a standard GCP course that can be offered to all appropriate individuals across all regions.

A web-based course that includes comprehensive testing and practical application scenarios could work best. All parties would have access to the training 24/7, and the course would be updated as new information becomes available. To make sure GCP training remains effective, a standard interval for retraining would be established and maintained through a central database. Investigator and site staff as well as clinical operations staff would benefit by completing and being certified in a single course that applies to all studies from all sponsors.

A standardized methodology is more efficient on many levels, including cost, scheduling, and time invested in completing the training. The initial cost to develop the standard training may be high in order to satisfy requirements of all countries and regions, but the downstream benefit is incalculable in terms of reduced training time, standardization of knowledge, and credible certification of clinical staff available to all sponsors.

Since its inception in 1990, the ICH has evolved the standards that constitute GCP. The ICH could be the logical international body to take the steps necessary to design and implement a universal GCP training program and a global database of certified clinical personnel.

— Jeanne Green is Senior Director of Clinical Operations and Janice Stack is the Training Director both at ExecuPharm.

DATA ANALYSIS

Optimizing Investigator Fees

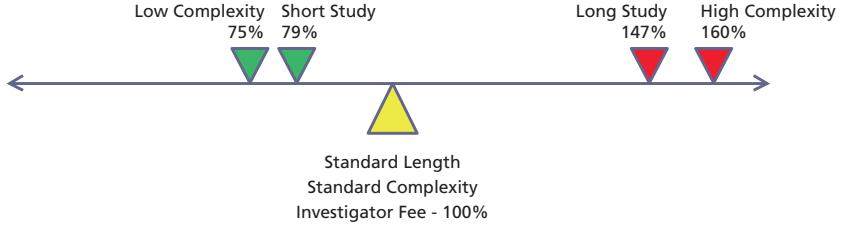
A well documented 2008 study titled "Sensible Approaches for Reducing Clinical Trial Costs," http://ctj.sagepub.com/content/5/1/75.abstract, found that investigator payments account for a staggering 48% of total trial costs. So it goes without saying that sponsors and CROs can't afford to get the investigator payment level wrong. For sponsors and CROs, not paying market-rate investigator fees impacts both the financial health of the organization and the ability to recruit high-performing and experienced sites. Pay too much and your R&D budget evaporates. Pay too little and it will be difficult to recruit experienced sites.

But planners need to know when to offer more and when to offer less. Industry Standard Research has recently published a study that identifies the factors that drive investigator fees higher and lower and benchmarked these fees across 11 therapy areas.

Intuitively it makes sense that study length and complexity would both influence investigator fees. ISR's study quantified just how much. Investigators indicated that both study length and complexity have a dramatic impact on the amount of the investigator fees. For long and/or complex studies, investigator fees can run 50% to 60% higher than for more standard studies.

Knowing what levers push and pull investigator fees—and by how much—will help optimize the use of budgets industry wide and maybe even improve recruitment rates along the way.

—Industry Standard Research, www.ISRreports.com.



Source: ISR Reports

Respondents were asked: Let's assume for a medium length [complexity] study the site receives 100% compensation per patient on average. Please increase or decrease this relative compensation percentage for shorter and longer study lengths [higher and lower complexity studies] to represent how the compensation per patient changes, or doesn't change.

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appliedclinicaltrialsonline.com

Healing Europe's Jobs Disease

Healthcare is seen as one of the most promising sectors to help boost EU employment.

The constant refrain of European politicians is the urgent need to create jobs—no surprise in a continent with high and rising unemployment. Across the European Union, 25 million people were jobless this autumn, and in Spain and Greece there is now a quarter of the working population without jobs.

Inevitably, the search is on for sectors that offer the best hopes of boosting employment—and healthcare is increasingly seen as one of the most promising sectors to examine. The pharmaceutical industry in Europe already sets a fine example. According to figures from its principal European federation, EFPIA, its members employed 660,000 people directly in 2011.

Germany is the largest employer, generating more than 100,000 direct pharma sector jobs, and is closely followed by France, with 97,000. The United Kingdom and Italy come next, each with more than 66,000. And Spain, Switzerland, Poland, and Belgium each provide more than 30,000 jobs. Ireland, Hungary, Romania, and Denmark each generate more than 20,000 as well.

Not only does the sector create direct jobs, but it generated three to four times more employment indirectly—upstream and downstream, says EFPIA. This is attributed largely to its research function, and, EFPIA points out, many of these indirect jobs are of high value, in areas such as clinical science or in academia. The presence of a highly-skilled workforce was one of the key factors in the industry investing €27.5 billion in R&D in Europe last year, it says.

The industry story gets better and better, claims EFPIA. Direct employment has risen to its current level from just over 500,000 in 1990—something like a 35% increase in a decade. And at the same time, the number of direct employees in research has risen too—from 76,000 to 116,000, an even steeper rate of increase.

Wider healthcare sector

Andrzej Rys, the director responsible for health systems in the European Commission (and one of the senior officials behind the proposal to update the clinical trials rules), has been extolling the merits of the healthcare sector as an employer, too. "Health professionals play an important role in the EU economy, accounting for about 17.1 million jobs," he said in a statement in November.

The prospects are good for further employment too, he went on: "With an aging population—the number of people aged 65 and over is projected to almost double over the next 50 years, from 87 million in 2010 to 153 million in 2060—and the rising demand for healthcare, the sector will remain a driver for providing jobs in years to come."

But he underlined the need for greater skills to meet the evolving workforce demand. "The economic crisis has put health systems under pressure to make fundamental reforms in the way they deliver healthcare. New forms of care delivery and new technologies coupled with organizational changes will depend on a highly qualified health workforce equipped with the right skills," he said.

More broadly, the health sector has been specifically recognized as a potential source of employment salvation through healthcare jobs. EU ministers have been promoting the idea energetically, with formal conclusions inviting member states and the commission to support the development of policies on the health workforce. Ministers have shown they are interested in quality as well as quantity. Their focus is on how to assess competence profiles for workers, how to improve planning on the basis of identified health needs, and how to build for the long term. They suggested that the commission should create a platform for cooperation between member states on forecasting health workforce needs and health workforce planning.

As a result, healthcare now appears in the European Commission's strategy for boosting employment across the EU. An "employment package" launched by the commission earlier in 2012 contains recommendations to national governments to coordinate their action on job creation, labor-market reforms, investment in skills, and employment policies and funding. The recommendations aim to provide job seekers with more training and more job opportunities, and to ensure that those in work would get help acquiring the skills they need to stay up-to-date with changing job requirements.

This scheme targets the health sector as a generator of jobs in the longer

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term. An action plan for the EU health workforce sets out actions to support European cooperation to ensure a sustainable health workforce in the EU. The elements include—in line with ministers' urgings—improved workforce planning and forecasting through a dedicated European platform; better anticipation of health professionals' skill needs, through closer collaboration on education, training, and health; and improved recruitment and retention of health professionals by mapping innovative strategies.

Consultation

These reflections on the employment aspect of healthcare have been going on for several years now. Back in 2008, the commission recognized that progress on improving health and providing better access to healthcare for all cannot be made without a workforce of sufficient capacity and skills. Since then, the commission issued a consultation document that sought wide views on how to tackle these issues facing the health workforce in the EU. The paper suggested that the growing shortage of health workers was a central problem for health systems—a point endorsed by most groups and individuals who responded to the consultation, with repeated alerts to inadequate numbers, particularly of specialist doctors and nurses. One of the main messages to emerge was the danger from an unfortunate coincidence: the predicted increase in chronic illness and concomitant demand for healthcare from Europeans' longer life spans are going to occur just as much of the European health workforce is itself approaching retirement age. On current projections, there will be a lack of new health professionals to replace them, it is feared. As health needs multiply and the replacement of health staff is not guaranteed, more universities, training schools and teachers will be needed, and it will also be important to plan which specialized skills will be the most necessary.

Another of the problems highlighted was the lack of data on healthcare employment. Respondents urged the European Commission to promote the collection of better quantitative and qualitative data to support decision-making and improve working conditions, which are seen as a prerequisite for improved recruitment and retention. There was wide consensus that better data are also needed on staff mobility—which can be positive in helping adapt supply to demand, with professionals going where they are most needed, and often enhancing their skills through exposure to other approaches. However, there is a related risk that unfettered mobility can create imbalances and inequalities in terms of availability of health staff.

Thirty five doctors' organizations replied to the public consultation. Among their principal worries were the risk that shifting tasks to nonmedical staff would negatively impact the quality of care and patient safety, and the threat that new technologies—with all their many merits—could impair doctor/patient confidentiality. They urged an update to the minimum training requirements for doctors, to take account of scientific progress and the subsequent evolution of medical training, and they recommended EU-wide recognition for certain professional qualifications, along with better linguistic competence (since the 27 member states of the European Union enjoy 23 official languages, with dozens more regional and minority languages and variants). Doctors also suggested action to raise awareness in schools about career opportunities in the health sector, as well as more vigorous efforts to retain the existing workforce.

As a footnote, as it were, to so much consensus, there was one area where the consultation revealed sharply divided views: the extent to which entrepreneurialism should be encouraged in healthcare provision. Starting from the evident fact that many health workers run their own practices and employ staff, the consultation suggested encouraging more entrepreneurs to enter the health sector in order to improve planning of healthcare provisions and to create new jobs. It even went so far as to recommend removing the barriers to entrepreneurial activity in the health sector. But while many doctors and individuals thought this was an attractive option, entrepreneurship proved to have negative connotations for many others, and fears were expressed that the commission was calling for deregulation of health services, and threatening patient safety.

The commission is still reflecting on the results of the consultation, to see just where and how the EU can contribute to tackling the challenges identified. But by early 2013, some clear proposals are expected. Meanwhile, it has to solve another dilemma—how to ensure that healthcare workers can move around the EU without too much administrative complications over recognizing their qualifications. Five healthcare professions—doctors, dentists, pharmacists, nurses, and midwives—benefit from a special regime of automatic recognition. But the system has been criticized for being too slack by opponents, and too rigid by its supporters. The EU is attempting a compromise for these professions, by proposing to update the minimum training requirement—which were harmonized as long as 30 years ago. A new control is also proposed, requiring national health authorities to alert all other member states if a health professional has been prohibited from exercising his professional activity by a public authority or a court. But every new safeguard to protect the public amounts to a further obstacle to health professionals changing country, limiting that principle so precious to the EU of free movement of workers. Inevitably, therefore, the proposals have run into widespread opposition. ❑

Lisa Henderson

ISTOCKPHOTO/THINKSTOCK

2012 Salary and Career Development Survey

The rocky economy continues to wreak havoc on employment and drug development.

Statistics and headlines don't portray a pretty picture of the economies in Europe or in the United States. Adding in the next layer specific to the clinical research and trials industry, and the picture in the past two years continues to be complex and changing. It is not just one force—the economy—at play. Other aspects include spiking regulatory requirements; increasing global complexities; and the diminishing blockbuster drug model.

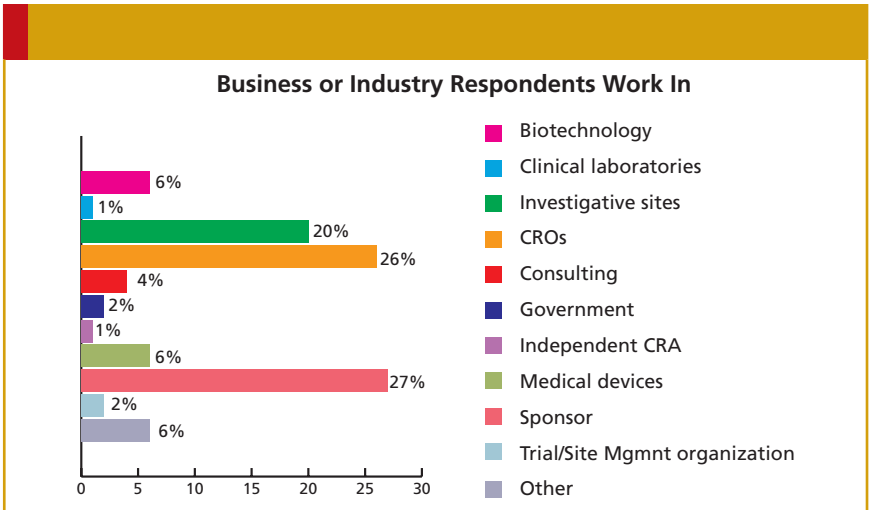
But the economy is certainly applying more than its fair share of pressure onto the conduct of drug development. The other dimensions are the technologies, outsourcing strategies, and mergers and acquisitions that have resulted from the downward forces.

Annual job losses in the overall pharmaceutical industry in November 2011 were 20,000, which were significantly lower than the cuts posted from 2010's 50,000 number. The pharmaceutical industry ranked sixth on the 2010 list of annual job-cut rankings, below government, financial, retailing, aerospace/defense, and healthcare.

For the time period January 2011 to July 2011, the pharmaceutical industry shed 18,264 jobs and for the same period this year 8,968. And while the reasons for job cuts were not cited by individual industries in the early August Challenger, Gray & Christmas jobs report, the top five reasons for job-cutting across industries are: restructuring, closing, cost-cutting, economic conditions, and loss of contract.

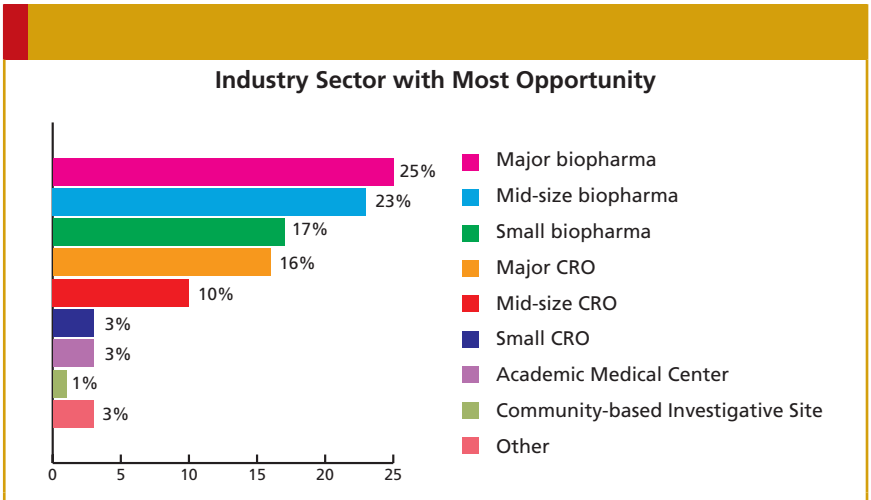
However, while job cuts may be leveling off in the pharmaceutical industry, planned hiring is not in the cards. In the jobs report, for industries planning to hire, pharmaceuticals were in the bottom three. In fact, in another report, earlier this year, smaller to mid-size biotech companies were the ones more likely to predict growth versus one-third of larger companies. In an Aon Hewitt report, less than 5% of the small- to mid-sized biopharma companies expected their staffing to decrease, compared to 15% of the larger sponsors.

