Volume 22 Number 7/8 July/August 2013

INSIDE: Risk-Based Monitoring

APPLIED CLINICAL TRIALS

Volume 22 Number 7/8 July/August 2013

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- Fragmented Study Conduct Landscape
- Comprehensive Evidence Development

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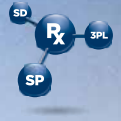

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BACK OR CURRENT ISSUES +1 (800) 598-6008, +1 (218) 740-6480 (outside USA)

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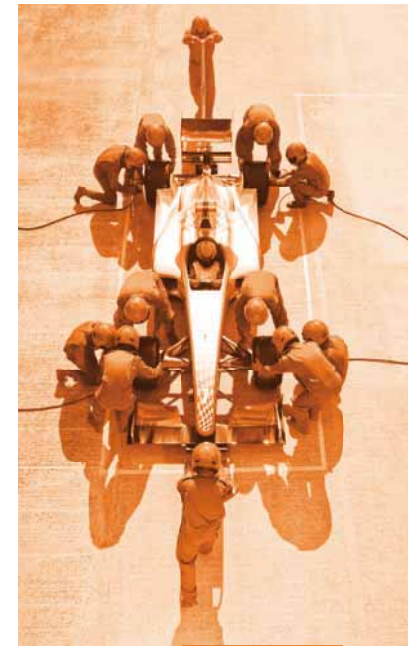
APPLIED CLINICAL TRIALS (Print ISSN: 1064-8542, Digital ISSN: 2150-623X) is published monthly except July/Aug and Dec/Jan combined, by Advanstar Communications Inc., 131 West 1st Street, Duluth, MN 55802-2065. Subscription rates: $70 for 1 year (12 issues), $120 for 2 years (24 issues) in the United States and possessions; $90 for 1 year, $140 for 2 years in Canada and Mexico; all other countries $130 for 1 year, $235 for 2 years. Single copies (prepaid only): $9 in the United States and possessions; $11 in all other countries. Add $6.50 per order for shipping and handling. **Periodicals postage paid** at Duluth, MN 55806 and additional mailing offices. **POSTMASTER:** Please send address changes to *APPLIED CLINICAL TRIALS*, P.O. Box 6115, Duluth, MN 55806-6115. PUBLICATIONS MAIL AGREEMENT NO. 40612608, Return Undeliverable Canadian Addresses to: IMEX Global Solutions, P. O. Box 25542, London, ON N6C 6B2, CANADA. Canadian G.S.T. number: R-124213133RT001. Printed in the U.S.A.

APPLIED CLINICAL TRIALS

VOLUME 22, NUMBER 7/8



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COVER STORY

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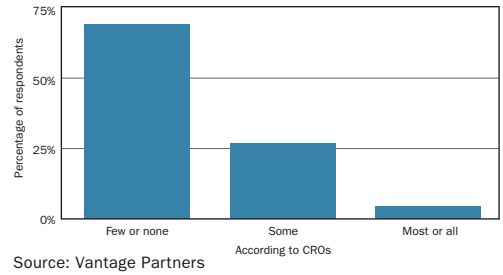

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eLearning

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This webcast discusses non-restorative sleep and how it affects the sleep disorder therapeutic market, www.appliedclinicaltrialsonline.com/impact.

How Registries and Observational Studies Inform Clinical Decisions

This webcast provides information and case studies on how genetic disease research is impacting data collection for patients, www.appliedclinicaltrialsonline.com/benefits.

Gamification, A Tool for Effective Patient Retention

Although there are already lots of applications for gamification in pharma, the most natural and generally untapped opportunities lie in clinical trial retention. When there is a captive patient audience there is an opportunity to provide real value without needing to try and sell a product. What's more, there is a real need to keep patients motivated and happy while they are on a trial to help prevent false negative reporting caused by trial fatigue.

At Langland we often get asked to create a reminder or calendar app to aid compliance and keep everyone motivated. Unfortunately, not many people really want to go to the effort of downloading an app or regularly visiting a website because they often don't understand the benefit of doing so. This can result in the creation of an expensive tool that not many people will use and that therefore won't deliver what is needed.

Gamification is the natural add-in as it helps build a framework around reminder/calendar functionality. However, it can be all too tempting to just bolt on a scoring matrix, rewards structure, and leader board in the hope that patients will happily compete against themselves to complete their retention tasks for us. Unfortunately, such approaches are not creative and can skew results, leading many pharma companies to be rightly nervous of investing in any game-based retention program.

Mark Evans, *Digital Strategy Director, Langland*

Visit http://bit.ly/12RW9m9 for the full version of this article

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Risk-Based Monitoring in One Place

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RISK-BASED MONITORING

Blogs

Here's the dilemma. How do CRA's get the stated two years experience before a pharmaceutical company will hire them? In the time-pressured environment of clinical research, there is a reluctance to invest time and money in training new graduates. What do you think? Visit www.appliedclinicaltrialsonline.com/blogs.

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GLOBAL NEWS

Controversy Grows Over How Best to Share Data

Are clinical trial data shared sufficiently today? That was the topical question asked in a debate between two international experts who took opposing views published by bmj.com on July 9.

"Dumping millions of pages of clinical trial information into the public domain without providing appropriate scientific and clinical context or guidelines for meta-analysis could lead to second guessing of the expert decisions of national regulators worldwide, undermining patient trust and confidence in the safety and effectiveness of approved medicines," noted John Castellani, president of the Pharmaceutical Research and Manufacturers of America (PhRMA). "Mandatory public disclosure of intellectual property, confidential commercial information, and proprietary scientific methods found in clinical trials could stifle discovery and open the possibility of competitors or unscrupulous actors using the information for their own products in other markets or countries."

Processes for data sharing or disclosure must take account of patients' informed consent and the reality that re-identification of patients based on anonymized information is possible, he added. Threats to patient privacy will jeopardize willingness to participate in clinical trials, which would delay the availability of new therapies.

Without appropriate protection for intellectual property to incentivize the enormous investment risk involved, biopharmaceutical companies will be discouraged from investing in the next generation of new medicines, wrote Castellani. The current system has led to more than 340 new medicines approved by FDA over the past decade, with 39 new medicines in 2012 alone, and has contributed to over 30 new medicines approved for HIV in the past three decades, based on the work of 2,400 completed trials, he argued.

"No government or academic institution has the resources or multidisciplinary expertise to conduct the clinical trials needed to develop the new medicines patients need. Only the biopharmaceutical industry can take on this considerable risk at such a scale, and only a carefully balanced regulatory and competitive environment can foster the future investments in this research necessary to produce new treatments to benefit current and future patients," stated Castellani.

Presenting the opposing view was Ben Goldacre, PhD, research fellow at the London School of Hygiene and Tropical Medicine, who thinks the lack of progress on transparency has been startling and the problem of missing trials is one of the greatest ethical and practical problems facing medicine today. Evidence is necessary to make informed decisions about medicines, but current estimates suggest that around half of all trials for the treatments being used today have gone unpublished, and that trials with positive results are twice as likely to be published, he pointed out.

Legislation mandating greater transparency, such as the law requiring trial results to be posted on clinicaltrials.gov, has been largely ignored, and he calls for trials from the past to be fully disclosed because more than 80% of the medicines prescribed this year came onto the market more than a decade ago. Furthermore, claims that it is enough for regulators to see all the information on trials expose patients to real and unnecessary risks because problems with evidence are also identified by academics and doctors working outside of regulatory bodies, he noted.

Clinical study reports should be shared publicly, and information about individual patients must be added where necessary. Goldacre explained that 1.6 million pages of this material have already been shared by the EMA, and GlaxoSmithKline has also committed to share all clinical study reports as part of the AllTrials campaign.

On the issue of patient privacy, he does not call for individual patient records from trials to be published openly, but he does point to several examples of sensible and cautious sharing of detailed datasets among professionals. "The AllTrials movement is driving the solution forwards: patients need industry to engage constructively with this widespread consensus, on the practical details—urgently—so that we can all move on," he wrote.

EMA has released a draft policy on the publication and access to clinical-trial data for a three-month public consultation (http://bit.ly/13Yj3cE). Groups and individuals have until September 30 to send their comments to ctdatapolicy@ema.europa.eu. Earlier this year, EMA announced its commitment to the proactive publication of data from clinical trials submitted in support of a marketing authorization application, once the decision-making process has ended, and it thinks the release of data is vital to establish trust and confidence in the system.

According to a statement on the Agency's website, "The draft policy has been designed to balance out the commitment to give widest possible access to data for independent scrutiny with the need to protect personal data as well as legitimate commercially confidential information."

—*Philip Ward*

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VIEW FROM WASHINGTON

Guidance and Strategies for Spurring Development of New Therapies

Everyone is looking to rev up the biopharmaceutical development pipeline, and the FDA is working hard to do its part. The agency is publishing guidances and updating rules to clarify its approaches for testing new drugs, many required by the FDA Safety & Innovation Act of 2012 (FDASIA) and its user fee programs.

To move drug candidates through the review process more efficiently, FDA issued a much-anticipated guidance in June that compares the objectives and requirements of four FDA programs to expedite the development and review of new drugs and biologics: fast track, accelerated approval, priority review, and the relatively new breakthrough therapy designation (http://1.usa.gov/12IZNWi). A chart lists qualifying criteria, sponsor actions, and the features and benefits of each designation. In the process, the guidance defines when a condition can be considered "serious," how to determine whether "existing" treatment is "available," and what kinds of conditions qualify as an "unmet medical need."

There's also new guidance for biopharma companies looking to co-develop two or more investigational drugs, designed to spur research on combination therapies to treat complex critical diseases such as cancer, serious infections, and cardiovascular disease. The guidance advises sponsors on determining when codevelopment might be appropriate and how to conduct nonclinical and clinical studies to test the safety and efficacy of individual compounds and the drugs in combination.

To assist the growing number of pharma companies looking to develop therapies for rare diseases, FDA updated its 1992 orphan drug regulations with a new rule published in the Federal Register, June 12, 2013. The revision aims to define more clearly what constitutes an "orphan subset" and clarify policies for obtaining designation as an orphan drug. Another new proposed rule meets a FDASIA requirement to speed the development of new pediatric treatments by requiring sponsors to submit pediatric study plans earlier in the testing process.

Additional documents advise sponsors on providing patients with access to promising critical therapies still being tested. One draft guidance issued in May clarifies FDA's process for permitting expanded access to investigational new drugs for patients seeking treatment, and another discusses policies for companies seeking to charge for investigational drugs made available under expanded access.

To avoid premature disclosure of investigations into research misconduct by individuals, FDA has issued a final rule that permits it to keep certain investigatory material confidential. Normally, the Privacy Act gives individuals the right to information compiled on them by a federal agency, but FDA is exempt in cases where research fraud might be involved and disclosure would jeopardize the integrity of FDA research misconduct proceedings.

Tackling conditions

Then there's a range of advisories on developing drugs to treat specific conditions or diseases. Last month, the Center for Biologics Evaluation and Research (CBER) issued a draft guidance on designing early-phase clinical trials for cellular and gene therapy products. CBER acknowledges that the distinctive features of these products may warrant different approaches to choosing a study population, using a control group, dose selection, monitoring, and study follow-up.

Another draft guidance aims to encourage development of new antibacterial therapies, supporting a FDASIA program for generating new antibiotics. It encourages innovative research approaches, such as pooling data from various sites, adopting new endpoints, and using animal data to complement clinical results.

Recent guidances also discuss developing drug products for rheumatoid arthritis and for antiretroviral drugs for treating HIV. Sponsors can gain additional insight into new research strategies through FDA public meetings designed to gain input on patient-focused strategies for developing HIV treatments and therapies for lung cancer.

Rescuing abandoned drugs

Another much-discussed strategy for spurring new drug development is for academic scientists to take a fresh look at compounds that pharma companies started to develop, but dropped along the way. Now the National Institutes of Health (NIH) drug "repurposing" initiative has moved forward, with a first round of grants totaling $12.7 million from the National Center for Advancing Translational Sciences (NCATS). The awards will support nine projects to conduct further research on compounds that pharma companies have stopped testing, largely due to poor efficacy or for business reasons.

Astra Zeneca, Eli Lilly, Johnson & Johnson's Janssen, Pfizer, and Sanofi are supplying the compounds for these first projects, which will be tested collaboratively in pre-clinical through Phase II studies (http://1.usa.gov/12GVji5). Industry has been skeptical that the NCATS repurposing program will bear fruit, but the initiative has strong backing from NIH Director Francis Collins as a strategy for accelerating discovery of new therapies for critical diseases.

—Jill Wechsler

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TRIAL OPTIMIZATION

Paperless Clinical Trial Optimization–Thinking Outside the Box

The FDA realized the need to modernize clinical trials as part of its Critical Path Initiative, with the goal to better prepare investigators to safely and effectively perform clinical studies of investigational products. The European Medicines Agency is working on ways to streamline clinical development, for example, with a recently released draft, "Reflection Paper on GCP Compliance in Relation to Trial Master Files (Paper and/or Electronic) for Management, Audit, and Inspection of Clinical Trials," http://bit.ly/15s52Ic. The paper hints at and paves the way to move towards a fully electronic trial master file process.

more than 75% of 121 global investigative sites TransPerfect surveyed in October 2011 confirmed they use electronic data capture, 100% of the sites shared that regulatory binders and essential documents are still handled on paper. The majority of the sites indicated this was a sponsor/CRO requirement, even though the sites prefer to receive documents electronically.

There would also be a greater struggle to support multiple vendors. In a recent survey presented at the DIA 2013 Annual Meeting, data showed that sites typically work with between six and 10 different vendors when executing a study. Multiply this across studies and the number of vendors and contact points can be quite large, not to mention the number of passwords to be maintained.

Best practices for clinical study and development conduct can streamline administrative burdens.

While sponsors, regulatory authorities, and CROs are collaborating, initiatives to streamline the interactions required during clinical trials for investigative sites are happening in a limited fashion at best. This is due to the sparse tools and high level of administrative activity.

Over the past 10 years, clinical trials have become more global, driven by changes in regulatory timelines to start up studies faster, provide better access to study subjects, and reduce costs.

More studies are seeing an increased number of investigative sites with fewer subjects per site, as compared to Phase II and Phase III studies conducted a decade ago. This impacts not only the sponsors and CROs, but global investigative sites as well in a number of ways.

Paper problem

One such result would be an increased administrative burden with paper. While

Lastly, there would be a more cumbersome record archival and retrieval process. In order to comply with regulatory record retention requirements that differ by country, many sites keep investigative site files stored and archived in either their institution or in off-site storage. In the event of an audit, sites that share archival and retrieval would find it challenging to retrieve certain files—and some sites even indicated they would be unable to find documents.

Going paperless

There are a few best practices that stakeholders in the clinical trial process can be doing to evolve and adapt to these changes. One such change is to implement paperless regulator binder and essential document processes. From study startup through closeout, today's global e-clinical solutions provide opportunities for a completely paperless process.

Another option is to improve flow by using one study phone number. Regardless of the number of vendors involved, sites should use one phone number either globally or locally.

Today, call flow and routing in an IVR would allow for one number and based on the menu, support multiple languages and support for all vendors. This would triage calls to different vendors involved in study support as needed, eliminating the need for the site personnel to call different numbers.

Finally, it helps to establish one centralized portal. Currently, vendors retain their own portals, resulting in one study with many different portals. Giving sites one global portal with different security rights allows investigative sites and study teams to go to one place for any study or program information. This reduces it to one password per study and if the portal is used across studies, even further streamlines work for the sites.

Transforming clinical studies processes will require critical thinking outside of the 20-year-old box.

The good news is there is technology available to help. The implementation of best practices for clinical study and development conduct can streamline administrative burdens for investigator staff as well as study teams, and hopefully yield reduced costs in conducting global clinical development.

—*Michael Smyth, General Manager, TransPerfect's Life Sciences Solutions Division, e-mail: LifeSciSolutions@transperfect.com.*

DATA ANALYSIS

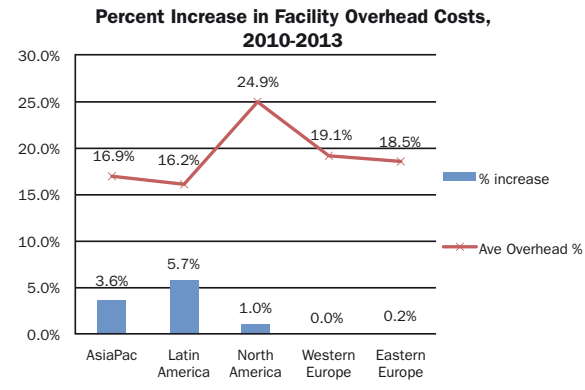
Determining Suitable Overhead Rates for Study Budgets

The viability of a research program can hinge upon a drug sponsor's success in negotiating a fair market price—including overhead rates—with investigators.

Indeed, overhead rates (for expenses not directly related to conducting a clinical study) can range anywhere from 25% to 40% of the site's overall budget. So, knowing where site overhead expenses fall within that range can be the key difference between developing a realistic budget for grants that sites will accept and developing a study budget that is grossly over or under funded.

IMS Health analyzed overhead rates by region, incorporating data from over 60 countries, 16 therapeutic areas, and more than 150,000 grants. Figure 1 shows the increase in overhead rates by region over the past three years. While the U.S. has generally had the highest overhead costs (24.9%) for all study phases, costs are rising most rapidly in emerging economies. As has been the case in other regions, we can expect these increases to level off once sites in these areas are more stable.

—IMS *Health (for more information contact clinicaltrials@us.imshealth.com)*



Source: IMS GrantPlan

Figure 1. Overhead costs should be considered when selecting the best countries and sites for trials.

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Looking Further Into Transparency

The EMA is committed not just to greater accessibility of data, but proactive publication.

Everyone in Europe, it seems, is looking at transparency. It isn't just the revelations about US espionage of EU institutions that have provoked the frenzy—although tensions have certainly been intensified as a result of the new attentions to who is hiding what from whom. But as this column noted last month, transparency had already become one of the dominant themes of the current debates over new clinical trial rules for the European Union. Confusingly, transparency is also the focus of the EU directive on pricing and reimbursement of medicines, which is also under review at present (the so-called Transparency Directive governs how much information national authorities have to provide over how they reach their pricing and reimbursement decisions). Even more confusingly, controversy has flared over the last few weeks about the merits of the EU Transparency Register—the list of EU lobbyists, including numerous drug firms; this is under new attack from campaigners demanding tighter controls over big business contacts with EU officials and politicians. Berlin-based Transparency International concluded in its annual corruption index, released in July, that medical and health services are subject to corruption across most of eastern Europe. And most recently, the European Medicines Agency (EMA) has released its draft policy on the publication and access to clinical trial data.

For the clinical trial community, this is likely to be among the most crucial transparency developments for a long time. EMA has been under repeated attack for years for sitting on data that other researchers—often those critical of EMA decisions—claimed rights of access to in the name of good science. When Guido Rasi took over as the new boss of EMA, one of his first public promises was to open up some of the information vaults. The policy paper that emerged in late June bears the hallmark of those promises, and is explicitly driven by a belief that the release of data is important in establishing trust and confidence in the system. Avid students of EU policy on medicines are advised to take a look at it. There is a limited window for submitting comments, which closes on September 30, 2013, and EMA expects the policy to come into force on January 1, 2014.

The EMA policy

The nub of the EMA commitment is not just greater accessibility of data, but proactive publication. Data will be released automatically, unless there is a compelling case for withholding. The default, in other words, becomes automatic publication. In this draft, what will be published is data from clinical trials submitted in support of a marketing-authorization application, once the decision-making process has ended. EMA describes its approach as "considered"—in that it claims to respect the views and concerns emitted so far on the subject. In reality, this boils down to a search for balance between the competing claims of access to data for independent scrutiny, the need to protect personal data, and the sensitivity of "legitimate commercially confidential information."

The draft policy offers three categories of clinical trial data. "Commercially confidential information" would cover details of an investigational medicinal product, some in vitro studies or bioanalytical data characterizing the product, suggests EMA. An "open access" category, covering any clinical trial data, information or documents that do not contain patients' personal data, would be downloadable from the EMA website once a European public assessment report had been generated on the product concerned. And 'controlled access' would cover information containing patients' personal data, such as individual patient data sets, patient line-listings, or case report forms, as well as documentation explaining the structure and content of data sets. For this category, to prevent retroactive patient identification, de-identification of data and a data-sharing agreement would also be required.

Complications

EMA's ambitions are, it admits, subject to some external complications—not unrelated to the fact that everyone in Europe seems to be looking at transparency.

One, of course, is "the ongoing legislative process to replace the current European directive on clinical trials," the draft EMA policy acknowledges with an almost perceptible sigh. As it goes on to point out, the position agreed in May by the European Parliament's health committee states that "in general the data included in clinical trial study reports should not

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be considered commercially confidential once a marketing authorization has been granted or the decision-making process on an application for marketing authorization has been completed." The committee's decision is not final. The Parliament as a whole still has to reach its formal position, which will probably take until the end of this year—and maybe longer. But the sentiment in the Parliament is strongly in favor of maximum transparency, inflamed by anger over PRISM, and resentment at the alleged readiness of Internet giants to comply with state demands for access to data.

Another of the potential impediments to the EMA plan lies with the European Union's courts. As EMA points out, with studied neutrality, "a number of court cases are currently ongoing that challenge the agency's 2010 access-to-documents policy. These cases will bring the opportunity for legal clarification of the concept of commercially confidential information." The reality is less neutral. AbbVie has led a frontal attack on EMA policy on information release, principally to defend its rheumatoid arthritis drug Humira (adalimumab). In April, AbbVie won provisional support from the EU court against the EMA's plan to prevent publishing data. Similar temporary protection was provided by the court to US biotech firm InterMune, which is likewise fighting EMA policy because it fears release of data on its idiopathic pulmonary fibrosis medicine, Esbriet (pirfenidone) will give advantages to competitors.

These interim injunctions have enraged campaigners for access to trial data. The European consumers organization, BEUC, has lined up alongside EMA in fighting the case, and "hopes to lend additional support in EMA's effort to continue its policy of openness." BEUC urges the merits of publication of clinical data reports to "help restore trust in public regulatory authorities; trust which has suffered because of medicines scandals such as Mediator in France." In addition, "public access to clinical data can lead to additional scrutiny of decisions about the approval of medicines," counteracting the trend under which "regulators often rely solely on the pharmaceutical company's own analysis of their products' benefit-harm balance." The tone demonstrates how febrile the atmosphere is becoming.

Good news from the European Union with the adoption of plans for Horizon 2020, the seven year multi-billion research project that should start next year.

Meanwhile, the European pharmaceutical industry's main trade body, the European Federation of Pharmaceutical Industries and Associations is finalizing its own approach to making clinical data available on drugs. This is likely to focus on separating information useful to researchers from information for the general public. One of the principal aims is to prevent competitors' access to unlimited data on such sensitive issues as production methods. But according to Christopher Viehbacher, Sanofi's CEO, the EFPIA President, sharing data between companies could also speed up research.

Streamlining

Against that tempestuous background, it is a relief to be able to comment briefly on an attempt to bring transparency to clinical trials in a less contentious manner. The British BioIndustry Association has just released a guide to running trials in the United Kingdom with a claim that "effectively navigating clinical infrastructure can streamline research and de-risk investment." It highlights the role of the National Office for Clinical Research Infrastructure (NOCRI) as a single point of contact offering a bespoke service to clinical research sponsors.

The guide takes the reader by the hand, from addressing study requirements and obtaining expert guidance through to late-state research. Along the way it explains the new service available since June to help life sciences companies with a single online application gateway for all studies, customized assistance including early feedback on study deliverability at protocol development stage, site intelligence, and a streamlined process for applications offering turn around in 15 working days. And it outlines the model Industry Collaborative Research Agreement designed to support clinical research collaborations involving industry, academia, and public health organizations across the United Kingdom. Its template clauses can be brought together to form a contract, offering a range of options for handling the ownership of any intellectual property rights resulting from the collaboration. It is an interesting example of the competitive sophistication that these days seems almost as vigorous as drug discovery itself, as countries and institutions fight for a share of the clinical trials market.

On the Horizon

Finally, good news this month from the European Union (a rare occurrence in itself these days) with the adoption of plans for Horizon 2020, the seven year multi-billion research project that should start next year—on the assumption some last-minute squabbles over funding are resolved in time. For the clinical trials community, this could mean some big new money in support of research projects. Watch out for IMI-2, the second phase of the Innovative Medicines Initiative that has backed public-private partnerships in early-state research over the last seven years. Part of Horizon 2020, IMI-2 promises to be bigger and better than its predecessor, with a budget of more than $3 billion—and a focus on target identification and biomarker research, innovative clinical trial design, and innovative medicines. That's the sort of transparency about the future that everyone likes.

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Explore Your Resources to Learn More About RBM

Applied Clinical Trials' Editors

Risk-based monitoring may be confusing people in the clinical trials industry because of the loss of on-site monitoring and the notion of 100% SDV because this is a traditional function of a CRA. However, as we have found in articles and research presented, SDV is not the reliable predictor of good, accurate data. But based on tradition, founded in the belief that FDA required 100% SDV, this idea that data must be verified by an on-site monitor that comes every six to eight weeks to an investigative site, regardless, has become standard practice.

Many sponsors and CROs are wondering where to start. With an idea that implementing this strategy is a good idea, but without the resources to uncover best practices.

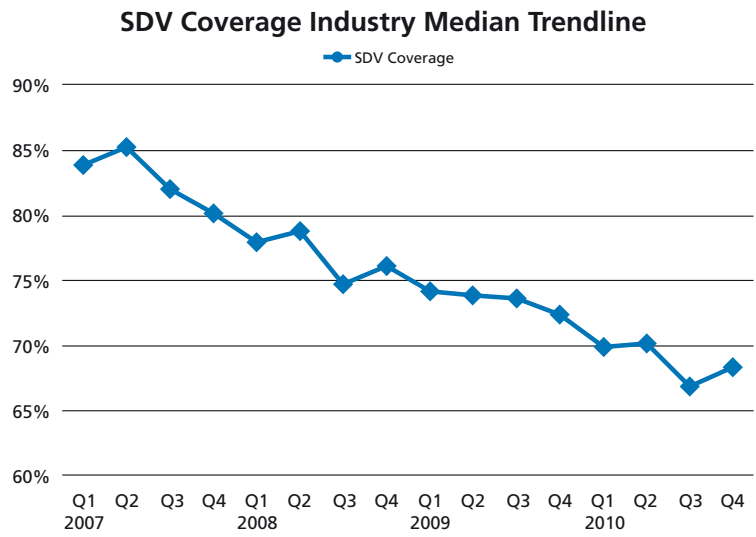
By implementing a risk-based monitoring solution, which more than a few people are wishing was termed "intelligent monitoring," a strategy of applying risk levels to incoming data produces better signals from that data that in turn improves the performance of a site, allocates resources more effectively, and turns out higher quality data for the trial.

With this strategy comes organizational change. Changes in technologies used, procedures followed, job functions, departmental roles, and more. But where to start? That is where many sponsors and CROs are finding themselves now. With an idea that implementing this strategy is a good idea, but without the resources to uncover best practices.

We hope that this insert on Risk-Based Monitoring in Clinical Trials provides insights into that question. The articles are written by company experts who provide their views on solutions, challenges and answers to where to start.

If you have the opportunity to attend the Risk-Based Monitoring in Clinical Studies conference in Philadelphia October 24 and 25 (http://bit.ly/18UEfsw for the brochure), the editors of *Applied Clinical Trials* will be on-hand to listen to your questions and experiences, as well as learn along with you what your peers and colleagues are doing in RBM. TransCelerate BioPharma, the organization of 16 pharmaceutical companies that recently released its methodology paper, will be on-hand to discuss their paper and share experiences from the project. So far, attendees from companies including ImClone Systems, Seattle Genetics, AbbVie, and Mount Sinai Medical Center have registered.

Another resource is listed in the Internet Resources on the next page, *Applied Clinical Trials* Risk Based-Monitoring Resource Community. That web section on our site is an aggregate of all the articles, blogs, videos, interviews and more that we have on this topic. We believe that this topic is going to be around for a long time, with plenty of discussion on advances as it develops. So, keep this insert, attend conferences, and bookmark our resource page so you can continue to learn.



Source: Medidata Insights Metric Warehouse, December 2012

Figure 1. SDV coverage has shown a continuous decline since 2007.

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CONTENTS

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The use of RBM may be the only way forward as long as the development of medicines relies on clinical testing.

Impact on the Future

Philip E. Doren, Teri O'Donnell, and Jamie Pearson

Our industry is challenged to make drug development a more efficient process while delivering high quality results on time and within budget. The common knowledge in the industry is that clinical trials have become more complex and drug development costs continue to rise. However, the results and deliverables may not meet the levels of quality required for successful marketing applications. Put simply, the costs of failure are costing us all too much. The CRO industry as a whole must refine its services and deliverables and take the time to complete due diligence on the front end, in order to streamline the trial process and deliver projects as promised. As an industry, we have to increase our levels of strategic and tactical knowledge so that the insight we provide to our clients will ultimately deliver development programs of the highest caliber. Risk-based monitoring (RBM) is an approach that can actually save time and cost as it contributes to the efficient conduct of clinical trials.

Monitoring and its purpose

Sponsors of clinical trials must provide oversight to protect the rights, welfare, and safety of human subjects and the quality and integrity of data that are obtained during the trial.[1, 2] With the technology and tools that have become available over the past 25 years, pharmaceutical development need not be bound to the same methods of monitoring that were being used in the 1980s. This is why the FDA and EMA are encouraging the use of modern methods for monitoring the progress, safety, and quality of clinical trials. In spite of encouragement from regulatory authorities, adoption of RBM and other innovative approaches has been slow. If we don't use them, we cannot benefit from them.