With all of the downsizings, and seemingly less or non-growing staff to handle the workload, the larger pharmaceutical companies are tasked with merging internal capacities, weeding out redundant departments and positions, and figuring out what to do with the capabilities in which they will no longer invest. Among these companies, outsourcing is the key to getting work done.



Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 1.



Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 2.

In a January 2012 Annual Global CEO Survey from PriceWaterhouseCoopers, it found that 43% of biopharma CEOs had outsourced a business process function in 2011. This compares with all other industries, where CEOs reported 35% to the outsourced business function question.

In a survey that *Applied Clinical Trials* conducted in August, results found the following top three outsourced functions: full-service CRO, 41.3%; monitoring, 21.7%; and subject recruitment, 13%.

All of this outsourcing activity translates into additional downstream trends. The first is the ability of both the sponsor and its outsourced partner to effectively manage the outsourced relationships. And second, is that it could mean a boon of sorts to contract research organizations.

Both trends come to light in separate surveys. The first we conducted in August, where we asked: "Has your need to provide oversight of these sourcing relationships changed over the last two years?" The responses were weighted toward a definite increase at 62%.

And the second trend, what it means to CROs, the Salary and Career Development Survey conducted in September and October by CenterWatch and *Applied Clinical Trials* found that respondents working for CROs were significantly more likely to see a positive change in the economy compared to sponsors or investigative site respondents.

In his September 2012 column, Ken Getz offered a more targeted analysis of the CRO market size in the United States. From Tufts CSDD data, it surmised a total of 21,000 US jobs in the clinical research segment; 643 total companies, and the total share of US personnel comprises 13% worldwide. Its analysis, which includes regulatory services, has the clinical research market valued at $6.5 to $8 billion. Approximately 17% of the companies providing these services are publicly traded.

In other reports, the forecasts are for growth in global CRO market size and penetration. Business Insights forecasts the market to be $35 billion next year, and Frost & Sullivan anticipates Compound Annual Growth Rate of 10.5% through 2017. William Blair & Co. expects the current outsourcing penetration rate to increase by a few percentage points over the next year or two, and CRO management commentary suggests that over the next five to seven years the outsourcing penetration percentage could increase to more than 60%. Its model currently anticipates a 10% increase in penetration from 2010 through 2015. What this all means is that pharma is relying on CROs and service providers more than ever in its clinical research.

Methodology

Applied Clinical Trials has conducted the Salary and Career Development Surveys on a biannual basis since 2006.

Majority Respondent Profile
Employed Full-Time
By a Pharma Sponsor
As a Manager or Project Manager
With 14.5 Years Experience
And 7 years with Their Current Company

Table 1.

Salary	Wave II	
Position	**Median Salary 2010**	**Median Salary 2011**
Project Manager	$ 88,620	$ 94,191
Manager	$ 96,716	$ 98,000
Clinical Research Coordinator	$ 50,800	$ 51,750
Medical/Clinical Operations Director	$ 150,000	$ 166,000
Clinical Research Associate	$ 74,750	$ 81,000
Associate Director	$ 129,000	$ 138,000
Quality Assurance/Quality Control Officer	$ 90,000	$ 95,778
Scientist/Researcher	$ 64,241	$ 69,660
Vice President	$ 184,000	$ 195,025
Business Development/Operations	$ 99,590	$ 103,200
Data Manager/Clinical Data Specialist	$ 67,500	$ 69,500
Independent Contractor	$ 109,500	$ 92,500
Chief Executive Officer	$ 170,000	$ 180,000
Biostatistician	$ 112,136	$ 106,879
Sales	$ 112,000	$ 125,000
Analyst	$ 95,000	$ 97,000

Source: Applied Clinical Trials/CenterWatch Salary and Career Survey, 2012

Table 2.

For our surveys in 2010 and 2012, we partnered with CenterWatch to develop the questionnaire and analysis of the data. Their own report from this shared data will be published in their January/February 2013 issue.

The 2012 Salary and Career Development Survey was conducted during the months of September and October 2012. The survey was conducted online and was e-mailed to a broad range of clinical research professionals worldwide (Figure 1). A total of 1,068 professionals responded to the survey. Close to three quarters of responses originated from the United States and the majority of the sample was employed full-time. A third of the survey respondents possessed a bachelor's degree as their highest level of education completed and over half of the sample had some type of advanced degree, indicating a highly educated group overall. Survey respondents averaged 15 years of experience in their profession and averaged seven years with their current employer (Table 1). The survey instrument contained a variety of questions relating to job satisfaction, job security, career direction, challenges in the work environment, and the economy's impact on careers and the clinical research industry in general.

According to the CenterWatch research analyst conducting the past two surveys, the 2012 results were largely very similar to the 2010 survey—the sample composition was generally the same as the last survey in terms of industry/type of business/years experience and tenure at current company. The following differences will be highlighted in this article:

- Salary
- Job security
- Global trial challenges
- The economy

Salary

Overall, salaries have increased from 2010 to 2011. The proportion of respondents who received supplemental income this past year is the same as in the past survey.

Table 2 and Table 3 show the positions for which we surveyed, along with the increases between the two years. Also, we surveyed changes by industry sector, illustrated in Figure 3. All in all, there were increases to median salaries even with the negative economic news. For US regions, the largest gainer was the Northwest, followed by the Midwest, Northeast, Southwest and the Southeast, where median salaries remained static.

Job security

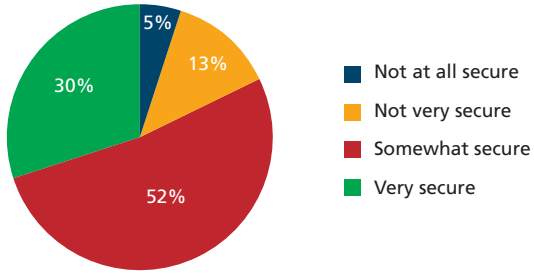
With the losses and downsizings reported for the last three years, we asked respondents how secure they felt about their current position. Respondents in this year's survey were more optimistic about job security compared to two years ago. A significantly higher proportion of respondents perceived their job security to have improved

Sector	Median Salary 2010	Median Salary 2011
Biotechnology	$ 96,000	$ 101,653
Clinical laboratories	$ 91,500	$ 92,500
Clinical Study/Investigative Site	$ 58,000	$ 60,000
CRO	$ 98,000	$ 100,000
Drug Dev./Clinical Trials Consultant	$ 96,425	$ 82,000
Government	$ 79,000	$ 79,000
Medical Devices	$ 104,700	$ 108,771
Pharmaceutical sponsor/biopharmaceutical/ biologics	$ 110,500	$ 117,922
Trial/Site management organization	$ 75,000	$ 78,000

Source: Applied Clinical Trials/CenterWatch Salary and Career Survey, 2012

Table 3.

How Secure Do You Feel Your Job is With Your Current Employer?



Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 3.

compared to two years ago (Figure 3). Once again, as with the overall economic view, when looking at the results by industry, respondents working for CROs were significantly more likely to respond that they were very secure in their current jobs.

For this response the changes between 2010 to 2012 were non-existent. But, when asked about job security compared to three years ago with clinical research professionals in general, all respondents noted an uptick in the positive side of the spectrum.

By industry, 42% of CRO respondents felt very secure with their current employer, versus 31% of site respondents and 18% of sponsors. These numbers improved greatly when checking the "somewhat secure" rating to 46% for CROs, 55% for sites, and 60% for sponsors.

When asked about the security for clinical research professionals for the past two years, the same industry sectors reported significantly increased to 44% of CRO respondents; 35% for investigative sites; and 46% for sponsors.

Global trial challenges

There is no mistaking that clinical trials have gone global, with no signs of turning back. While the current distribution of clinical trials registered on ClinicalTrials.gov features most trials still conducted in the United States, Europe, and Canada, the current value for the outsourcing market in China is pegged at $400 million.

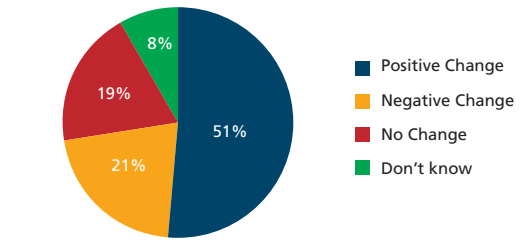
However, there has been noted concern that global trials are not all they are cracked up to be.

In Ken Getz's March 2012 column, he reflected on the rush to global trials as a panacea for faster enrollment numbers. However, the enrollment could be deceiving. As he wrote: "Sponsors and CROs have focused on enrollment rates but less on setting up and coordinating the infrastructure in remote regions to support these sites. One of the largest global CROs reported that on a recent pivotal trial it took three times longer to establish the infrastructure and work with health authorities and regulatory agencies in remote regions. A clinical supply manager recently told me that study drug shipping times to remote regions took up to twice as long."

Getz also noted in a Tufts CSDD 2011 study that examined 16,000 investigative sites participating in 155 global Phase II and Phase III clinical trials found the following:

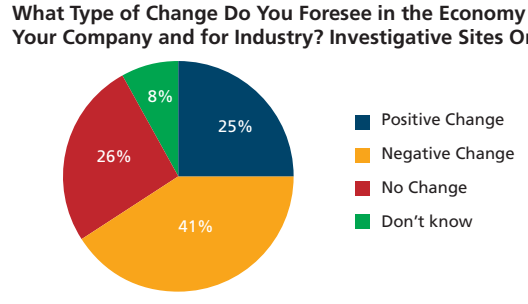
- Eighty-five percent of all sites eventually achieved target enrollment rates, however less than half did so within the planned clinical trial timeline.
- Fifteen percent took more than twice as long as planned.
- Eleven percent of global sites on average did not enroll a single patient.

Other surveys have shown that sponsors do have greater challenges in the shipping and logistics of the global clinical trial supply chain. Also, concerns exist regarding regulatory agencies in the United States



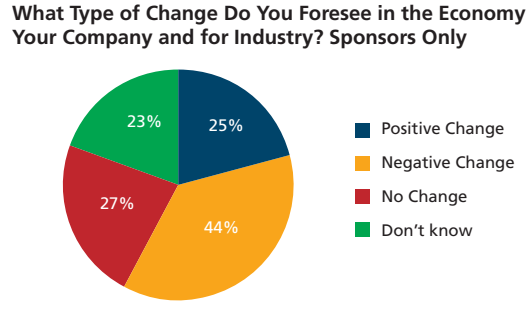
Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 4.



Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 5.



Source: Applied Clinical Trials, CenterWatch survey, 2012.

Figure 6.

and Western Europe acceptance of data from clinical trials in emerging markets.

Regardless of what sponsors are considering about global trials at the higher levels, so far as our survey goes, the increase in global trials did not make the top three short list of challenges facing clinical trials professionals today. Nor has the increase in this specific challenge shown a change from the last survey, a mere 4% increase.

However, when asked specifically if the professionals were facing increasing, decreasing, or the same amount of challenges from global trials, the majority (46%) said it was increasing. Only 2% noted a decrease. The most significant challenges associated with the increase in global trials included the increased workload; changing regulatory requirements or managing various regulatory requirements; achieving global consistency; and technology challenges.

The economy

As mentioned, the economy has more than the actual financial effect on the industry. The economic performance of a company leads to its changing business strategies and operational practices to get more value and efficiency.

As mentioned, the respondents from CROs more highly reported a positive change in the economy (Figure 4, Figure 5, and Figure 6). It could be from all the other factors listed above…an increase in outsourcing; an increase in workload; a decrease in pharma staffing sizes. While we can't pinpoint the reason from this survey, we hope that the positive feelings spill over to the other market sectors and well into the next two years, when we conduct the next survey.

Editor's note: Additional figures for the survey are available in the online version of this article.

DECEMBER 2012 ADVERTISING SECTION OF
APPLIED CLINICAL TRIALS

Corporate profiles

CROs and Product & Service Providers

From the **Staff**

From the staff of *Applied Clinical Trials,* we would like to extend our wishes for a prosperous and joyful new year to all of our readers as we enter into 2013. This past year has been one of many changes for *Applied Clinical Trials* and the clinical trials industry, and we'd like to thank you for allowing us to be your guide through these changing times.

Our Corporate Profiles section provides readers with the essential, up-to-date information about the companies that provide services to the clinical trials community. We compile this section to give readers the opportunity to gain a deeper understanding about the products, services, and capabilities of key vendors in the industry by profiling each company and highlighting their histories, present, and future.

Please contact the *Applied Clinical Trials* staff with your questions and comments. We look forward to hearing from you.

We hope this can be a valuable resource to you.

Best Regards and Cheers,

The Staff
Applied Clinical Trials

CORPORATE PROFILES

Applied Clinical Trials

Magazine Description

ACT is the leading global publication serving professionals who develop and conduct clinical trials. *ACT* reaches a global circulation approximating 18,250 subscribers, 12 times a year, offering practical peer-reviewed advice and information for trials professionals.

ACT's readers work in corporate management, marketing, drug research, clinical trials management, eClinical, project management, GCP auditing, and regulatory affairs. Among its readers, 59.2% work in pharma/biopharm/biologics companies and 14% are with CROs.

Now in its 21st year of service to the clinical trials industry, *ACT* continues to deliver editorial coverage of the latest industry trends, technologies, legislation, and regulations that affect global clinical trials.