Risk-based monitoring—what is it?

Risk-based monitoring identifies the sources of risk that diminish the objectives of clinical development programs. Those objectives have already been stated: "protect the rights, welfare, and safety of human subjects and the quality and integrity of data." After these sources are identified, they are monitored during the course of a development program. This is where the "risk" aspect of RBM originates—risk is not part of RBM because less information is examined than would conventionally be examined and therefore it is "riskier" but costs less, so it is justified. Rather RBM carefully examines:

- What sources impose meaningful threats to the objectives of clinical development?
- What signals from those sources will be considered and how frequently they will be considered?
- What level of signal intensity from those sources will trigger an action, such as increased monitoring (on-site or remote) attention, or intervention and correction?

Risk-based monitoring may be difficult to understand because it regularly uses multiple methods to meet monitoring requirements that are present; it is not just one technique. The EMA noted,[2] potential "adaptations to conventional GCP methods" when RBM is used. In doing so, the EMA suggests these might include adaptations to on-site monitoring visits, sample/focused/targeted source document verification, or centralized monitoring (both manual and electronic are possible). The various methods that can be employed may reduce the number of on-site visits

required, however, crucially, this doesn't mean less information is being monitored. To obtain the expected benefits, the way in which the necessary information is monitored, compiled, analyzed, and interpreted must be better than conventional methods. Given the tools we have today, including major advancements in electronic data capture, we know that many of the associated tasks can be completed more frequently and at less cost through RBM than through conventional, on-site monitoring methods. Centralized monitoring can improve our ability to capture data anomalies, fraud, and safety concerns, and identify these threats more rapidly because of the whole-study or whole-program view, and because of the continuous, timely stream of data flowing into the centralized group. The fact that these broad issues can be detected and addressed throughout the course of a study means that the traditional end-of-study flurry of activity that can be so demanding and prone to error can be reduced in its magnitude. "Last minute" is no longer a required expectation.

Operational metrics can also be collected and interpreted by a centralized group. This characteristic enables the delivery of information to on-site monitoring personnel, resulting in more critical, productive, and efficient site visits.

Risk-based monitoring should not be considered a turn at the roulette wheel. It is not a throw of the dice, or even the development of computationally intense statistical algorithms aimed at establishing a sampling method, which itself reduces the amount of work required on a clinical study. RBM is instead a set of methods that, when applied throughout the planning and conduct phases, results in safer, less costly, and more successful studies; with the emphasis on higher quality.

How to achieve RBM effectively

Key aspects for the successful implementation of RBM include:

- Identification of variables related to program (or project) risks.
- Assessing those elements that impact regulatory compliance, protocol compliance, patient safety, and data integrity.
- Review data as they are collected, not waiting until the end of the program; this is especially critical for large studies with many patients involved.
- Anomalies in study characteristics trigger a site visit or other intervention.

Based on these requirements, effective integration and management of information is crucial to the successful implementation of RBM. This not only applies to hardware systems but also to software and people. It is essential to centralize and integrate disparate data sources so that the information they contain can be analyzed, interpreted, and acted upon. This is the focus of work currently underway at SynteractHCR. The Intelligent Clinical Development Plus (ICD+) platform of services and systems allows the compiling and use of the information necessary for conducting RBM on behalf of our customers.

To some extent, this goes against trends in our industry. It is common to fractionalize the people and information that are elements of a drug development program in order to obtain only a least cost solution. With this approach it is too hard to integrate all data and information across company lines when multiple vendors are involved. Instead, a platform where information is assembled and distributed to allow the opportunity to meet the objectives of the drug development programs is ideal.

The future of successful clinical monitoring depends on improving its efficiency and using it to reduce the amount of time that it takes to get new therapies to market. RBM offers a high quality approach that allows the streamlining of trials while providing a broad view of integrated data and resources. As long as new drug development relies on human clinical trials, RBM may be one of the best ways to reach those goals.

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Risk-based monitoring ushers in the move from the traditional experimental design.

Paradigm Shift

Mark Penniston

Clinical trials follow the premise of scientific discovery: there is a hypothesis that a product will perform to an expected result. An experiment is performed to verify the hypothesis. Results from the experiment refine the hypothesis leading to theory-driven experiments yielding confirmation that the product performs as expected. Human trials require dual theories; not only must the product work but it must also be safe.

> Predictable study results require verification that critical values are correct—not that all variables are correct.

Does the product work?

Most of us were taught in the beginning of school that we must control the parameters of a science experiment; the beakers must be sterile, the water distilled, etc., ensuring control of the environment to achieve predicted repeatable results. Similarly, the clinical trial process looks for control of all inputs. Monitoring processes concentrating on 100% source data verification were born from these practices. However, it is slowly being recognized that predictable study results require verification that critical values are correct—not that all variables are correct.

Is the product safe?

If the experiment is controlled and values verified, does this ensure product safety? Or, does it confirm that what we postulated as risks in study design are appropriate but not what the true safety profile is? If monitoring safety does not affect outcomes of product effectiveness, then vigilance of information coming in becomes a higher priority.

Risk-based monitoring and program optimization

A clinical trial experiment is defined by its protocol and the supporting plans to execute the various aspects of its design. Risk-based monitoring (RBM) is a shift in paradigm from the traditional experimental design and execution to clinical trials in that it brings focus. RBM is a collection of techniques to bring focus to what is important to the study, ensuring critical data is correct and uncovering missing or hidden data to provide the fullest safety profile of the product. One method to perform this is through quality by design: begin with the protocol to state the initial questions that need to be answered and pursue the answers through the execution of the trial.

The risks for a clinical trial can be broken down into four parts:

- Product not aligning with intended population
- Incomplete or incorrect data capture
- Data signals and patterns during study are not detected
- Action not taken

The first item is dependent upon the science of the product. As trial designs allow for more fluidity to respond to the information collected by new technologies (biomarkers and statistical techniques), we expect to see trial optimization change dramatically over time.

The other items are within our control using current technologies. Data capture systems now allow for edit checks, allowing queries back to the sites verifying data correctness. As data is collected, patterns can be seen on what the experiment is telling us. These patterns can be both biological and operational. Reviewing a particular lab and its values on scatter plots with normal range values brings one series of patterns of data to respond to. A singularly high hematocrit value in a blood pressure study may mean nothing; whereas, a pattern of high or low values will bring pause. Similarly, operational patterns can reveal potential risks. A site that consistently enters data months after patient visits may indicate risk and need for additional monitoring. In both examples, risks can be predetermined so that reports can drive attention to the abnormalities. For a successful clinical trial, one must continuously look at risks and make adjustments to the monitoring plans and communications.

There are many factors to consider when operationalizing decreasing study data collection risk. Most of these can be navigated by planning and processes. Well-defined data monitoring roles are clearly placed on this list in a discussion of source data verification versus source data review. Verification implies the quality control of transcription from source data to the electronic data capture system, while review is a process that should be performed by individuals with a medical background. The first asks what is missing during transcription; the second asks what is missing based on supplementary data. A patient taking migraine medication within an hour of dosing study medication should perhaps have an adverse event recorded for the migraine as well. This medical review can be performed off-site, in a central area, either by clinical data management or clinical monitoring depending upon the qualifications of the personnel. What is important is that this be a data-driven review. Communication plans and processes must be in effect to ensure such information is brought forward to bring focus.

A second factor should be the continuous risk assessment via critical variables, safety trends, and site performance. Here, statistics can be of assistance. The review of trends and compounded derived variables allows the statisticians to predict future behavior of data based on recent past information. This can be complex Bayesian predictions or simple continuous variable patterns as used in baseball. The use of standard data formatting assists tremendously in the operational implementation of such predictions.

Through medical data review, risk assessment, and analytical methodologies, a trial can decrease what risk may occur.

The use of data standards should be the third factor in study optimization. Including CDISC data standards into the processing allows quicker reuse of complex code and portability for trials not just in analyses but for operational review too. Building reusable, dynamic reports to assist a medical data reviewer searching for patterns in the data requires a solid foundation of the data definition. The tools for stating when additional monitoring is necessary need to be easy and reusable so that time spent training is minimized and data searching is optimized. As the promise of electronic medical health records becomes more of a reality, standards will drive this ability to detect signals even quicker.

Risk-based monitoring and continuous program optimization hold the promise of expedited findings to give patients new products. Through medical data review, risk assessment, and analytical methodologies, a trial can decrease what risk may occur while potentially shortening trial time and costs.

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The reality of risk-based monitoring: history and successful implementation for late phase research.

RBM in Late Phase

Maria C. Harrison, Kathleen A. Mandziuk, and Dat Nguyen

A number of factors are leading to a paradigm shift in the way that clinical research is conducted. The adoption of EDC technologies that provide real-time access to data and the increasing cost of research has forced the industry to look at optimized methods of conducting clinical research. In addition, several studies have shown that 100% source data verification (SDV) may not result in higher data quality. All of these factors have led to increased interest in risk-based monitoring (RBM) strategies.

As seen in recent regulatory guidance (i.e., FDA's draft guidance,[1] the EMA reflection paper,[2] and MHRA Risk Adapted Approaches[3]), there is growing support for the utilization of multiple monitoring approaches. In addition, industry initiatives such as the Clinical Trials Transformation Initiative (CTTI) and the recent TransCelerate position paper[4] have provided preliminary guidance on how to incorporate RBM in clinical research. This growing regulatory support, and industry interest in reduced costs and higher quality, has been the impetus to increased attention toward RBM.

However, increased enthusiasm for RBM has not yet translated into implementation for all organizations. The recent Industry Standard Research (ISR) survey that examined the attitudes of pharmaceutical and biotechnology professionals found that 73% of the respondents believed that RBM is risky from an operational standpoint, suggesting that although many research professionals are interested in RBM, they are very cautious about its implementation or have a lack of understanding in how best to implement RBM into their studies.

PRA's Late Phase Services (LPS) team members have been utilizing RBM strategies since the early 1990s, driven by the growth of large-scale post-marketing and Phase IIIb research. For these studies, the large number of sites/prescribers, high volume of patients, long study duration, and accompanying collection required an innovative approach that did not rely on 100% SDV or frequency-based on-site visits to support data quality.

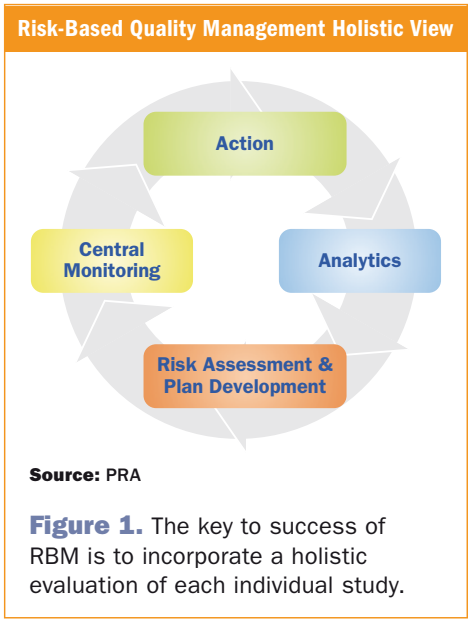
Holistic approach

The key to success of RBM is to incorporate a holistic evaluation of each individual study (Figure 1), beginning with a multi-disciplinary risk assessment and associated plan development. This process is not only conducted at the onset of a study, but also reevaluated and modified as needed due to changes in study design or standard of care.

There are a number of considerations that should be evaluated during the risk assessment and planning phase. It is especially important to consider the study's critical data points, including the primary study objectives and safety data, as well as the critical processes that impact patient safety and support data quality. The plan should then be developed across functional areas and stakeholders to ensure that all findings of the risk assessment are addressed.

Central monitoring

Since limited onsite visits will occur, there needs to be a centralized monitoring function in-house that supports the prescribers/sites throughout each phase of the study. Central monitoring is critical to the success of RBM, but it has been defined and implemented in many ways throughout the industry. PRA's LPS team has developed a successful approach to centralized monitoring by incorporating a dedicated internal team of Site Management Associates (SMAs) who are trained in optimized start-up and training, ongoing site management, holistic data review, and proactive study support. SMAs uti-



Source: PRA

Figure 1. The key to success of RBM is to incorporate a holistic evaluation of each individual study.

lize customized analytical tools to centrally evaluate the clinical data and site status in real-time. Upon review, the SMA may trigger an escalation action such as site retraining or an on-site visit by the CRA. This ongoing interaction between the SMA and the site staff has shifted the primary relationship and immediate support for the site from the CRA to the SMA.

Analytical tools

During the planning phase of a study utilizing RBM, a variety of functions (such as scientific affairs, therapeutic experts, statisticians, data managers and clinical operations) help the project team define the protocol-specific risks. Specific to these identified risks, a variety of analytical tools to identify site issues and triggers requiring on-site visits are developed. Considering SMAs review a substantial amount of data, these analytical tools are essential to quickly identify and escalate issues and trends that may require an escalation action. Each study is unique and will require customized analytical tools. Examples of on-site triggers may include patient enrollment (e.g., a site that enrolls >50% faster than the overall study average might trigger a visit to determine why the site is enrolling so quickly), serious adverse events (e.g., event rates <30% of the overall average) and large backlog of data entry or query resolution.

High-value site monitoring activities

RBM is an evolution in monitoring as we know it today. RBM is not just a reduction in on-site monitoring, but a paradigm shift towards a different operational approach and organizational structure that focuses on the ongoing holistic review of clinical data, with centralized monitoring supplemented by on-site monitoring visits as needed.

The ultimate result of RBM will alter site monitoring visit activities that focus on low-value activities (e.g., 100% SDV that allows only minimal time for focusing on critical data variables) towards high-value activities focused on key variables, including time to consult with study staff, review data, and evaluate site processes.

Conclusion

In addition to promoting high-quality study results, RBM has been shown to reduce the cost of clinical studies by as much as 20-30% in service fees. It has been our experience that in order to be successful in RBM, it cannot be implemented merely through less on-site monitoring. As the industry continues to move towards this approach over the next several years, the role of the CRA will continue to evolve. Organizational structures will therefore need to shift to align with RBM, allowing for processes and analytical tools that shift the focus to central monitoring activities.

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Central statistical monitoring can improve RBM solutions by efficiently detecting errors, sloppiness, tampering, and fraud.

The Practical Implementation of Risk-Based Monitoring

Francois Torche

Data quality matters most in determining study success and ensuring patient safety. However, patient numbers continue to rise, CRFs are becoming more complex with each new study and, with the use of sites around the globe, these elements significantly impact the ability to guarantee the quality and integrity of clinical trial data while containing costs. Until recently, the standard paradigm for clinical site monitoring was to do routine site visits every four to 10 weeks with 100% source data verification (SDV) in most cases. This process typically accounts for 30% of a sponsor's overall costs but results in less than 3% of any data changes post-monitoring visit. This antiquated and inefficient paradigm costs the industry hundreds of millions if not billions of dollars. As budgets become more difficult to manage and data issues grow by the day, regulatory authorities and most in our industry no longer believe that traditional "on-site monitoring" and "100% SDV" are the best solutions. Humans are less efficient at detecting erroneous data than an automated process and are the most expensive resource employed in any trial. Computer algorithms, by contrast, are relentless in their interrogation of the data and are much more cost-effective.

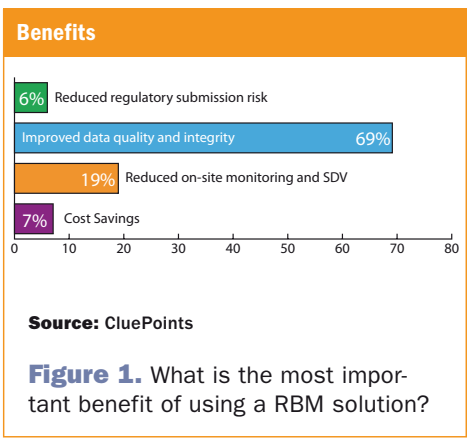

Figure 1. What is the most important benefit of using a RBM solution?

The FDA guidance for industry and the EMA reflection paper encourage the use of risk-based monitoring tools as well as increased efficiency in the form of reduced SDV. The documents bring to our attention the fact that sponsors should be focusing or "targeting" their on-site monitoring activities. One of the most common ways to do so is by remote monitoring. This means taking a look at the data off site and determining where the issues may be prevalent. They also refer to data management metrics and trending which includes things such as subjective key risk indicators (KRIs). Then, of course, there is central statistical monitoring. Sponsors need to look at their data in numerous ways in order to target on-site monitoring visits effectively. By doing so, the goal is not only to reduce 100% SDV levels but to de-risk their studies by improving data quality at significantly lower costs.

In contrast with KRIs, which only indicate the potential for risk, independent central statistical monitoring determines the expected values of each variable by assessing and examining the data from all sites in order to identify statistical outliers. This concept has been perfected by CluePoints over the last 10 years using the patent-pending process within the SMART™ engine. Complex and proven statistical algorithms drill down into individual patient data to detect issues that could put the study at risk and create a road block to successful submission. This approach re-

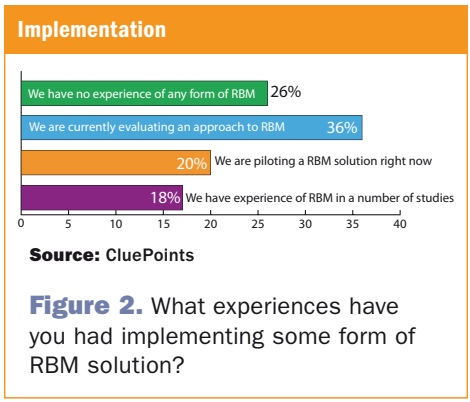

Figure 2. What experiences have you had implementing some form of RBM solution?

quires minimal work for the study team in gaining objective information in order to optimize on-site monitoring by targeting centers at risk. In addition, sponsors who strategically outsource to CROs are finding increased efficiencies by utilizing central statistical monitoring as an oversight tool to regularly check the quality of their data.

Key risk indicators are applied because they focus on important known risk factors, for example, the proportion of AEs or SAEs collected. There is no question that the safety reporting in a clinical trial must be looked at very carefully. However, unlike other providers, CluePoints provides an independent, EDC-agnostic approach to central statistical monitoring that is based on the actual clinical data and not subjective indicators. The idea behind this is that all variables are indicative of quality—whether it is lab data, clinical data, baseline data, or treatment outcomes; everything goes into this analytical system and all data are deemed equally important. In a clinical trial, everything that is collected should be worth collecting, and therefore worth checking—central statistical monitoring ensures the ability to determine the quality and integrity of the data and ensure that monitoring efforts focus on errant sites quickly and efficiently.

CluePoints has been utilized in several dozen studies with sponsors such as GSK Vaccines and Gilead Sciences. Brian Nugent, Associate Director, Clinical Operations at Gilead has explained his experience with CluePoints and how he and his study teams have practically implemented a central statistical monitoring solution in three quick and easy steps—setup, analysis and report. During the setup stage, the sponsor's data manager and CluePoints discuss the structure of the datasets and their contents and the data is uploaded. During analysis, CluePoints select statistical tests and variables, browse and filter results, and generate outputs. The sponsor is provided with a detailed report that lists any outliers. Data discrepancies are clearly defined and the graphs and summary results are well displayed and informative.

In Gilead's first study with CluePoints, there were 120 centers and 660 tests conducted, generating 79,200 p-values. The tables of p-values were very detailed and CluePoints provided expert interpretive guidance to make this information easily digestible—both known and unknown risks and issues were detected in this study. "Rather than to fight the fire once the fire started, we really wanted to uncover the data; which we did, and we addressed a number of things," Nugent said. "We now plan to integrate KRIs and central statistical monitoring into our everyday study quality and risk management plans and of course we expect to have improved data quality and certainly at a lower cost."

Many companies already have KRIs in place and central statistical monitoring can further improve risk-based monitoring solutions by more efficiently detecting errors, sloppiness, tampering, and even fraud. When utilizing central statistical monitoring during a study, sponsors can take corrective action, such as that taken by Gilead, in a timely manner to prevent issues becoming deep-rooted and re-analyze data regularly as part of an iterative process. The sponsor or CRO can perform focused site monitoring visits, identify CRA and site retraining needs, or develop site tools to provide clarification on protocol and study processes. CluePoints can also be used as a final data quality check at the end of a study.

During a recent webinar, CluePoints surveyed over 300 industry colleagues from clinical operations, data management, and statistics regarding their experience with risk-based monitoring and the benefits of a centralized statistical monitoring approach (Figures 1 and 2).

Francois Torche, *is the CEO of CluePoints, 185 Alewife Brook Parkway, Suite 410, Cambridge, MA, e-mail: francois.torche@cluepoints.com.*

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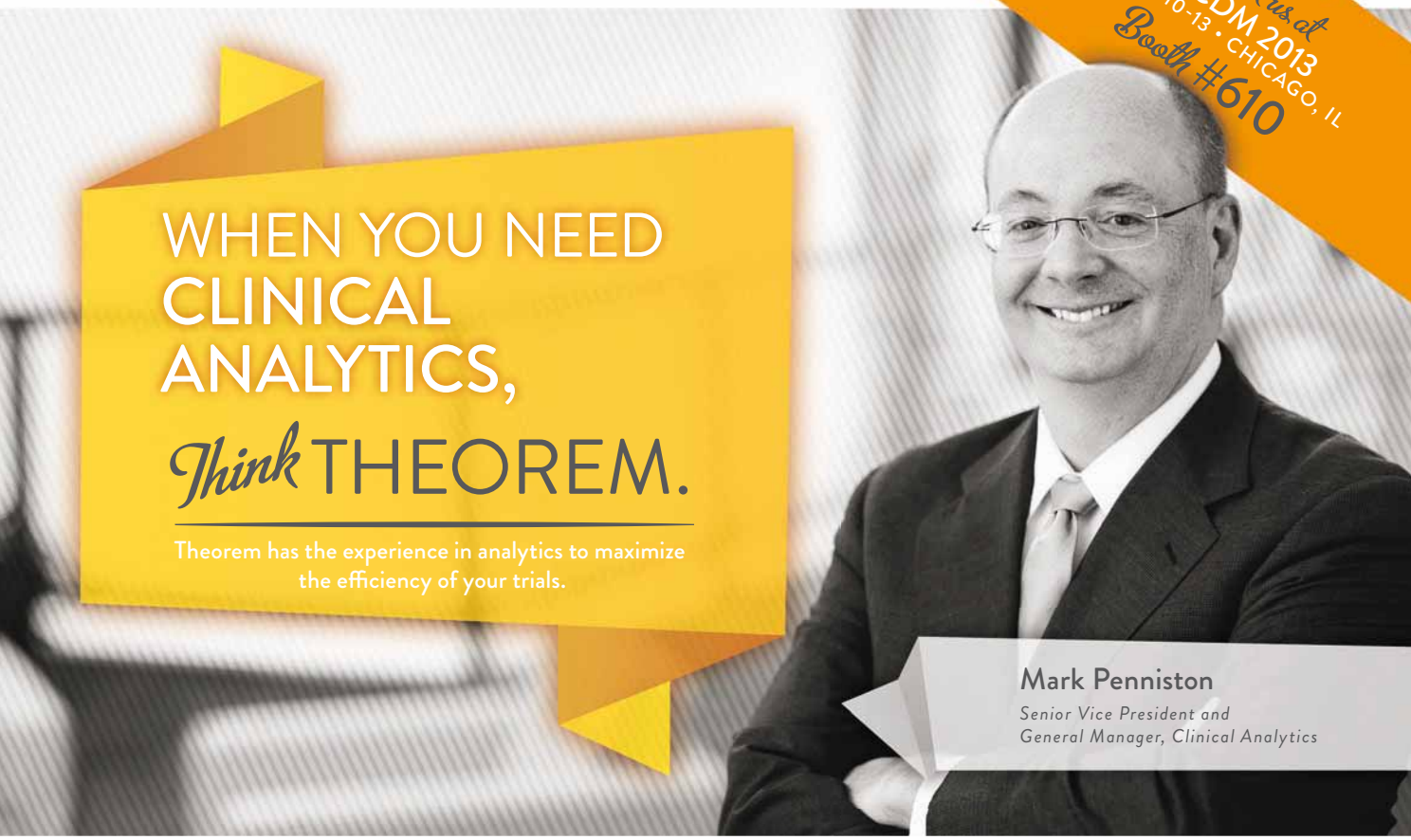

Mark Penniston
Senior Vice President and General Manager, Clinical Analytics

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Drug Development in China

China will overtake the pharmaceutical market worldwide and be one of the largest consumers of branded pharmaceuticals in the world in the next 10 to 15 years.

Kent Thoelke, Executive Vice President, Scientific and Medical Affairs for PRA International, discussed with *Applied Clinical Trials* how pharmaceutical companies can take advantage of a parallel drug development strategy in China in order to save time and money.

Can you explain the current strategies sponsors take in registering a drug?

China has been somewhat of a mystery to most pharmaceutical and biotech companies over the last decade or so. There have been a number of pharma companies that were early adopters of China who have achieved drug development strategies both domestically as well as part of global strategies and have been quite successful.

For most companies, however, the challenges of lengthy timelines for CTA approvals in China have relegated the China portion of drug development strategies to the back burner. Most companies have focused their clinical trials on the United States, Western Europe, and slowly to Eastern Europe; and then go back to China later on after their trial has been completed and they filed for their registration, NDA, EMA approval.

Kent Thoelke, Executive Vice President, Scientific and Medical Affairs for PRA International

That strategy has been quite successful because the largest pharmaceutical markets in the world historically have been the United States and Western Europe. Leaving China for the later part of their development strategy has seemed reasonable.

Why would sponsors now consider a different strategy in China?

Within the next 10 to 15 years China will very quickly overtake the pharmaceutical market worldwide and be one of the largest consumers of branded pharmaceuticals in the world. Certainly by late 2020, they will be the number one consumer of pharmaceutical products in the world. From a market perspective, China has become much more important from a registration strategy for new drugs.

At the same time over the last number of years, the regulatory authority in China, the SFDA, has become much more efficient at its review process. So whereas historically it would take 12, 18, 24 months for clinical trial application (CTA) approvals, those timelines have come down significantly for small molecules hovering closer to seven to nine months, or 12 months from outset.

Can you explain the parallel development pathway that leads to drug approval and marketing in China?

There are a number of pathways. Every discussion with the SFDA is very individualized so the pathways can vary. In the general concept, there is the global drug development program, which is standard for most companies. That includes a Phase I safety study somewhere in the United States or Western Europe and then a Phase II, IIa/IIb, IIIa/IIIb and then approval.

In including China as part of a Phase III development, the key is to build enough time in the recruitment process to absorb the seven

to 12 months that it will take for the CTA in China. Then a sponsor can file the Phase III trial in China to include Chinese sites as part of its global Phase III trial. If at least 100 pairs of patients are accrued, which is fairly standard for the small molecule studies, those 200 patients can support registration in China. Then it becomes part of an inclusive parallel strategy.

At the same time, for Phase II sites in China, explore and work with the SFDA to collect a subset of those patients for a PK analysis to submit as part of the safety.

If there are enough patients in China and safety is included, once the trial is completed, and the sponsor has filed it in the United States or Europe and has a Certificate of Pharmaceutical Product Approval somewhere else in the world, the sponsor then goes to the Chinese authorities to file data collected from the Chinese sites for Chinese registration. That will shave several years off that process for the Chinese registration.

The other parallel process that can be done and has been done by a number of companies taking the general Phase III protocol design, if there is a missing dose, for an example, so Phase II dose finding studies aren't completed, sponsors can potentially file the Phase III study in China as part of the CTA prior to the completion of your Phase II study and then go back and amend the Phase III process and the CTA that is filed with the Chinese government. Basically, if the Phase II is almost complete and there's going to be a nine to 12 month lag time for approval for the CTA in China, the potential to go ahead and file early if it's just going to be an amending dose exists. And that could save several months on your final approval in China as well.

However, it's a riskier strategy in that it costs $150,000 or $200,000 for that filing. So if the Phase II data turns out to be negative and Phase III doesn't occur, those costs for the CTA with SFDA would be lost. But on the flip side, if the investment is made, and saves several months, it's well worth it.

All of those different pieces are somewhat of a moving target. So every product is different, every strategy is different, every indication is different. And so for most of these companies, it's important to discuss very early on with a partner who has experience in China the different strategies, regulatory pathways, and implications of each because there certainly is not one solution for all companies, indications, or drugs.

How should sponsors approach their outsourcing partnerships in China?

Working with a CRO partner that has an established reputation, established experience within China is critical. If you have local affiliates, certainly, their experience and their interactions with SFDA are critically important to be able to make this process as efficient and smooth as possible.

But a CRO partner—if they have the experience in China—is really kind of the hub to all of the spokes. Whether it is the importation of drug and the importation licenses; export of a genetic material; blood sample; coordinating a local lab; logistic shifting of a key supply material or samples that need to be treated and then exported—all of those pieces really should be managed quite closely by the CRO on the ground in China because it is so complex and because there are so many things that need to be done just right in order to ensure that the data capture can substantiate the claims the client is making for approval.

Overall, what do you think of China for drug development moving forward?

It's not a one-stop shop answer here for Chinese regulatory in China. There are clear guidelines set forth by the SFDA. There is a lot of experience in working with China. The SFDA reviewers may not always be therapeutically aligned, so it may require sponsors to have important dialogues with the reviewers to help educate them on the therapeutic process or the mechanism of action of the drug and how it interacts or is implicated within the drug pathways or the treatment paradigms outlined.

But much of what happens in China, although it's getting better every day, can still be mysterious. It's not always easily predictable. But then again, other regulatory bodies around the world also can be less than predictable.

The process of true parallel development with registration is a relatively new concept so it's important to find drug companies that are willing to make that investment upfront. That is probably the largest challenge for CRO companies right now that are trying to help their partner sponsor companies really take advantage of the ability to shave off months and months of time for their Chinese registration. It's an interesting time for global drug development and China will become so critical for that pathway.

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Lifting Up a Fragmented Study Conduct Landscape

The next 18 to 24 months may bring profound changes for investigative sites.

Despite the premium that sponsors and CROs now place on driving higher levels of study conduct efficiency and performance, the odds are greatly stacked against them given the structure and characteristics of today's global investigative site community.

Recent research on the global study conduct service provider market paints a picture of a landscape that has been spinning its wheels for 30 years, unable to mature or achieve scale efficiency and operating sophistication (e.g., standardized procedures, financial and management controls). The site landscape has been in a perpetually nascent and fragmented state.

Stakeholders across the enterprise are looking to change the situation by focusing on a range of initiatives to transform the study conduct landscape. Which approaches will achieve lasting and substantive improvement? A look at the current state of the landscape and how it is managed may hold some insight.

Fragmented and independent

In 2013 the total number of active principal investigators (PIs) participating in FDA-regulated studies worldwide reached its highest level in history. There are now nearly 28,000 unique investigators each conducting fewer trials on average than in prior years. Annual growth in the number of active principal investigators between 2002 and 2012 has been modest (0.8%) compared with rapid growth (9.7% CAGR) between 1992 and 2002.

Emerging regions, including Asia and Eastern Europe, have seen the highest relative growth in the number of FDA-regulated investigators since the late 1990s due to the small bases from which they started. The proportion of investigators based in North America has been declining steadily from 84% of the total international community of FDA-regulated investigators in 1998 down to 61% in 2012.

> There are now nearly 28,000 unique investigators each conducting fewer trials on average than in prior years.

Less than a third of all investigative sites around the world are part of a network. The vast majority are stand-alone sites, with limited infrastructure, operating autonomously. The typical investigative site has only one principal investigator and two staff members involved either on a full or part-time basis as study coordinators.

For more than a decade, the United States was the only geographic area where independent investigators comprised the majority of FDA-regulated sites. This is no longer the case as sponsors and CROs have looked to place more of their trials in emerging regions.

Kenneth A. Getz
MBA, is the Director of Sponsored Research at the Tufts CSDD and Chairman of CISCRP, both in Boston, MA, e-mail: kenneth.getz@tufts.edu

The majority (53%) of all FDA-regulated investigative sites operate as for-profit, independent, community-based entities unaffiliated with academic systems. University, hospitals, and government clinics have been gradually losing their share of industry-funded clinical trials. Two-thirds of all global FDA-regulated investigators in 2006 were based in academic settings compared to 47% of the total in 2012.

Varied and inefficient performance

Investigative site performance on any given clinical trial varies widely and underscores the inherent and high risk associated with study conduct activity. Sponsors and CROs widely recognize that success is directly tied to patient enrollment and every clinical trial has its share of poor performers.

A 2012 Tufts Center for the Study of Drug Development study of several hundred global clinical trials found that sponsors are forced to double the planned enrollment period on average in order to give investigative sites enough time to recruit study volunteers and complete a given clinical trial. Even with long cycle-time extensions, one out of every 10 (11%) sites, on average, in any multi-center clinical trial will fail to enroll a single patient and one-out-of-four (39%) will under enroll. The other half of sites in a given multicenter study will either eventually meet the enrollment target or will exceed it.

The migration of industry funded clinical research into the private sector has been largely driven by performance and economics. Overhead rates have been lower, and performance quality higher, among independent investigators. Study start-up cycle time and enrollment performance among independent investigators is faster than that experienced in university centers, hospitals, and government clinics. Independent PIs tend to

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negotiate and approve study contracts and budgets nearly twice as fast as their academic counterparts. For-profit sites have higher activation rates with 9% failing to enroll at least one patient per clinical trial compared with 13% of sites in academic settings. Independent sites also have higher enrollment achievement rates with nearly all (96%) eventually meeting patient enrollment targets. Less than 75% of academic centers eventually meet their patient enrollment targets.

Wide regional performance differences are also common. The Tufts CSDD study found that North American investigators have the fastest study start-up times and higher than average enrollment performance. European and Asia Pacific investigators have relatively slow start-up times and average enrollment performance. Latin American investigators tend to have relatively high enrollment performance following slow start-up cycle times.

FDA for investigator non-compliance and fraud is nearly 10 times higher than the level of complaints observed in the 1990s due in part to increased reporting from ethical review boards, institutions, and study monitors.

Problematic management practices

Although most markets mature and consolidate to drive scale economies and efficiencies, during the past three decades the investigative site landscape has failed to do so. Community-based investigative sites eager to participate in clinical trials have largely avoided the risks associated with mergers and consolidation.

Traditional site management practices have contributed greatly to current landscape conditions and have unintentionally facilitated instability and harmed the viability of site operations. Until recently, most sponsors and CROs have largely treated investigative sites as commodity service providers, where the lowest cost prevails; contracts and budgets are offered on a take-it-or-leave-it basis; and payment for work performed is delayed. These practices have invited lower cost, and inexperienced, novice investigators lacking training and infrastructure.

A growing number of stakeholders acknowledge the limitations of a fragmented and immature landscape.

Turnover rates among the global pool of FDA-regulated investigators are also high and vary by region. Overall, approximately 40% of PIs choose to never conduct another clinical trial after a given 1572 submission year. Turnover rates are particularly high in Asia Pacific, Europe, and Latin America where more than half of all investigators submitting a form 1572 never return to the research enterprise. High turnover rates—in part a function of challenging regulatory compliance requirements and a difficult operating environment—drive site selection and management costs and inefficiencies, and contribute to an unstable and fragmented site landscape.

Since 2005, an average of 257 complaints for PI non-compliance and fraud has been filed with the FDA each year. Protocol non-compliance, data falsification, and poor drug accountability are the top areas of noncompliance cited. The number of complaints filed with the

Sponsors and CROs have hedged patient recruitment risk by enrolling larger numbers of sites; each site enrolls smaller numbers of patients rendering study grants less attractive to those sites that have established infrastructure and require a fixed number of patients to recoup their initial study start-up investment.

A recent CenterWatch study found that investigative site operating costs have been rising by 5% annually during the past five years at the same time that average study grant amounts have declined by 3% each year. Nearly 40% of sponsor payments are greater than 90 days overdue and 5% to 7% of study grant payments invoiced are written off by sites as bad debt each year.

Certification, collaboration, and consolidation

There have been many ideas and much speculation recently about ways to improve this fragmented and immature landscape. Some approaches are more passive than others:

Policymakers and educators—including the Clinical Trials Transformation Initiative, the Association of Clinical Research Professionals, and the Alliance for Clinical Research Excellence and Safety—have set their sights on training, certification, and accreditation to elevate and set minimum standards of site experience. The Society of Clinical Research Sites seeks to unify the investigative site community and, in doing so, inform practice improvements and collaborative effectiveness.

TranCelerate BioPharma and commercial database providers see the enhancement of site selection practice as a critical step required to improve site performance prediction. The Metrics Champion Consortium is eyeing standardized site performance metrics as a critical management resource.

Several sponsor and CRO companies—including Sanofi, Roche, Quintiles, and Parexel—have been implementing new relationship models and establishing site partnerships to streamline study start up timelines, nurture longer-term collaborations, lock in preferred pricing, and guarantee repeat study activity. And with the backing of private equity, select CROs and large global and national site networks appear poised to acquire premier investigative sites and drive consolidation.

Although the jury is out on which initiatives will have the greatest impact, a growing number of stakeholders acknowledge the limitations of a fragmented and immature landscape. It's clear that investigative sites can expect a lot of attention and change during the next 18 to 24 months.


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Risk-Based Approaches

Julie M. Brothers, Dean A. Gittleman, Thomas Haag, Darlene Kalinowski, Ioannis Karageorgos, Robert King, Lisa Lucero, Debbie McCann, Paula McHale, Jules Mitchel, Patrick Nadolny, Selina Sibbald, and Brett Wilson

The eClinical Forum Risk Based Monitoring Taskforce offers some best practices for ensuring clinical data quality.

Companies engaged in commercial clinical research have, since the introduction of formalized good clinical practices (GCP), adopted highly defensive practices around the monitoring of clinical trials. The reasons, while diverse, include fear based on perception and interpretation of regulatory requirements. These processes have played a very large role in the high costs associated with clinical trials, without delivering commensurate value. Reasons are many, but surely include propagation of practices established during the years that trials relied on paper-based case report forms (CRFs) without considering optimization of the processes to take advantage of the technology provided by electronic data capture (EDC). All of this has resulted in the institutionalization of high cost, unproven value, manpower-intensive practices that do little to serve the interests of subject safety or quality data. Pharmaceutical, biotech, and medical device industries experiencing unprecedented economic upheaval can no longer justify practices that deliver little value at exorbitant cost. Rather than continuing to spend time, energy, and money focusing on minutiae (e.g., the ability of site personnel to properly transcribe observations from one medium to another), those engaged in clinical trial conduct must re-focus their energies on the aspects of the clinical trial that matter most, such as protocol compliance, subject safety, data timeliness, and data integrity. Through the use of more up-to-date methodologies and technologies, companies can effectively address these concerns while saving both time and money. This article addresses the regulatory and business rationales for adopting monitoring-related tools and processes that, if implemented thoughtfully, should deliver higher-quality trial data, faster, and at significantly lower cost.

Most areas of business and government—including finance, insurance, public health, agrochemicals, manufacturing, and pharmacovigilance—apply risk-management principles, leveraging mathematical principals (namely statistical inference) in circumstances where it is simply impossible to ensure the quality of a large volume of services or products by exhaustingly checking the accuracy of every item. Clinical research-related industries, operating under GCP, appear as a notable exception for the following reasons:

- The honest and honorable intent to ensure the highest possible quality and safety for products that have a direct impact on the life and well-being of us all
- The pre-GxP beginnings of pharmaceutical research based on the use of paper CRFs
- Misinterpretations of regulations
- Fear of failure based on results of regulatory inspections

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Germany

"For many reasons clinical development has experienced substantial challenges over the last couple of years. Looking at the changing and ever more demanding regulatory landscape, the trend of shifting major operational pieces of clinical development to China and India and innovative concepts such as "virtual" trials, it becomes evident that many more changes are expected. Our overall programme theme "Rebooting Clinical Development" will address all this: it may require a "reboot" and a deep breath of fresh Irish air to see where we are and in which direction we may need to go. Those with an interest in medical information and communication will find a full programme dedicated to them in Dublin." - Detlef Nehrdich

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DIA 7TH ANNUAL CLINICAL FORUM PROGRAMME OVERVIEW

Theme 1 | Clinical Operations

Estrella Garcia, Head of Global Clinical Operations, Almirall S.A., Spain
Holger Maria Rohde, Medical Operations Officer, TEVA Pharma GmbH, Germany

The evolving regulatory and technology landscape in clinical development is becoming more and more challenging. The theme will discuss several initiatives and how they are affecting the efficiency and management of clinical trials: how the risk based monitoring approach is being implemented by the industry, how health economy evaluation dossiers are considered in clinical development plans, how virtual communities are being implemented in overall trial management, and how patients' involvement and performance in clinical trials is key to success. New approaches on how to inform, involve, maintain and monitor patients will be presented.

Theme 2 | Technical Operations

Julianne Hull, CEO, WenStar Enterprises, UK
Rolf Banholzer, Global Head CQA Computerized System Services, Novartis Pharma AG, Switzerland
Graham Bunn, VP Partnerships, Perceptive Informatics, UK
Pierre-Yves Lastic, Associate Vice-President, Chief Privacy Officer, Sanofi, France
Breffni Martin, Legal Representative, Optuminsight Strategic Regulatory Services, Ireland
Peter Stokman, Head Global Data Management & Standards Oss, Merck Sharp and Dohme, the Netherlands

Encompassing CDM, eClinical, validation and technologies, this theme aims to address the key aspects of technical operations throughout the lifecycle of a clinical development programme. Sessions and presentations will provide recent experience on planning and implementation of risk based monitoring, really achieving a paperless clinical trial, using technology to drive process and delivery optimisation, eSource, CDISC and ensuring real time data availability, agile and script free validation, and cloud computing and the changing regulatory environment.

Theme 3 | Medical Affairs

Heike Schön, Managing Director, LUMIS International, Germany
Jens Reinhold, Medical Director ZAO Bayer, Bayer Healthcare Pharmaceuticals Russia, Russian Federation
Jan Geissler, Director, The European Patients' Academy On Therapeutic Innovation (EUPATI), Belgium

Medical affairs is the discipline combining concepts of clinical research and real-life healthcare requirements. It is the transformation of what was accomplished during the clinical trials and the approaches to meet market requirements. This often requires finding innovative ways of involving patients, of identifying new opportunities to gather data through innovative study approaches, e.g. virtual studies, and of bridging the pharmacovigilance requirements from clinical trial results to post marketing evaluations. The theme will be topped off by experts reflecting on best approaches to delivering high value publications from clinical trials and post marketing studies.

Theme 4 | Medical Information

Aaron Cockell, Medical Information Regional Director, EMEA, Pfizer Inc., UK
Janet Davies, Director, Medical Information & Medical Affairs Project Management, EMEA, Gilead Sciences, UK

The European Medical Information and Communication Conference takes place as part of the Annual Clinical Forum. We are in the 7th year of this unique meeting organised by medical information professionals specifically for medical information professionals. Speakers share hands-on experience with current challenges as well as successes in medical information departments. Participants are encouraged to take part in workshops and discussions within the sessions on: the value of medical information, pharmacovigilance legislation, evidence based medicine and MI, MI quality, medical information in emerging markets, regional and global management aspects, technology and social media and the popular Putting Theory Into Practice session.

Theme 5 | Medical Writing

Mary Gardner Stewart, Divisional Director, Medical Documentation, H. Lundbeck A/S, Denmark
Sandra Hecker, US Agent, Regulatory Consultant, Hecker & Associates, LLC, US

The medical writing sessions will focus on the current hot topics within medical writing. These topics include the implications and impact of the new EU pharmacovigilance guidelines on various safety documents, including risk management plans (RMPs), an update on current issues related to clinical trial registries, including a heads up on what to expect with the coming EudraCT V9 and keeping registry postings in mind when preparing protocols and clinical study reports, regional considerations for global submissions, with particular focus on Asia, storyline documents (for example, briefing or regulatory response documents) for use in pre-submission meetings and non-guidance driven interactions with the regulatory authorities, submission challenges, including managing multiple indications and sharing of best practices for the response process for eCTD questions in the EU, and sharing of best practices on how to successfully handle the often difficult review process.

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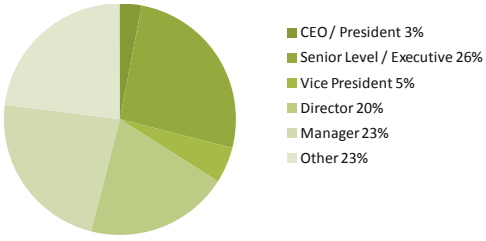

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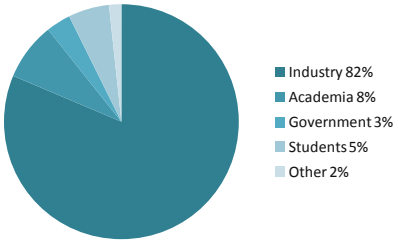

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Quality risk management has been rather limited in the area of GCP. Until recently, research and development personnel (as well as their representatives/CROs) have believed that they were required to engage in 100% verification of all records and reports obtained in the context of Phase I-IV clinical research.[1]

These deeply ingrained beliefs have led to practices that are not only prohibitively expensive, but also fail to deliver value that can justify these costs. As a result, the pharmaceutical and device industries have institutionalized practices and behaviors that deliver low value at exorbitant cost. These costs include both the direct and indirect expenses associated with monitoring investigative sites, as well as the opportunity costs associated with these antiquated practices. Exhaustive manual verifications have shown their limits in particular when it comes to identifying (in a timely manner):

- Issues related to protocol compliance
- Safety related signals and trends across large datasets
- Intra- and inter-rater variability
- Potential fraud

The almost concurrent release in 2011 of draft guidance documents from two of the three major GCP regulatory agencies related to "risk-based monitoring" has triggered numerous discussions among clinical research operatives and peers, including sponsors of drug and device clinical research, contract research organizations (CROs), and academic clinical research organizations.

A survey conducted by the Clinical Trials Transformation Initiative[7] indicated that there was a large and somewhat inconsistent range of monitoring practices during the conduct of clinical trials. The survey found that monitoring practices vary in intensity, focus, and methodology and include:

- Frequent, comprehensive on-site visits to all clinical investigator sites by company personnel or representatives (e.g., clinical monitors or clinical research associates)
- Targeted on-site visits to higher-risk clinical investigators (e.g., where centralized monitoring indicates problems at a site)
- Centralized monitoring of clinical data by clinical, data management, and statistical personnel at some location other than the study site

For major efficacy and safety trials, companies typically conduct on-site monitoring visits at approximately four to eight week intervals, at least partly because of the perception that frequent on-site monitoring with 100% source document verification (SDV) is the regulator's preferred way for sponsors to meet their monitoring obligations. In addition, overall source document review (SDR) remains as an on-site monitoring obligation. However, FDA also recognizes that data from critical outcome studies (e.g., National Institutes of Health-sponsored trials, Medical Research Council-sponsored trials in the United Kingdom, and International Study of Infarct Survival), which had no regular on-site monitoring and relied largely on centralized and other alternative monitoring methods, have been relied on by regulators and practitioners.

The general nature of the guidance documents is a potential gift to sponsor organizations. It encourages the industry to define strategies for risk-based monitoring, and perhaps create standards, that can be customized for individual protocols. Sponsors can now take full advantage of EDC as centralized monitoring tools are developed to capture intra- and inter-site outcomes, as a quality window on GCP.

The unrealistic fear of regulatory agency findings at the time of pre-approval inspections leads to a more conservative approach that is both necessary and required. A paradigm shift must take place whereby sponsors realize that inspection findings are not to be feared, but are ways to improve processes, and collaborate with the regulatory agencies to better define clinical trial operations and patient safety.

The eClinical Forum in the context of its chartered mission to serve the pharmaceutical and device industries focuses on those systems, processes, and roles relevant to electronic data capture, data handling, and regulatory submission of clinical trial data. The eClinical Forum has already submitted comments directly to both the FDA and EMA, and released a white paper to promote awareness of the concepts shared by both regulatory documents. By doing so, the eClinical Forum can assuage any apprehension expressed by the more traditionalist organizations which continue to interpret the regulations and predicate rules as calling for full verification and monitoring. We propose that by discussing the key elements of the guidance documents and by proposing best practices on actual tasks (whats and how-tos), we can greatly contribute to demystifying and adopting risk-based quality management of clinical trials. This approach should also allow the regulatory authorities to get access to honest, unbiased, substantiated previews of the organizational and procedural response by industry stakeholders as well as provide previews that are the product of reflective listening to regulatory expectations and that underline the challenges and work effort required by organizations as they adopt, adapt, and measure up to the guidance documents. As a result, the eClinical Forum should contribute actively to the further alignment between the regulatory agencies and the pharmaceutical and device industries.

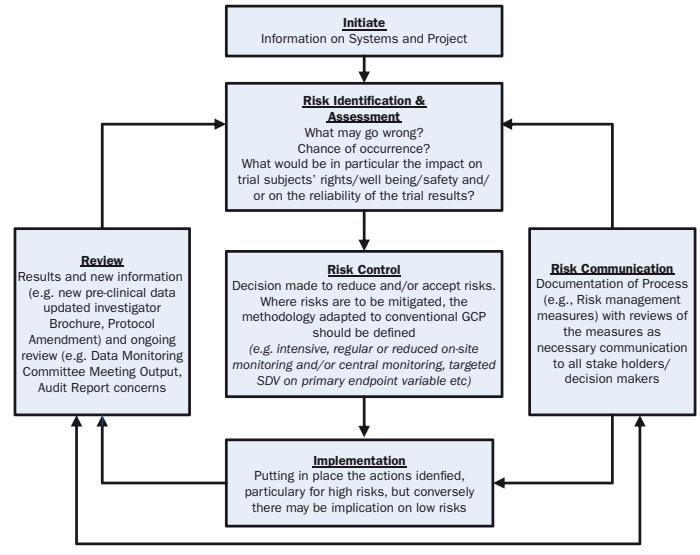
Although the guidance document was assessed versus previous and current corporate procedures and best practices, it was necessary or timely to advocate specifically how individual companies might choose to implement changes or adaptations to their quality/risk management. We expect that the roles within each organization that will be asked to perform those tasks will differ, with some companies deciding to assign responsibilities to monitoring, programming or data management job profiles.

From its inception, EDC provided an opportunity for clinical research operations to re-evaluate the tasks traditionally performed by the data management and site monitoring roles.

Moving towards adoption of integrated quality risk management systems calls for further, bolder, and continuous adaptation of systems, workflows, and people. Moving from the ingrained notions of traditional source document review and point-to-point SDV to one of quality processes (focus on optimizing site processes, QC of site compliance, detection of fraud, IMP distribution chains, etc.) will encourage us to:

- Delineate QA from QC in a risk-based quality system.
- Identify standard approaches to centralized and on-site monitoring activities.
- Assess how information technology tools and associated processes can best support centralized and risk-based data review.
- Determine which metrics (thresholds/error rates) and alerts will drive the documentation of quality as well as trigger corrective actions when the quality thresholds are not met.
- Evaluate the impact on the preparation and planning for protocol-driven research.

Risk-Based Quality Management Process for Clinical Trials



Source: EMA Reflection Paper, "Risk Based Quality Management in Clinical Trials"

Figure 1. Quality risk management is a systematic process for the assessment, control, communication, and review of risks to the quality of the product.

What is risk and what is quality?

Risk is someone or something that creates or suggests a hazard. Sponsors of clinical investigations are required to provide oversight to ensure adequate protection of the rights, welfare, and safety of human subjects and the quality and integrity of the resulting data submitted to regulatory agencies; in other words, avoidance of a hazardous situation.[2] As a result, risk must be defined and maintained across all stakeholders.

Quality is degree of excellence. According to the FDA guidance, quality is a systems property that must be built into an enterprise and cannot be achieved by oversight or monitoring alone.[1] Quality is something that needs to be maintained throughout the lifecycle of the product. The evaluation of the risk to quality should be based on scientific knowledge and connected to the protection of the patient.

There is a need to pause to consider the difference between quality control and quality management. Quality control allows the ability to outline a process to spot check data and operation by reviewing a slice in time. Quality management on the other hand, is used to direct, control, and monitor quality as a more fluid and dynamic activity.

The ICH Q9 guideline merges the two control processes as it speaks to quality risk management as a standard practice.[3] Q9 provides guidance with examples that attempt to outline risk management across the pharmaceutical industry. Figure 1, taken from the EMA Reflection Paper,[4] is an excellent starting place for organizations to turn as they design quality risk management; a systematic process for the assessment, control, communication, and review of risks to the quality of the drug (medicinal) product across the product lifecycle.

The ICH Q9 and EMA reflection paper guidance documents provide good direction on what to address when crafting a quality risk-management plan. However, neither truly addresses regulatory expectations for minimal requirements to accomplish this in a holistic manner. While it is one thing to talk about managing risk through traditional data management and site monitoring processes, it is quite another to propose a concrete way to manage risk through trend setting (electronic transparency on entry time, account use, etc.) and standard metrics (time between tasks, accuracy of input, etc.). Variability in the extent to which organizations approach quality risk management may confuse the situation even more. Fear of having decisions not meet regulatory approval also may keep some companies from updating their approach to quality management. In addition, the payoff may not be as large as indicated.

While there is no clear indication that quality is inadequate today, there is evidence that the industry overspends to perform tedious reconciliation between source and sponsor data that do not significantly affect the outcome of clinical trials.[5]

Elements of the integrated quality plan

Traditional monitoring plans outline what the sponsor considers to be their responsibility and action plan for ensur-

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Sample Table of Contents for an Integrated Risk Based Data Quality Plan

1. Risk mitigation strategy
   a. Include specific metrics that will be evaluated during the course of the study to address identified risks, defined tolerance limits, and identified corrective action plan(s) when tolerance limits are exceeded.
   b. Identify individual(s) responsible for implementation and tracking of defined risks and corrective actions, when implemented.
   c. Define issue escalation triggers and procedures.
   d. Define tracking of, and follow-up of corrective action plans.
2. On-site monitoring
   a. Identify paper versus electronic source.
   b. Clearly identify tasks to be performed and how results will be documented.
3. Centralized monitoring
   a. The terms "protocol deviations" and "protocol violations" should be defined, and methods/procedures to be used to track these items be clearly stated.
4. Quality by design meeting
   a. How will follow-up actions resulting from quality by design meetings be communicated back to appropriate party/by whom? For example, if trend analysis suggests on-site monitoring is indicated, who is responsible to communicate this back to site monitor and what information will be provided to site monitor.
5. Documentation and communication
   a. Communication plan requirements (e.g., time frames, issues communicated to which parties, communication format, etc.) should be defined.

ing site compliance with the protocol including GCP and other applicable regulations. We should consider the value of combining elements of monitoring, data management, and statistical plans into a comprehensive integrated quality plan. It is important not to jeopardize the relationship between sponsor and the clinical sites and care should be taken to ensure that this remains in the forefront of the plan. For example, a communication plan is useful to document standard communication when there is no need for a site visit. This could be used to praise the site for good work and maintain monthly communication. Minimally, a consistent point of contact should be assigned to the site to represent the face of the sponsor.

It is important to emphasize that monitoring plans are not unique to the CRA role but also can provide an overall cross functional plan that emphasizes what must be done in order to assure that the data received from clinical research sites are of high quality and integrity. The monitoring plans include not only what is expected to occur at a site level, but also within the data system and program level.

A quality monitoring plan, which can be part of the clinical monitoring plan, may include information from traditional plans that had previously been separated into role or task based activity, for example, each therapeutic area may be different so several quality plans may be needed on that basis. In considering the monitoring plan, adequate risk assessment must be performed prior to the start of the study, in order to ensure patient protection as well as the quality and integrity of data. Our recommendation is that monitoring plans should exist at the program, protocol, and site levels, and outline what will be included in on-site monitoring as well as central monitoring.

Program level plans. This plan addresses overall quality aspects of the program and should be developed at the start of the clinical program. Risks that are known or anticipated for the disease population and investigational product under study should be documented and clear instruction given as to what, why, and how those risks should be monitored. As a general outline, a program level plan could minimally include the following:

- Planning—a priori identification of risks of the investigational product.
- Design—define protocol eligibility criteria, efficacy, and safety risk factors during design; for inclusion in the eCRF and edit build, as well as define key protocol deviations anticipated for study.
- Execution—clear direction in the oversight and monitoring of parameters leading up to study endpoints, integrated study level monitoring plan, clear direction on evaluating fraud.
- Analysis—clear definition of data measurement and reporting, defined elements of statistical analysis of protocol endpoints, safety, etc.
- Disclosure—publish outcome data, bringing all the above together in the clinical study report (CSR).

Companies may wish to consider creating standard quality checks pertinent to all programs, and which may also include therapeutic area specific sections to be selected as relevant. Ensuring that the entire study team understands the principles and purpose of the program level monitoring plan will help avoid duplication and encourage study teams focus effort where it is most effective.

This is an ideal opportunity to take a step back from familiar routines and look hard at current processes; assess what is valuable and what is not; invest in processes that bring most value from a quality perspective. The goal is to develop an integrated clinical data monitoring plan, based on compound and historical knowledge, which can respond proactively to data signals during trial execution.

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Study level plans. This plan should be specific to a particular protocol and draw upon the information from the program level plan as to what is needed to ensure quality. We suggest that the study level plans are categorized as those activities that occur during study startup, study execution, and study closure. This plan allows flexibility for site level variations, (e.g., highly compliant and performing sites, new sites with little experience, high volume sites, and non-compliant sites). The following specific minimal list of topics should be addressed in such a plan:

- Site selection factors—include key protocol requirements that affect decision making on site selection.
- Site training considerations—include information on how the site is prepared to conduct trial.
- Information on all forms of data review.
- Identification of critical data—safety, endpoint related.
- Delineation of what is reviewed on-site versus central.
- Site closure activities.
- Assessment of site understanding of protocol.
- Assessment of fraud.

By focusing on study level tasks, rather than roles, study managers will be able to assign responsibilities to the most appropriate team member(s). This adds flexibility to the process, while ensuring that there are no omissions. It also will allow for role changes/combinations in the future. Plans should be easily readable and referable—limit bulk text; use graphics and bullet points. If a suitable electronic tool can be used, it should be feasible to pull out a sub-set of tasks for each function on the study from the overall plan.