Major Issues

ACT has a major bonus distribution program for 2013. Additional copies will be distributed at the following important industry meetings:

- January: EFGCP Annual Conference, CBI 7th Annual Cardiovascular Risk Assessment Summit
- February: HIMSS, DIA Annual EuroMeeting, CBI 8th Annual Biosimilars and Follow-on Biologics, CBI 8th Annual Forum on Late Phase Research/ Real World Data, CBI ClinTech 2013
- March: ACRP Global Conference, C.R.O.W.N.
- April: IIR Partnerships in Clinical Trials, BIO International Convention, ICR Annual Spring Conference, CBI 8th Annual Forum on Global Clinical Trials Registries and Results Databases, CBI 10th Anniversary Forum on Patient Reported Outcomes
- May: MAGI Clinical Research Conference East, ASCO Annual Meeting, CBI 5th Annual Clinical Trial Budgeting and Project Management
- June: DIA Annual Meeting
- September: RAPS: The Regulatory Convergence, SCDM Fall, IIR Clinical Business Expo, IIR Partnerships in Clinical Trials Asia, DIA EDM, CBI 15th Registries and Post Approval Studies Congress
- October: CPhI Worldwide, MAGI Clinical Research Conference West, AAPS Annual Meeting
- November: CBI 3rd Annual Interactive Response Technologies for Clinical Trials, CBI 6th Annual Clinical Trial Budgeting and Project Management

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DATE FOUNDED
1992

ACM Global Central Lab

Corporate Description

ACM Global Central Lab specializes in delivering high quality central laboratory testing services in support of clinical research studies. ACM Global offers a flexible approach, with a focus on detail and customer service. Operating in more than 60 countries, ACM's analytical team performs 20 million diagnostic tests each year spanning all medical disciplines, including pathology, microbiology and molecular diagnostics, flow cytometry, specialized biomarkers, and pharmacogenomics. ACM Global keeps trials on schedule by conducting and managing all tests from central lab facilities with a seamless data management process and single global database.

Major Markets Served

Pharmaceutical, biotech, and contract research organizations in all regions of the Americas, Eastern and Western Europe, Israel, Russia, India, China, Southeast Asia, Australia, and New Zealand.

Major Services

With a staff of 500 laboratory experts, ACM Global offers a broad and customized menu of safety and specialty tests for clinical trials, including:

Central lab services:

- Project management
- Logistics
- Reporting
- Data management
- Biostorage/specimen management

Specialty testing:

- Clinical chemistry
- Hematology
- Endocrinology
- Allergy testing
- Coagulation
- Immunology
- Serology/virology
- Flow cytometry
- Anatomic pathology
- Cytopathology
- Microbiology and molecular diagnostics
- Toxicology

ACM global central laboratory

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NUMBER OF EMPLOYEES
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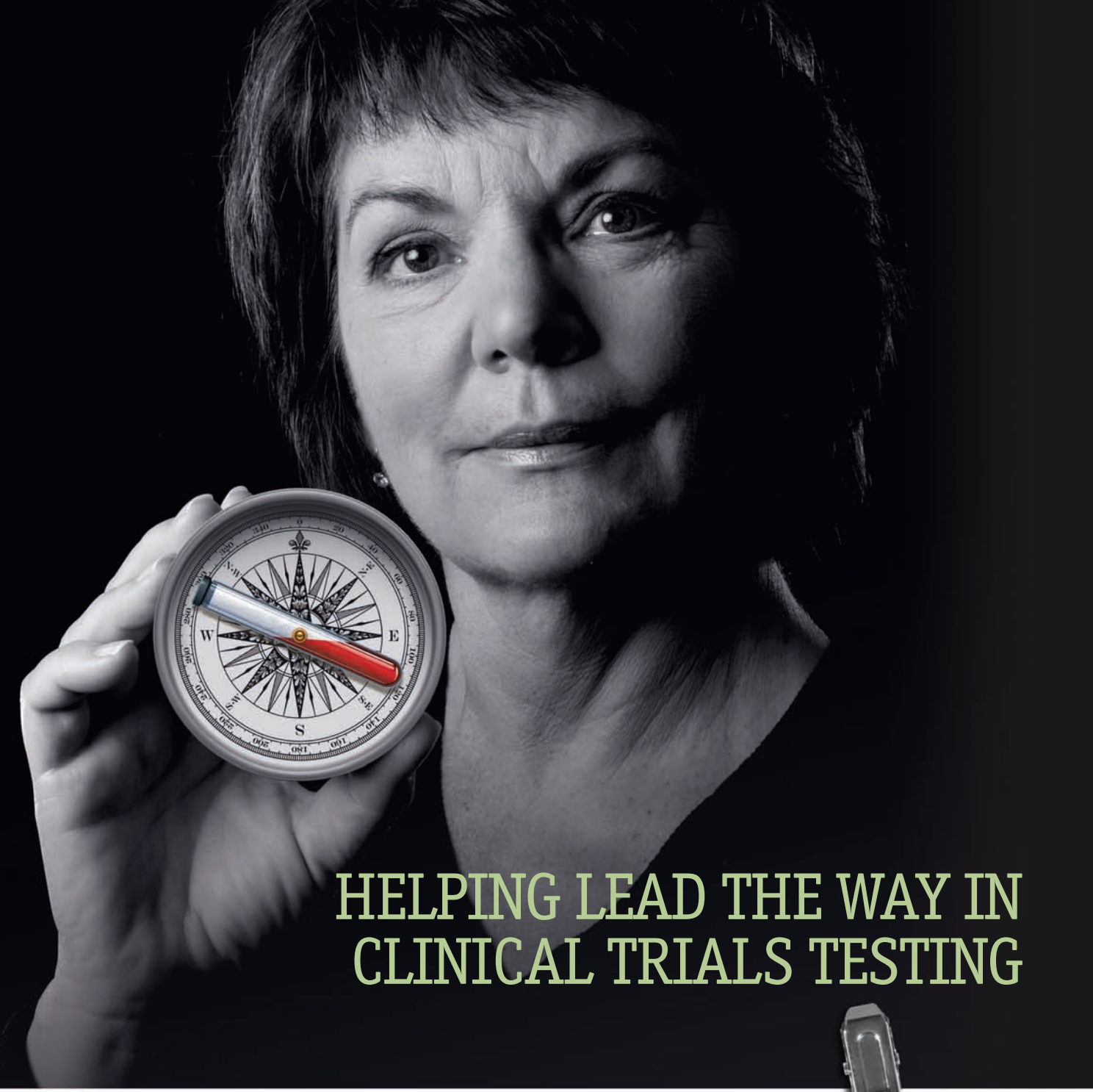
DATE FOUNDED
1997



HELPING LEAD THE WAY IN CLINICAL TRIALS TESTING

As a Senior Project Manager, it's my responsibility to ensure my team and I run the laboratory portion of a client's Protocol so as to provide the highest quality laboratory data within the client's timelines.

At ACM Global Central Laboratory we focus solely on delivering the highest-quality central lab services. We handle the intricacies of specimen testing and logistics on a global scale.

I'm committed to managing of all aspects of a client's study, from initial discussions of sponsor requirements, through to data delivery and will act as a central point of contact throughout. **That's how I help ACM Global Central Lab lead the way in clinical trials testing.**

To find out more visit us at acmgloballab.com/PMACT

ActiGraph

Corporate Description

ActiGraph is a leading provider of objective patient monitoring solutions for the global research community. Trusted by thousands of academic and scientific institutions in more than 65 countries, ActiGraph physical activity and sleep/wake monitoring hardware and software are the most widely used and extensively validated actigraphy measurement systems available. Through its collaborative relationship with the scientific community and a highly skilled and responsive team of hardware engineers, software developers, and customer support staff, ActiGraph delivers innovative patient monitoring solutions that improve clinical trial effectiveness, efficiency and data quality.

ActiGraph Patient Monitoring Solutions

ActiGraph objective monitoring solutions can be implemented across a wide range of research and clinical scenarios to deliver highly accurate, quantifiable insight into the real-world behaviors of patients and study participants. Our suite of extensively validated, wireless enabled physical activity and sleep/wake monitoring actigraphy devices, coupled with a powerful analysis software and synchronized mobile and cloud communication platform, delivers accurate, objective behavioral and physiological measures including amount and intensity of activity, energy expenditure, posture, steps taken, heart rate, and sleep efficiency in near real time. ActiGraph's innovative mobile communication platform provides instant feedback to the patient and allows the study team to view data remotely and communicate directly with the patient through a secure study-centric web portal. Our robust customer-driven analysis software provides a comprehensive selection of tools for high resolution batch analysis, data management, and reporting.

ActiGraph patient monitoring solutions are highly customizable, and we offer a variety of data capture, real-time mobile and web-based communication, analysis, management, and reporting tools which can be configured to achieve the specific objectives of each trial.

ActiGraph Solution Benefits

- **Optimize Patient Enrollment**—Objective physical activity and sleep behavior profiles help the research team identify the most qualified patient candidates during the recruitment process.
- **Increase Patient Safety**—Objective health measures delivered in near real time allow the study team to quickly identify subtle behavioral indicators of drug efficacy or potential adverse events during intervention.
- **Improve Data Quality**—Augment subjective patient reported outcome data with continuous objective measures to increase contextual meaning and enhance overall data quality.
- **Make Timely Decisions**—In-field remote monitoring of objective patient data helps the study team detect unfavorable outcomes quickly and make critical, cost saving decisions on the future of a trial.

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DATE FOUNDED
2004

AtCor Medical

AtCor Medical, The Blood Pressure Core Lab

Corporate Description

AtCor Medical offers an integrated, global view of blood pressure in clinical trials, with technology that is the gold standard in central blood pressure and arterial stiffness measurement, as well as best-in-class ABPM technology.

AtCor's SphygmoCor® XCEL, measures brachial and central aortic blood pressures automatically with an easy-to-use, brachial blood pressure cuff-based system. The SphygmoCor® XCEL system also measures carotid to femoral pulse wave velocity simply and quickly, using carotid tonometry and a femoral cuff which can be placed over lightweight clothing.

AtCor offers 24-hour ambulatory blood pressure measurement with the Sun Tech Medical® Oscar 2™ system. This comfortable ABPM system promotes patient compliance during home monitoring and has been validated to all three internationally recognized standards.

AtCor also provides comprehensive clinical trials support services worldwide: advanced technologies, trial site training, real-time site support, and data quality management using our secure WISDOM data transfer system.

AtCor's SphygmoCor® systems have been used in major clinical trials for the last decade and have been featured in over 600 studies published in peer-reviewed journals. AtCor's unique technologies and the high quality of its service have won the loyalty of leading pharmaceutical clients throughout the world.

AtCor Medical. New insights, New solutions.

AtCor MEDICAL

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Almac

One Company. Limitless Benefits.
Almac offers an integrated supply chain management solution that draws from the expertise of our best-in-class clinical trial supplies and IVR/IWR based services. Our integrated solution does more than just combine related services under one roof; it incorporates supply planning, technology implementation, and project oversight into a unified study start-up and management approach that optimizes the supply chain at each level.

Almac has over 20 years of experience in the management of clinical trial supplies and IXRS® technology. Our clinical supplies management and technology services have been deployed in over 8,000 trials and in over 80 countries globally. With a wide range of therapeutic experience and industry-leading experts in supply-chain management, Almac offers clients a specialized solution to efficiently plan, forecast, and manage supplies during clinical trials.

Clinical Technology Solutions
- IXRS® (Interactive Voice and Web Response Systems)
- Biostatistical services
- Patient enrollment and screening
- Adaptive trial design
- Randomization and drug assignment
- Data integration
- ePRO (Electronic Patient Reported Outcomes)
- Clinical helpline
- Patient management/compliance

Clinical Trial Supply Solutions
- Manufacturing and blinding solutions
- Comparator sourcing
- Packaging of clinical supplies (blistering, bottling, and carding)
- Over-encapsulation
- Labeling of clinical supplies
- Cold chain management
- QP Release (with analytical support)
- Shipping temperature electronic monitoring system (STEMS)
- Global distribution and depot network
- Returns, accountability, and destruction
- Drug supply management

Corporate Description
The Almac Group provides a broad range of services from R&D, biomarker discovery and development, API manufacture, formulation development, clinical trial supply, and IXRS® technology (IVRS/IWRS), to commercial-scale manufacture. Almac provides services to more than 600 companies, including all the world leaders in the pharmaceutical and biotech sectors.

The company employs over 3,400 individuals and is headquartered in Craigavon, Northern Ireland. US operations are based in Pennsylvania, North Carolina, and California. Almac's North American Headquarters is located in Souderton, PA. Almac will expand its Asian operations by opening offices in Singapore and Japan in early 2013.

To find out more about Almac visit www.almacgroup.com.

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NUMBER OF EMPLOYEES
3,400+

DATE FOUNDED
1989

Making **Clinical Trials**

Work Better™

For the **Patient**. For the **Site**. For the **Sponsor**.

Almac makes clinical trials work better and improves compliance by engaging patients across multiple modalities - anywhere, anytime, on any device - while enhancing site workflow efficiency and empowering sponsors with real-time data to make intelligent decisions. Through a combination of world-class **IXRS**® technology, Almac Interactive Reporting, and 24/7/365 trial support, Almac assures that our clients' investments in patients, sites, and clinical supplies are maximized.

IXRS® • Patient Enrollment and Screening • Statistical Services
• Randomization and Drug Assignment • ePRO • Patient Management/Compliance
• Drug Supply Management • Clinical Hotline

FOR FURTHER INFORMATION VISIT OUR WEBSITE OR CONTACT ALMAC ON:

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- Cytotoxins and potent compounds
- Storage
- Distribution
- Returns management and destruction

Corporate Description

The pharmaceutical industry trusts AndersonBrecon for the packaging solutions that increase their products' speed to market and opportunities for success. Only AndersonBrecon brings the proven experience that comes with more than 50 successful product launches a year and over four decades in the healthcare business. Leading technology and continued investment enables us to address global packaging needs throughout the product life cycle—from Phase I clinical trials through commercialization and ongoing supply. Our clients view us as an extension of their business and a collaborative partner, with the shared goal of improving patients' lives.