Site level plans. This plan should be specific to each investigative site, combining information from Program/TA level plans and the protocol(s) that the specific site is involved with. There is a large degree of variety in the way regional, country, or hub monitoring units are being organized, therefore a critical aspect of the risk assessment will be the concurrent (and possibly competitive) workload and commitments that shape the possibilities and constraints of both the sponsor/CRO and site staff when collecting and reviewing data. Another key consideration in defining a site level risk management plan is to never project any task or activity over time as being flat or a product of the volume of data flow only. What's more, it is an oversimplification (with potentially disastrous results) to even consider data quality as being inversely proportionate to its volume. Some of the minimally required aspects to cover in the site level plan are:

- Site experience in therapeutic area and/or compound.
- Studies by the same sponsor conducted concurrently (internal competition) and/or publicly available information on the site being involved in similar protocols/programs for other sponsors or being a sponsor of a research program themselves (external competition). Add risks about misconceptions on the objectives and endpoints of the different protocols and study populations. Avoid the trap of considering a group of protocols as a convenient early access program for the compound under investigation.
- Own monitoring resource workload and financial, schedule, and data access constraints.
- Site staff attrition.
- Site staff "fatigue" over time.
- External factors that can generate bias or change a site's standpoint for a compound (patient advocacy groups and/or social networks, regional regulatory and/or governmental changes in their stance towards therapeutic options and research, brand or generic competition pressure).

Of paramount importance is a clear documentation and escalation strategy to the study and program teams. Escalation should not be considered to be a "for information" activity only as it risks accentuating instead of overcoming the compartmentalization between central and distributed monitoring management. The documentation of all issues and corrective actions as well as the elaboration of preventive planning at the site level is therefore not hierarchically dependent or "trailing" to the program and study level plans.

Risk identification and mitigation works in both directions; it can well be that a monitor works on more studies within the compound than a study manager and their perspective is of vital importance in the success of a clinical development strategy.

Assessment of risk tolerance: triggers and metrics

In addition to including the information described above, the clinical data monitoring plan should contain details to categorize risk, thereby allowing the sponsor to have clear criteria by which to trigger site visitation and remediation.

Triggered monitoring adopts three key approaches that differ from traditional monitoring. Rather than:

- Having monitors conduct periodic monitoring visits based on a schedule rather than a need, site monitoring is undertaken in response to key metrics (e.g. data quantity, subject enrollment, and safety signals), which can be used to predict risk.
- Treating all sites the same, the triggered model recognizes that some sites pose more of a risk than others (e.g., by virtue of metrics such as workload, quality and safety issues, and patient enrollment and retention) and focuses attention on them accordingly.
- Treating all safety events equally, the triggered model catches safety signals as they happen and triggers a site visit.[6]

Utilizing categories and ranking of clinical data, based on experience and empirical findings, sponsors can compute a composite risk score that will quickly and easily point them to potential issues. A high risk score does not automatically mean that a particular site is problematic, but it serves as an indicator to look further into the particular items of note.

These categories should be defined by the sponsor and include but are not limited to:

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- Trigger points for on-site monitoring and what requires SDV and SDR
- Information on monitoring priorities
- Definitions of monitoring assessment of site quality
- Definition of deviations occurring within the tolerance range as acceptable

It is recommended that study teams include a triggers and metrics section in their protocol level plan to provide detail that are used to evaluate when an increase in on-site monitoring visits should occur. While certain triggers may result in an immediate on-site visit, such as a major safety or GCP concern; other factors may require review and interpretation by the monitoring team and could result in increased training or site contact/coaching to supplement on-site visits. The plan should address the weight of the trigger and resulting outcome and actions to be taken by the monitor. The list below highlights areas related to site quality, data integrity and subject safety for consideration by the study teams. It is not expected that these metrics would be included in the CSR.

Site activity and personnel:

- Staff turn-over

Subject rates:

- Higher/lower enrollment than expected (ensure proper screening and validity of subjects)
- Higher/lower percentage of screen failures across sites
- High discontinuation rate across sites (ensure proper screening, adherence to the study procedures, subject retention)

Edit-checks/Queries:

- Site-to-site rate disparity
- Average time from query generation to response (could indicate training issues)
- Query rates (critical metric for defining thresholds which will flag sites for additional monitoring/auditing): high number of manually generated queries as a result of SDV and SDR (could indicate that additional transcription errors may exist); automatically generated queries via edit checks (could indicate poor data quality or error in edit check specification); re-query rates (could indicate training issues)

Important measures of safety:

- High occurrence of adverse events (AE) (potential safety concerns, proper study procedures, and reporting)
- Lower-than-average number of adverse events (review for unreported AEs)
- High number of SAEs (potential immediate trigger)
- Reconciliation issues from SAEs to CRFs

Important measures of efficacy:

- Unexpected data variability
- Unexpected data uniformity
- Outliers for specific fields and trending to see if the same data is entered for multiple patients (to identify fraud)

Data-entry timeliness:

- CRF entry compliance (centralized monitoring cannot be performed unless all data are entered in a timely manner)
- Pattern of delays
- Data entered in boluses rather than at a rate that reflects actual subject visits (see also "fraud")

Protocol compliance:

- Site audit findings
- High number of protocol deviations: as identified by the monitors and manually entered into CTMS; data driven from edit checks within EDC; study drug preparation, dosage, administration related deviations (potential immediate trigger)
- Review for patterns of deviations or violations demonstrating lack of understanding of protocol, or compliance failures

Study teams should include a triggers and metrics section in their protocol level plan to provide detail used to evaluate when an increase in on-site monitoring visits should occur.

- High number of GCP issues or other site issues

Suspected misconduct or fraud:

- Repeated measures display unexpected uniformity, lack of variability, especially when coupled with higher-than-expected enrollment
- Data entered in boluses rather than at a rate that reflects actual subject visits (see also "data-entry timeliness")

As well as triggers that indicate when a site monitoring visit should occur, there also are triggers to indicate when the percentage of SDV should increase or decrease for a specific site. Although some items on this list overlap with the list above, these triggers are more specific to the data authenticity and integrity and can identify potential training issues, compliance, and fraud.

Triggers to increase the percentage of SDV currently being performed at a site:

- High rate of SDV errors where the CRF value does not match source
- High rate of data revisions for a field after the first submission (could indicate poor quality of data entry or possibly fraud)
- Data anomalies for primary endpoint values, study drug dosage, and calculations
- The number of data revisions due to manual queries (from SDV)
- Lower-than-average number of adverse events
- Audit findings for site audits (some audit findings might question the quality of the site which should then in turn question the quality of the data)
- Third party data reconciliation issues

Clinical data and processes that should always be subject to more monitoring:

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Assessment of risk tolerance: examples

Scoring can serve as a way to find a potentially problem site and at minimum take a look at the core issues being identified. It may be possible then to apply common formulas such as failure mode and effects analysis or sponsor specific risk assessments as well as normalization factors. Scoring is not the only way to define when and why on-site monitoring should be performed. It is up to the sponsor to determine how to use the triggers and metrics discussed in this section. Risk indicators can be applied to the site performance, applied by the monitor, and/or an overall composite site assessment.

Examples of risk indicators are:

- Critical—data related to any critical indicator weighs high in computing risk at a site.
- High—data related to a high-risk indicator has the potential to point to a site with risk potential.
- Medium—data related to a medium risk indicator has the potential to point to a site with possible risk potential.
- Low—data related to a low risk indicator has the potential to point to a site with possible risk potential or at minimum possible re-training needs.

Although the protocol level plan will include details to help assess when on-site monitoring visits should increase or decrease, it is important to establish a mechanism to ensure monitors are following the plan and are compliant with the process. Since this will be such a paradigm shift for monitors it may be a difficult adjustment for them and they will need training, support, and continuous oversight to reinforce these changes. Creating SOPs and training materials will be essential to the success of risk-based monitoring and steps should be taken to verify consistency among teams. An example of how this could be done is by including time during regular team meetings for monitors to review and provide status updates on their sites as well as any actions they are taking as a result of their in-house review. This would provide an opportunity for the monitors to learn from each other and at the same time allow their manager to validate that the team is following the plan that has been established and that the proper actions are being performed as a result of their findings. It is imperative that the monitors review the data continuously so they can detect trends and create remediation plans when necessary and a team review such as this will ensure accountability and compliance.

Systems and processes in support of risk-based and centralized data monitoring

Risk-based monitoring includes centralized and on-site monitoring of source records, which are two complementary activities that ensure data quality and integrity. Overall centralized and risk-based data monitoring activities need to:

- Increase quality (clearly identify and address risks)
- Ensure data origin, validity, quality, and accuracy
- Be verifiable, reproducible, and documented
- Be risk-based and reactive
- Be as easy as possible to implement
- Allow/support fraud detection
- Ensure ease of internal/external inspection of the source (sponsor audit/regulatory inspection)
- Be more efficient (better use of resources)

However, from a process stand point, centralized monitoring is intended to be performed remotely from the investigational site while SDR and SDV are to be completed on-site. Centralized monitoring may include comparing data across multiple sites and countries while SDV is focused on one site and one variable at a time. As a result, systems have to adjust to both process needs.

High-level system requirements for centralized monitoring should include:

- Integrating with existing systems (EDC, CTMS, etc.)
- Reviewing study data across sites (EDC, IVRS, ePRO, etc), coded or not
- Aggregating operational data (e.g., query metrics, data entry cycle time, screen failure rate, etc.) and study data (e.g., adverse events, protocol deviations, reasons for early study termination, etc.)
- Aggregating operational data across studies (e.g., look at site data across multiple studies)
- Generating basic statistics across data elements and data types
- Establishing role-based data reviews (e.g., able to limit access to aggregate data to those performing centralized monitoring)
- Setting thresholds for alerts (e.g., x times outside the standard deviation, Y% above or below study average)

High level system requirements for on-site monitoring should include:

- EDC systems supporting custom SDV strategies (declining SDV, complexity based SDV, form based SDV, etc.)
- On-site monitoring and SDV strategies for each study (SDV baseline—e.g. 100% for first three patients)
- Quantification of the allowable source error (i.e., SDV error rate: Percentage of transcription error made by the site)
- Adjustment of on-site monitoring strategy at the patient, site or country level based on quantified error rates (i.e., the actual "risk")
- Change and reason for changing monitoring strategies during the study

Reflective review of systems versus the FDA guidance and EMA reflection paper

What approaches support centralized review? There are a number of central data review roles that may vary by sponsor.

These include pharmacovigilance, clinical research, medical monitoring, data management, data science (DS), and remote CRA. Additionally, review of metrics may fall upon the biostatistics/data management group in cooperation with clinical operations in order to assure implementation of the on-site and centralized monitoring strategies per the clinical data monitoring plan.

Requirements of this multi-leveled array of data should include roles-based controls on data across multiple data platforms including CTMS; customized vendor reports (IXRS and ePRO, for example); EDC database and reports; safety database; raw data outputs; metadata summaries; data listings; dashboard displays; and validated SAS tables, listings, and figures. These roles also need to be configured by study as well. Since there are many sources of data, thought needs to be given to making the access simple and secure—and ideally, accessible remotely.

Systems supporting centralized review:

- Centralized electronic data capture systems (ideally)
- Standardized clinical database for all sites
- Standardized safety database for all sites
- CTMS
- Development and implementation of quality performance measurement system
- Standardized data (classes and methods) across sites and CROs
- Standardized training programs (for EDC and clinical conduct)
- Standardized data management (e.g., standardized archiving processes, data processing deadlines, etc.)

What systems support do you need to have a reasonable level of comfort with centralized review? In order to implement centralized review, the sponsor should have a good understanding of what attributes are required to evaluate current systems and capabilities and determine the need for any further enhancements. Systems/process attributes that may be required for centralized review:

- EDC: training and/or certification of reviewers; audit trail with ability to track multiple types of reviewers (roles differentiation); site/sponsor interoperability; system configurable to change monitoring processes during the study
- EDC/clinical and safety databases: safety reporting data listings; efficacy reporting data listings; other data listings as determined by data monitoring plan; query trend reporting; missing data reporting
- Risk management plan (i.e., assessment, identification, mitigation) and metrics

Are our recommendations consistent with the guidance papers? In the "Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring" FDA draft guidance,[1] there is clear support for innovating the monitoring practices. In fact, in this guidance it is stated that by moving away from 100% SDV, we can "improve a sponsor's ability to ensure the quality and integrity of clinical trial data." The section on centralized monitoring (IV.A.[1]) suggests specific types of data review that are most suitable for central review (these include ranges, missing data, unusual statistical distributions, and site quality metrics). Along with the support for innovation, there also comes the burden of documenting how we will achieve these improvements. In section IV.B, the guidance emphasizes the importance of starting with the protocol to define the critical efficacy and safety endpoints and to then follow through with a clear data monitoring plan, quality plan, and risk mitigation plan in order to document with what frequency and intensity these endpoints and other critical data points will be followed throughout the trial. Additionally, the monitoring plan should cover both on-site and centralized monitoring activities. Ideally, the monitoring plan will describe what method of monitoring will be employed for the pre-identified critical data and also how any findings will be documented and communicated.

In order to implement centralized review, the sponsor should have a good understanding of what attributes are required to evaluate current systems and capabilities and determine the need for any further enhancements.

Some considerations for planning and documenting monitoring tasks:

- Tasks/systems must support the criteria set out in the data monitoring plan, quality plan and risk mitigation plan as outlined in this article
- Specified frequency of review
- Specified review roles
- Documentation of drivers/triggers for reduced on-site monitoring visits and those requiring increased on-site monitoring visits
- Documentation of drivers/triggers for adjusting centralized monitoring activities
- Documentation for traceability of decisions made and actions taken. Greater reliance on CTMS and DMP/QP/RMP documentation demonstrating that we are following the set criteria

Conclusion

In this article, we have laid out the case for re-examining the standard monitoring processes that have been in place for many years, and which have not been able to evolve past paper-based clinical trials. Since the inception of the use of EDC, our industry has had the opportunity to fundamentally

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shift our overall thinking regarding what we mean by data quality, and the processes and tools that we employ for ensuring clinical trial data fit for purpose. For a variety of reasons, monitoring processes have not been able to fully benefit from technology's ability to enhance efficiency, effectiveness and data quality.

This article provides very useful detail regarding the elements to consider in developing newer, risk-based (alternatively known as data-driven) approaches to clinical trial monitoring. At a high level, though, the drivers are quite simple: we can do better; and we must do better, for the costs associated with maintaining status quo processes are not sustainable. With the support from regulatory bodies, we have a wonderful confluence of opportunity and incentive—recent regulatory guidances have encouraged our industry to adopt more rational processes, and that by doing so we better position ourselves to shorten timelines, enhance data quality, and dramatically reduce costs.

One key element to adopting new monitoring practices is transparency. We must ensure that our study protocols include sufficient detail about how we will ensure the quality of our data and the integrity of our trials.

While contemplating the contents of this article, it is important to keep in mind that to obtain the most benefit, we must be diligent in following through on our plans. If the results of your organization's risk assessment raise a red flag about the competency of (and associated data quality arising from) one of your sites, this awareness produces no value in and of itself. Its value derives from having plans for dealing with the results, and the intent to implement those plans.

One key element to adopting new monitoring practices is transparency. We must ensure that our study protocols include sufficient detail about how we will ensure the quality of our data and the integrity of our trials.

To make the kinds of quantum leaps required of us, we will need to overcome native fears and move from our comfort zones. We should take some comfort, though, that the recent guidance documents reflect serious regulatory intent to help move our industry forward. For example:

The "Guidance for Industry Oversight of Clinical Investigations—A Risk-Based Approach to Monitoring" FDA draft guidance,[1] states that by moving away from 100% SDV, we can "improve a sponsor's ability to ensure the quality and integrity of clinical trial data."

The inference is clear—100% SDV represents a hindrance in the eyes of FDA to achieving data quality and trial integrity. We have opportunity, incentive, and a reasonably clear path for making significant enhancements in overall performance by adopting the kinds of plans and tools described in this article. And, we have every reason to believe that by doing so we can speed up clinical trials, improve data quality and dramatically reduce costs.

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Editor's Note: A white paper on this topic is available for downloap at http://www.eclinicalforum.org/Default.aspx?id=76&tabid=59.

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SOPs in Clinical Research

Gabriele Schmidt, Dieter Baier, Arthur Hecht, and Michael Herschel, MD

Survey appraises the use of SOPs in clinical research from the sponsors' point of view.

Clinical project managers, monitors and assistants in the pharmaceutical industry involved in conducting clinical trials are experiencing increasing regulation. This seems to be more of a hindrance than a help in their daily work. As well as being expected to be aware of the manifold legal requirements and international regulations such as the German Drug Law (AMG), GCP Regulation, ICH GCP, various European directives, and FDA guidelines to boot, in the case of global trials, employees are also confronted with an array of sponsor-generated quality management documents which frequently seem to consist of a tangled web of rules and regulations. The result is employee dissatisfaction and demands for improvement of the content, a reduction in the number of SOPs, and improvement in the way the content is presented. This situation is due in no small measure to the fact that there has been little or no debate to date on what constitutes "adequate quality" of an SOP system.

The literature has comparatively little to say about what an optimal SOP system can and should look like. Most authors limit themselves to very basic suggestions (e.g., short, meaningful sentences, clarity, use of illustrations)[1] or alternatively very detailed instructions,[2] which are ignoring basic elements of instructional design. GCP requires "the setting up and maintenance of quality control systems supported by written SOPs,[3] but provides virtually no guidance on SOP system design.

Only a few articles looked into the complex regulatory environment of the pharmaceutical industry[4] and the resulting principles of writing effective SOPs.[5,6]

SOP benchmarking project

The German Association of Research-Based Pharmaceutical Manufacturers—Verband Forschender Arzneimit-telhersteller (VFA)—appointed a taskforce from the Clinical Research and Quality Assurance subcommittee to look into the topic. The VFA is an organization of 45 research-based pharmaceutical companies whose studies, between them, make up a significant portion of clinical trial activity in Germany. Responses in this survey were obtained from several companies who belong to the leading pharmaceutical companies in Europe. The aim of the SOP Benchmarking project was to evaluate existing SOP systems on the basis of existing best practices and benchmarking, and to develop proposals for potential improvements. Existing SOP systems including the associated training were to be analyzed and improvement proposals were to be designed as appropriate on that basis. Another important issue was to determine whether specific SOP concepts were associated with higher "satisfaction" on the part of the parties concerned in their respective functions. The survey was conducted in late autumn of 2009 to determine the current state of affairs among VFA member companies, identify the mood/opinion of their employees with respect to the current situation, and present proposals as to what sponsors could do to change their SOP systems or remedy any deficiencies and inadequacies.

Real-World Genetic Disease Research: Benefits of a Patient-Centric Research Platform

ON-DEMAND WEBCAST

Register free at http://www.appliedclinicaltrialsonline.com/benefits

EVENT OVERVIEW:

Real-world observational studies present an interesting challenge to sponsors. They may involve a large number of patients, multiple dimensions of data sets and many logistical challenges, such as long study duration and global implementation across many sites. With new patient-centric and personalized genetic research study designs, patients expect to participate and interact with their research data to understand treatment progress and their disease in new ways, while investigators expect a higher-grade set of research tools, reports and direct access to the data collected.

This webinar will present the challenges and considerations involved in applying a real-world observational platform to genetic disease and provide several examples of these systems from such sponsors as the Inova Translational Medicine Institute, Genzyme (a Sanofi company) and Synageva BioPharma.

Key Learning Objectives:

Guests will

- Learn the specific data capture and study considerations in real-world observational research;
- Discover the business drivers behind several example systems from sponsors that include the Inova Translational Medicine Institute, Genzyme (a Sanofi company) and Synageva BioPharma; and
- See highlights of the joint observational platform developed by Medidata Solutions and Digital Infuzion.

Who Should Attend:

- Clinical Operations
- Data Management
- Medical Affairs
- Commercial Development

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Patrick Chassaigne
Director,
Partner Program
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Questionnaire 1

- Questions about the person/position.*
- Where are the studies planned/conducted?
- What types of document? Consisting of how many pages (estimated) are in use.
- How many SOPs? Comprising of how many pages (estimated) are there in specific areas (individual areas such as monitoring, audits, etc.).
- How many SOPs? How many pages does a study manager/clinical research project manager have to know, in which their tasks are defined?
- How has the number of SOPs (local and/or global) changed over the past 12 months?
- What percentage of processes is overregulated in your opinion?
- For which processes would you eliminate SOPs completely, and how many SOPs/SOP pages do you think would be cut if that were to be done?
- Which processes are not currently covered in SOPs, but should be in your opinion?
- Who writes SOPs?
- What has been the experience in the process of creating an SOP?
- How do affiliates deal with global SOPs that contradict national laws?
- How many weeks does it take on average from completion by the author until release, and how many weeks on average from release to implementation?
- What are the reasons for revising SOPs?
- How is SOP content taught, and how does the use of various teaching methods break down in percent?
- Intervals for refreshing SOP knowledge and review of learning outcomes?
- Whose SOPs are used during collaboration with CROs?

* Information encrypted; classification to the two questionnaires via code

Source: Schmidt, et al.

Table 1. The questions asked key company clinical trial management personnel.

Questionnaire 2

- Questions about the person's function, job experience, and corporate position.*
- Satisfaction with the clinical SOP system.
- Involvement of the respective function in the sponsor's SOP compilation/revision process.
- Personal take on clinical SOPs in terms of length, level of detail, comprehension, clarity, coherence, usefulness, stronger restrictions in respect of legal framework for conducting clinical trials.
- Necessity, frequency, and reasons for SOP deviations.
- Number of necessary deviations applied for annually in order to be able to conduct required tasks.
- Number of superfluous SOPs in the respondent's opinion which have to be complied with in that person's day-to-day work in the performance of clinical trials.
- Estimated actual amount of time compared with the amount of time the person would consider reasonable for SOP training measures.

* Information encrypted; classification to the two questionnaires via code

Source: Schmidt, et al.

Table 2. Information collected from clinical operations staff.

The questions related only to SOP systems used to conduct Phase I to Phase IV clinical trials and did not cover health outcome studies or non-interventional studies.

Description of project/survey conduct

Two questionnaires were designed for the survey: Questionnaire 1 (Table 1) about the cost and benefit of SOPs looked at the existing structure and size/scope of the company's existing SOP system in terms of GCP, SOP management, and presentation of SOP content. The addressees were management and organizational employees (e.g., medical directors, directors of clinical investigation, and quality assurance directors).

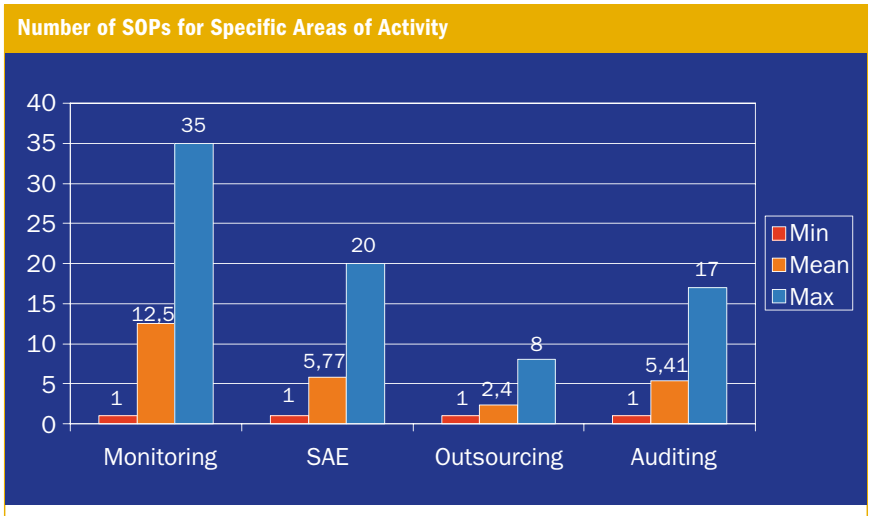
Questionnaire 2 was addressed at clinical research employees (i.e., monitors and project managers of the sponsor and freelancers/employees of CROs involved/in sourced by the sponsor for study projects). Questions were asked about handling and satisfaction with the existing SOP system/training methods, and respondents were asked to make proposals for possible future systems and methods.

Replies from the two surveys were encrypted by VFA via company code so that it was possible to match management responses to employee responses, but without revealing the identity of individual companies and persons in the evaluation.

Results

A total of 18 companies took part in the survey, the majority of which is represented by a member in the already mentioned subcommittee. The results hence reflect relevant experience of SOP systems in the pharmaceutical industry. In nine cases the company was the local affiliate of a global corporation. Three to four responses per company were received from the employees invited to take part in the survey in the operative line departments (67 total); the majority were company project managers and/or clinical monitors with an average of 10 years of job experience.

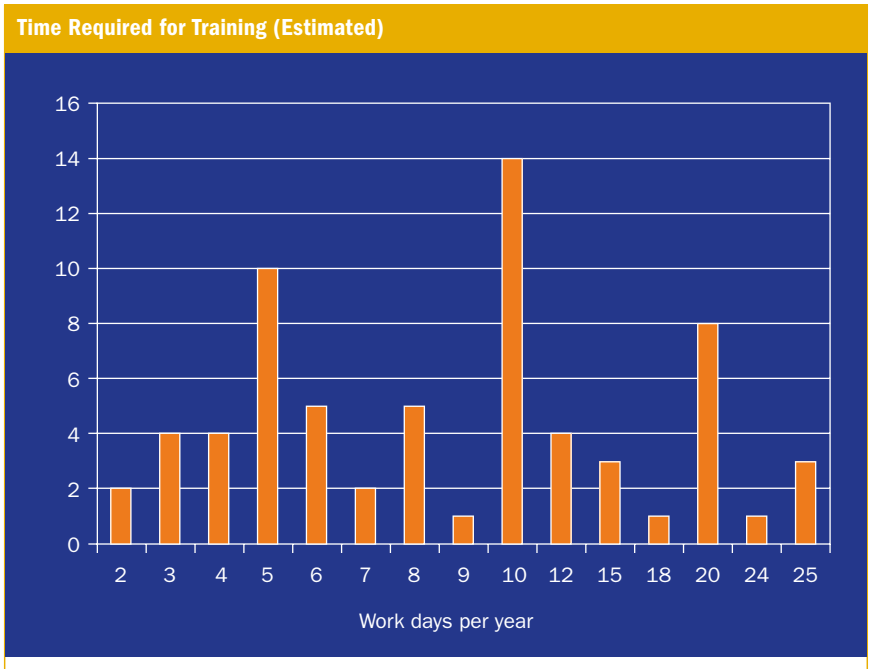
Estimation/user satisfaction with the currently established SOP system. Irrespective of their function or role in clinical research and time with the company, 19% of respondents were fully, 57% partly, 16% less, and 8% not at all satisfied with the current SOP system in their company. The main criticisms of existing SOP systems concerned the complexity and lack of clarity of individual documents/SOP systems, which made it more difficult for users to rapidly seek and find the relevant sections/instructions required for day-to-day work or in a specific on-site situation. In many cases, instructions concerning parts of processes (e.g., study initiation) are spread out among different sections of an SOP or even among a number of different documents (SOPs, instructions, appendices, etc.).



Source: Schmidt, et al.

Figure 1. For monitoring, the scale ranged from one to 35 SOPs and from 10 to 700 pages.

SOPs with large numbers of pages did not necessarily receive poorer ratings. Instead, SOPs were criticized for being unclear and/or overloaded with abbreviations and jargon. Documents intended to be globally applicable were frequently mentioned in this context; respondents said global documents tend not to contain clear information/delimitations for each area (global/local functions). The associated need for additional material on local processes was seen to result in unreasonable multiplication of process descriptions. Users saw clear potential for improvement in implementing a level of document detail suited to the specific tasks and responsibilities, combined with a rapid and accurate search feature. Almost half of the respondents reported little or no personal involvement in the creation of SOPs. A mere 15% of those involved in document compilation said they were actual authors; most were involved only in the review/feedback process. Involvement in SOP compilation did however not correlate with level of satisfaction.



Source: Schmidt, et al.

Figure 2. An average of 11 days per year is devoted to training.

SOP length/level of detail. Only 27% of respondents were happy with system size/scope and less than half (48%) were happy with the level of detail. Detailed evaluation showed that monitors tended to be more satisfied with lengthy SOPs than project managers. The same applied for satisfaction in relation to time spent working in the company. The SOP system was increasingly felt to be too lengthy with increasing time spent working in study management. In contrast to size/scope, there were no major differences in satisfaction between monitors and project managers in respect of level of detail. Here again, however, there was a trend toward dissatisfaction with overly detailed descriptions as a function of time spent working for the company (> 10 years of job experience).

Comprehensibility/clarity of SOPs. Twenty five percent of respondents said existing SOPs were not coherent and comprehensive. This opinion was more commonly expressed by project managers than by monitors. There was no correlation with time spent with the company. Thirty five percent of respondents said the SOPs were not clearly structured, monitors more so than project managers. Systems with fewer pages (in reference to monitoring) also tended to be rated more favorably.

Are SOPs useful in your daily work? SOPs were primarily found to be useful (approximately 85%), irrespective of duration of job experience, even more so by monitors than by project managers.

Are SOPs more restrictive than the legislative framework? About two-thirds of respondents said internal company SOP systems were more restrictive than applicable law. Project managers tended to find them even more restrictive than monitors.

There was a trend for a negative rating of all the sub-elements of scope/size, level of detail, comprehensibility, clarity, usefulness, and restrictiveness from employees who were dissatisfied with the SOP system overall.

Existing SOP systems in clinical research. The global and/or local SOP systems for conducting trials that exist alongside legislative requirements differ greatly between companies. The survey shows that there is neither a uniform hierarchy/structure in respect to SOP documents, nor in terms of nomenclature of document types. To name just a few, the terms employed include SOP, policy, operating instruction, and working instruction. There is also a plethora of different annexes such as flow charts, tables, job aids, completion guides, etc. The reported estimated length of SOP systems ranged from a few pages to complex SOP constructions with an estimated number of up to 8,500 pages.

Comparison of job areas and processes with a largely predictated scope of regulation (e.g., monitoring, SAE reporting, audit conduct, and collaboration with third parties/CROs) gives a similar picture. Again, there are huge differences between SOP systems. For monitoring (site selection/pre study visits, study conduct, study completion, and close out visit), the scale ranged from one to 35 SOPs (Figure 1) and from 10 to 700 pages. The mean number of SOPs a study manager/project manager in clinical research had to be familiar with was approximately 50 SOPs/480 pages.

Increase and overregulation of processes—potential for reductions. Whether and how subjective dissatisfaction in recent years correlates with SOP proliferation is evident from the following statements from management staff. About 40% said there had been no change regarding the estimated number of global or local SOPs. Thirty percent had an increase of less than a 10%; 30% of more than 10% increase per year. None had a reduction in the past 12 months. Respondents said processes were overregulated (not including those relating to clinical trials but not originating in clinical research) in about 5% (median) of all processes described.

Few ways of streamlining processes or eliminating SOPs showed up. Half of the companies' management staff surveyed saw little or no potential for reductions (two SOPs on average). The vast majority was unable to identify SOPs that could be done without. In contrast, clinical operations staff felt that a median of 10% of SOPs they have to comply with in their day-to-day clinical trial performance were superfluous.

UPDATE IN SLEEP MEDICINE:

Impact of Nonrestorative Sleep for Mental Health

Definition, Diagnosis, Evaluation, Treatment and Clinical Trials

ON-DEMAND WEBCAST

Register Free at www.appliedclinicaltrialsonline.com/impact

Key Learning Objectives:

After the webinar, participants should

- Know about a key manifestation of insomnia, nonrestorative sleep, and how to diagnose and measure it
- Understand the relevance of nonrestorative sleep for affected individuals with regard to work performance, mental health, and quality of life
- Be able to include and measure nonrestorative sleep and its consequences on daily activities and quality of life in clinical trials for the treatment of non-restorative sleep in many sleep disorders

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For questions, contact Kristen Farrell at kfarrell@advanstar.com

EVENT OVERVIEW:

When people report that their sleep is not refreshing and they don't feel rested even if the duration of their sleep is normal and if this occurred on at least 3 mornings per week for at least one month – a diagnosis of "nonrestorative sleep" (NRS) is most probable. The population prevalence of NRS is reported as 10.8% and it affects between 11 and 25% of the insomnia population, making it a topic of increasing interest in the multi-billion dollar market for sleep disorder therapeutics. NRS can be associated with the two other key complaints of insomnia: difficulty initiating sleep (DIS) and/or difficulty maintaining sleep (DMS). Besides primary insomnia, potential other causes of NRS include sleep restriction, sleep apnea, periodic limb movements or restless legs syndrome, to mention a few. However, according to DSM-IV criteria and based on recent epidemiological results, NRS can be the sole and distinct sleep complaint in primary insomnia with a prevalence of approximately 2 to 3%.

Individuals with NRS experience significant daytime functional impairment including impaired work productivity, sleepiness, irritable mood, physical and mental fatigue, and role impairment.

The webinar will introduce the concept of NRS, describe diagnostic criteria and tools to measure its severity, and discuss treatment options. Challenges of clinical studies on NRS will also be presented. The webinar will be lead by an internationally highly recognized expert in Sleep Medicine, Dr. Thomas Roth, the Director of the Sleep Disorders and Research Center at Henry Ford Hospital, Detroit, USA. Dr. Roth is at the forefront of clinical research in NRS and (co-) author of the most relevant publications in this area.

Presenters

Thomas Roth, Ph.D.
Chief, Division Head
Sleep Disorders and Research Center, Henry Ford Hospital
Detroit, Michigan, USA

Prof. Ralf Kohnen, Ph.D.
ReSearch Pharmaceutical Services Inc.,
Fort Washington, PA, USA
Psychology Department, University of
Erlangen-Nuernberg, Germany

Moderator

Lisa Henderson
Editor-in-Chief
Applied Clinical Trials

Who Should Attend:

- Physicians, Clinical Scientists and Project Managers at pharmaceutical and biotechnology companies involved in or planning clinical drug trials in Sleep Medicine
- Neurologists, psychiatrists, sleep doctors and study investigators who are interested in emerging developments in diagnosis and new therapies for Nonrestorative Sleep

Conversely, gap analysis revealed little or no need to extend the SOP system. Only two companies reported a specific need for regulation in particular areas.

SOP compilation and SOP quality. According to the respondents, corporate headquarters are responsible for SOP authorship in 60% of the surveyed companies. More than 70% of the surveyed companies involve the line departments and about 50% involve quality assurance in SOP compilation. One-quarter of the companies involve SOP writer specialists in drawing up SOPs. Affiliates and subsidiaries are involved in the generation of global SOPs in addition to corporate headquarters. Sixty five percent said they were included in discussions about new SOPs, and their feedback is adopted/integrated in documents in more than 70% of cases. The expertise of SOP authors was largely rated favorably; only 10% of respondents said SOP authors tended to be far removed from reality.

In about 70% of companies, additional local processes and SOPs are generated to supplement the corporate regulations in order to reflect and implement local/regional needs and legislative requirements.

SOP deviations and violations. Three-quarters of the surveyed monitors and project managers said they sometimes had to deviate from an SOP in their day-to-day work. The main reasons cited for necessary deviations were "unfeasibility," as well as (lack of) time, effort, and cost. About 45% of employees said they never deviated from an SOP. Almost the same number (about 42%) said they deviated one to two times per year, and only a few said they had to deviate more than three times or five times per year.

Deviations resulting from a discrepancy between global SOPs and local legislation are handled in different ways. About 50% of companies draw up local modifications. About 30% put national laws ahead of company instructions and implement this policy without any formal modification/amendment of the global SOP.

SOP cycle and change management. Respondents said one reason for violations and dissatisfaction among those working with SOP systems was the compilation process itself or the generation period/revision cycle. About 40% of management employees said that new or revised SOPs were often implemented unexpectedly and without "prior warning" by corporate headquarters. The SOP generation period from first draft through feedback periods to approval and release lasts 10 weeks on average. Lead times from announcement to enforcement of an SOP were four weeks on average.

In addition to regular review of SOPs at intervals of two to three years, there are other important reasons for revision. In more than 80% of reported cases, a change in legislation was the reason for an SOP revision or creation of a new SOP. A similar situation applied (almost 90%) with respect to structural changes within companies that entailed adaptation of processes and responsibilities.

SOP training. Two-thirds of the companies surveyed said learning SOP content was primarily the job of the individuals concerned. Nonetheless, formal learning was deemed the best method of learning (80% of companies that said this was mostly or occasionally the case). Two-thirds of companies rejected the prospect of ad-hoc training provided only to meet an acute need and if a particular process was specifically required.

Seventy five percent of employees also said self-study was one of the most important ways of learning SOPs. Even more respondents (88%), however, said face-to-face training was the best learning method. Less than half of respondents (43%) said e-learning was the best method. However, acceptance of this method increased if it was linked with review of learning outcomes (58%).

Despite significant variation among the surveyed clinical research management, self-study accounted for the major part of training effort, accounting for a median of 70% of total time required, followed by e-learning (median of 40%) and face-to-face/classroom training (median of 15%). Training with formal review of learning outcomes accounted only for a median of 7.5% of training events.

Regardless of training events, the surveyed companies said the SOP competency of employees is not reviewed systematically. One-third do not regularly check competency, 15% only in isolated cases, if the manager notices deficits or an audit identifies any deficiency. Fifteen percent of companies check their employees' knowledge of the main SOPs at least once a year. Training units are repeated every one to two years in 56% of companies, and at intervals longer than two years in another third.

The open-end answers clearly show that learning modalities cannot be viewed in isolation from the complexity or novelty of content, from the overall structure of the training system, or from the individual employee's level of experience: "The best setting to choose depends greatly on the content of the SOPs." Respondents also explicitly suggested combination with other learning modalities: self-study and online training for induction, face-to-face training to deepen understanding and for discussion.

An average of 11 days per year is devoted to training, but this figure varied significantly among the respondents (Figure 2). The three-peak distribution shows peaks at five, 10, and 20 days. Monitors and project managers were asked which quantity of training they would consider to be the most appropriate. The answer was approximately nine days, again with significant variation. The breakdown here again shows systematic differences between the relevant user groups.

Cooperation with CROs. In respect of cooperation with CROs, it emerged that sponsor SOPs were used as a basis for study conduct in approximately two-thirds of cases. CRO SOPs were used in less than one-third of cases.

Discussion of results

The baseline hypothesis (i.e., that SOP systems in GCP as they now exist would be rated inadequate by corporations and users) is not strongly supported. Although analysis of survey outcomes reveals deficiencies in the system and a need for improvement and change in some areas, the benefit of SOPs is nonetheless accepted. Nor did the survey results confirm the often cited suspected widespread overregulation of SOP systems.

Not every SOP system is the same, and not every SOP is equally suitable for every organization. What works for one company need not be the best solution for another.

Authors of SOPs tread a thin line in general, because user expectations and needs are as diverse as the spectrum of SOPs in existence. The needs of career starters differ from those of employees who have worked in the company or in clinical research for longer. Differences are also apparent in terms of the roles and responsibilities of respondents, for instance between monitors and project managers. Globally operating companies face the challenge of implementing global policies into local practice in a way that accommodates local legal requirements and best practice but at the same time does not violate global SOPs.

The various aspects are looked at in greater depth in the following:

Acceptance. SOPs are described overall as too lengthy. The subjective feeling of many respondents seems to be that "less is more."

Many respondents cited the difficulty in finding individual process steps within an SOP system as being a key problem. "Details of a single process need to be searched for in multiple SOPs." "Search features in the electronic SOP repository are ineffective." "Sometimes it is not easy to find the right SOP you need for a particular process."

The size/scope of SOP systems evidently differs greatly between companies indicating that SOP systems can display significant differences and may not always be directly comparable. The total number of SOPs and in particular the estimated number of pages—8,500 for one company—showed a wide range of variation. The only explanation is that SOPs may be written as no-frills "instructions" (who does what and how), as well as guidance (e.g., every single document, be it a simple letter to an investigating site, trial protocol template, or CRO communication plan). The latter policy may lead to a situation where important information and instructions for employees are hidden in a multiplicity of annexes/working instructions/templates to SOPs, which employees have to read and wade through even though they may not be immediately relevant to the specific (sub) task in hand. The former bears the risk of heterogeneous implementations.

As already mentioned at the outset, existing regulations do not dictate the depth of regulation in SOPs. ICH GCP section 5.1.1 merely states that sponsors are obliged to implement an effective quality management system with written SOPs. Thus, the decision on depth of regulation is a task of the company.

There may be several conditions under which companies increase the depth of regulation. For various reasons, in the case of inspection requirements, companies tend to set down processes in the greatest of detail and meticulously define every single step. This extends to detailed specification of formats for templates/forms. The aim is to provide employees with every possible aid in order to prevent errors.

It is therefore no surprise, as the survey shows, that the level of detail is seen to be either helpful or restrictive depending on the individual employee's level of experience. A high level of regulation also carries the risk of making more mistakes and unintentionally violating an SOP. This increases the need for deviations either on the basis of pre-approved waivers or post-hoc documented violations.

Globally operating companies have an additional problem: global SOPs and procedures may need to be expressed in very general terms to ensure that they cover all responsibilities and areas throughout the organization and should not interfere with country-specific regulations. The result is that local employees may find the global SOP to be inadequate and may encounter local situations that are not sufficiently addressed in global SOPs. To get around this problem, 70% of companies draw up local supplements. In case global SOPs do interfere with local regulatory requirements, the latter prevail.

Size and structure. Analysis of the survey shows that the quantity and variability of process descriptions does not seem to correlate with employee satisfaction with the SOP system. Although the subjective impression is that the amount of regulation in companies has increased in recent years and is continuing to increase, it is felt that there is little leeway for reducing SOP systems. Very few respondents made specific proposals for SOPs that could actually be done without.

In most companies, the existing SOP systems fully cover regulatory needs. Only a few marginal areas/exceptions were mentioned which still have to be covered by SOPs in individual companies.

SOP management. The survey showed that some SOPs are implemented with no lead time and may be implemented even in normal situations within as short a period as four weeks. In the authors' experience, this would generally be an insufficient period of time to give employees the chance to familiarize themselves with the new procedure and complete the necessary training.

There may be good reasons why SOPs are modified at very short notice, for instance, an imminent regulatory requirement or the need to avoid damage to study participants.

Apart from the need to scrutinize the wish to change SOPs, sufficient time should be left between finalization and the date of coming into effect of an SOP. At least eight weeks is suggested.

Training

Training of all parties involved in the process is indisputably a key responsibility of sponsors. It derives from the requirement that sponsors must ensure that all involved parties are properly qualified.[7] However, there are no specific requirements as regards the methods used to qualify staff. Inspectors tend to attribute non-compliance with process descriptions to inadequate training. Such a conclusion is too simplistic—it is important to analyze the underlying chain of circumstances as a means of initiating appropriate, reactive, or proactive measures.

Specifications hence need to be developed independently. It is important in this context to accommodate different learning types and availability of the insights of experts in the psychology of learning.[8] A flexible learning system with a variety of learning modalities should be offered.

Both training providers and recipients recognize the responsibilities of employees in the learning process. Accordingly, self-study (read and sign, etc.) is very important and widespread. However, this learning method lacks feedback on learning outcomes, which could be the reason for the lower acceptance among users. Nor is there any means of checking learning intensity or identifying misunderstandings regarding content. However, self-study is nonetheless essential as a basis for learning.

In this survey, face-to-face/classroom training had the highest level of acceptance. The main reason seems to be the feedback on learning outcomes, which can be gained from following class discussion and asking questions about the content. The drawback of this learning modality is the comparatively high cost. The results of this survey indicate that the use of this method has become rather rare.

Online training, on the other hand, evidently seems to have become widespread. There are still acceptance problems among users nonetheless, in particular if the training provides no means of checking learning outcomes. Interestingly, online training programs with options to review learning outcomes have significantly higher acceptance rates than those without.

The survey results also clearly show that training measures should not be analyzed in isolation from their particular context. Complexity or novelty of processes and availability of complementary training modalities are key factors in constructing a flexible training system.

There seems to be high congruence between providers and recipients of training with regard to the amount of time required. On average, the actual time required from the training recipient's point of view exceeds the nominal amount by only two days (11 versus nine days). This is a good result. On average, the time required for training according to the results of this survey is about 5% of total working hours, with a very evident wide range of variability among the companies.

Analysis of frequency of training and refresher cycles indicates that "not forgetting" is the primary element addressed. A two- to three-year cycle may be appropriate, but is not based on hard evidence.

Conclusion

The starting point for this survey was the impression that employees are relatively dissatisfied with their SOP systems. A detailed survey—which would appear to be representative given the extent of feedback obtained—indicates that satisfaction may not be dependent on the size and structure of the SOP system. It does identify potential for improvement in this area of such importance for the quality of clinical trials.

Some suggestions can be derived from the above results, which will be closer looked at in a second article (Proposals for an Ideal SOP System):

- Responsibility, workflow, and personal accountability should be clearly defined in an SOP.
- SOP should address certain groups of users and contain only information relevant for those.
- SOPs should be user friendly, as short as possible, and as detailed as needed for clarity.
- SOPs should be oriented to a process and not to specific functions.
- SOPs should be easy to search and according to simple process maps.
- Training should be combined with adequate feedback and learning control.

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Business and People Update

People


John Samar


Sam Whitaker


Steve Rosenberg


Rabinder Buttar

• **ICON plc** (Dublin, Ireland) announced the appointment of **Neil McCullough**, PhD, as Executive Vice President of Quality and Compliance and Corporate Training. In this role, McCullough will provide strategic direction for quality management, quality assurance, and corporate training across all ICON lines of business.

• **CTI Clinical Trial and Consulting Services** (Cincinnati, OH) announced the following new hires: **Renee Torres**, Biostatistician II; **Roy Wells**, Senior Auditor, Quality Assurance; **Angela Bowens**, Clinical Safety Scientist; **Cynthia Fairbairn**, Study Coordinator; **Cheryl Chapman**, Clinical Safety Associate; **Michelle Clifford**, Research Associate; and **Chika Okere**, Research Associate. The company also announced the following promotions: **John Williams** was promoted to Assistant Director, Clinical Monitoring; **Allison Schroeder** was promoted to Associate Manager, Marketing and Corporate Communications; **Joseph Schroeder** was promoted to Contract Specialist; **David Flick** was promoted to IT Support Analyst; and **Michel Connor** was promoted to Assistant Project Manager.

• **Chiltern International Limited (Chiltern)** (London, UK, and Wilmington, NC) announced the promotion of **Alecia Barbee** from Executive Director of Biometrics to VP of Global Biometrics. In this role, Barbee will have global oversight of data management, data programming, biostatistics, and e-clinical functions in Chiltern.

• **CROnos Clinical Consulting**, (Hamilton, NJ) announced that **Pamela Keenan** has joined the company as Vice President, Scientific Affairs.

• **Neurovations** (Napa, CA) announced the addition of **Renée Bell** as its Director of Clinical Research.

• **Southern Research Institute** (Birmingham, AL) announced that **Arthur J. Tipton**, PhD, has been selected by its board of directors to serve as President and CEO. Tipton replaces **John A. Secrist, III**, PhD, who served as President and CEO for seven years. Secrist announced his retirement earlier this year after 34 years of service at Southern Research.

• **Clinical Research Advantage (CRA)** (Tempe, AZ) announced the addition of **Craig J. Smith**, CPA, MBA, as the company's Chief Financial Officer.

• **PHT Corporation** (Boston, MA and Geneva, Switzerland) announced the addition of **Steven Rosenberg** to the company in the role of Chief Operating Officer.

• **PSI CRO** (Zug, Switzerland) announced the appointment of **Andrea Cracraft** as Director, Clinical Operations North America.

• **goBalto Inc.** (San Francisco, CA) announced its new Customer Success division, designed to nurture and expand customer relationships through consultative account management practices, and to ensure continuous customer enthusiasm. **Ken McFarlane** joins the goBalto team as Senior Director of Customer Success. Also joining the team is **Ashley Davidson** as Director of Customer Success.

• **OmniComm Systems, Inc.**. (Fort Lauderdale, FL) announced that **Kuno van der Post**, PhD, has been promoted to Senior Vice President of Business Development.

Alliances

• **OmniComm Systems, Inc.** (Fort Lauderdale, FL) and **Reliable Lifesciences Consulting (RELICO)** announced their new strategic partnership. The partnership will allow OmniComm to offer EDC project management and support, and add to their own European-based support services. It also will allow RELICO to offer study build and support services to its clients, as well as access to the intuitive EDC suite.

• **The Association for the Accreditation of Human Research Protection Programs (AAHRPP)** (Washington, DC and New York, NY) and the **ViS Research Institute** announced a strategic alliance to further protect research participants by providing easy access to information on the quality and standards of organizations that conduct clinical trials. ViS has developed an online analytics platform to streamline the feasibility assessment of research sites. Because of the alliance, ViS profiles of research sites will now include information on whether the site has earned AAHRPP accreditation.

Awards

• **Greenphire**, (King of Prussia, PA) provider of payment tech-

nologies for the clinical trials industry, announced three industry recognitions. The company's CEO, **Sam Whitaker**, has been selected as a finalist for the Ernst & Young Entrepreneur of the Year Awards 2013 in the Greater Philadelphia region. The company's CFO, **John Samar**, has been named as a finalist in the *Philadelphia Business Journal's* CFO of the Year Award program. In addition, **Shawn Milochik**, Vice President of Software Engineering, was awarded the *Philadelphia Business Journal's* Top IT Innovator Award.

• **Rho** (Chapel Hill, NC) announced that CEOs **Russell W. Helms**, PhD, and **Laura Helms Reece**, DrPH, were named as finalists for the Ernst & Young Entrepreneur of the Year Award for the Southeastern United States.

• **Pharmaceutical Product Development (PPD)** (Wilmington, NC) announced the *Computerworld* Honors Program has named PPD a 2013 Laureate. The annual awards celebrate visionary applications of information technology that promote positive social, economic, and educational change

• **Quintiles** (Research Triangle Park, NC) has received the 2013 Informatics Innovation Award for "Enterprise Data Integration" recognizing its efforts, through the Quintiles Infosario solution, to integrate both clinical research and healthcare data across numerous institutions and at a high scale.

• **ClinTec International** (Glasgow, Scotland) announced that Founder and CEO, **Rabinder Buttar**, PhD, won the "Female Entrepreneur of the Year" award at the Scottish Business Awards 2013.

Company News

• **The Society for Clinical Data Management** (Brussels, Belgium) hosted its first conference outside of the United States May 31 to June 1 in Mumbai, India. Over 150 expert professionals and industry leaders, representing 50 companies and seven countries, gathered around the Changing Landscape of Clinical Data Management.

• **The Clinical Data Interchange Standards Consortium (CDISC)** (Austin, TX) announced plans to implement CDISC SHARE. After a comprehensive proposal and evaluation process, SOA Software's Semantic Manager product was chosen as the SHARE technology platform by a selection committee consisting of CDISC leaders and volunteers, with substantial support from TransCelerate BioPharma Inc. SHARE, or Shared Health And Research Electronic Library, a cornerstone of the CDISC technical roadmap, will be a global electronic repository for developing, integrating, and accessing CDISC metadata standards in electronic format.

New Facilities

• **Celerion** (Lincoln, NE) announced the addition of a containment room at the Belfast, Northern Ireland, UK facility. The new containment room will allow Celerion to develop programs that require studies utilizing biologics, as well as vaccines with primary and secondary containment. The containment room is a modular facility comprising a negative pressure processing room which houses a Biosafety Level (BSL-2) cabinet. The addition of the room further enhances the current GMP licensed site by enabling the processing of live Class 2 and Class 3 biological products.

• **TKL Research** (Rochelle Park, NJ) is constructing a new clinical research facility in Fair Lawn, NJ, that will include a state-of-the-art, 30-bed, Phase I unit as well as multiple outpatient clinical examination rooms.

• **Novotech** (Sydney, Australia) has expanded its Asia reach into Hong Kong and the Philippines, building on its established network which already includes a presence in Singapore, South Korea, Taiwan, Thailand, India, and Malaysia.

• **Quanticate** (Boston, MA and Research Triangle Park, NC) announced the relocation of its US office with a move to North Carolina's Research Triangle Park. This expansion follows a number of partnerships that are being developed with Top 10 pharmaceutical companies to provide global functional support, particularly in the areas of biostatistics and statistical programming.

New Products

• **ERT** (Philadelphia, PA) announced enhancements to AVERT, its electronic suicide risk assessment system. Having already been used by over 32,000 clinical trial patients, AVERT is now available in both audio (phone) and visual (web/tablet) patient interfaces, offering greater flexibility to developers of new biopharmaceutical products.

• **ArisGlobal** (Stamford, CT) announced the availability of agCenter 3.1, a clinical research investigator site portal that facilitates and streamlines the communication and collaboration between sponsors and their clinical study sites. The investigator portal is the newest addition to ArisGlobal's Total Clinical™, a platform for clinical research that includes EDC, CTMS, ePRO, medical coding, trial disclosure, supply chain management, and safety reporting—all accessed via agWorld™, a central clinical portal.

• **Biofficient Inc.** (Boston, MA) announced the successful launch of its new platform to accelerate the outsourcing process for the biopharmaceutical drug development process. Biofficient.com, which hosts the platform, offers a streamlined solution to the arduous process of matching clinical trial sponsors' specific needs with a comprehensive database of contract services provided by a global list of industry vendors.

• **CRF Health** (Plymouth Meeting, PA) announced several enhancements to their TrialMax eCOA solutions. Updated features: ability to send SMS and e-mail reminders to patients across all TrialMax eCOA solutions to keep patients engaged; new TrialMax Slate study dashboard displaying the questionnaire status of all patient visits; on-demand access to study specific training; and patient and site user experience improvements.

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Comprehensive Evidence Development: Progress and Opportunities

The goal is to have an evidence development framework that can answer a range of questions simultaneously.

Richard Gliklich, MD
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With the introduction of Accountable Care Organizations in the United States—and increasing evidentiary requirements from payer organizations around the world—this is both an exciting and nerve-wracking time to be in the healthcare industry.

The business of treating patients has always been about providing care of the highest quality, but the paradigm shift in the industry today is forcing all those who are part of providing care to prove the value of that care through demonstrable real-world outcomes.

Not only do we face newly empowered stakeholders with different priorities, but old stakeholders with new priorities for the information that will drive their decisions. At the same time, the methods we must employ to develop evidence have also expanded from randomized trials to prospective observational studies and registries, to harvesting big data—including rapidly accumulating electronic health records. Ultimately, the goal is to have an evidence development framework that can answer a range of questions simultaneously and provide a more efficient, timely, and complete picture for better decision making—from approval to coverage to use.

As physicians and group practices intensify their efforts to provide patient outcomes data to satisfy this challenge, myriad initiatives and projects are underway globally to assist all stakeholders in assessing the efficacy, safety, and cost-effectiveness of medical interventions. Yet much work remains to be done. The FDA, for example, recognizes the agency's need to better assess the risk/benefit profile of new interventions (in addition to safety and efficacy), but Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research, stated at the recent Post-Approval Summit at Harvard Medical School that the agency needs better tools and training to assess new types of evidence.

Regulatory and resource challenges notwithstanding, significant progress toward developing comprehensive evidence for medical interventions can be seen in numerous areas. The ongoing Registry in Glaucoma Outcomes Research study aims to compare three treatment paths and outcomes among patients with open-angle glaucoma. This type of study will not only provide longer-term outcomes data for interventions with differences in access and costs, but will also identify sub-populations of patients who may benefit from one path versus another. The identification of treatment response—on an individual level and in the real world—is one of the hallmarks of the new world of clinical research.

Isolated streams of data, however, only provide a glimpse of an intervention's overall profile. By leveraging electronic health records, biobanks, patient registries, and data from randomized clinical trials, among others, all relevant questions about individual response to a medical intervention can be answered.

In response, biopharmaceutical companies must gain comfort with real-world outcomes data being used as a basis for reimbursement, pricing decisions and ultimately physician decision-making. Biopharma has gotten very comfortable over the past decade in approaching regulatory authorities for guidance. They must now engage in the same types of conversations with payers, providers, and patient advocacy groups—in the very early stages of a product's lifecycle—to ensure that the evidence needs of these stakeholders are being addressed in the development of new therapeutics. Coupled with a strategy to collect, analyze, and openly share outcomes data, ongoing dialogue, and coordination amongst all members of the healthcare ecosystem will ultimately enable evidence-based treatments to get to the right patients, at the right price.

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A Desk Reference for the Clinical Trials Community

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2013 Directory & Buyers Guide

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From the Editors

Welcome to ***Applied Clinical Trials'* 2013 Directory & Buyers Guide**. Contained within is a great deal of information to facilitate your search for CROs, IRBs, Labs, and Sites and for suppliers and outsourcers of Clinical Packaging, Consulting, Contract Research Services, IT, Lab Supplies, Subject Recruitment, Training & Education, and Career Recruitment & Staffing.

We hope that the 2013 Directory & Buyers Guide proves to be an essential and invaluable part of your desktop reference tools.