Major Products/Market Served

We offer global packaging and distribution services, supporting programs in over 100 countries worldwide through our global distribution network. Project management and support services are offered across two continents, ensuring seamless trial support for your program.

Major Services

Packaging Services

- Blister packaging
- Pouch/sachet filling

Program Support

- Project management
- Package design and development
- Cross-continent CT services
- Labeling services including randomization, code breaks, and multi-language capabilities
- On-site laboratory services including analytical, microbiological, method development, import, ICH stability testing, and EU product release
- Child resistant/senior friendly packaging
- Comparator product procurement
- Over-encapsulation and placebo capsule manufacture
- Cold Chain including 2 to 8 C, -20 C, and -80 C
- QP services
- Web-based connectivity
- Twelve global facilities audited by regulatory agencies including FDA, MHRA, DEA, Home Office, and ISO

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NUMBER OF EMPLOYEES
1,200

DATE FOUNDED
1967

AndersonBrecon®
AmerisourceBergen Consulting Services

We Are AndersonBrecon

AndersonBrecon is a global healthcare packaging company that partners with pharmaceutical and biotech manufacturers to increase their products' speed to market and opportunities for commercial success. With 12 state-of-the-art facilities across North America and Europe, AndersonBrecon offers a broad range of services to support packaging needs throughout the product life cycle – from Phase I clinical trials through commercialization and ongoing supply.

Manufacturers trust AndersonBrecon for the proven experience, exceptional quality systems and continued technology investment they bring to their packaging solutions, along with the strength and stability that comes from being part of the AmerisourceBergen family of companies.

AndersonBrecon is the alignment of the Anderson Packaging USA and Brecon Pharmaceuticals UK companies. To learn more visit **www.andersonbrecon.com.**

Performance that builds trust. Partnerships that create success.

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AndersonBrecon®
AmerisourceBergen Consulting Services

Barnett International

Corporate Description
Barnett Educational Services is a leader in training and resources for clinical research professionals. The Barnett approach is unique in that in combines content development expertise with a high level of subject matter experience, engaging instructional design, and a multi-platform approach.

Major Services
Our education and training portfolio offers diverse options for all types of learners:

- One- and two-day live seminars held multiple times throughout the calendar year, in convenient locations
- One to three hour interactive web seminars, conveniently taken from your home or office computer
- Regularly updated leading industry reference guides and publications
- Customized training solutions, delivered right to you at your site:
  - o Custom on-site or web-based training
  - o Curriculum compliance assessment and development
  - o eLearning module development
  - o Virtual meetings support services
  - o SOP development and training
  - o Mock audit and compliance training services

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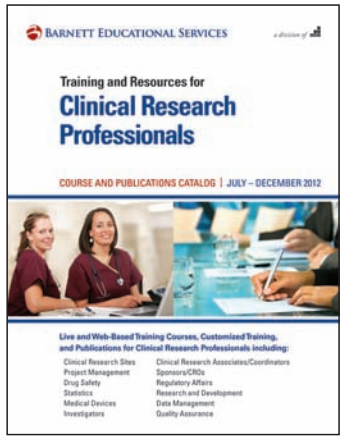
DATE FOUNDED
1979

BARNETT EDUCATIONAL SERVICES

Connecting Learning to Clinical Research Outcomes



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Barnett's On-Demand **GCP Refresher Training**

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- Application-based assessment that tests participants' understanding of how GCP is applied in workplaces

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Barnett International: A division of Cambridge Healthtech Institute
250 First Avenue • Suite 300 • Needham, MA 02494 USA • Phone: (800) 856-2556

BarnettInternational.com

BioClinica, Inc.

BIOCLINICA®

Corporate Description

BioClinica, Inc. is a global provider of integrated, technology-enhanced clinical trial management solutions. BioClinica operates regulatory-body-compliant imaging core labs on two continents, and supports worldwide eClinical and data management services from offices in the United States and Europe. As an imaging core lab and electronic data capture pioneer, BioClinica offers the technology and the expertise resulting from more than 22 years of experience. Whether you are a sponsor or a CRO, a virtual company or a global enterprise, or are looking for a single solution or a suite—BioClinica offers value and dependability.

Products and Services

eClinical solutions, a full range of products designed to manage clinical data and make trials easier:

- Express EDC (electronic data capture)
- OnPoint CTMS (clinical trial management system)
- Trident IWR/IVR (interactive web/voice response)
- Optimizer (clinical supply chain simulation and forecasting)
- Clinical data management and coding

Imaging core lab services, supporting medical image management for clinical trials:

- Scientific expertise in major therapeutic areas
- WebSend electronic image transport, archiving, and collaboration system

BioClinica focuses on trial processes that benefit from the application of technology and closely-related expertise, including:

- Specialized, built-for-purpose, clinical trial applications
- Broad scientific support: consultation, protocol design, and imaging charters
- Scalable, high-availability, and managed hosting for SaaS offerings
- Operational study support: project management, data management, electronic form design, logistics, and more
- Global technology support: multilingual, 24/7/365, help desk, training, operations

As a leading independent Imaging Core Lab (ICL), BioClinica offers medical image management services for the lifecycle of your clinical trial supporting a wide range of imaging modalities. BioClinica services include the collection, processing, analysis, and regulatory submission of medical images and related clinical data, customized to the needs of your study.

Advanced eClinical solutions from BioClinica support your organization and augment your existing resources. In addition to leading technology, available services include: study builds, site assessments, system deployment, end user and site training, lab imports, global help desk support, data management, SAS services, study close out, and more.

BioClinica's portfolio helps sponsors and CROs to address many of the challenges that arise in the conduct of global clinical trials. BioClinica solutions scale, integrate, and support the improved efficiency and flexibility required for modern clinical trials. Complementing best-in-class technology is an architecture that communicates in real-time between applications and maximizes data visibility and utility via SharePoint with built-in connectivity to Outlook and other Microsoft Office applications. Each solution can be customized according to your unique needs. To learn more please visit bioclinica.com.

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NUMBER OF EMPLOYEES
500

DATE FOUNDED
1990

Biomedical Systems

Corporate Description

Biomedical Systems is a global provider of centralized diagnostic services for clinical trials Phases I–IV as well as post-marketing safety studies. Our methods have improved data accuracy, shortened timeframes, and lowered costs for sponsors. Biomedical Systems offers unprecedented stability at all levels of our organization, from low turnover rates among our clinical project managers to the same name and ownership for over 35 years. We partner with all top 10 pharmaceutical companies and have experience with various regulatory agencies.

Worldwide Reliability since 1975

For over 35 years, Biomedical Systems has been innovating the acquisition, analysis, and management of essential clinical data in support of sponsors' regulatory filings. Currently, we have headquarters in North America and Europe as well as support and logistics offices in Japan and India which resupply equipment to challenging areas around the world in a timely, cost effective manner. Biomedical Systems' global, multi-lingual staff speaks 26 languages facilitating communication to deliver better quality data. We have managed over 14,000 clinical sites in 95 countries and can offer services and support 24 hours a day, 7 days a week, 365 days a year. Biomedical Systems has earned a position as a worldwide leader in the clinical trials industry by investing in well trained people, innovative technology, and global infrastructure.

Innovating Centralized Diagnostics

Biomedical Systems has set the healthcare industry standard providing clients with the ability to increase cost efficiencies and bring studies to database lock on an advanced timeline by combining any of our over 20 modalities in one study. Biomedical Systems' pioneering spirit is based on a strong history as a privately held company that focuses on clients and people. We continue to invest in advanced technologies to meet the ever-changing needs of our clients.

Diversified Centralized Services

Cardiac Safety and Efficacy

- Digital 12-lead ECG
- TQT/intensive studies
- Holter monitoring
- Cardiac event monitoring
- Ambulatory blood pressure monitoring
- ECG stress testing
- Impedance cardiography
- Wireless ECG monitoring

Pulmonary Function Testing

- Spirometry
- Challenge testing
- Nitric oxide
- DLco/lung volumes
- Peak flow with eDiary
- Pulse oximetry
- Forced oscillometry

Medical Imaging

- Echocardiography
- CT
- MRI
- PWP Recordings
- Ultrasound
- Video and photography
- Angiography
- DXA
- PET or PET/CT
- SPECT
- X-Ray
- Nuclear medicine

Digital Pathology

- Liver
- Lung
- Kidney
- Lymph node
- Small bowel
- Bone core
- Large bowel
- Endometrium

Neurophysiology

- EEG
- Audio evoked potential
- Sleep medicine
- Ambulatory EEG
- Video EEG
- Electromyography

ePRO Solutions

- Web-based ePRO
- Home ePRO
- Site ePRO

Scientific Affairs

- Protocol development
- Protocol review
- General consulting
- Clinical development strategy
- Data analysis and interpretation
- Biostatistics
- Report writing
- Assistance with regulatory agency communication
- Data and safety monitoring board meeting support and training

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NUMBER OF EMPLOYEES
400

DATE FOUNDED
1975

biomedical systems
Worldwide Reliability since 1975

Catalent Pharma Solutions

Corporate Description

Catalyst + Talent. Our name combines these ideas. Catalent is the global leader in development solutions and advanced drug delivery technologies, providing world-wide clinical and commercial supply capabilities for drugs, biologics, and consumer health products. With over 75 years serving the industry, we have proven expertise in bringing more customer products to market faster, enhancing product performance, and ensuring reliable product supply.

We serve thousands of innovators, both established and emerging, in over 80 markets, including 49 of the top 50 pharmaceutical and 41 of the top 50 biotech companies. Our team of over 1,000 talented scientists has supported more than half of the innovative drug and biologic approvals since 2004, and we have more than 450 active development programs for new customer products. We have 18 development teams in 10 markets. Our 25-plus global sites serve over 1,000 customers in over 80 countries supplying more than 60 billion units annually. Our significant intellectual property includes over 1,400 patents and patent applications.

Whether you are looking for a single, tailored solution or multiple answers throughout your product's lifecycle, we can improve the total value of your treatments—from discovery to market and beyond.

Catalent. More products. Better treatments. Reliably supplied.™

Development

With our broad range of expert services—including analytical, biologics, pre-formulation, and formulation—we drive faster, more efficient development timelines and produce better products. Our robust GPEx® mammalian cell line engineering technology accelerates large molecule drugs from discovery to clinic and our unique Optiform™ technology ensures maximum API optimization. With our deep expertise and our extensive formulation capabilities across a wide range of dose forms, we can solve even the most complex bioavailability, solubility, and permeability challenges.

Delivery

We are a world leader in drug delivery solutions with a proven track record of helping our customers create better treatments by boosting bioavailability, solubility, and permeability; improving ease and route of administration; and increasing patient compliance. Our unique delivery technologies—including RP Scherer softgel and OptiShell™ capsules, Zydis® fast-dissolve, controlled release, including OSDrC® OptiDose™ flexible dose delivery and OptiMelt™ hot melt extrusion, as well as inhaled and injectable dose forms—improve how products work in and for patients.

Supply

We reliably supply our customers through operational and quality excellence, and we have regulatory inspection results exceeding the industry average. As a seamless extension of your supply chain, we offer global, integrated manufacturing and packaging solutions to take your product from design to clinical trial, to plant, and to pharmacy. We manufacture oral, sterile, and inhaled dose forms and produce biologics for pre-clinical and clinical studies.

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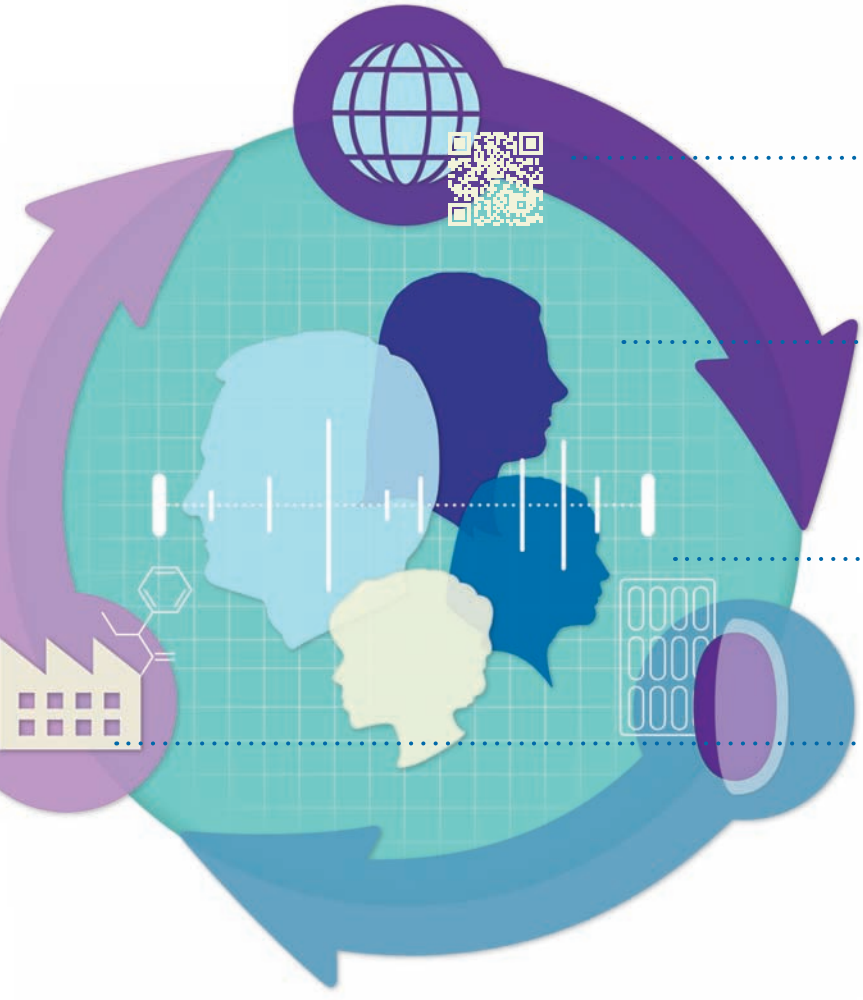

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Integrated with clinical manufacturing, analytical, and regulatory consulting, we provide you with a faster path to clinic and beyond.