Kind regards,

Applied Clinical Trials' Editors

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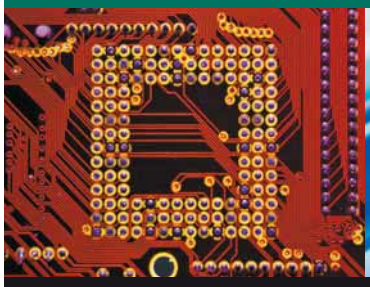

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Web Site: www.prcclinical.com
Contact: Curtis Head

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1721 NE 40 Pl
Fort Lauderdale, FL 33334
Business: 954-249-6243
Fax: 954-337-0312
E-mail: info@flqes.com
Web Site: www.flqes.com
Contact: Edward Wentz

SAS INSTITUTE
100 SAS Campus Dr
Cary, NC 27513-2414
Toll-free: 800-727-0025
Business: 919-677-8000
Fax: 919-677-4444
E-mail: mccenter@sas.com
Web Site: www.sas.com

SYSTAT SOFTWARE
1735 Technology Dr Ste 430
San Jose, CA 95110
Toll-free: 800-797-7401
Business: 408-452-9020
Fax: 800-797-7406
E-mail: info-usa@systat.com
Web Site: www.systat.com
Contact: Greg Barton

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Eywiesenstrasse 5
Ravensburg 88212 Germany
Business: 49-7513-7000
Fax: 49-7513-700-4000
E-mail: info@vetter-pharma.com
Web Site: www.vetter-pharma.com
Contact: Oskar Gold

WESTERN STATES CLINICAL RESEARCH
9201 W 44 Ave
Wheat Ridge, CO 80033
Business: 303-940-9773
Fax: 303-940-0308
E-mail: research@wscrinc.com
Web Site: www.wscrinc.com
Contact: Cheri Casey


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Company Index

ACM GLOBAL CENTRAL LAB
160 Elmgrove Park, PO Box 14624
Rochester, NY 14624
Business: 800-525-5227
E-mail: info@acmgloballab.com
Web Site: www.acmgloballab.com
Contact: Eric Helfst
Laboratories: Central

ACORN CRO
6555 Quince Ste 400
Memphis, TN 38119
Business: 415-592-8777
E-mail: mhurn@acorncro.com
Web Site: www.acornresearch.net
Contact: Mia Hurn
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/ Contracts, **CROs:** General, Phase I-V, **Subject Recruitment**

ACTIGRAPH
49 E Chase St
Pensacola, FL
Business: 850-332-7900
Fax: 850-332-7904
E-mail: sales@theactigraph.com
Web Site: www.actigraphcorp.com
Contact: Genevieve Murray
Information Technology: EDC (PDAs, eDiaries)

ACUMEN HEALTHCARE SOLUTIONS LLC
14252 23 Ave N
Plymouth, MN 55447
Business: 763-559-8232 Ext 24
Fax: 763-559-2821
E-mail: wgk@acumenhealthcare.com
Web Site: www.acumenhealthcare.com
Contact: William Kobi
Information Technology: EDC (PDAs, eDiaries)

ACURIAN
2 Walnut Grove Dr Ste 375
Horsham, PA 19044
Business: 215-323-9000
E-mail: info@acurian.com
Web Site: www.acurian.com
Contact: Kirk McPoyle
Subject Recruitment

AIATRANSLATIONS
5A Marudy Dr, PO Box 5255
Clinton, NJ 08809
Business: 908-955-5201
Fax: 908-955-0210
E-mail: jaclyn.berberian@aiatranslations.com
Web Site: www.aiatranslations.com
Contact: Molly Naughton
Training & Education

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1195 Washington Pike Ste 110
Bridgeville, PA 15017
Toll-free: 800-245-2283
Business: 412-257-3000
Fax: 412-257-2283
E-mail: info@all-pak.com
Web Site: www.all-pak.com
Contact: Doug Firth

ALLIANCE HEALTH PARTNERS
605 Wood Branch TRL
Suwanne, GA 30024
Business: 888-246-7101
E-mail: info@ahealthpartners.com
Web Site: www.ahealthpartners.com
Contact: Zizi Joseph
Career Recruitment & Staffing; Consulting; Contract Research Services: CRF Design, CT Protocol Design, **CROs:** General, Medical Device, Niche, Phase I-V

ALLIANCE HEALTHCARE INFORMATION LLC
One Ivybrook Blvd Ste 100
Warminster, PA 18974
Business: 215-347-1100
Fax: 215-347-1110
E-mail: info@alliancehealthinfo.com
Web Site: www.alliancehealthinfo.com
Contact: Mary Anne Greenberg
Contract Research Services: Medical Writing, **Subject Recruitment**

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33 Wood Ave S 6th Flr
Iselin, NJ 08830
Toll-free: 877-223-1990
Business: 732-744-3435
Fax: 732-744-3436
E-mail: info@allphaseclinical.com
Web Site: www.allphaseclinical.com
Contact: Jeff Smith
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Other, **Training & Education**

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25 Fretz Rd
Souderton, PA 18964
Business: 215-660-8500
E-mail: info@almacgroup.com
Web Site: www.almacgroup.com
Contact: Michele Lichtenfield
Clinical Packaging: Labeling, Packaging, **Contract Research Services:** CT Protocol Design, Data Collection, Data Monitoring, **CROs:** Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS
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ALMEDIS
5 Ulitsa Malaya Pirogovskaya Ul Office 22
Moscow 119435 Russian Federation
Business: 7-495-937-43-18
Fax: 7-495-937-43-19
E-mail: info@almedis.ru
Web Site: www.almedis.ru
Contact: Anna Shagako
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/ Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Training & Education**

ALPHA IRB
1001 Avenida Pico Ste C #497
San Clemente, CA 92673-6956
Business: 949-542-3882
Fax: 949-940-0134
E-mail: info@alphairb.com
Web Site: www.alphairb.com
Contact: Marianne Thornton
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AMAREX CLINICAL RESEARCH
20201 Century Blvd 4th Flr
Germantown, MD 20874
Toll-free: 866-AMAREX1
Business: 301-528-7000
E-mail: info@amarexcro.com
Web Site: www.amarexcro.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, **CROs:** General, Medical Device, Phase I-V

AMERICAN COLLEGE OF CLINICAL PHARMACOLOGY
416 Hungerford Dr Ste 300, PO Box 1637
Rockville, MD 20850
Business: 240-399-9070
Fax: 240-399-9071
E-mail: klery@accp1.org
Web Site: www.accp1.org
Contact: Krista Lery
Other Services & Products

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1200 Harger Rd Ste 415
Oak Brook, IL 60523-1818
Business: 630-928-1000
Fax: 630-928-0020
E-mail: clinicaltrials@americanmedical research.com
Web Site: www.americanmedicalresearch.com
CROs: Phase I-V, **Sites**

AMERICAN UNIVERSITY OF HEALTH SCIENCES
1600 E Hill St
Signal Hill, CA 90755
Business: 562-988-2278
Fax: 562-988-1791
E-mail: hhou@auhs.edu
Contact: Holly Hou
Training & Education

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One Amgen Center Dr
Thousand Oaks, CA 91320-1799
Business: 805-447-1000
Fax: 805-447-1010
Web Site: www.amgen.com
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ANACLIM
6325 Digital Way Ste 401
Indianapolis, IN 46278
Business: 317-275-9100
Fax: 317-275-9101
Web Site: www.anaclim.com
Contact: Simone Guillot
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Negotiating Budgets/ Contracts, Pharmacovigilance, **CROs:** General, Niche

ANALYTICA INTL
Meeraner Platz 1
Lörrach D-79539 Germany
Business: 49-7621-98687-0
Fax: 7621-9339-1039
E-mail: info@de.analyticaintl.com
Web Site: www.analyticaintl.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, **CROs:** Medical Device, Niche, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment; Training & Education**

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4545 Assembly Dr
Rockford, IL 61109
Business: 815-484-8900
Fax: 815-484-8904
E-mail: sales@andpkg.com
Web Site: www.andersonpackaging.com
Contact: Justin Schroeder
Information Technology: IVRS

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5 Independence Way Ste 300
Princeton, NJ 08540
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E-mail: americas@apcerpharma.com
Web Site: www.apcerpharma.com
Contact: Suneet Walia
Other Services & Products

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7830 Camino Real Apt 405
Miami, FL 33143
E-mail: info@appointmentsearch.com
Web Site: www.appointmentsearch.com
Contact: Manny Ormaza
Information Technology: Other, Software Program Development

APTIV SOLUTIONS
1925 Isaac Newton Sq Ste 100
Reston, VA 20190
Business: 703-483-6400
Fax: 703-435-4031
E-mail: inquiry@aptivsolutions.com
Web Site: www.aptivsolutions.com
Contact: Peter Gonze
Career Recruitment & Staffing; Contract Research Services: CRF Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, Other

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Greenwich, CT 06831
Business: -203-422-6600
E-mail: info@aptuit.com
Web Site: www.aptuit.com
Contact: Stuart Needleman
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Dublin D2 Ireland
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Fax: 353-1670-8575
E-mail: info@argutusmed.com
Web Site: www.argutusmed.com
Contact: Joe Keenan
CROs: General, Medical Device, Niche, Phase I-V, **Laboratories:** Bioanalytical, Biomarkers, **Laboratory Supplies**

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9444 Waples St Ste 160
San Diego, CA 92121
Business: 858-638-7602
Fax: 858-638-7675
E-mail: info@ariannecorp.com
Web Site: www.ariannecorp.com
Contact: J Summer Rogers
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/ Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Other, **IRBs; Subject Recruitment; Training & Education**

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Stamford, CT 06902
Business: 203-588-3000
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Web Site: www.arisglobal.com
Contact: Matt Michael
Information Technology: CTMS, EDC (PDAs, eDiaries), Other

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Westgate House 44 Hale Rd
Hale WA14 2EX United Kingdom
Business: 44-161-927-5070
Fax: 44-161-927-5071
Web Site: www.armstrongcraven.com
Career Recruitment & Staffing

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8 parvis de Saint Maur
94120 France
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E-mail: info-arone@arone.com
Web Site: www.arone.com
Information Technology: EDC (PDAs, eDiaries), Software Program Development

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San Francisco, CA 94107
Business: 415-839-8161
Fax: 415-723-7110
E-mail: sales@arx.com
Web Site: www.arx.com
Contact: Eliya Fishman
Information Technology: Other

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rue Camille Hubert 7
Les Isnes 5032 Belgium
Business: 32-8-140-9410
Fax: 32-8-140-9411
E-mail: info@aseptictech.com
Web Site: www.aseptictech.com
Contact: Fanny Huynen

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Fax: 91-40-2355-0501
E-mail: bd@act-india.com
Web Site: www.act-india.com
Contact: Venkatraman Sunder
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **IRBs; Laboratories:** Central, **Sites; Subject Recruitment; Training & Education**

ASPIRE IRB
11491 Woodside Ave
Santee, CA 92071
Business: 619-469-0108
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E-mail: email@aspire-irb.com; jim@aspire-irb.com
Web Site: www.aspire-irb.com
Contact: Jim Dobyns
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2501 N Hayden Rd Ste 102
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Business: 480-874-9400
Fax: 480-874-9414
E-mail: evonne.roberts@assistek.com
Web Site: www.assistek.com
Contact: Evonne Roberts
Information Technology: EDC (PDAs, eDiaries)

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105 Saint Peters St
St Albans AL1 3EJ United Kingdom
Business: 44-1727-896-080
Fax: 44-1727-896-026
E-mail: admin@acdm.org.uk
Web Site: www.acdm.org.uk
Contact: Tina Clayton
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Niche, Phase I-V, **Training & Education**

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Web Site: www.gcppl.org.pl
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Fax: 202-464-2309
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Web Site: www.acrohealth.org
Contact: John Lewis
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Web Site: www.acrpnet.org
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Fax: 44-1727-859333
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Web Site: www.astralisgroup.com
Contact: Mark Knapper
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Itasca, IL 60143
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Fax: 630-228-8872
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Web Site: www.atcormedical.com
Contact: Doug Kurschinski
Laboratories: Core

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Charlottesville, VA 22903-4971
Toll-free: 877-274-1572
Business: 540-213-0150
Fax: 540-213-0152
E-mail: hewit@atlanticresearchgroup.com
Web Site: www.atlanticreseachgroup.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V

AUREUS RESEARCH CONSULTANTS
2237 N Hullen St Ste 301
Metairie, LA 70001
Toll-free: 877-284-1815
Business: 504-833-1528
Fax: 504-833-1567
E-mail: brucem@aureusresearch.com
Web Site: www.aureusresearch.com
Contact: Bruce McDonald
Contract Research Services: CRF Design, Data Monitoring, **CROs:** Medical Device, Niche, Phase I-V, **Sites; Training & Education**

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43 Manning Rd
Billerica, MA 01821
Toll-free: 877-287-4661
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Web Site: www.aushon.com
Contact: Alan Poon
Laboratories: Bioanalytical, Biomarkers, Cardiovascular-ECG, Central, Core, Imaging

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62 Forest St #300
Marlborough, MA 01752
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Fax: 508-597-5856
E-mail: info@averionintl.com
Web Site: www.averionintl.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** IVRS

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624 E Park Ave, PO Box 7122
Libertyville, IL 60048
Toll-free: 888-859-4656
Business: 847-362-2128
Fax: 847-362-7788
E-mail: jclausing@axmarketing.com
Web Site: www.recruitpatients.com
Contact: Jeffrey Clausing
Contract Research Services: Data Collection, **Information Technology:** IVRS, **Subject Recruitment; Training & Education**

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520 White Plains Rd Ste 500 A
Tarrytown, NY 10591
Toll-free: 877-429-9436
Business: 914-478-7600
Fax: 866-251-8392
E-mail: susan@axxiem.com
Web Site: www.axxitrials.com
Information Technology: CTMS, Other, Software Program Development

B & C GROUP SA
Watson & Crick Hill Rue Granbonpre 11
Mont-St-Guibert B-1348 Belgium
Business: 32-10-237-444
Fax: 32-10-237-430
E-mail: info@bnc-group.com
Web Site: www.bnc-group.com
Laboratory Supplies

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1540 McDaniel Dr
West Chester, PA 19380
Business: 610-430-1847
Fax: 610-430-1970
E-mail: info@bmclaughlin.com
Web Site: www.bmclaughlin.com
Contact: Kristen Molina
Contract Research Services: Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **CROs:** Medical Device, Niche, Phase I-V

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Lake Success, NY 11042
Business: 516-719-1052
Fax: 516-719-1281
E-mail: info@nullbarclab.com
Web Site: www.barcusa.com
Contact: Kenneth Kim
Contract Research Services: Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **Laboratories:** Bioanalytical, Biomarkers, Central, **Laboratory Supplies; Sites**

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Web Site: www.barnettinternational.com
Contact: Kathy O'Brien
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Fax: 44-1727-797549
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Web Site: www.barrettwebb.com
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2701 Kent Ave
West Lafayette, IN 47906
Toll-free: 800-845-4246
Business: 765-463-4527
Fax: 765-497-1102
E-mail: jbrewer@basinc.com
Web Site: www.basinc.com
Contact: Jon Brewer
CROs: General, **Laboratories:** Bioanalytical, Biomarkers, **Laboratory Supplies**

BAXA CORP
14445 Grassland Dr
Englewood, CO 80112
Toll-free: 800-827-8220
Business: 303-617-2156
E-mail: heidi.budreau@baxa.com
Web Site: www.baxa.com
Contact: Heidi Budreau
Training & Education

BAXTER HEALTHCARE CORP
One Baxter Pkwy DF4-3 W
Deerfield, IL 60015
Toll-free: 800-4-BAXTER
Business: 847-948-4770
E-mail: onebaxter@baxter.com
Web Site: www.baxterbiopharmasolutions.com
CROs: General, Niche, **Laboratories:** Bioanalytical

BBK WORLDWIDE
320 Needham St Ste 150
Newton, MA 02464
Business: 617-630-4477
Fax: 617-630-5090
E-mail: info@bbkworldwide.com
Contact: Elizabeth Gargill
Information Technology: Other, **Subject Recruitment; Training & Education**

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70 Church St
Flemington, NJ 08822
Business: 800-788-1729
Fax: 908-788-5281
E-mail: ericm@beardsworth.com
Web Site: www.beardsworth.com
Contact: Eric Monroe
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, **Subject Recruitment**

BEAUFORT ADVISORS LLC
500 E Main St Ste 1301
Norfolk, VA 23510
Business: 757-228-3250
Fax: 757-961-7479
E-mail: info@beaufortadvisors.com
Web Site: www.beaufortadvisors.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development

BENCHMARK RESEARCH
1015 E 32 St Ste 309
Austin, TX 78705
Business: 512-478-5416
Fax: 512-478-4352
Web Site: www.benchmarkresearch.net
Contact: Mark Lacy
Subject Recruitment

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1028 Shiroli, Rajgurunagar 410 505
Pune, 410505 India
Business: 91-02135-304340
Fax: 91-02135-224068
E-mail: gcsquery@bilcare.com
Web Site: www.bilcaregcs.com
CROs: Phase I-V, **Information Technology:** IVRS

BIO-KINETIC EUROPE LTD
14 Great Victoria St
Belfast BT2 7BA Northern Ireland
Business: 44-2890-818385
Fax: 44-2890-238123
E-mail: clients@biokineticeurope.com
Web Site: www.biokineticeurope.com
Contact: Moira Burke
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Medical Writing, **CROs:** Niche, Phase I-V

BIO-OPTRONICS
1890 S Winton Rd Ste 190
Rochester, NY 14618
Business: 585-272-1960
Fax: 585-272-7273
E-mail: sales@bio-optronics.com
Web Site: www.bio-optronics.com
Contact: Tom Gabruk
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Other, Software Program Development, **Subject Recruitment; Training & Education**

BIO/DATA CORP
155 Gibraltar Rd
Horsham, PA 19044
Toll-free: 800-257-3282
Business: 215-441-4000
Fax: 215-443-8820
E-mail: customer.service@biodatacorp.com
Web Site: www.biodatacorp.com
Contact: William Trolio
Contract Research Services: Data Collection, Medical Writing, **CROs:** General, Medical Device, Niche, **Information Technology:** Other, Software Program Development, **Laboratory Supplies; Training & Education**

BIOCAIR
The Business Centre Church End
Cambridge CB1 3LB United Kingdom
Business: 44-1223-245-223
Fax: 44-1223-245-211
E-mail: cambridge@biocair.com
Web Site: www.biocair.com

BIOCHEMED SERVICES
172 Linden Dr Ste 101
Winchester, VA 22601
Toll-free: 888-628-7948
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Fax: 540-667-8646
E-mail: info@biochemed.com
Web Site: www.biochemed.com
Contact: Philip Lloyd
Laboratory Supplies

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Cambridge, MA 02141
Business: 617-444-8727
E-mail: train@biocis.org
Contact: Philippa Wisseh
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Monitoring, **CROs:** Niche, **Information Technology:** Software Program Development, **Training & Education**

BIOCLINICA
826 Newtown-Yardley Rd
Newtown, PA 18940
Business: 267-757-3038
Fax: 267-757-3007
E-mail: laura.johnston@bioclinica.com
Web Site: www.bioclinica.com
Contact: Laura Johnston
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development, **Laboratories:** Central, Core, Imaging

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Newton, MA 02460-1458
Toll-free: 888-719-6300
Business: 617-527-6300
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E-mail: info@bioforcesolutions.com
Web Site: www.bioforcesolutions.com
Contact: Michael Morgan
Career Recruitment & Staffing; Contract Research Services: Medical Writing

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E-mail: info@biofortis.fr
Web Site: www.merieuxnutrisciences.fr
Contact: Murielle Cazaubiel
Contract Research Services: CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, **CROs:** General, **Laboratories:** Bioanalytical, Biomarkers, Central

BIOMEDICAL RESEARCH INSTITUTE OF AMERICA
BioMed IRB
7676 Hazard Center Drv, PO Box 600870
San Diego, CA 92160
Toll-free: 800-643-0730
Business: 619-282-9997
Fax: 619-282-9998
E-mail: mailbox@biomedirb.com
Web Site: www.biomedirb.com
Contact: Jeremy Markovich
IRBs

BIOMEDICAL SYSTEMS
77 Progress Pkwy
St Louis, MO 63043
Toll-free: 800-877-6334
Business: 314-576-6800
Fax: 314-576-1664
E-mail: info@biomedsys.com
Web Site: www.biomedsys.com
Contact: Bob Mills
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **Laboratories:** Bioanalytical, Biomarkers, Cardiovascular-ECG, Central, Core, Imaging

BIOPHARM SYSTEMS
2000 Alameda de las Pulgas Ste 154
San Mateo, CA 94403-1270
Toll-free: 877-654-0033
Business: 650-292-5300
Fax: 650-292-5301
E-mail: info@biopharm.com
Web Site: www.biopharm.com
Contact: Michelle Zubatch
CROs: General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Software Program Development, **Training & Education**

BIOPHASE SOLUTIONS
5405 Morehouse Dr Ste 135
San Diego, CA 92121
Business: 858-552-2000
Fax: 858-552-0033
E-mail: contact@biophaseinc.com
Web Site: www.biophaseinc.com
Career Recruitment & Staffing

BIORESEARCH MONITORS
201 Markham Hollow Rd
Tully, NY 13159
Business: 315-696-8139
Fax: 315-696-8722
E-mail: qaaudits@aol.com
Web Site: www.qa4gcp.com
Contact: Paul Gittelson
Contract Research Services: Data Collection, Data Monitoring, **CROs:** Niche

BIOSIGNA
Lindwurmstrasse 109
Munich 80337 Germany
Business: 49-892-371-9277
Fax: 49-892-371-9278
E-mail: contact@biosigna.de
Web Site: www.biosigna.com
Contract Research Services: Data Collection, Data Monitoring, **CROs:** Medical Device, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Software Program Development, **Laboratories:** Bioanalytical, Cardiovascular-ECG, Central, **Training & Education**

BIOSKIN GMBH
Burchardstrassse 17
Hamburg 20095 Germany
Business: 49-40-606-897-0
Fax: 49-40-606-897-30
E-mail: info@bioskin.de
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Niche, Phase I-V

BIOSTORAGE TECHNOLOGIES
2910 Fortune Circle W Ste E
Indianapolis, IN 46241
Toll-free: 866-697-2675
Business: 317-268-5500
Fax: 317-390-1868
E-mail: info@biostorage.com
Web Site: www.biostorage.com
Contact: Ann Whitfield
Clinical Packaging: Labeling, Packaging, Safety, Transportation, **Consulting; Laboratories:** Bioanalytical, Biomarkers

BIOWIZARD
400 E Lancaster Ave Ste 300
Radnor, PA 19087
Business: 610-971-1605
E-mail: info@biowizard.com
Web Site: www.biowizard.com
Contact: Jeff Boily
Other Services & Products

BITRIAL CRO
Fenyes u 10
Budaors 2040 Hungary
Business: 06-234-44123
Fax: 06-234-44419
E-mail: info@briotrial.hu
Web Site: www.bitrial.hu
Contract Research Services: CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Niche, Phase I-V

BLUE HERON LTD
Heronwood St Leonard's Hill
Windsor SL4 4AT United Kingdom
Business: 44-1753-868-960
Fax: 44-1753-859-172
E-mail: blueheron@lineone.net
Web Site: www.blue-heron.co.uk
Contact: Lynne Dowse
Career Recruitment & Staffing

BOSTON UNIVERSITY METROPOLITAN COLLEGE
1010 Commonwealth Ave
Boston, MA 02215
Toll-free: 888-883-0218
Business: 617-353-6001
Fax: 617-358-1961
E-mail: disted@bu.edu
Web Site: www.bu.edu/online
Training & Education

BRACKET
575 E Swedesford Rd Ste 200
Wayne, PA 19087
Business: 610-225-5900
Fax: 610 225 5950
E-mail: info@bracketglobal.com
Web Site: www.bracketglobal.com
Contact: Jen Burstedt
Information Technology: IVRS, Other, **Training & Education**

BRISTOL-MYERS SQUIBB
345 Park Ave
New York, NY 10154
Toll-free: 800-332-2056
Business: 212-546-4000
E-mail: customer.relations@bms.com
Web Site: www.bms.com
Career Recruitment & Staffing

C3I
25 Lindsley Dr
Morristown, NJ 07960
Business: 973-401-6000
E-mail: sales@c3i-inc.com
Web Site: www.c3i-inc.com
Contact: Dave Hanaman
Other Services & Products

CAHG
220 E 42 St, NY 10017
Business: 646-428-8918
E-mail: suri.harris@cahg.com
Web Site: www.cahg.com
Contact: Kathleen Drennan
Contract Research Services: CT Protocol Design, Negotiating Budgets/Contracts, **Subject Recruitment; Training & Education**

CAMARGO PHARMACEUTICAL SERVICES
9825 Kenwood Rd Ste 203
Cincinnati, OH 45242-6252
Toll-free: 888-451-5708
Business: 513-561-3329
Fax: 513-561-3367
E-mail: services@camargopharma.com
Web Site: www.camargopharma.com
Contact: Ken Phelps
Contract Research Services: CT Protocol Design, Data Monitoring, Medical Writing, **CROs:** Niche, Phase I-V

CAMPBELL UNIVERSITY SCHOOL OF PHARMACY
PO Box 1090
Buies Creek, NC 27506
Toll-free: 800-334-4111
Business: 910-893-1200
Web Site: www.campbell.edu/pharmacy
Training & Education

CANADIAN SHIELD ETHICS REVIEW BOARD
4145 N Service Rd St 200
Burlington L7L 6A3 Canada
Business: 905-681-8661
Fax: 905-681-8668
E-mail: admin@cserb.com
Web Site: www.cserb.com
Contact: Jan Beeforth
IRBs; Training & Education

CAPRICORN LAB EQUIPMENT LTD
One Glasshouse Studios Fryern Ct Rd
Fordingbridge SP6 1QX United Kingdom
Business: 44-1425-650-088
Fax: 44-1425-650-092
E-mail: info@capricorn-labs.co.uk
Web Site: www.capricorn-labs.co.uk
Laboratory Supplies

CAPSUGEL
Pfizer
535 N Emerald Rd
Greenwood, SC 29646
Toll-free: 800-845-6973
Business: 888-783-6361
Fax: 888-783-6360
E-mail: marketing.amer@capsugel.com
Web Site: www.capsugel.com
Contact: Christina Watson
Other Services & Products

CARDIABASE
78 Ave Du Xxeme Corps
Nancy 54000 France
Business: 33-3-83-39-10-10
Fax: 33-3-83-37-36-36
E-mail: pascal.soiriot@cardiabase.com
Web Site: www.cardiabase.com
Contact: Pascal Soiriot
Contract Research Services: Data Collection, Data Monitoring, **CROs:** Medical Device, Niche, Phase I-V, **Laboratories:** Cardiovascular-ECG, Core

CARDIALYSIS BV
PO Box 2125
Rotterdam 3000 CC The Netherlands
Business: 31-10-206-2828
Fax: 31-10-206-2844
E-mail: info@cardialysis.nl
Web Site: www.cardialysis.com
Contact: M Koenders
CROs: General, Medical Device, Niche, Phase I-V

CARDINAL HEALTH SPECIALITY SOLUTIONS (BECKLOFF ASSOCS)
7400 W 110 St Ste 300 Commerce Plaza II
Overland Park, KS 66210
Business: 913-451-3955
Fax: 913-451-3846
E-mail: info@beckloff.com
Web Site: www.cardinalhealth.com/beckloff
Contact: Christopher Kavlick
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Medical Writing, **Training & Education**

CARDIOLABS
357 Riverside Dr Ste 1000
Franklin, TN 37064-5451
Toll-free: 800-304-1098
Fax: 800-430-5753
E-mail: info@cardiolabs.com
Web Site: www.cardiolabs.com
Contact: G Vander Elst
Laboratories: Cardiovascular-ECG

CARDIONICS
Rue Gabrielle Petit 4
Brussels B-1080 Belgium
Business: 32-2-426-75-75
Fax: 32-2-426-40-40
E-mail: info@cardionics.eu
Web Site: www.cardionics.eu
Contact: Jules Vanhoebrouck
Contract Research Services: Health Metrics, **CROs:** Medical Device, **Information Technology:** Other, **Laboratories:** Cardiovascular-ECG

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Charlotte, NC 28226
Business: 704-366-3001
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E-mail: ymccracken@carolinasresearch.com
Web Site: www.carolinasresearch.com
Contact: Yvonne Mccracken
Contract Research Services: CT Protocol Design, **Training & Education**

CATALENT PHARMA SOLUTIONS
14 Schoolhouse Rd
Somerset, NJ 08873
Business: 732-537-6200
E-mail: solutions@catalent.com
Web Site: www.catalent.com
Contact: Kristin Federico
Sites

CCBR - SYNARC
7707 Gateway Blvd Third Flr
Newark, CA 94560
Business: 415-817-7949
Fax: 415-817-8999
E-mail: info@synarc.com
Web Site: www.synarc.com
Laboratories: Bioanalytical, Biomarkers, Core, Imaging, **Subject Recruitment**

CCS ASSOCS
1923 Landings Dr
Mountain View, CA 94043
Business: 650-691-4400
Fax: 650-691-4410
E-mail: info@ccsainc.com
Web Site: www.ccsainc.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** Niche, Phase I-V, **Subject Recruitment; Training & Education**

CELERION
621 Rose St
Lincoln, NE 68502
Business: 402-476-2811
Fax: 866-358-7993
E-mail: info@celerion.com
Web Site: www.celerion.com
Contact: Farzana Azam
Consulting; Contract Research Services: CT Protocol Design, Data Collection, Medical Writing, **CROs:** General, Phase I-V, **IRBs; Laboratories:** Bioanalytical, Biomarkers, Cardiovascular-ECG, Core, **Subject Recruitment**

CELLULAR TECHNOLOGY LTD
20521 Chagrin Blvd
Shaker Heights, OH 44122-5350
Toll-free: 888-791-4005
Business: 216-791-5084
Fax: 216-751-1373
E-mail: info@immunospot.com

Web Site: www.immunospot.com
Contract Research Services: CT Protocol Design, Data Collection, Data Monitoring, **Laboratories:** Biomarkers, Central, Core, **Laboratory Supplies; Training & Education**

CEMO S A
10 Blvd de Stalingrad
Choisy le Roi 94600 France
Business: 33-1-4884-7723
Fax: 33-1-4892-2202
E-mail: contact@cemo.fr
Web Site: www.cemo.fr
Contact: Arnaud Houlle
CROs: Niche, **Laboratories:** Bioanalytical, Biomarkers, Central, **Laboratory Supplies**

CENDUIT
4825 Creekstone Dr Ste 400 Chelsea Pl
Durham, NC 27703
Business: 919-998-3860
E-mail: info@cenduit.com
Web Site: www.cenduit.com
Contact: Rebecca Galloway
Information Technology: IVRS

CENTERPHASE SOLUTIONS
600 E Crescent Rd Ste 205
Upper Saddle River, NJ 07458
Business: 973-629-3777
E-mail: information@centerphasesolutions.com
Web Site: www.centerphasesolutions.com
Contact: Jeff Tarlowe
Information Technology: Other, **Subject Recruitment**

CENTERWATCH
10 Winthrop Sq 5th Flr
Boston, MA 02110
Toll-free: 866-219-3440
Business: 617-948-5171
Fax: 617-948-5101
E-mail: amy.fontaine@centerwatch.com
Web Site: www.centerwatch.com
Contact: Amy Fontaine
Career Recruitment & Staffing; Subject Recruitment; Training & Education

CERNER CORP
2800 Rockcreek Pkwy
North Kansas City, MO 64117
Business: 816-221-1024
Fax: 816-571-6453
Web Site: www.cerner.com
Contract Research Services: Data Monitoring, Pharmacovigilance, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Subject Recruitment; Training & Education**

CERTUS INTL
9 Cedarwood Dr Ste 8
Bedford, NH 03110
Business: 603-627-1212
Fax: 603-627-8484
E-mail: inquiries@certusintl.com
Web Site: www.certusinc.com
Contact: Amber Nicole Cannan
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs; Laboratories:** Central, Core, Imaging, **Subject Recruitment**