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CFS Clinical

Transforming the Business of Clinical Trials™

Corporate Description

CFS Clinical (CFS) is a specialty provider focused on the business and financial management activities for clinical trials. The company offers a unique blend of contract, regulatory, and cutting-edge investigator grant payment management services, which operate in unison to accelerate cycle times, manage compliance and risk, and stimulate investigator relationships. With our focused expertise, innovative processes, and integrated technology we are able to provide high quality, efficient, and cost effective service solutions that address critical study startup and financial issues affecting the clinical trials process.

CFS Global Payment Services (GPS)

Global Payment Services leverages a team of experts to provide a highly-controlled and fully-integrated global payment-processing system, enabling your organization to more effectively manage business intelligence and remain in compliance with aggregate spend and transparency requirements. CFS Payment InSite™ is our trusted grant payment platform that serves as the backbone to our Global Payment Services offering. Through CFS Payment InSite™, the company's exclusive investigator payment platform, CFS delivers global payments to sites quickly, accurately, and with robust online reporting. Benefits of Payment InSite™ and GPS include:

- Industry experts who understand the complexity of global payments
- Improved investigator relationships
- Unparalleled transparency
- Enhanced traceability for payments

CFS Contract and Regulatory Services (CARS)

Contract and Regulatory Services address the critical contracting, budgeting, and regulatory requirements essential for study startup. By outsourcing these business processes to CFS Clinical, sponsors can initiate studies much more quickly and effectively. CFS Startup InSite™ technology platform supports CARS experts by providing enhanced negotiation and document tracking capabilities along with enterprise site profile management to reduce redundant activities that have been inherent in the process. Benefits to Startup InSite™ and CARS include:

- Real-time visibility to startup documents
- Enterprise site profiling
- Integrated document clause management
- Electronic workflow
- eSignature

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NUMBER OF EMPLOYEES
75

DATE FOUNDED
2001

Advantage, you.

When you partner with CFS Clinical (CFS) you have access to our global capabilities, team of experts, and state-of-the-art technologies that help streamline your clinical operations and bring your products to market faster. We are the market leader and trusted partner in providing turnkey business and financial management services for clinical trials — from study startup to grant payment management and beyond. Our CFS InSite™ systems deliver unparalleled transparency, quality, and efficiency to your study site activation and global payment processes.

Contact us today to learn how CFS can give you a true competitive advantage.

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CFS CLINICAL

Transforming the Business of Clinical Trials®

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In the UK: 7/9 North Saint David Street, Edinburgh, Scotland, EH2 1AW, UK P: 0131 202 6178

clinicalRSVP

Corporate Description

clinicalRSVP (Clinical Research Subject Verification Program) is an electronic subject clearinghouse designed to prevent dual enrollment of subjects across multiple concurrent research studies. In other words, it is a tool for clinical investigators to objectively authenticate that their subjects aren't double dipping in more than one clinical trial at the same time.

clinicalRSVP works with various sites, CROs, and sponsors to improve study data accuracy and participant safety through dual enrollment prevention capabilities.

Biometric Advantage

clinicalRSVP utilizes USB plug-and-go biometric readers that offer speedy and accurate digital subject identification.

Why is biometric digital subject identification important?

- Reliable subject identification across sites—subjects looking to dual enroll will oftentimes use a different name or present a fake ID as a way to enroll in multiple concurrent clinical trials. Biometric identification offers an additional safeguard against this type of subject behavior.
- Overcomes demographic manual entry error—error rates in manual data entry have been well documented. A biometric identification component overcomes this limitation, and ensures that all subjects are accurately identified.
- Overcomes demographic changes—persons may change their legal name or other legal identification information. A biometric identification component overcomes this limitation.
- Speed—scanning a subject's fingerprint provides instant identification. There is no need to complete lengthy data capture fields in order to identify subjects by demographics alone.

Dual Enrollment Prevention Expertise

- Over three years of successful network administration
- Extensive experience with Phase I-IV studies
- Over 110,000 subjects searched and authenticated by clinicalRSVP
- Over 1,200 studies authenticated using clinicalRSVP
- Over 1,000 cases of dual enrollment prevented
- Regional and national operational track record
- One hundred percent satisfaction rate across sites, CROs, and sponsors

Features

- Real-time web access
- 21 CFR Part 11 compliant
- Includes maintenance and validation
- Full technical support
- Subject discrepancy resolution and 24/7 subject hotline

Research Benefits

- More reliable, protocol compliant study data
- Increased participant safety
- Better adherence to clinical development timelines
- Minimized risk of adverse events due to overlapping subject participation

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DATE FOUNDED
2009

Corporate Translations, Inc.

Corporate Description

Corporate Translations is a certified Women's Business Enterprise founded in 1990 to specifically fulfill the life science industry's demand for high-quality translation solutions. Corporate Translations' specialized approach and methodical operating procedures have allowed the company to achieve an uncommonly high level of quality and preferred supplier status for the most innovative biopharmaceutical companies in the world.

The Preferred Supplier of Translation Solutions

Corporate Translations' ISO 9001:2008 and EN 15038:2006 quality management system acts as the foundation for ensuring the company's unparalleled quality, 99% on-time delivery rate and stellar customer satisfaction score of 9.03 out of 10. We have demonstrated our commitment to quality and dedication to customer service, which have led us to become the preferred supplier for Pfizer, Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, Merck, and Novartis, among others.

Services

Translation—Corporate Translations determines the most appropriate translation and desktop publishing solutions for a wide variety of documents including informed consents, drug protocols, pharmaceutical product information, marketing materials, training, eLearning modules, and much more. We ensure accurate, timely, and cost-effective translations every time through our tried and tested methodology that includes:

- Document translation
- Digital media translation
- Back translation
- Editing
- Proofreading
- Desktop publishing
- Translation memory management
- Systematic translation archiving

Linguistic validation—Corporate Translations is the trusted authority on the linguistic validation of clinical outcomes assessments (COAs). Having completed over 10,000 instrument translations, our state-of-the-art methodology is endorsed by regulatory bodies worldwide. Corporate Translations addresses many of the challenges surrounding patient reported outcomes (PRO) instrument translation by offering:

- Face validation
- Harmonization
- Back translation
- Cognitive debriefing
- Validation reports and certifications
- Survey research expert review
- ePRO translation consultation

Translation management system—Corporate Translations offers *my*CTi—Translation Management System, a customized and secure web-based portal that bundles all our best-of-breed technologies into one customer-friendly website. Through *my*CTi—Translation Management System, users are able to:

- Request quotations and submit associated documents via secure and encrypted transfer capabilities
- Approve quotations
- Transfer documents securely
- Track current projects
- View past project activity
- View accounting information, including spending reports
- Obtain detailed performance information

CORPORATE TRANSLATIONS

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DATE FOUNDED
1990

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> *"This was a great event for sharing innovative ideas, meeting people across the industry and building new relationships. A well-organized and informative meeting with high-quality speakers."*
>
> — Miguel Orri, Senior Director, Clinical Sciences, Pfizer

For more information and to register, visit

April 21-24, 2013 | Orlando World Center Marriott
www.clinicaltrialpartnerships.com

CROMSOURCE

Corporate Description

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and staffing solutions. As a well-established full-service CRO, CROMSOURCE is unique in guaranteeing clients that their trials are delivered on time and to the contract price with no CRO initiated change orders (our End-to-End Guarantee). CROMSOURCE operates through offices across all regions of Europe and North America and delivers a comprehensive breadth of services. CROMSOURCE supports the full spectrum of clinical development, from first in human conducted in our exceptional early phase unit, through all subsequent phases of pre- and post-approval research internationally.

Strategic Services

End to End Guarantee

CROMSOURCE projects are delivered on time and to the contract price. Guaranteed.

One Trial One Price

Part of our end-to-end guarantee. CROMSOURCE guarantees that the contract price is the final price. There is no change order culture at CROMSOURCE.

Expert Trial Rescue

CROMSOURCE regularly rescues projects for clients dissatisfied with the progress of ongoing studies. Our team quickly assess the situation and gets such trials back on track.

Feasibility Plus

Feasibility Plus is provided free and at the proposal stage. Feasibility Plus provides accurate country and site selection data, and allows precise budget and timeline forecasts.

Core Services

Clinical Development Services

- Biostatistics
- Clinical monitoring
- Data management
- Drug management
- Feasibility
- IT
- Legal representation
- Logistics
- Medical monitoring
- Medical writing
- Pharmacovigilance
- Project management
- Quality assurance
- Regulatory affairs
- Site selection

Early Phase Services

- ADME studies
- Bioavailability
- Bioequivalence
- Dose ranging/multiple dose tolerance
- Drug-drug interactions
- First in human (SAD, MAD)
- Food effect studies
- Patient studies
- Pharmacokinetics/pharmacodynamics
- Proof of concept
- QTc studies

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NUMBER OF EMPLOYEES
600

DATE FOUNDED
1994

ERT

Corporate Description

ERT is a global technology-driven provider of health outcomes research solutions and services supporting biopharmaceutical and medical device organizations to achieve their new medical product development and commercialization objectives. ERT harnesses leading technology coupled with reliable processes and scientific/regulatory expertise to collect, analyze, and report on clinical trial data to support the determination of health outcomes critical to the approval, labeling, and reimbursement of new medical products. ERT is the acknowledged industry leader in:

Multi-Mode ePRO Solutions

ERT has combined scientific and regulatory expertise with innovative technology to deliver multiple modalities of reliable and practical electronic solutions for capturing Clinical Outcome Assessment (COA) data which includes patient reported outcomes, clinican reported outcomes, and observer reported outcomes (PROs, ClinROs, and ObsROs). Only ERT offers all proven ePRO modalities, including mobile handhelds, tablets, IVRS, digital pen, and web to ensure that the ideal technology is applied in each study. With unbiased consultancy in selecting the appropriate modality, you can eliminate patient compliance issues, avoid inaccurate, incomplete, or illegible data, and ultimately produce better-informed data, be it from a patient, physician, or caregiver.

Suicidality Monitoring

ERT's pioneering electronic self-rated version of the Columbia Suicide Severity Rating Scale (eC-SSRS) facilitates compliance with regulatory requirements for prospective monitoring of suicidal ideation and behaviors (SIB). The validated eC-SSRS solution, developed in collaboration with the scale's lead author, is a cost-effective and reliable method of prospectively monitoring for suicidality, and is specified as an appropriate means for capturing this important data in the FDA's revised guidance on SIB.

Scientific and Regulatory Consulting

ERT offers the consulting services of several pioneers in COA research. Our thought leaders will support the decision making in the creation, execution, and documentation of a COA strategy and assist in interpreting and applying regulatory guidance. Specifically, ERT offers unmatched consulting in COA instrument development/selection/modification, paper-electronic migration, and regulatory communication/support.

Centralized Cardiac Safety 2.0

ERT's Centralized Cardiac Safety 2.0 utilizes newly developed software technology, within its best in class EXPERT® operating platform. The technology enables the collection of real time, consistent, and high-quality information, easing site operations and delivering better value to biopharmaceutical companies. As a result of the improved data quality and processes associated with the use of centralized cardiac safety, significant cost savings can be recognized.

Respiratory Solutions

ERT is the industry leader in centralized spirometry. From device customization to clinical data analysis, ERT provides products and services that ensure the most accurate data and efficient trial management in the industry. ERT's respiratory services offer quality control, real-time views of data through a user-friendly web portal, and Best Test Reviews (BTR) of unacceptable data.

For more information about ERT's leading solutions visit: www.ert.com

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NUMBER OF EMPLOYEES
828

DATE FOUNDED
1977

Eurofins Global Central Laboratory

Corporate Description

At Eurofins Global Central Laboratory, laboratory science is our sole focus. With over 20 years of experience and scientific expertise, we utilize our global central laboratories to continually attain the most cost effective and efficient solutions for your clinical trial needs. We are dedicated to providing all laboratory testing needed in clinical trials and have developed one of the broadest testing portfolios available in the pharmaceutical industry today. By combining all laboratory testing in one project, we offer synergetic benefits with regard to turnaround time of results, harmonized procedures, logistics, and reporting.

Eurofins Global Central Laboratory supports its customers with six wholly-owned facilities in the United States, Europe, India, Singapore, and China. With three central laboratories operating in the Asia-Pacific region, Eurofins Global Central Laboratory is considered one of the top central laboratory organizations in the world. If required, we extend our global coverage through standardized local central laboratory partners to reduce costs, accelerate logistic timelines, or to accommodate local needs for a given study.

Laboratory testing services capabilities

Global clinical safety and specialized testing—Full package of routine and non-routine laboratory testing:

- Clinical chemistry, hematology, immunochemistry, urinalysis, coagulation testing
- Flow cytometry
- Biomarkers
- Hormones, cell markers, cytokine profiling
- Infectious disease serology
- Genomic testing

Biomarker Services

- PD—target engagement biomarkers, proof-of-mechanism, and proof-of-concept biomarkers
- Biomarkers in clinical trials (exploratory and clinical end-point)
- Fit-for-purpose validation and analysis of commercially available biomarker assays
- Broad range of applied technologies: ELISA, MSD, luminex, flow cytometry, and LC-MS/MS

Bioanalytical Services

- Method development, transfer, and validation
- TK/PK
- Bioequivalence studies
- Daily therapeutic drug monitoring in clinical trials
- Dried blood spots

Biopharmaceutical Services

- PK analysis of biopharmaceuticals, including monocloncal antibody (MoAb) drugs, oligonucleotide drugs, biologics, biosimilars
- Immunogenicity testing of biopharmaceuticals and biosimilars
- Vaccine-mediated immunogenicity (non-infectious disease)
- Screening and confirmation assays
- Functional bioassays (cell-based assays)

Global Infectious Disease Services

- Central laboratory microbiology to support clinical trials
- Clinical virology services
- Non-clinical specialty tests for compound profiling, cidality, resistance development, drug interactions
- International antimicrobial surveillance programs
- Extensive repository of clinically relevant bacteria
- Scientific consultancy

Clinical Trial Supporting Services

- Logistics support and courier management
- Investigator site support
- Multilingual regional helpdesks on three continents
- Sample management and storage
- Project management
- Data management
- Global LIMS
- Real-time validated global results database via secured data portal
- Global QA and QC, global standard operating procedures

DEDICATION YOU CAN RELY ON.