CERULEAN ASSOCS LLC
PO Box 498
Williamsburg, VA 23187-0498
Business: 757-645-2864
E-mail: info@ceruleanllc.com
Web Site: www.ceruleanllc.com
Training & Education

CEUTICAL LABS
2300 Valley View Lane Ste 230
Farmers Branch, TX 75234
Business: 972-241-8374
Fax: 972-241-0619
E-mail: info@ceuticallabs.com
Web Site: www.ceuticallabs.com
CROs: General, Medical Device, **Laboratories:** Bioanalytical, **Training & Education**

CFS CLINICAL
1000 Madison Ave 1st Flr
Audubon, PA 19403
Business: 888-650-1860
Fax: 610-650-1895
E-mail: info@cfsclinical.com
Web Site: www.cfsclinical.com
Contact: Kevin Williams
Contract Research Services: Negotiating Budgets/Contracts, **CROs:** General, Niche, Phase I-V, **Information Technology:** Software Program Development

CHESAPEAKE IRB
7063 Columbia Gateway Dr Ste 110
Columbia, MD 21046
Business: 410-884-2900
E-mail: info@irbinfo.com
Web Site: www.chesapeakeirb.com
Contact: Lauri Carlile
IRBs; Training & Education

CHILTERN INTL
1241 Volunteer Pkwy Ste 950
Bristol, TN 37620
Business: 423-968-9533
Fax: 423-968-3567
E-mail: susan.ojanen@chiltern.com
Web Site: www.chiltern.com
Contact: Susan Ojanen
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment**

CIRB
1111 Pennsylvania Ave NW
Washington, DC 20004
Business: 202-739-5619
Fax: 202-739-3000
E-mail: info@consortiumofirb.org
Web Site: www.consortiumofirb.org

CIRION CLINICAL TRIAL SERVICES
3150 Delaunay
Laval H7L 5E1 Canada
Business: 450-682-2231
Fax: 450-902-3060
E-mail: businessdevelopment@cirion.com
Web Site: www.cirion.com
Contact: Lise Dallaise
CROs: General, **Laboratories:** Bioanalytical, Biomarkers, Central

CIS CLINICAL INVESTIG.SUPPORT GMBH
Kaiserstr 43
Wien 1070 Austria
Business: 43-1523-401-5
Fax: 43-1523-401-599
E-mail: cis-qa@aon.at
Web Site: www.cis-qa.com
Contact: Andreas Nahler
Consulting; Contract Research Services: Medical Writing, **CROs:** Niche, **Other Services & Products; Training & Education**

CISYS LIFESCIENCES
eClinical Research Technologies
8386 Six Forks Rd Ste103
Raleigh, NC 27615
Business: 919-870-1436
Fax: 919-870-8626
E-mail: inquire@cisys.com
Web Site: www.cisys.com
Contact: Jim Kelley
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development

CITATION CLINICAL LABELING SYSTEMS
95-14 Executive Dr
Edgewood, NY 11717
Business: 631-293-4646
Fax: 631-293-4277
E-mail: richb@citlabels.com
Web Site: www.citlabels.com
Contact: Richard Bolnick

CLICK COMMERCE
1925 NW Amberglen Pkwy Ste 400
Beaverton, OR 97006
Toll-free: 800-590-5400
Business: 503-748-3900
E-mail: sales@clickcommerce.com
Web Site: www.clickcommerce.com
Contact: Sharon Russell
Information Technology: Other, **IRBs; Sites**

CLINDATRIX
6 Jenner St Ste 200
Irvine, CA 92618
Business: 949-428-6600
Fax: 949-428-1239
E-mail: christi.whittemore@clindatrix.com
Web Site: www.clindatrix.com
Contact: Christi Whittemore
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Training & Education**

CLINFORCE LLC
4815 Emperor Blvd
Durham, NC 27703
Toll-free: 800-964-2877
Business: 919-941-0844
Fax: 919-941-0071
E-mail: response@clinforce.com
Web Site: www.clinforce.com
Contact: Ben Spradley
Career Recruitment & Staffing

CLINFOSOURCE
1075 Cheshire Cir
Danville, CA 94506
Business: 925-272-9251
E-mail: info@clinfosource.com
Web Site: www.clinfosource.com
Contact: Marty McGee
Training & Education

CLINICA SPACE
6465 Greenwood Plaza Ste 400
Centennial, CO 80111
Toll-free: 877-277-7585
E-mail: valevie.quintanilla@ontargetjobs.com
Web Site: www.clinicaspace.com
Contact: Valevie Quintanilla
Career Recruitment & Staffing

CLINICAL BROKERS
202 Carnegie Center Ste 304
Princeton, NJ 08540
Toll-free: 888-508-2566
Business: 609-924-8900
Fax: 609-924-8929
E-mail: sales@talonpro.com
Web Site: www.clinicalbrokers.com
Career Recruitment & Staffing

CLINICAL CONTRACT RESEARCH ASSN
PO Box 1055
Oadby LE2 4XZ United Kingdom
Business: 44-116-271-9727
Fax: 44-116-271-3155
E-mail: mail@ccra.org.uk
Web Site: www.ccra.org.uk
Contact: Susan Dilks

CLINICAL DATAFAX SYSTEMS
25 Main St W Ste 500
Hamilton L8P 1H1 Canada
Business: 905-522-3282
Fax: 905-522-7284
E-mail: info@datafax.com
Web Site: www.datafax.com
Contact: Wayne Taylor
Contract Research Services: CRF Design, **Information Technology:** CTMS, EDC (PDAs, eDiaries)

CLINICAL DEVICE GROUP
2128 W Evergreen Ave
Chicago, IL 60622-3047
Business: 773-489-5721
Fax: 773-489-5982
E-mail: cdginc@clinicaldevice.com
Web Site: www.clinicaldevice.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, **CROs:** Medical Device

CLINICAL INK
100 N Cherry St Ste 520
Winston-Salem, NC 27101
Business: 800-301-5033
E-mail: info@clinicalink.com
Web Site: www.clinicalink.com
Contact: Ed Seguine
Information Technology: EDC (PDAs, eDiaries), Other

CLINICAL PERFORMANCE PARTNERS
855 Emory Point Dr Ste 3428
Atlanta, GA 30329
Business: 817-946-4782
E-mail: info@clinicalperformancepartners.com
Web Site: www.clinicalperformancepartners.com
Contact: Beth Harper
Subject Recruitment; Training & Education

CLINICAL R&D SERVICES CORP
31 Monhegan Ave
Wayne, NJ 07470
Business: 973-696-0824
Fax: 973-696-8541
E-mail: info@clinicalrdservices.com
Web Site: www.clinicalrdservices.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, **IRBs; Subject Recruitment**

CLINICAL REFERENCE LAB
8433 Quivira Rd
Lenexa, KS 66215
Toll-free: 800-445-6917
Business: 913-492-3652
Fax: 913-492-4308
E-mail: clinicaltrials@crlcorp.com
Web Site: www.crlcorp.com
Contact: Erica Watson
Laboratories: Bioanalytical, Biomarkers, Central

CLINICAL RESEARCH CONSULTING
101 Federal St Ste 1900
Boston, MA 02110-1821
Business: 508-865-8907
Fax: 508-865-8908
E-mail: mazurka@eclinicalresearchconsulting.com
Web Site: www.eclinicalresearchconsulting.com
Contact: Lisa Mazurka
Contract Research Services: CRF Design, CT Protocol Design, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Niche, Phase I-V, **Training & Education**

CLINICAL RESEARCH CONSULTING
Karlstr 46
Karlsruhe D-76133 Germany
Business: 49-721-7569308
Fax: 49-721-7569309
E-mail: info@clinicalresearch.de
Web Site: www.clinicalresearch.de
Contact: Joern Gatermann
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Medical Device, Phase I-V

CLINICAL RESEARCH GROUP (CRG)
5225 NE Second Ave
Fort Lauderdale, FL 33334
Business: 954-492-9750
Fax: 954-603-1069
E-mail: info@orgcrg.com
Web Site: www.orgcrg.com
Contact: Lynn Bachrach
Contract Research Services: Negotiating Budgets/Contracts, **CROs:** Niche, **Subject Recruitment**

CLINICAL SERVICES CONSULTING LLC PRINCIPAL
15 Fiske Rd
Lexington, MA 02420
E-mail: kathryn@kgdavisconsulting.com
Web Site: www.kgdavisconsulting.com
Contact: Kathryn Davis

CLINICAL SUPPLIES MGMT
342 42nd St S
Fargo, ND 58103
Toll-free: 701-235-8014
Business: 701-235-8002
Fax: 866-IUSECSM
E-mail: info@csmondemand.com
Web Site: www.csmOnDemand.com
Contact: Jennifer Lauinger
CROs: Phase I-V

CLINICAL SYSTEMS
377 Oak St
Garden City, NY 11530-6543
Business: 516-745-6200
Fax: 516-227-2620
E-mail: joseph.iacobucci@clinsys.net
Web Site: www.clinsys.net
Contact: Joseph Iacobucci
Clinical Packaging: Labeling, Packaging, **Information Technology:** Other

CLINICAL TRIALS OF TEXAS
7940 Floyd Curl Dr Ste 700
San Antonio, TX 78229
Business: 210-949-0122
Fax: 210-949-0181
E-mail: ctt@cttexas.com
Web Site: www.saresearch.com
Subject Recruitment; Training & Education
See ad on page 43

CLINICALRSVP
401 E Las Olas Blvd Ste 130-395
Fort Lauderdale, FL 33301
Toll-free: 888-308-7787
Business: 954-727-5785
Fax: 888-308-7787
E-mail: contact@clinicalrsvp.com
Contact: Darran Boyer

CLINILABS
423 W 55 St 4th Flr
New York, NY 10019
Business: 646-215-6400
Fax: 646-215-6401
E-mail: info@clinilabs.com
Web Site: www.clinilabs.com
Contact: Jeanine Estrada
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment; Training & Education**

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Web Site: www.clinipace.com
Contact: Birgit Hennecke-Janzer
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **Subject Recruitment; Training & Education**

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Business: 49-7615-031-877
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Web Site: www.clinit.net
Contract Research Services: CT Protocol Design, Data Collection, Data Monitoring, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, Software Program Development, **Training & Education**

CLINITEC PTY LTD
29 Bertram St Ste 15
Chatswood 2067 Australia
Business: 61-2-8889-3660
Fax: 61-2-8210-5127
E-mail: enquiry@clinitec.com.au
Web Site: www.clinitec.com.au
Information Technology: EDC (PDAs, eDiaries), IVRS, Other, Software Program Development

CLINIWORKS
245 First St Ste 1800
Cambridge, MA 02142
Toll-free: 877-549-1153
Business: 617-395-8400
E-mail: info@cliniworks.com
Web Site: www.cliniworks.com
Contract Research Services: Data Collection, Data Monitoring, Pharmacovigilance, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Other, Software Program Development, **Subject Recruitment**

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321 Norriston Rd Ste 100
Spring House, PA 19002-2793
Business: 215-855-9054
Fax: 215-855-9053
E-mail: info@clinlogix.com
Web Site: www.clinlogix.com
Contact: Evan Cauterucci
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Medical Device, Phase I-V, **Subject Recruitment; Training & Education**

CLINOVO
1208 E Arques Ave Ste 114
Sunnyvale, CA 94085
Toll-free: 800-987-6007
Business: 888-317-7517
E-mail: contact@clinovo.com
Web Site: www.clinovo.com
Contact: Sophie McCallum
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development, **Training & Education**

CLINPOL RESEARCH SP Z O O
ul Junaków 2
Sopot 81-812 Poland
Business: 48-58-622-00-78
Fax: 48-58-622-00-79
E-mail: kontakt@clinpol.com
Web Site: www.clinpol.com
Contact: Pawel Zagozdzon
CROs: Niche, **Subject Recruitment**

CLINRES-FARMACIJA DOO
Radnicka cesta 43
Zagreb 10000 Croatia
Business: 385-1-23-96-900
E-mail: info@clinres-farmacija.hr
Web Site: www.clinres-farmacija.hr
Contact: Romana kajfez
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Sites**

CLINSTAR
1990 N California Blvd Ste 608
Walnut Creek, CA 94596
Business: 415-981-9515
E-mail: contact@clinstar.com
Web Site: www.clinstar.com
Contact: Erin King
CROs: General, Niche, Phase I-V

CLINSYS CLINICAL RESEARCH
One Crossroads Dr # 2A
Bedminster, NJ 07921-2688
Business: 908-947-7777
Fax: 908-947-7593
E-mail: mwinfree@clinsys.com
Web Site: www.clinsys.com
Contact: Mitchell Winfree
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **Laboratories:** Bioanalytical, **Subject Recruitment; Training & Education**

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Web Site: www.clintec.com

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Web Site: www.clintrak.com
Contact: Eric Deschamps

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3805 S Kansas Expy Ste A
Springfield, MO 65807
Toll-free: 877-566-1970
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E-mail: mbeach@clinvest.com
Web Site: www.clinvest.com
Contact: M.E Beach
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Niche, **Sites**

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Garden Grove, CA 92845
Business: 913-314-6755
E-mail: johnpottier@cnstrial.com
Web Site: www.cnstrial.com
Contact: John Pottier
CROs: General, Medical Device, Niche, Phase I-V, **Sites**

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Level 2 255 Bourke St
Melbourne 3000 Australia
Business: 61-3-9664-1300
Fax: 61-3-9664-1301
E-mail: syeo@cogstate.com
Web Site: www.cogstate.com
Contact: Sam Yeo
Information Technology: Software Program Development

COLORADO ALLERGY & ASTHMA CENTERS Research
1667 Cole Blvd Bldg 19 Ste 200
Lakewood, CO 80401
Business: 303-420-3131
Fax: 303-420-1984
E-mail: gailf@coloradoallergy.com
Web Site: www.coloradoallergy.com
Contact: Gail Facciolo
Career Recruitment & Staffing; Contract Research Services: CRF Design, Data Collection, Health Metrics, Negotiating Budgets/Contracts, **CROs:** General, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **Sites; Subject Recruitment; Training & Education**

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Indialantic, FL 32903
Business: 321-952-2490
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E-mail: sales@completeinspectionsystems.com
Web Site: www.completeinspectionsystems.com
Contact: Gary Parish

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PO Box 3090
Iowa City, IA 52244-3090
Business: 319-626-8888
Fax: 319-626-8750
E-mail: businessdevelopment@compleware.com
Web Site: www.compleware.com
Contact: John Weiler, MD
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E-mail: info@cis-partners.com
Web Site: www.cis-partners.com
Contact: Christine Pahl

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235 Alma St
Palo Alto, CA 94301
Business: 877-201-3560
E-mail: info@comprehend.com
Web Site: www.comprehend.com
Contact: Rick Morrison
Information Technology: Other, Software Program Development

COMPREHENSIVE CLINICAL DEVELOPMENT
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Miramar, FL 33027
Business: 954-266-2620
E-mail: pturk@comprehensivecd.com
Web Site: www.ComprehensiveCD.com
Contact: Patrick Turk
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Contact: Janice Jones

CONCENTRICS RESEARCH
9335 Delegates Row
Indianapolis, IN 46240
Toll-free: 800-800-5525
Business: 317-706-3201
Fax: 317-705-2180
E-mail: julie.aker@concentricsresearch.com
Web Site: www.concentricsresearch.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Niche, Phase I-V, **IRBs; Subject Recruitment**

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Business: 240-575-1918
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Web Site: www.consentsolutions.com
Contact: Susan Brink
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777 Main St Ste 600
Fort Worth, TX 76102
Toll-free: 866-498-5559
Business: 817-887-8017
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E-mail: sales@consignmed.com
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One Triangle Dr Ste 100
Durham, NC 27713
Toll-free: 888-303-2224
Business: 919-465-4310
Fax: 919-465-4311
E-mail: irb@cgirb.com
Web Site: www.cgirb.com
Contact: Rebecca Sipes
IRBs

CORAM CLINICAL TRIALS
555 17th St Ste 1500
Denver, CO 80202
Toll-free: 877-569-2738
Business: 303-672-8805
Fax: 949-462-8855
E-mail: coramclinicaltrials@coramhc.com
Web Site: www.coramclinicaltrials.com
Contact: Jill Barnes
Contract Research Services: At-Home Study Services, Medical Writing, **CROs:** Niche, **Training & Education**

CORE ORTHOPAEDIC MEDICAL CENTER
332 Santa Fe Dr Ste 110
Encinitas, CA 92024
Business: 760-943-6700
Fax: 760-632-4292
E-mail: fawad@coreorthopaedic.com
Web Site: www.coreorthopaedic.com
Contact: Farouk Awad
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **IRBs; Laboratory Supplies; Sites; Subject Recruitment; Training & Education**

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Laval H7V 4A6 Canada
Business: 450-973-7505
Fax: 450-973-7506
E-mail: info@corealispharma.com
Web Site: www.corealispharma.com
Contact: Yves Roy
Other Services & Products

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Princeton, NJ 08540
Toll-free: 877-632-9432
Business: 609-936-2600
E-mail: info@corelabpartners.com
Web Site: www.corelabpartners.com
Contact: Kevin Duffy
Contract Research Services: CT Protocol Design, Data Collection, **CROs:** Phase I-V, **Laboratories:** Cardiovascular-ECG, Core, Imaging, **Training & Education**

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Web Site: www.corptransinc.com
Contact: Ted Gawlicki
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3 Todd Campus Acre Rd
Glasgow G20 OXA United Kingdom
Business: 44-1419-467-888
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Web Site: www.cpsresearch.co.uk
Contact: Tom McCulloch
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Fax: 800-763-4103
E-mail: kwhalen@cra-solutions.com
Web Site: www.cra-solutions.com
Contact: Kimberly Whalen
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Cranleigh GU6 8SS United Kingdom
Business: 44-1483-548804
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E-mail: help@cranleighrecruitment.co.uk
Web Site: www.cranleighscientific.co.uk
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Plymouth Meeting, PA 19462
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Contact: Heather Bilinski
Information Technology: EDC (PDAs, eDiaries)

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Web Site: www.crimsonlanguage.com

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Saratoga Springs, NY 12866
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Fax: 518-583-0394
E-mail: info@criteriuminc.com
Web Site: www.criteriuminc.com
Contact: Ronny Schnel
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development

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Warrenton, VA 20187
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Fax: 540-428-2834
Web Site: www.crofessionals.com

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Verona 37135 Italy
Business: 39-045-822-2811
Fax: 39-045-822-2812
E-mail: cromsource@cromsource.com
Web Site: www.cromsource.com
Contact: Margherita Mosconi
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development, **Training & Education**
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Zug CH-6300 Switzerland
Business: 41-41-725-3525
Fax: 41-41-725-3520
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Web Site: www.crossover-cri.com
Contact: Jean-Pierre Tassignon
Consulting; Contract Research Services: Medical Writing, **Sites**

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Tampa, FL 33634-7523
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Fax: 813-864-4434
E-mail: shane.senior@crosstreecapital.com
Web Site: www.crosstreecapital.com
Contact: Shane Senior

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2 Greenwich Centre Bus Park 53 Norman Rd
London SE10 9QF United Kingdom
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E-mail: info@cryostore.co.uk
Web Site: www.cryostore.co.uk
Contact: Malcolm Wilkinson
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Lake Forest, CA 92630
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Web Site: www.cryoport.com
Contact: Ken Carlson

CSM
342 42nd St S
Fargo, ND 58103
Toll-free: 866-I-USE-CSM
Business: 701-235-8002
Fax: 701-235-8014
E-mail: contactus@csmondemand.com
Web Site: www.csmondemand.com
Contact: Stacey Majkrzak
CROs: General, Niche, Phase I-V

CURELINE
290 Utah Ave #300
South San Francisco, CA 94080-6801
Business: 650-875-6400
Fax: 650-875-6484
E-mail: anna-khan@cureline.com
Web Site: www.cccptrials.com
Contact: Anna Khan
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Niche, **Laboratories:** Biomarkers, Imaging

CYTEL
675 Massachusetts Ave
Cambridge, MA 02139
Business: 617-661-2011
Fax: 617-661-4405
E-mail: info@cytel.com
Web Site: www.cytel.com
Contact: Mike Weitz
Contract Research Services: CT Protocol Design, Data Monitoring, Medical Writing, **CROs:** Niche, **Information Technology:** Software Program Development, **Training & Education**

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Yverdon-les-Bains 1400 Switzerland
Business: 41-24-424-26-88
E-mail: info@d-target-prg.com
Web Site: www.d-target.com
Contact: Daphnee Lehmann
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Medical Device, **Training & Education**

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Rutherford, NJ 07070
Business: 201-508-6000
E-mail: info@datacom-usa.com
Web Site: www.datacom-usa.com
Contract Research Services: CRF Design, **CROs**

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56/56A Thompson St
Drummoyne 2047 Australia
Business: 61-2-9719-2800
Fax: 61-2-9719-2811
E-mail: info@datapharm.com.au
Web Site: www.datapharmaustralia.com
Contact: Helen Allars
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment; Training & Education**

DATATECH SEARCH AND SELECTION
The Barn Barton Lane Old Basing
Basingstoke RG24 8AE United Kingdom
Business: 44-1256-314640
Fax: 44-1256-314649
E-mail: admin@datatech.org.uk
Web Site: www.datatech.org.uk
Contact: Sue Spice
Career Recruitment & Staffing; Subject Recruitment; Training & Education

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Mayfield Heights, OH 44124
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Fax: 440-442-3482
E-mail: marketing@datatrak.net
Web Site: www.datatrak.net
Contact: Lisa Pahl
Contract Research Services: CRF Design, Data Collection, Data Monitoring, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development

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Fleming Business Centre Burdon Terr Jesmond
Newcastle upon Tyne NE2 3AE United Kingdom
Business: 44-191-212-8200
Fax: 44-191-212-8201
E-mail: information@datatrial.com
Web Site: www.datatrial.com
Contact: Courtney Smith
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Health Metrics, Medical Writing, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Training & Education**

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Minneapolis, MN 55404
Toll-free: 888-345-2567
Fax: 866-852-3241
E-mail: kevin.goudreau@davita.com
Web Site: www.davitaclinicalresearch.com
Contact: Kevin Goudreau
Contract Research Services: Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Phase I-V, **Laboratories:** Biomarkers, Central, **Subject Recruitment**

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San Francisco, CA 94105
Business: 484-567-6343
Fax: 415-538-1810
E-mail: sales@decisionview.com
Web Site: www.decisionview.com
Contact: Dave Hilmer
Information Technology: CTMS, Other, **Subject Recruitment**

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Contact: Juliet
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Owings Mills, MD 21117
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Fax: 410-654-5335
E-mail: michellei@designingevents.com
Web Site: www.designingevents.com
Contact: Michelle Issing
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Web Site: www.intelsius.com
Contact: Lisa Karabedian

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E-mail: diaeurope@diaeurope.org
Web Site: www.diahome.org
Contact: Daniel Hartman
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Mississauga L4W 5P4 Canada
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Fax: 905-625-3767
E-mail: info@diteba.com
Web Site: www.diteba.com
Contact: Sam Ricchezza
Laboratories: Bioanalytical

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Web Site: www.dlife.com
Contact: Chris Pulaski
Sites

DNAVISION SA
Ave George Lemaitre 25
Charleroi B-6041 Belgium
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Fax: 32-71-347879
E-mail: info@dnavision.be
Web Site: www.dnavision.be
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Contact: Wayne Pearson
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Web Site: www.dorevitch.com.au
Contact: Robyn Wootton
Laboratories: Central

DR MANFRED KOEHLER GMBH
Pharma Biometrics Consulting
Hornusstrasse 16
Freiburg D-79108 Germany
Business: 49-761-50318-613
Fax: 49-761-50318-7-613
Web Site: www.koehler-freiburg.de
Contract Research Services: At-Home Study Services, CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Training & Education**

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Cologne D-50672 Germany
Business: 49-2219-128-710
Fax: 49-2219-128-711
E-mail: info@oandp-cro.com
Web Site: www.oandp-cro.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development, **Subject Recruitment; Training & Education**

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Philadelphia, PA 19102
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Contact: Sara Perkel
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Contact: Lisa Zoks
Training & Education

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Malvern, PA 19355
Business: 484-913-0210
Fax: 484-913-0224
E-mail: info@dsg-us.com
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Contact: Jack Minster
Contract Research Services: CRF Design, Data Collection, **CROs:** Niche, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Other, Software Program Development

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300 Interpace Pkwy Bldg C 1st Flr
Parsippany, NJ 07054
Business: 973-265-1060
Fax: 973-402-0880
E-mail: bsager@dspclinical.com
Web Site: www.dspclinical.com
Contact: Beth Sager
CROs: General, Medical Device, Niche, Phase I-V

DUKE CLINICAL RESEARCH INSTITUTE
2400 Pratt St, Rm 0311 Terr Level
Durham, NC 27705
Business: 919-668-8700
Fax: 919-668-7116
E-mail: suzanne.pfeifer@duke.edu
Web Site: www.dcri.org
Contact: Suzanne Pfeifer
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **Laboratories:** Biomarkers, Cardiovascular-ECG, Core, Imaging, **Training & Education**

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Cambridge, MA 02142
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Fax: 617-576-0304
E-mail: info@dyadsystems.com
Web Site: www.dyadsystems.com
Contact: Janet Chien
Contract Research Services: Data Collection, Data Monitoring, **CROs:** Medical Device, Niche, Phase I-V, **Information Technology:** Software Program Development, **Subject Recruitment**

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Bound Brook, NJ 08805
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E-mail: gambra@clinplus.com
Web Site: www.dzs.com
Contact: Greg Ambra
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, **CROs:** Medical Device, Niche, Phase I-V

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Fax: 732-764-6755
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Contact: Bob Borysko
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development

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29 High St
Welwyn AL6 9EE United Kingdom
Business: 44-1438-840984
Fax: 44-1438-840429
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Contact: John Hawkins
Career Recruitment & Staffing

EASTERN MICHIGAN UNIVERSITY
Clinical Research Administration Program
206 E Marshall Bldg
Ypsilanti, MI 48197
Business: 734-487-4096
Fax: 734-487-4095
E-mail: ssonstein@emich.edu
Web Site: www.emich.edu/hs/CRESindex.html
Contact: Stephen Sonstein
Training & Education

ECHOMAIL
701 Concord Ave
Cambridge, MA 02138
Business: 617-354-8585
Fax: 617-354-8899
E-mail: britney.allen@echomail.com
Web Site: www.echomail.com
Contract Research Services: Data Collection, Data Monitoring, **Information Technology:** Software Program Development

ECLINFORCE
10110 Molecular Dr Ste 214
Rockville, MD 20850
Toll-free: 866-977-CTMS
Business: 301-315-2029
Fax: 301-762-1812
E-mail: info@eclinforce.com
Web Site: www.eclinforce.com
Contact: Kevin Kelly
Information Technology: EDC (PDAs, eDiaries), Other, Software Program Development

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Saint Jakobs-Strasse 199
Basel CH-4052 Swaziland
Business: 41-61-666-6401
E-mail: gm@eclinso.com
Web Site: www.eclinso.com
Contact: George Masoura
Information Technology: EDC (PDAs, eDiaries), **Laboratories:** Imaging

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Hollywood, FL 33019
Business: 954-920-2122
Fax: 954-920-3122
E-mail: ssinger@effectiveresearch.com
Web Site: www.effectiveresearch.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V

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PO Box 2334
Mount Pleasant, SC 29465-2334
Business: 843-849-7382
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Web Site: www.eliteresearchnetwork.com
Contact: Chris Hoyle
Other Services & Products

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Business: 214-689-3620
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E-mail: clinical_info@emsinet.com
Web Site: www.emsinet.com
Contact: John Corcoran
Contract Research Services: Data Collection, **Subject Recruitment**

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Berlin 10243 Germany
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E-mail: information@entimo.com
Web Site: www.entimo.com
Contact: Dimitri Kutsenko
Information Technology: Other, Software Program Development

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Raleigh, NC 27615
Business: 919-673-4001
Fax: 206-338-3663
E-mail: pweldon@eolusinc.com
Web Site: www.eolusinc.com
Contact: Phyllis Weldon
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development, **Training & Education**

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625 W Ridge Pike Bldg E Ste 402
Conshohocken, PA 19428
Business: 610-832-2100
E-mail: llaluna@epharmasolutions.com
Web Site: www.epharmasolutions.com
Contact: Lisa La Luna
Contract Research Services: Negotiating Budgets/Contracts, **CROs:** Niche, **Information Technology:** Other, Software Program Development, **Subject Recruitment; Training & Education**

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175 Freshwater Blvd
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Contact: Matthew Jurkiewicz
Laboratory Supplies

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3101 Broadway Ste 630
Kansas City, MO 64111
Business: 816-753-5329
E-mail: busdev@eriban.com
Web Site: www.eriban.com
Contact: Tim Wurst
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General

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1818 Market St Ste 1000
Philadelphia, PA 19103
Business: 215-972-0420
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E-mail: eresearch@ert.com
Web Site: www.ert.com
Contact: Sheryl Walder
Consulting; Information Technology: EDC (PDAs, eDiaries), IVRS, Software Program Development, **Laboratories:** Cardiovascular-ECG

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San Diego, CA 92120
Business: 619-255-5903
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Web Site: www.estudysite.com
Contact: Dan Robitaille
Sites; Subject Recruitment

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Business: 514-337-0442
Fax: 514-336-1142
E-mail: rkolanitch@ethicaclinical.com
Web Site: www.ethicaclinical.ca
Contact: Ron Kolanitch
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Phase I-V, **Subject Recruitment**