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NUMBER OF EMPLOYEES
450

Forte Research Systems, Inc.

Corporate Description

Founded in 2000 and headquartered in Madison, Wisconsin, Forte Research Systems, Inc. develops and markets clinical and translational research management software.

By adopting a highly collaborative product development process, Forte gathers, distills and fine tunes the best ideas from world-class research institutions to deliver solutions addressing key operational challenges.

Specialized Clinical Trial Management Systems

Forte's Allegro® family of products are easy-to-use, intuitively designed, cloud-based systems that support clinical research operations excellence. Each Allegro product is designed exclusively for the user community for which it is intended.

Allegro CTMS@Site—for Investigator Sites and Research Groups

Today's investigator sites are accepting a larger number of studies, implementing tighter financial controls, and overseeing regulatory compliance more intensively. As sites track ever-increasing amounts of information for their internal monitoring and reporting, they need a system that gives them more control over their data than paper or spreadsheets can provide. At the same time, they need a system that is easy to use and doesn't take a lot of time or resources away from the conduct of clinical research.

That is why Forte Research Systems developed Allegro CTMS@Site® for investigator sites and research groups to help address the key challenges they face today.

Allegro CTMS@Network—for Site and Trial Management Organizations and Investigator Site Networks

In order to successfully manage clinical trials across multiple sites, numerous requirements must be met associated with demand generation, site selection, study start-up, and project management. Information about individual sites and across the network is always needed but can be difficult to obtain, often requiring even more effort from the sites. In addition, network organizations often spend a large amount of time finding and selecting the appropriate sites and working toward study start-up.

That is why Forte Research Systems developed Allegro CTMS@Network® for site and trial management organizations, and investigator site networks. The system facilitates streamlined site selection, timely study start-up cycles, and up-to-date tracking of protocol activity.

OnCore—for the Research Enterprise

The OnCore® eclinical solution has been meeting the needs of academic medical centers, CTSAs, research hospitals, and cancer centers for over a decade. In addition to sophisticated CTMS functionality designed for the clinical research enterprise, OnCore also has fully integrated patient registries, biospecimen management, billing compliance, paperless committee management, data management, and EDC functionality.

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DATE FOUNDED
2000

Specialized Clinical Trial Management Systems

Allegro CTMS@Network

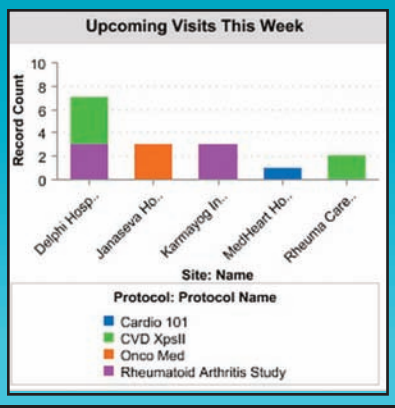
Site Management Organizations and Investigator Site Networks

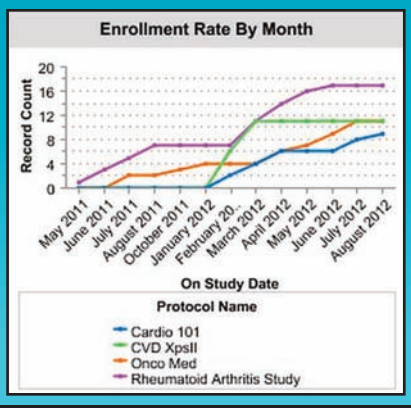
Maintain control across all sites in everything from study start-up activity and project management through site payment. Account for all costs up front, reconcile payments, and automate payments to sites, investigators, vendors and subjects. Get visibility and improve processes with dashboards, streamlined workflows, and project management tools.

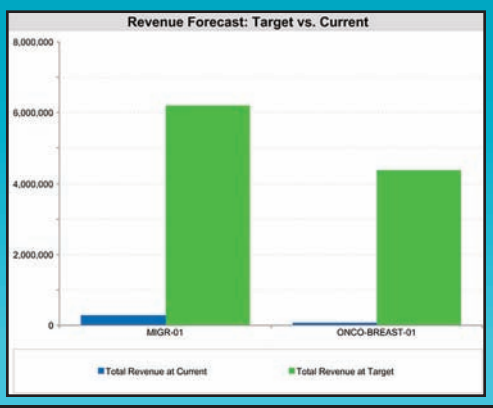
Allegro CTMS@Site

Investigator Sites and Research Groups

Get real-time visibility into study conduct across the entire trial portfolio. Maintain the financial health of clinical trial operations with insights into budgets, invoicing and payments. Improve efficiency and compliance with facilitated visit management, reporting, audit trails, document management, effort tracking, and now, patient reimbursement cards.







To learn more about the Allegro family of cloud-based, easy-to-use clinical trial management systems, visit www.ForteResearch.com/ctms-allegro.

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Insight
sees a
better path
At ICON, we use our insight to find the best way forward. As a trusted adviser in assessing market value and price positioning, we've developed strategies for over 50 new product launches and applied our insight to over 400 development and in-market products across more than 40 disease areas.
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IntegReview Ethical Review Board

INTEGREVIEW

Committed to the Protection of Research Subjects

Corporate Description

Established in 1999, IntegReview Ethical Review Board is an independent IRB dedicated to providing unsurpassed ethical review services. The ethical principles employed by IntegReview that govern the conduct of human research are those identified in the Belmont Report; respect for persons, beneficence, and justice.

IntegReview has been fully accredited by the Association for Accreditation of Human Research Protection Programs (AARHPP) since 2007.

Quality and integrity are essential to the services IntegReview provides. Human research is a field that relies on accuracy, honesty, individualized attention to details, and the ability to respond quickly and effectively in a rapidly changing professional landscape.

IntegReview provides superior customer service without compromising ethical values.

Capabilities

- Daily meetings
- Electronic submissions
- 24 to 48 hour turnaround
- REB for Canadian sites
- Latin American site review
- Review of Phase I-IV research, single and multiple investigators
- Medical device research
- Expedited review procedure for research that qualifies
- Informed consent composition
- Document translation
- Rigorous quality assurance
- Multiple levels of quality control
- Dedicated project team
- Continuous process improvement
- Pre-review and consultation
- Real-time delivery to Internet portal
- Same day site review

Employees at IntegReview work in a fast-paced, highly responsive, open, and adaptive culture that is reflected in the company's mission statement to provide unsurpassed ethical review services while acting as an advocate for research participants.

Each committee is comprised of highly knowledgeable individuals with experience and expertise that exceeds 250 years. Additional expertise is available from other consultants when required. The organizational structure represents a multiple-member team that supports each committee.

All committees are registered with OHRP and FDA. Our last FDA inspection conducted in 2009 resulted in no findings.

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Certified WBENC Women's Business Enterprise

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DATE FOUNDED
1999

Marken

MARKEN®

Global Life Science Supply Chain Solutions

Corporate Description

Marken, a leading global clinical supply chain service provider, is dedicated to the pharmaceutical and life sciences industries. With decades of experience in the logistics, transport, and distribution of temperature-sensitive, life-saving pharmaceuticals; clinical trial supplies; and specimen collection, Marken can meet your needs. Our services include:

- Delivery of APIs, fine chemicals, and bulk drug products.
- Customs and regulatory support including reclaiming of VAT and Duties.
- Storage and delivery of clinical trial materials to investigator sites and patients.
- Collection and delivery of test specimens to central labs.

By integrating depot and logistics services, Marken offers its customers solutions that can extend the reach of clinical trials to even the most remote areas.

Marken Makes it Happen

- Temperature-sensitive assets arrive within specification, at temperatures ranging from deep frozen to controlled ambient.
- Marken's worldwide depot network provides access to over 49,000 investigator sites in over 150 countries around the world.
- State-of-the art information systems give customers immediate access to the status of shipments as well as inventory levels of critical assets.
- Marken's management team has over 150 years of combined experience in the pharmaceutical and logistics industries, allowing us to see your shipments through your eyes.

Marken

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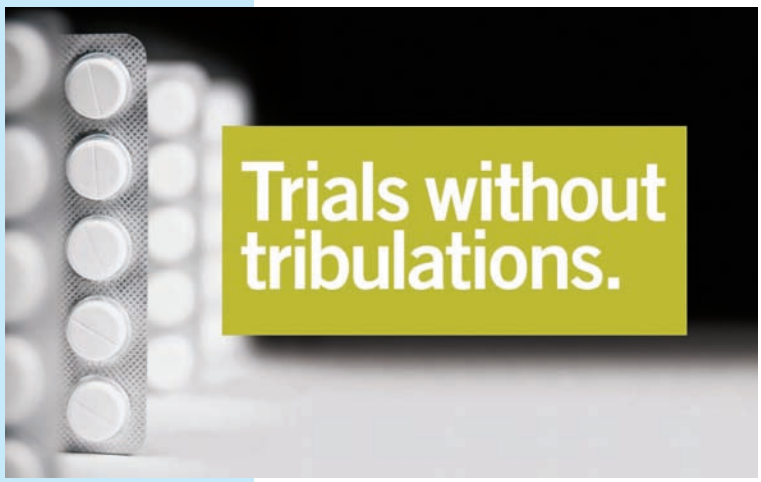
NUMBER OF EMPLOYEES
400

DATE FOUNDED
1980

Myoderm



Corporate Description

Myoderm is a world leader in the sourcing, distribution, and management of pharmaceutical products and supplies for clinical trials, including biosimilar trials. Our clients span the globe and include biotech companies, CROs, clinical trial packagers, and a majority of the world's top 10 pharmaceutical companies.

At Myoderm, we pride ourselves on our proven ability to secure the products and supplies our clients require with superior speed, efficiency, and economy. Through our deep expertise, innovative approach, and commitment to personalized service we offer two unique sourcing solutions to meet our clients' needs.

Services and Capabilities

GlobalSource—GlobalSource uses our international network of manufacturers and suppliers to access any quantity and type of drug you need for clinical trials. This includes branded, generic, and OTC products in all therapeutic classes and dosage forms, as well as hard-to-find medications.

GlobalSource Benefits

- Access to restricted/hard-to-find drugs through our relationships.
- Transparent pricing.
- Consultative guidance to analyze individual challenges and pinpoint customized solutions.
- Product integrity maintained with our secure GMP facilities.
- In-depth knowledge of global markets.

CentralSource—CentralSource is a revolutionary turnkey service that centralizes the sourcing, distribution, and inventory management of rescue, concomitant, and standard-of-care therapies for clinical trials. With CentralSource, all drugs and supplies are consolidated at our distribution facility, which then directly supplies each trial site on an ongoing, as-needed basis.

CentralSource Benefits

- Volume cost savings from consolidated sourcing.
- Standardized products ensure trial integrity.
- Drug pooling across multiple protocols minimizes waste.
- Detailed reporting and established resupply levels ensure accountability.
- Recall monitoring and lot traceability protect trial integrity and patient safety.
- Invoice consolidation and detailed reporting streamline administration.

MYODERM
The Optimal Source

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Europe: globalsales@myoderm.com

WEBSITE
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DATE FOUNDED
1987

Quintiles Outcome

SAFE AND EFFECTIVE IN THE REAL-WORLD

Corporate Description

Quintiles Outcome offers the expertise and experience in real-world and late-phase research you need to determine the right approach for the right question, to achieve your research objectives. Ensuring the right approach to the right question requires a comprehensive understanding of healthcare stakeholder needs. Deep therapeutic knowledge and understanding of the key issues combined with clinical experience from a global team of physicians drives more effective and efficient research. Whether monitoring safety and evaluating benefit/risk or demonstrating effectiveness and gaining market access or proving efficacy in new indications/new formulations, our experts provide the most comprehensive approach to evidence development.

Approaches

- Interventional trials
- Observational research and registries (prospective and retrospective)
- EHR and database studies
- Chart reviews

Research Questions

- Safety
- Benefit-risk
- Cost effectiveness
- Comparative effectiveness
- Efficacy
- Quality
- Value

Programs

- Registries: patient, disease, product, and pregnancy
- Post-approval and Phase IV studies
- Observational studies
- Phase IIIb/expanded access
- Market access
- Quality measurement and improvement initiatives
- Benefit risk management/RiskMAPS/REMS
- Safety and surveillance
- Health outcomes/health economics
- Quality of life
- Patient reported outcomes (PRO)
- Patient retention
- Performance tracking systems
- Instrument validation studies
- Controlled distribution programs
- Post-marketing/regulatory commitment
- Health interventions
- Performance-linked access systems
- Comparative effectiveness research

Markets served

We partner with life sciences companies, providers, healthcare organizations, specialty associations, hospital associations, pharmacist associations, managed care organizations, state departments of public health, quality improvement organizations (QIOs), payers, and government agencies across the globe to research products (drug, biologic, or medical device), healthcare services, diseases or conditions, and exposure.

Scientific leadership

Our Scientific Affairs team, comprised of epidemiologists, biostatisticians, pharmacists, health economists and clinicians, leads or assists in the development of scientific concepts and study protocols and guides study execution, analysis, and interpretation. They also provide guidance, as needed, through study start-up and conduct to overcome practical obstacles, support study analysis and reporting, and disseminate information through articles and presentations.

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WEBSITE
www.quintiles.com/outcome

PCM TRIALS

PCM TRIALS
QUALITY MOBILE RESEARCH

Corporate Description

PCM TRIALS takes trial visits to subjects, wherever they are (e.g., home), and has been providing home visits since 2008. PCM TRIALS' approach of directly hiring and certifying certified mobile research nurses (CMRNs), rather than subcontracting to local home health agencies, removes significant risk and administration normally associated with clinical trial home visits. Sponsors, CROs, and sites can be confident that home visits are carried out with the same quality and care as on-site visits. PCM TRIALS is a division of a national industry leader in specialized healthcare services: Professional Case Management.

Major Products/Markets Served

PCM TRIALS' CMRNs have completed thousands of home visits across a wide range of therapeutic areas. Mobile research services through PCM TRIALS are available throughout the United States, Canada, and overseas with our partners. By offering home visits with PCM TRIALS, sponsors, CROs, and sites see a significant improvement in recruitment and retention, which accelerates trials and reduces costs. PCM TRIALS' experienced central office staff and highly skilled CMRNs are dedicated to providing exemplary service to clients, investigator sites, and subjects.

Major Services

- CMRNs perform any trial services that are within their scope of practice and can be done with portable equipment (e.g., IP infusion, IP injection, draw and process specimens, centrifuge, ECG, INR, educate, assess for AEs/concomitant medications, etc.).
- PCM TRIALS' experienced clinical research staff coordinates and oversees the home nursing visits from the central office in Denver, CO to assure the proper provision of services in accordance with protocol, GCP, trial contract, and applicable regulations.
- A quality plan, quality controls, and quality assurance is standard for each trial.

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WEBSITE
www.PCMTRIALS.com

NUMBER OF EMPLOYEES
1200

DATE FOUNDED
2008

PRA

Corporate Description

PRA is transforming clinical trials through its people, innovation, and transparency. It serves clients across all phases of drug development in over 80 countries by combining therapeutic and operational expertise with local knowledge. PRA's 40+ drug approvals demonstrate its successful approach to clinical research.

PRA supports its global reach through flexible and reliable service, ensuring that sponsors achieve their long-term goals. With skilled project management and advanced technological tools, it achieves seamless delivery and operational transparency throughout the organization. PRA's dynamic services and forward-thinking approach to drug development programs are making a difference to healthcare patients worldwide.

Major Products/Markets Served

PRA performs studies in all therapeutic areas across all continents and phases (I-IV) of drug development.

Over the last 30+ years, PRA has amassed a level of expertise that has enabled it to work on a variety of compounds, including biosimilars, ranging from niche treatments to blockbuster drugs.

Major Services

PRA's core services:

- Bioanalysis, including biomarkers
- Phase I-IV study management
- Phase I clinic and bioanalytical lab "pairings" in the United States and Europe
- Therapeutic expertise (feasibility studies, protocol design, and scientific support)
- Post-approval study/registry management
- Safety and risk management/ pharmacovigilance

Services that Differentiate

- PRA's approach to project management underlies its commitment to exceeding clients' strategic and project delivery needs, while supporting and developing its employees. The model also clearly delineates ownership and accountability for clients and employees, providing greater efficiency for a global organization.
- A proven expert at executing complex, global oncology and multiple sclerosis trials.
- PRA's Clinical Informatics: the combination of current and historical patient data with proprietary methods leveraged to evaluate and select the best options for patient access.
- Unit on Demand Model: creates a specialized phase I environment within hospitals for early phase patient population study recruitment.
- Microdosing: complex, FIH studies and studies with delicate PK/PD objectives.

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EU: +44 (0) 118 918-1001

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WEBSITE
clearlypra.com

NUMBER OF EMPLOYEES
4,700+

DATE FOUNDED
1976

Quorum Review IRB

Corporate Description

Quorum Review IRB is a privately-held, independent ethics review board fully accredited by AAHRPP. Our mission is to safeguard the rights and well-being of research participants while enhancing the clinical research process. We provide sponsors, CROs, institutions, and sites with reliable, responsive service to support efficient study start-up and management. With 14 board meetings a week, Quorum Review provides 24-hour site start-up, 36-hour amendment review, same-day site changes, single point of contact for sponsors, and secure web portal for online submissions, downloads, and status.

Since 1992, Quorum Review has served the clinical research industry in providing ethics review of proposed and ongoing research and delivering documentation of the ethics boards' decisions and actions under strictly regulated standards. In 1992, Quorum's founders saw a need for an IRB that protected human participants while providing high-touch customer service. That's exactly what Quorum delivers. Each member of our team brings a wealth of experience in clinical research human participant protection—as well as the knowledge, reliability, accuracy, and speed that matters when getting products to market.

With a focus on performance, we've developed these core values:

- Ethical protection of human research subjects
- Customer service
- Continuous quality improvement
- Promotion of organizational capability

Our boards are composed of diverse individuals who collectively represent a wealth of experience and expertise in the clinical research process. The research Quorum Review oversees is in accordance with US and Canadian human research subject protection regulations, guidelines set forth by the International Committee on Harmonisation (ICH) and principles of Belmont Report.

We've maintained "Full Accreditation" by the Association for the Accreditation of Human Research Protection Programs (AAHRPP) since 2006, which signifies that Quorum Review IRB demonstrates overall excellence in providing the most comprehensive protections for research participants while facilitating the highest quality research processes.

Quorum Review IRB's Core Offerings include:

- AAHRPP fully accredited IRB services through 2014
- Fourteen board meetings per week
- Twenty-four-hour site start-up, 36-hour amendment review, and same day site changes
- Industry-leading regulatory experience
- Adaptable approach that supports institutional research
- Extensive IRB experience in all phases and therapeutic areas
- Dedicated oncology board based in Cambridge, MA
- Dedicated Phase I service team
- Abbreviated post marketing/registry forms
- Secure, easy-to-use, online portal with smart-forms and 24/7 document access
- Single point of contact for the life of any study
- 100% quality control of all documents
- Best-in-class study support and guidance available from 8 a.m. to 8 p.m. EST

At Quorum Review, performance is in our DNA, as we have demonstrated through our commitment to high standards of patient protection and regulatory compliance. Through the last two decades, Quorum Review has innovated to simplify and streamline quality research review for participants, sites, and sponsors alike. Renowned for best-in-class service and support, we are passionate about our work and the accuracy and speed of our service, and we are proud of the customer focus that has grown our business.

Quorum Review IRB
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www.QuorumReview.com

DATE FOUNDED
1992

REGISTRAT-MAPI

Corporate Description

REGISTRAT-MAPI provides a complete spectrum of services to optimally design and implement Phase IIIb–IV clinical studies, registries, post-marketing studies, safety surveillance, risk management programs, and patient reported outcomes. REGISTRAT-MAPI provides strategic solutions to its global clients to optimize clinical and commercial benefits that contribute to a successful product launch and support ongoing clinical and commercialization efforts.

REGISTRAT-MAPI is the only CRO exclusively dedicated to late phase clinical research design and operational services. Our personnel collectively apply years of multidisciplinary experience working specifically with the complexities and nuances of large observational and clinical studies.

Focused Expertise

- Post-marketing requirement studies (PMR, PASS)
- Phase IIIb–IV studies
- Disease/product registries
- Pregnancy registries
- Risk management programs
  - o REMS, EU-RMP, PLAS
- Safety surveillance studies
- Market access
  - o Product utilization studies
  - o Pharmacoeconomic studies
  - o Retrospective studies
  - o Database studies
  - o Chart reviews
- Comparative effectiveness research (CER)
- Rare/orphan disease expertise/expanded access programs
- Epidemiology studies
- Patient reported outcomes
- Product commercialization

Specialized Services

- Strategic consulting
- Clinical services
- Safety management
- Project management
- Regulatory management
- Site enrollment and training
- Site and patient retention strategies
- Data management
- Statistical programming
- Biostatistics
- Medical writing and publications
- Quality assurance
- Direct-to-patient contact management
- Epidemiology

Innovative Technologies

- **Site management technologies**
  - o REGISTRAK®
  - o Investigator/site enrollment portal technologies
- **Data collection technologies**
  - o Electronic data capture (EDC) system design/implementation
  - o Electronic patient reported outcomes (ePRO) solutions
  - o Interactive voice/web response systems (IVRS/IWRS)
  - o Fax scanning
- **Reporting technologies**
  - o Data visualization technology

REGISTRAT-MAPI

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Spectra Clinical Research

Nicholas Brownlee, PhD, President

We pride ourselves in working side-by-side with our customers to understand their specific needs and move their trial toward success.

Corporate Description

Spectra Clinical Research provides central laboratory services to pharmaceutical companies, academic institutions, and other medical organizations conducting Phase I–IV clinical trials. Backed by over a decade of clinical trial expertise and 30 years of central laboratory services to the dialysis community, we are able to support diverse clinical trials of all sizes.

Spectra Clinical Research acts as a unique resource for organizations conducting clinical trials. As a division of Spectra Laboratories, we leverage the capacity and technology of a large organization while maintaining the flexibility and responsiveness of a small specialty laboratory. We continually review and streamline our processes to ensure timely, accurate results. Furthermore, our advanced testing platforms, specimen management, online data management application, and dedicated team of service specialists help move each trial toward a successful outcome.

Markets Served

Spectra Clinical Research provides central laboratory services to pharmaceutical, biotechnology, research, government, and academic organizations. We have participated in trials spanning a wide range of therapeutic areas including nephrology, gastroenterology, oncology, women's health, and central nervous system (CNS) disorders. Our global support network ensures continuous, reliable service for clinical trials in locations worldwide including North America, Israel, South America, Europe, Australia, South Africa, Asia, and India.

Products and Services

- A dedicated project manager prepares all study-specific documents, coordinates activities with partner laboratories, and attends investigator meetings.
- Specially trained personnel shepherd each sample through the laboratory.
- Designated customer service representatives assigned to each study ensure personalized assistance throughout the trial.
- Support for numerous esoteric tests includes soluble transferrin receptor, aluminum, zinc, I-PTH, and others.
- Microbiology department offers 24/7 testing services for bacteriology.
- Pediatric testing services.
- ELISA and EIA tests can be set up and validated.
- Advanced web-based reporting and data management.

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research.com

How high?

At Spectra Clinical Research, we believe you deserve more than clinical expertise from your **central laboratory** partner. You deserve responsiveness and flexibility. That's why our dedicated project managers and customer service specialists make it a point to understand your unique needs and deliver unmatched support every step of the way. It's also why we're always updating our state-of-the-art facilities and streamlining our processes to deliver accurate results—on time, every time.

Give us a call today, and see how high we'll jump for you.
1-800-517-7157 or visit www.spectraclinicalresearch.com

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www.spectraclinicalresearch.com

spectra®
clinical research
Spectra Clinical Research is a division of Spectra Laboratories

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NUMBER OF EMPLOYEES
400

DATE FOUNDED
1995

Corporate Description

As a full-service CRO, we partner with you to ensure your trials are managed efficiently and meet objectives. Founded in 1995, Synteract has longstanding experience and a high rate of repeat business. We have managed more than 1,400 projects across all phases of clinical development, and have contributed to 24 product approvals. Shared Work—Shared Vision is more than a tagline at Synteract; it's the way we do business, a promised standard that includes ongoing support from a specialized team dedicated to meeting or exceeding your expectations.

Services

- Project management
- Clinical operations
- Data management
- IVRS/IWRS
- Medical monitoring
- Medical and regulatory affairs
- Medical writing
- Biostatistics
- Safety

Major Therapeutic Areas

We have broad experience guiding companies in drug, diagnostic ,and device trials for a wide range of therapeutic areas, including a notable emphasis in oncology, central nervous system, cardiovascular, respiratory, and ophthalmology.

A Leader in Rescue Studies

Over our history, we have saved many studies; in fact, we rescued 29 studies since 2009 alone. Switching CROs is not an easy decision; there are many considerations to be weighed before making a change. Even when a project seems like it has gone off the rails, it does not necessarily mean that it needs to be rescued. We help you to identify contributing factors and implement solutions to address the issues to keep the project moving forward, as well as address the impact to the project timeline and budget that may result from any changes.

Relationships Matter

We work with you to set expectations, customize project plans, and identify deliverables. Our high rate of repeat business and referrals—greater than 90%—is proof of our integrity.

Technology Experts

We offer flexible technology solutions to support efficient management of your trials. Our teams support multiple industry-recognized software and technology platforms. Our hybrid EDC platform allows multiple modes of data entry in one study, including web based, paper, and fax, to make data capture easy at a low cost.

Always Accessible

Your dedicated project team is directly accessible and always responsive. Executives and senior leadership alike are equally committed to our "Shared Work—Shared Vision" philosophy; it truly is the way we do business.

What We Say is What We Do

Perhaps our most important differentiator, we deliver what we promise. Trust us to deliver high quality yet personal service as an extension of your team.

Online Resources

Download our data sheets, brochures, and white papers at: www.synteract.com/News-Events/Resources.

Synteract
SHARED WORK – SHARED VISION

Theorem Clinical Research

When you need to simplify your most complex trials, THINK THEOREM.

Corporate Description

Theorem Clinical Research Inc. is a leading midsized provider of comprehensive clinical research and development services with offices in more than 30 countries and a customer base comprised of some of the world's leading pharmaceutical, biotech, and medical device companies. A leader in medical device and drug-device combination trials in addition to a notable capability in pharmaceuticals and biologics, Theorem has deep expertise in a broad range of therapeutic areas and in all phases of development. Some of the industry's top scientists and most advanced clinical analytics capabilities help ensure smooth-running, successful trials.

Clinical Trial Services

- Project management
- Clinical monitoring
- Clinical supply
- Data management
- Clinical analytics
- Regulatory services
- Global clinical grant administration
- IDMC-DSMB and CEC management
- Clinical quality assurance
- Pharmacovigilance
- Medical writing
- Medical monitoring
- CDISC

Study Initiation Services

- Feasibility
- Investigator recruitment
- Site activation
- Local country clinical trial applications
- Project kickoff and planning process

Early-Phase Studies

- First-in-human
- Single/multiple ascending dose
- Experimental medicine
- Drug-drug interaction
- Pharmacokinetics/pharmacodynamics
- Food effect
- QT
- Proof-of-concept
- Bioavailability/bioequivalence

Early-Phase Therapeutic Expertise

- Cardiovascular
- Musculoskeletal
- Ophthalmology
- Vaccines
- Nephrology
- Oncology
- Virology
- Hepatology
- Obstetrics/gynecology
- Respiratory/pulmonary
- Endocrine
- Neurology
- Psychiatry

Late-Phase Capabilities

- Health outcomes
  - o Pharmacoeconomics
  - o Patient reported outcomes
  - o Quality of life
  - o Cost-effectiveness analyses
  - o Epidemiological trials
  - o Time and motion studies
- Peri-approval trials
  - o Patient/disease registries
  - o Expanded access programs
  - o Treatment INDs
  - o Observational studies
  - o Phase IV trials

Phase IIIb/IV Experience

- Cardiovascular
- Dermatology
- Gastroenterology
- Hematology
- Internal medicine
- Oncology
- Radiology
- Surgery
- CNS
- Endocrinology
- Genitourinary
- Immunology
- Musculoskeletal
- Psychiatry
- Respiratory
- Transplant

Strategic Sourcing Solutions

- Temporary staff augmentation
- Functional service provision
- Functional project provision

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NUMBER OF EMPLOYEES
900+

DATE FOUNDED
2011

BUSINESS AND PEOPLE UPDATE

People

◗ **DAC Patient Recruitment Services** (Dallas, TX) announced that **Diana Anderson**, PhD, will transition from her role as President to that of Patient Recruitment Consultant to the company she founded 20 years ago.

◗ **Biomedical Systems**, (St. Louis, MO) a global provider of digital medical imaging technologies and centralized diagnostic services, has named **Joseph A. Pierro**, MD, its chief medical officer for Biomedical's North American operations. In his role, Pierro and his team will advise clients on their clinical trial protocols, supporting studies conducted in the fields of cardiology, oncology, imaging, and pulmonology.

◗ **Chiltern International Limited**, (London, UK) a global contract research organization, announced that **Dieter Seitz-Tutter**, PhD, and **Alexandra Adams**, PhD, have joined Chiltern.

◗ **Copernicus Group IRB**, (Research Triangle Park, NC) an independent institutional review board, announced the promotion of **Yvonne Higgins** to Vice President, Quality Management. In addition to her promotion, Higgins has been appointed as CGIRB's Institutional Official.

◗ **ICON plc**, (Dublin, Ireland) a global provider of outsourced development services to pharmaceutical, biotechnology, and medical device industries, announced leadership appointments to its Asia Pacific and Latin American teams. **Wei Ming Goh** has been appointed Vice President, Asia Pacific, and **Dennis Hurley**, PhD, has been appointed Vice President, Latin America.

◗ **RadSite**, (Houston, TX) certification and accreditation agency for imaging quality, announced two new additions. **Eliot Siegel**, MD, has joined the team as Chief Quality Officer. Siegel will help oversee and promote the integrity of all quality-based programs and research initiatives for RadSite. **Bruce Reiner**, MD, a board certified radiologist, has also joined the team as Director of Accreditation. Reiner will help ensure RadSite's quality-benchmarking program conforms to current best practice standards.

◗ **Chiltern International Limited**, (London, UK) announced a succession of Chief Executive Officer, with **Glenn Kerkhof** stepping down and **Jim Esinhart**, PhD appointed.

◗ **PharmaNet/i3**, (Princeton, NJ) inVentiv Health's clinical segment, announced that **Jamil Hantash**, MSc, MBA, has joined the company as the Director of Immunochemistry Operations at the Princeton bioanalytical laboratory.

◗ **AIT Bioscience**, (Indianapolis, IN) announced that **Ron Bowsher**, PhD, has partnered with the company as a Senior Research Advisor bringing with him a background in biotherapeutic drug research in both traditional pharmaceutical and the CRO industries.

◗ **Advanced Clinical**, (Deerfield, IL) provider of clinical research solutions, announced additions to its leadership team: **Susan Seroskie**, RN, has been hired as Executive Vice President, Strategic Resourcing; and **Susan Paulson**, PhD, has been hired as Executive Director, Clinical Pharmacology and Nonclinical Development.

◗ **Clinlogix**, (Spring House, PA) a clinical research organization, brought **Julie McCusker**, RpH, onboard as Senior Director, Safety Services.

◗ **Comprehend Systems**, (Palo Alto, CA) has named **Rich Enz** as Vice President of Quality Assurance to support the development of pioneering cloud-based analytics tools.

◗ **CTI Clinical Trial and Consulting Services** (Cincinnati, OH) announced the following new hires: **Betina Dellarossa**, MD, has joined CTI Latin America as Manager, Business Development; **Els Roggeman** has joined as Clinical Project Manager Europe in Belgium; **Julia Höchst** has joined as Clinical Trial Assistant in Germany; **Michelle Schutz** has joined Clinical Research Associate in Germany; **Nathalie Minasian**, PhD, has joined as Clinical Project Manager Europe in France; **Adenike Igoh** has joined Clinical Project Manager in United Kingdom. CTI also promoted **Emily Wiggins** to Human Resource Generalist.

exl pharma

2nd Annual C.R.O.W.N

Clinical Research Operations & Worldwide Networking

5 STREAMS - 1 SUMMIT - ALL ACCESS

- 6th Lean Sigma for Life Science R&D
- 4th Collaborative Site/Sponsor Partnerships
- 7th Forecasting & Optimizing the Clinical Supply Chain
- 9th Clinical Alliances in Emerging Regions
- 4th Digital Engagement & Social Media in Clinical Trials

MARCH 20-22, 2013

LOEWS PHILADELPHIA HOTEL

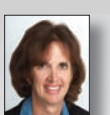
PHILADELPHIA, PA

2013 C.R.O.W.N FEATURED PLENARY SESSIONS

PATIENT PERSPECTIVE

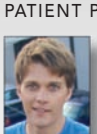
Improving Clinical Research through the Voice of the Patient

MODERATOR:

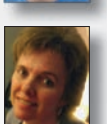


LINDA STRAUSE, PhD
Executive Director and Head, Clinical Operations
VICAL INCORPORATED

PATIENT PANELISTS:



SEAN AHRENS
Founder
CROHNOLOGY



JERI BURTCHELL
E-Patient
GILENYA AND ME

KERRI SPARLING
Patient Opinion Leader
SIX UNTIL ME

EXECUTIVE PANEL

The Current Strategy and Future Direction of Clinical Research Activity

EXECUTIVE PANELISTS:

PAUL BURTON
Vice President, Clinical Transformation Leader and Head, Trials Coordination and Site Management for the Americas
JOHNSON & JOHNSON

RAKESH DIXIT, PhD DABT
Vice President, R&D, Global Head, Biologics Safety Assessment
MEDIMMUNE

SUE WHITT
Vice President, Continuous Improvement, Strategy, Portfolio & Performance
ASTRAZENECA PHARMACEUTICALS

2013 C.R.O.W.N ATTENDEE BENEFITS

- Customize Your Agenda Across 5 Different Programs at NO EXTRA COST
- 70+ Unique Educational Sessions Spanning the Clinical Research & Operations Landscape
- Plenary Sessions including "Voice of the Patient", Executive Panel, and 1st Annual C.R.O.W.N Awards
- 5+ Pre-Conference Workshop Sessions Tailored to Your Professional Focus
- 10+ Networking Opportunities including Meals, Breaks, and Receptions
- Shared Exhibit Hall Guaranteeing Access to Over 300 Attendees
- ALL IN ONE C.R.O.W.N LOCATION!

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ALMAC Partnering to Advance Human Health

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epharmasolutions

perceptive INFORMATICS

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Leading Media Partner

Applied Clinical Trials

LEARN MORE AT **WWW.CROWNCLINICAL.COM**

PHT Corporation (Boston, MA and Geneva, Switzerland) announced **Susan Dallabrida**, PhD, has joined as Senior Scientific Advisor in PHT Consulting Services.

Advanced Clinical (Deerfield, IL) announced that **Melissa Lamb**, Director of Data Management, has been named to the Board of Trustees for the Society for Clinical Data Management.

Medidata Solutions (New York, NY) announced that **Eileen Schloss**, human resources and business administration executive, has been named Executive Vice President of Human Resources.

Acquisitions

• **CRA Holdings, LLC**, (Tempe, AZ) announced that it has acquired Radiant Research, Inc. CRA Holdings also owns Clinical Research Advantage (CRA), another major player in the SMO market. By combining these two entities under the same investment portfolio, the organizations collectively have 57 sites with more than 550 research professionals and a plan for growth.

Alliances

• **SpringFire Laboratory Network**, (Austin, TX) announced the addition of ReproSource Fertility Diagnostics of Boston to its network of affiliate laboratories, which provides specialized testing services to clinical trial sponsors and clinical research organizations.

• **Clinical Research Management (ClinicalRM)**, (Hinckley, OH) a full-service CRO providing services for basic and applied research, clinical trials, and regulatory support, announced it will support prime Ke`aki Technologies, LLC with its award of CIO-SP3 contacts for both Small Business and Small Disadvantaged Business categories.

• **BioClinica, Inc.**, (Newton, PA) a global provider of clinical trial management solutions, today announced that TauRx Therapeutics has signed agreements with BioClinica to use Trident IWR/IVR and Imaging Core Lab (ICL) solutions to support its upcoming Phase III clinical trials

.

Awards

• **Clinical Research Advantage**, (Tempe, AZ) Vice President, **Kim Kundert,** RN, BSN, CCRC, has been named as a finalist in the Female Executives of the Year category in the 9th annual Stevie Awards for Women in Business. The awards honor women executives, entrepreneurs, and the companies they run—worldwide.

• **OmniComm Systems, Inc.**, (Fort Lauderdale, FL) announced that its TrialMaster Study Data Tabulation Model Export Utility won the Bronze medal at the 2012 Society for Clinical Data Management's 2012 Data Driven Innovation Award Ceremony.

• **ERT** (Philadelphia, PA) announced it has been named the Life Sciences Company of the Year by the Pittsburgh Technology Council's Tech 50 Awards Program. ERT received the award based on the successes and innovations demonstrated by invivodata, Inc., which was acquired by ERT in July 2012.

• **Quotient Bioresearch**, (Cambridgeshire, UK) provider of early stage and specialist drug development services, has been presented with three awards at the East Cambridgeshire Business Awards. Quotient won awards in both categories they were finalists for; **Michael van der Merwe,** PhD, Associate Director of Business Development won Business Person of the Year, and the company won Employer of the Year. The Awards also saw Quotient receive the Business of the Year award for the second consecutive year.

• **The Advanced Group** (Chicago, IL) has been recognized by the *Chicago Tribune* as one of the Top Workplaces to work in the Chicago metropolitan area for the third consecutive year. Advanced is the only staffing organization to make the Top Workplaces list.

• **Quintiles** (Research Triangle Park, NC) has been recognized as one of the World's Best Multinational Workplaces by the Great Place to Work Institute, finishing 23rd on the list. The ranking is the world's largest annual study of workplace excellence and identifies the top-25 best multinationals in terms of workplace culture. This is Quintiles' second appearance on the list.

Company News

• **ACM Global Central Lab**, (Rochester, NY) has expanded its clinical trials services with the introduction of Drug-Induced Organ Toxicity (DIOT) Monitoring. The DIOT Monitoring program provides trending reports for any conventional biomarkers tested, which is tailored to client requirements.

• **OmniComm Systems, Inc.**, (Fort Lauderdale, FL) announced its inclusion in Software Magazine's "Software 500" ranking of the world's largest software companies in 2012. The annual "Software 500" is a revenue-based ranking of the world's largest software and services suppliers and includes revenue from software licenses, maintenance and support, training, and software-related services and consulting.

• **LabConnect, LLC**, (Seattle, WA) launched its new service, Scientific Operations Support (SciOps), to offer functional outsourcing services to the pharmaceutical research industry.

New Products

• **ArisGlobal**, (Stamford, CT) a provider of software solutions to the life science industry, announced the availability of Total Clinical 3.0, offering additional enhancements to its integrated eClinical platform.

New Facilities

• **WorldCare Clinical, LLC (WCC)**, (Boston, MA) an imaging CRO focused on maximizing the precision and accuracy of independent assessments in clinical trials, announced new locations in Brazil, Dubai, Poland, Spain, and Singapore.

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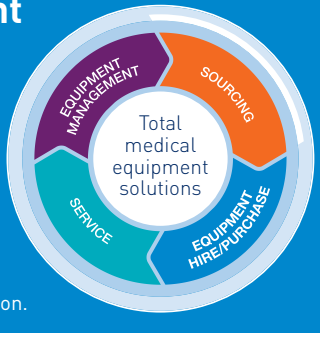

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Oh No Not Again...

Investigator training should not be a "one-off" session at the start of clinical trial.

Nicky Dodsworth
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ICH GCP, the backbone of clinical research in the ICH regions has been in place for more than 15 years. Repeated training on this standard has been conducted as we have no other way of recognizing whether the investigators who work on our studies are suitably qualified. Despite all this training the same findings keep occurring. The pharma industry needs to re-think its approach as our previous efforts have clearly not been effective.

Development of investigator training on aspects of GCP by an independent body that regulates the courses and provides tangible evidence of achievement as defined by the accrediting body is the way forward. We need to ensure that investigator attendance is not just passive, and that learning outcomes are clearly defined and are fit for purpose. Investigator training should not be a "one-off" session at the start of clinical trial, but a continual assessment with repeated re-certification at clearly defined time points.

When we think about the requirements of the "independent body" it is important that they have a suitable infrastructure with trainers who have the knowledge and expertise to deliver education. The GCP course should cover the required elements as "bite-sized learning" or a modular approach, so topics can be studied at convenient times. The nuances of GCP using real-life experience along with conducting testing at the beginning and at the end of each module will make this more applicable to investigators in their daily activities and will help to focus the investigator on the training being delivered.

Training will need to fulfill set requirements and be recognized by the pharma industry. Undoubtedly this is a cultural shift in the way the industry currently works, but there are several companies that are now starting to work together in this direction.

If this type of training is established we must ensure that this is not just to benefit the pharma industry. Training such as this will have mutual benefits to the investigator and their site staff and also increase public confidence in the way clinical research is conducted. When clinical research professionals attend training that provides them with a recognized accreditation this will also support the development of their career. Accreditations will need to be recognized by their employers and be transferable.

The pharma industry has been reticent about sharing best practices in the past and has been reluctant to work together on such projects. The involvement of "independent bodies" acting as an intermediary could be the way forward, the issue may be the fact that there are several of these organizations currently starting to be involved in this process which could be counterproductive. It may take a government or national body or a more global "independent" organization to finally make this work.

The spirit of harmonization has never been greater, so now is the time to work together to standardize investigator GCP training and establish mutually recognized certified courses that can deliver effective understanding of the requirements, enhancing the quality of data and patient safety. Industry support is vital in helping define and establish such training. It is to our advantage that we support this initiative as this has significant time and cost implications—the previous way we have worked has not been successful. Now is the time for change and we are the ones that can make it happen. ❑

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