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Consulting; IRBs; Training & Education

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Corte Madera, CA 94925
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Rome 00197 Italy
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Web Site: www.eucrof.eu
Contact: Stefano Marini
CROs: General

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6859 Quality Way
Portage, MI 49002
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E-mail: info@avtechlabs.com
Web Site: www.avtechlabs.com
Contact: Bill Pfund
CROs: General, **Laboratories:** Bioanalytical, Biomarkers

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Laboratories: Bioanalytical, Biomarkers, Central

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Contact: Rafael Hoebrechts
Training & Education

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Information Technology: EDC (PDAs, eDiaries), Other, Software Program Development, **Subject Recruitment**

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Hampton, VA 23666
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E-mail: info@ezpak.net
Web Site: www.ezpak.net
Contact: Doug Murphy
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development, **Training & Education**

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Contact: Gary Hughes
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Information Technology: IVRS

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Fax: 714-822-3843
E-mail: whogrefe@focusdx.com
Web Site: www.focusdx.com
Contact: Wayne Hogrefe
Laboratories: Bioanalytical, Biomarkers

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Fax: 302-926-7123
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Training & Education

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Burlington, MA 01803
Business: 781-685-4995
E-mail: louisehopper@formedix.com
Web Site: www.formedix.com
Contact: Louise Hopper
Consulting; Information Technology: Software Program Development, **Training & Education**

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1200 John Q Hammons Dr Ste 300
Madison, WI 53717
Business: 608-826-6000
Fax: 608-826-6005
E-mail: info@forteresearch.com
Web Site: www.forteresearch.com
Contact: Kerri Phillips
Information Technology: CTMS

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Business: 952-238-9010
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Web Site: www.fortressmedical.com
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Information Technology: CTMS, EDC (PDAs, eDiaries), Other, Software Program Development

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E-mail: sales@frontagelab.com
Web Site: www.frontagelab.com
Contact: Mark Crain
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Contact: Cris Wells
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Maryville, TN 37804
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Business: 865-380-2726
Fax: 865-380-9191
E-mail: rtaylor@geneuity.com
Web Site: www.geneuity.com
Contact: Ranee Taylor
Contract Research Services: Data Collection, Data Monitoring, Pharmacovigilance, **CROs:** Phase I-V, **Laboratories:** Bioanalytical, Biomarkers, Central, Core, Imaging

GENY RESEARCH GROUP
50 Tower Rd Ste 202
Newton, MA 02464
Business: 617-969-7939
E-mail: geny@genyresearch.com
Web Site: www.genyresearch.com
Contact: Vladimir Verbitsky
Contract Research Services: Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Phase I-V

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Sydney NSW 2000 Australia
Business: 61-2-9657-0300
Fax: 61-2-9657-0301
E-mail: info@georgeclinical.com.au
Web Site: www.georgeclinical.com
Contact: Jacqueline Thorn
CROs: Niche, Phase I-V

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Web Site: www.glenroy.com
Contact: Barb Woodruff
Clinical Packaging: Packaging

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Business: 609-921-6868
Fax: 609-921-3620
E-mail: E.Bailey@gctrials.com
Web Site: www.gctrials.com
Contact: Edward Bailey
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **Other Services & Products; Subject Recruitment; Training & Education**

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Wangenbourg Engenthal F-67710 France
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Fax: 33-3-8887-3178
E-mail: glocon@orange.fr
Web Site: www.global-consepts.com
Contact: Michiel Rook
Training & Education

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Irvine, CA 92612
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E-mail: info@globallanguages.com
Web Site: www.globallanguages.com
Contact: Inna Kassatkina
Consulting

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2101 Gaither Rd Ste 450
Rockville, MD 20850
Business: 301-424-9700
Fax: 301-296-4751
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Web Site: www.grs-cro.com

Contact: Marisa Goodenough
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Medical Device, Niche, Phase I-V

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Fax: 514-624-7633
E-mail: sales@globalvisioninc.com
Web Site: www.globalvisioninc.com
Information Technology: Software Program Development

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Web Site: www.globalcarect.com
Contact: Gail Adinamis
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E-mail: mail@globescientific.com
Web Site: www.globescientific.com
Contact: Dennis Klucznik
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Ann Arbor, MI 48104
Business: 734-222-6285
E-mail: scottrumsey@glpqualityconsulting.com
Web Site: www.glpqualityconsulting.com
Contact: Scott Rumsey
Contract Research Services: Data Monitoring, **Training & Education**

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Plantation, FL 33313
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Business: 954-327-9639
Fax: 954-587-6378
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Web Site: www.goodwinbio.com
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Business: 513-793-8900
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Web Site: www.goodwynirb.com
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Contact: Andrew Kimball
Information Technology: IVRS, Other, Software Program Development, **Subject Recruitment**

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Contract Research Services: CT Protocol Design, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Niche, **Training & Education**

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E-mail: info@grs-cro.com
Web Site: www.grs-cro.com
Contact: Marisa Pawlewicz
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, Other

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Fax: 91-40-6692-9900
E-mail: bdcrd@gvkbio.com
Web Site: www.gvkbio.com
Contact: Vijay Rajan Vanchi
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** General, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Laboratories:** Bioanalytical, Biomarkers, **Subject Recruitment**

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Contact: Keith Williams
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Laboratories: Bioanalytical

HAMMERSMITH MEDICINES RESEARCH
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Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Medical Writing, **CROs:** Niche, Phase I-V, **Laboratories:** Bioanalytical, Cardiovascular-ECG, Imaging, **Subject Recruitment**

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New York, NY 10010-6002
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Web Site: www.harrisinteractive.com
Contract Research Services: CT Protocol Design, Data Collection, Pharmacovigilance, **CROs:** Phase I-V, **Subject Recruitment**

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Web Site: www.harrisonclinical.com
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Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment**

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Web Site: www.hays.co.uk
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Web Site: www.healthdec.com
Contact: Billy Purser
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Mountlake Terrace, WA 98043
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Web Site: www.hrainc.net
Contract Research Services: Data Collection, **CROs:** Niche

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Web Site: www.hill-top.com
Contact: John Lyssikatos
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Sites; Subject Recruitment**

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Web Site: www.historx.com
Contact: Richard Carroll
CROs: Niche, **Laboratories:** Bioanalytical, Biomarkers

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Contact: Mark Eberhardt
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E-mail: info@iconplc.com
Web Site: www.iconplc.com
Contact: Niamh Murphy
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Contact: Damien Tremolet
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Web Site: www.iricanada.com
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Web Site: www.integrium.com
Contact: Greg Dodds
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Information Technology: Software Program Development

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Contact: Jodi Andrews
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Web Site: www.irbco.com
Contact: Todd McDaniel
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Contact: Jennifer Bruce
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E-mail: nancy@ivrcc.com
Web Site: www.ivrcc.com
Contact: Nancy Hudak
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Web Site: www.kai-research.com
Contact: Selma Kunitz
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Fax: 902-678-2839
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Web Site: www.kemic.com
Contact: Susan Goodall
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Web Site: www.kendle.com
Contact: Doug Moehring
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Contact: Bibiane Zakaria
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Web Site: www.kronosdata.com
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Contact: Giles Wilson
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Web Site: www.lskglobal.com
Contact: Cho Sung-Ho
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, **IRBs; Subject Recruitment; Training & Education**

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30 Indian Dr
Ivyland, PA 18974
Business: 215-396-8373
Fax: 215-396-8375
E-mail: inquiry@lyo-t.com
Web Site: www.lyotechnology.com
Contact: Edward Trappler
CROs: Niche, **Training & Education**

M2S
12 Commerce Ave
West Lebanon, NH 03784
Business: 603-298-5509
Fax: 603-298-5055
E-mail: caron@m2s.com
Web Site: www.m2s.com
Contact: Maryann Caron
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, **CROs:** Medical Device, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Laboratories:** Core, Imaging

MAGI
2249 1/2 Sutter St
San Francisco, CA 94115
Business: 650-465-0119
E-mail: ngoldfarb@magiworld.org
Web Site: www.magiworld.org
Contact: Norman Goldfarb
Training & Education

MAJARO INFOSYSTEMS
2350 Mission College Blvd Ste 700
Santa Clara, CA 95054
Business: 408-330-9400
Fax: 408-330-9410
E-mail: sales@majaro.com
Web Site: www.majaro.com
Contact: Katie Fortman
Contract Research Services: CRF Design, CT Protocol Design, Data Monitoring, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS

MAKROCARE
One Washington Park Ste 1502
Newark, NJ 07102
Business: 973-481-0100
E-mail: info@makrocare.com
Web Site: www.makrocare.com
Contact: Mahesh Malneedi
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Subject Recruitment**

MANIPAL ACUNOVA LTD
Mobius Towers SJR i-Park EPIP Whitefield
Bangalore 560066 India
Business: 91-80-69915700
Fax: 91-80-66915719
E-mail: customer@acunovalife.com
Web Site: www.acunovalife.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **IRBs; Laboratories:** Bioanalytical, Biomarkers, Cardiovascular-ECG, Central, Core, Imaging, **Laboratory Supplies; Subject Recruitment**

MANNKIND CORP
28903 N Ave Paine
Valencia, CA 91355
Business: 661-75-5300
E-mail: teasley@mannkindcorp.com
Web Site: www.mannkindcorp.com
Career Recruitment & Staffing

MAPI
Real World Evidence
2343 Alexandria Dr Ste 400
Lexington, KY 40504
Business: 859-223-4334
Fax: 859-514-4350
E-mail: kandersson@mapigroup.com
Web Site: www.mapigroup.com
Contact: Karin Andersson
Contract Research Services: Data Collection, Medical Writing, Pharmacovigilance, **CROs:** Niche, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **Subject Recruitment**

MARCO GMBH & CO KG INSTITUTE FOR CLINICAL RESEARCH AND STATISTICS
Moskauer Strasse 25
Dusseldorf D-40227 Germany
Business: 49-211-977-93-3
Fax: 49-211-977-93-51
E-mail: contact@marco-institut.de
Web Site: www.marco-institut.de
Contact: Manfred Wargenau

Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development, **Subject Recruitment; Training & Education**

MARKEN
521 RXR Plaza East Tower
Uniondale, NY 11556
Toll-free: 800-932-6755
Business: 800-932-6755
E-mail: info@marken.com
Web Site: www.marken.com
Contact: Ariette Vanstrien

MASTERCONTROL
6322 S 3000 E Ste 110
Salt Lake City, UT 84121
Toll-free: 800-825-9117
Business: 801-942-4000
Fax: 801-942-7088
E-mail: jclegg@mastercontrol.com
Web Site: www.mastercontrol.com
Contact: Jason Clegg
Information Technology: Software Program Development

MAX NEEMAN INTL
117 Edinburgh South Dr Ste 105
Cary, NC 27511
Business: 919-424-3302
Fax: 919-852-5574
E-mail: donald.swankie@neeman-medical.com
Web Site: www.neeman-medical.com
Contact: Donald Swankie
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **IRBs; Laboratories:** Central, **Sites; Subject Recruitment**

MAXISIT
203 Main St
Metuchen, NJ 08840
Toll-free: 877-629-4748
Business: 732-494-2005
E-mail: info@maxisit.com
Web Site: www.maxisit.com
Contact: Maulik Shah
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Niche, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development

MCCARTHY CONSULTING SERVICES
1151 Gorham St Unit 8
Newmarket L3Y 8Y1 Canada
Business: 905-836-0033
Fax: 905-836-0006
E-mail: mccarthy@mccarthyconsultant.com
Web Site: www.mccarthyconsultant.com
Contact: Matt McCarthy
Consulting

MCELROY TRANSLATION CO
910 West Ave
Austin, TX 78701
Toll-free: 800-531-9977
Business: 512-472-6753
Fax: 512-472-4591
E-mail: info@mcelroytranslation.com
Web Site: www.mcelroytranslation.com
Other Services & Products

MCKESSON PHASE 4 SOLUTIONS
One Concorde Gate 4th Flr
Toronto M3C 3N6 Canada
Toll-free: 800-811-9880
Business: 416-429-6172
Fax: 416-429-2745
Web Site: www.mckesson.ca
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, Software Program Development, **Subject Recruitment; Training & Education**

MCKESSON SPECIALTY HEALTH (US ONCOLOGY RESEARCH)
10101 Woodloch Forest
The Woodlands, TX 77380
Business: 281-863-1000
E-mail: corrine.beranek@mckesson.com
Web Site: www.mckesson.com
Contact: Corrine Beranek
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **Sites; Subject Recruitment; Training & Education**

MEADWESTVACO HEALTHCARE PACKAGING
501 S Fifth St
Richmond, VA 23219-0501
Business: 804-44-1000
E-mail: packaging@meadwestvaco.com
Web Site: www.mwvhealthcare.com

MEDELIS
4105 N 20 St Ste 215
Phoenix, AZ 85016
Business: 602-840-1101
Fax: 602-840-1102
E-mail: john.friesner@medelis.com
Web Site: www.medelis.com
Contact: John Friesner
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development, **Sites**

MEDFILES LTD
Volttikatu 5, PO Box 1450 FI-70701
Kuopio FI-70700 Finland
Business: 358-20-7446-800
Fax: 358-20-7446-801
E-mail: medfiles@medfiles.fi
Web Site: www.medfiles.fi
Contact: Tuija Keinonen
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Laboratories:** Bioanalytical, **Subject Recruitment; Training & Education**

MEDFOCUS LLC
8600 W Bryn Mawr Ste 700 S
Chicago, IL 60631
Toll-free: 800-256-4625
Business: 773-632-1800
Fax: 866-439-9491
E-mail: jobs@medfocus.com
Web Site: www.medfocus.com
Career Recruitment & Staffing; Contract Research Services: CRF Design, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** Niche

MEDICAL RESEARCH NETWORK
Talon House Presley Way, Milton Keynes
Buckinghamshire MK8 OES United Kingdom
Business: 44-1908-261-153
E-mail: enquiries@themrn.co.uk
Web Site: www.themrn.co.uk

MEDICAL STAFFING NETWORK/CLINICAL RESOURCES
901 Yamato Rd Ste 110
Boca Raton, FL 33431
Toll-free: 800-676-8326
Business: 561-322-1300
Fax: 561-322-1200
E-mail: webinfo@msnhealth.com
Web Site: www.msnclinicalresearch.com
Career Recruitment & Staffing; Contract Research Services: Data Collection, Data Monitoring, Medical Writing, **CROs:** Medical Device, Phase I-V

MEDICIGLOBAL
1014 W Ninth Ave
King of Prussia, PA 19406
Business: 484-674-6800
Fax: 484-674-6356
E-mail: lmoench@mediciglobal.com
Web Site: www.mediciglobal.com
Contact: Liz Moench
Subject Recruitment

MEDIDATA SOLUTIONS WORLDWIDE
79 Fifth Ave 8th Flr
New York, NY 10003
Toll-free: 866-515-6044
Business: 212-918-1800
Fax: 212-918-1818
E-mail: info@mdsol.com
Web Site: www.mdsol.com
Contact: Ed Viviani
Information Technology: CTMS, EDC (PDAs, eDiaries), Other
See ad on page 41

MEDIMIX INTL
333 NE 24 St Ste 208
Miami, FL 33137-4860
Toll-free: 888-MEDIMIX
Business: 305-573-5233
E-mail: bizdev@medimix.net
Web Site: www.medimix.net
Contact: Henry Gazay
Contract Research Services: Data Collection, Health Metrics

MEDMARC INSURANCE GROUP
Clinical Trial Insurance
14280 Park Meadow Dr Ste 300
Chantilly, VA 20151
Business: 312-301-9085
Fax: 703-652-1389
E-mail: gayd@medmarc.com
Web Site: www.medmarc.com
Contact: George Ayd
Other Services & Products

MEDNET SOLUTIONS
110 Cheshire Lane Ste 300
Minnetonka, MN 55305
Toll-free: 866-258-2735
Business: 763-258-2735
Fax: 763-258-2737
E-mail: contact@mednetstudy.com
Web Site: www.mednetstudy.com
Contact: Dirk Nelson
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other

MEDNETWORLD
510 First Ave N Ste 650
Minneapolis, MN 55403
Business: 855-849-6031
Fax: 612-435-7601
E-mail: info@mednetworld.org
Web Site: www.mednetworld.com
Contact: Chris Smith
Contract Research Services: Data Collection, Data Monitoring, Health Metrics, **Information Technology:** Other, **Subject Recruitment**

MEDPACE
5375 Medpace Way
Cincinnati, OH 45227
Toll-free: 800-730-5779
Business: 513-579-9911
Fax: 513-579-0444
E-mail: info@medpace.com
Web Site: www.medpace.com
Contact: Mary Kuramoto
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development, **Laboratories:** Bioanalytical, Biomarkers, Cardiovascular-ECG, Central, Core, Imaging, **Subject Recruitment**

MEDPOINT COMM
909 Davis St Ste 500
Evanston, IL 60201
Business: 847-869-4700
E-mail: info@medpt.com
Web Site: www.medpt.com
Contact: Bill Cooney
Information Technology: Software Program Development, **Training & Education**

MEDRIO
595 Market St Ste 1300
San Francisco, CA 94105
Toll-free: 877-763-3746
Business: 415-963-3700
Fax: 415-962-2089
E-mail: info@medrio.com
Web Site: www.medrio.com
Contact: Brett Foreman
Information Technology: CTMS, EDC (PDAs, eDiaries)

MEDSOURCE
16902 El Camino Real
Houston, TX 77058
Toll-free: 877-269-2987
Business: 281-286-2003
Fax: 281-488-1848
E-mail: elund@medsource.com
Web Site: www.medsource.com
Contact: Eric Lund
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Subject Recruitment**

MEDTRIALS
2828 N Harwood Ste 1200
Dallas, TX 75201
Business: 214-630-0288
Fax: 214-630-0289
Web Site: www.medtrials.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), Software Program Development, **Training & Education**

MEDVANCE LTD
Medvance House, Burn Grange, Doncaster Rd Burn
Selby YO8 8LA United Kingdom
Business: 44-1757-270-044
Fax: 44-1757-270055
E-mail: enquiries@medvance.co.uk
Web Site: www.medvance.co.uk
Contact: Mark O Reilly
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Medical Device, **Training & Education**

MEIRXRS
CRO
100 N Brand Blvd Ste 306
Glendale, CA 91203
Toll-free: 800-507-5277
Business: 818-247-1368
Fax: 928-585-2036
E-mail: info@meirxrs.com
Web Site: www.meirxrs.com
Contact: Rosemarie Christopher
Career Recruitment & Staffing; Contract Research Services: Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), **Training & Education**

MEK CONSULTING
Ethnikis Antistaseos 28
Vailissia 15235 Greece
Business: 30-210-810-5410
Fax: 30-210-810-5425
E-mail: enquiry@mekconsulting.com
Web Site: www.mekconsulting.com
Contact: Antoine El-Khazen
Contract Research Services: CRF Design, Data Monitoring, Negotiating Budgets/Contracts, **CROs:** Phase I-V

MERCK SERONO SA
Biotech Center
Chamerstrasse 174
Geneva 20 CH-6300 Switzerland
Business: 41-729-22-22
Fax: 41-729-22-00
E-mail: sara.mahy-lecointre@merckserono.net
Web Site: www.merckserono.net
Contact: Sara Mahy-Lecointre
Other Services & Products

MERCODIA
1590 Westbrook Plaza Dr Ste 201
Winston Salem, NC 27103
Business: 336-725-8623
Fax: 336-725-8673
E-mail: info_usa@mercodia.com
Web Site: www.mercodia.com
Contact: Carissa Jones
Laboratories: Biomarkers, **Laboratory Supplies**

MERGE HEALTHCARE
4000 Aerial Center Pkwy Ste 101
Morrisville, NC 27560
Business: 919-653-3400
Fax: 919-653-3620
E-mail: eclinical@merge.com

Web Site: www.merge.com/eclinical
Contact: Bruce Avery
Contract Research Services: CRF Design, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other

MERRILL BRINK INTL
One Merrill Circle Bldg 1455
St Paul, MN 55108
Toll-free: 800-688-4400
Business: 651-646-4501
Fax: 212-229-6630
E-mail: translations@merrillbrink.com
Web Site: www.merrillbrink.com
Contact: Vanessa Lontoc
Information Technology: IVRS, Other

MESM LTD
Unit G Buckshaw Link, Buckshaw Village
Chorley PR7 7EL United Kingdom
Business: 877-836-0762
Fax: 44-844-8444-793
E-mail: sales@mesm.co.uk
Web Site: www.mesmglobal.com
Contact: Kate Maughan
CROs: Medical Device, **Laboratory Supplies**

META SOLUTIONS
63 Grove St
Somerville, NJ 08876
Toll-free: 866-METASOL
Business: 908-393-9906
Fax: 908-725-0808
E-mail: kim.nitahara@metasol.com
Web Site: www.metasol.com
Contact: Kim Nitahara
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Pharmacovigilance, **Information Technology:** Other, Software Program Development, **IRBs**

MICHIGAN STATE UNIVERSITY
College of Nursing
A117 Life Sciences Bldg
East Lansing, MI 48824-1317
Toll-free: 800-605-6424
Business: 517-355-6525
E-mail: nurse.ce@hc.msu.edu
Web Site: nursing.msu.edu/cracrc.aspx
Contact: Deana Haner
Training & Education

MICRO MEDICAL LTD
Quayside Chatham Maritime
Chatham ME4 4QY United Kingdom
Business: 44-1634-893-500
Fax: 44-1634-893-600
E-mail: trials@micromedical.co.uk
Web Site: www.respiratorytrials.com
CROs: Medical Device, Niche, Phase I-V

MICROCONSTANTS
9050 Camino Santa Fe
San Diego, CA 92121
Business: 858-652-4600
Fax: 866-232-9497
E-mail: bd@microconstants.com
Web Site: www.microconstants.com
Contact: Ron Shevock

MICROSOFT CORP
One Microsoft Way
Redmond, WA 98052-6399
Toll-free: 800-642-7676
Business: 425-882-8080
Web Site: www.microsoft.com
Information Technology: Software Program Development

MIDLANDS IRB
8417 Santa Fe Dr Ste 100
Overland Park, KS 66212
Toll-free: 800-636-4445
Business: 913-385-1414
Fax: 913-385-9999
E-mail: cathyo@mlirb.com
Web Site: www.mlirb.com
Contact: Cathy Owen
IRBs

MISSION3
2198 E Camelback Rd Ste 205
Phoenix, AZ 85016-4746
Business: 602-957-2150
Fax: 602-957-2160
E-mail: info@mission3.com
Web Site: www.mission3.com
Contact: Chris Joslin
Information Technology: Other, Software Program Development, **Training & Education**

MIT SLOAN EXECUTIVE EDUCATION
238 Main St E48-501
Cambridge, MA 02142-1046
Business: 617-253-7750
Fax: 617-258-9739
E-mail: execed_execdir@mit.edu
Web Site: mitsloan.mit.edu/exceed
Training & Education

MMG
Patient Recruitment
700 King Farm Blvd Ste 500 5th Flr
Rockville, MD 20850
Business: 301-984-7191
Fax: 301-921-4405
E-mail: hwest@mmgct.com
Web Site: www.mmgct.com
Contact: Helen West
Contract Research Services: CT Protocol Design, Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **Information Technology:** Software Program Development, **Sites; Subject Recruitment**

MMS HOLDINGS
6880 Commerce Blvd
Canton, MI 48187
Business: 734-245-0310
Fax: 734-245-0320
E-mail: info@mmsholdings.com
Web Site: www.mmsholdings.com
Contact: Don McLean
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V

MONITORFORHIRE.COM
15 E Ridge Pike Ste 225
Conshohocken, PA 19428
Business: 610-862-0909
Fax: 610-862-0912
E-mail: requestinfo@monitorforhire.com
Web Site: www.monitorforhire.com
Contact: Scott Freedman
Career Recruitment & Staffing; Contract Research Services: Data Monitoring

MONITORING FORCE USA
6622 Southpoint Dr S Ste 230
Jacksonville, FL 32216
Business: 904-683-5565
Fax: 904-683-5586
E-mail: contact-usa@monitoringforce.com
Web Site: www.monitoringforce.com
Contact: Ralph Campaneria
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Subject Recruitment; Training & Education**

MORIAH CONSULTANTS
4481 Paloma Lane
Yorba Linda, CA 92886-2832
Business: 714-970-0790
E-mail: michael@moriahconsultants.com
Web Site: www.moriahconsultants.com
Contact: Michael Hamrell
Consulting; CROs: General, **Training & Education**

MORLEY RESEARCH CONSORTIUM
1175 Grimes Bridge Rd Ste 500
Roswell, GA 30075
Business: 404-625-0036
Fax: 404-855-4155
E-mail: jgreen@morleyrc.com
Web Site: www.morleyresearchconsortium.com
Contact: Jane Green
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **IRBs; Sites; Subject Recruitment; Training & Education**

MTZ CLINICAL RESEARCH SP. Z O.O.
ul Pawinskiego 5
Warsaw 02-106 Poland
Business: 48-22-572-5959
Fax: 48-22-572-5957
E-mail: info@mtz-clinical.pl
Web Site: www.mtz-clinical.pl
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Phase I-V, **Subject Recruitment; Training & Education**

MYODERM
48 E Main St
Norristown, PA 19401
Business: 610-233-3300
Fax: 610-233-3301
E-mail: sales@myoderm.com
Web Site: www.myoderm.com
Contact: Maryanne Walsh
Laboratory Supplies; Other Services & Products
See ad on pages 5, 7

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3300 Duval Rd
Austin, TX 78759
Toll-free: 866-726-6277
Business: 512-835-8026
Fax: 512-835-4687
E-mail: info@rulesbasedmedicine.com
Web Site: www.rulesbasedmedicine.com
Contact: Tiffany Morris
Laboratories: Biomarkers

NEA BAPTIST CLINIC
Clinical Research Center
1835 Grant Ave
Jonesboro, AR 72401
Business: 870-935-4150
Fax: 870-932-3608
E-mail: paul.koros@neabaptistclinic.com
Web Site: www.neabaptistclinic.com
Contact: Paul Koros
Contract Research Services: CRF Design, Negotiating Budgets/Contracts, **Sites; Subject Recruitment**

NEEDHAM & CO
42 N Hamilton St
Doylestown, PA 18901
Business: 215-489-1672
Fax: 215-489-8764
E-mail: info@needhamandco.com
Web Site: www.needhamandco.com
Subject Recruitment; Training & Education

NEEDMYDOCTOR
3232 N Elston Ave
Chicago, IL 60618
Toll-free: 888-633-3693
Business: 773-628-0404
Fax: 773-628-1495
E-mail: contact@needmydoctor.com
Web Site: www.needmydoctor.com
Contact: Joseph Sameh
Contract Research Services: Data Collection, Data Monitoring, **Information Technology:** EDC (PDAs, eDiaries), Other, Software Program Development, **Subject Recruitment**

NEOGENOMICS LABS
5 Jenner Ste 100
Irvine, CA 92618
Toll-free: 866-776-5907
E-mail: cro@www.neogenomics.org
Web Site: www.neogenomics.org
Laboratories: Biomarkers, Core

NERI
9 Galen St
Watertown, MA 02472
Business: 617-972-3013
Fax: 617-926-8246
E-mail: BD@neriscience.com
Web Site: www.neriscience.com
Contact: Dawn Porthouse
Contract Research Services: Data Collection, **CROs:** General, Medical Device, Niche, Phase I-V

NEUROPTICS
2082 Michelson Dr Ste 450
Irvine, CA 92612
Business: 949-250-9792
Fax: 949-250-9796
E-mail: info@neuroptics.com
Web Site: www.neuroptics.com

NEW ENGLAND IRB
85 Wells Ave Ste 107
Newton, MA 02459
Business: 617-243-3924
Fax: 617-969-1310
E-mail: info@neirb.com
Web Site: www.neirb.com
Contact: James Saunders
IRBs

NEW ORLEANS CENTER FOR CLINICAL RESEARCH
2820 Canal St
New Orleans, LA 70119
Business: 504-821-8158
Fax: 504-821-8343
E-mail: wbsmd@noccr.com
Web Site: www.noccr.com
Contact: Terry McCormick
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Bratislava 81000 Slovak Republic
Business: 421-232-662-621
Fax: 421-233-010-331
E-mail: level@nextlevelpharma.com
Web Site: www.nextlevelpharma.com
Training & Education

NEXTCEA
600 W Cummings Park #6375
Woburn, MA 01801
Toll-free: 800-225-1645
Business: 781-457-4010
Fax: 617-812-2684
E-mail: kenji.miwa@nextcea.com
Web Site: www.nextcea.com
Contact: Kenji Miwa
CROs: General, Niche, **Laboratories:** Bioanalytical, Biomarkers

NEXTRIALS
5000 Executive Pkwy Ste 540
San Ramon, CA 94583
Business: 925-355-3000
Fax: 925-355-3005
E-mail: info@nextrials.com
Web Site: www.nextrials.com
Contact: Alan Arroyo
Information Technology: EDC (PDAs, eDiaries)

NORTH CAROLINA STATE UNIVERSITY
Statistics
2311 Stinson Dr
Raleigh, NC 27695-8203
Business: 919-515-2528
Fax: 919-515-7591
E-mail: head@stat.ncsu.edu
Web Site: www.stat.ncsu.edu
Contact: Montse Fuentes
Training & Education

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Sandusky, OH 44870
Toll-free: 800-325-5737
Business: 419-626-6012
Fax: 419-626-0814
E-mail: jack@northcoastlab.com
Web Site: www.northcoastlab.com
Contact: Jack Runner
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Web Site: www.northropgrumman.com/health
Information Technology: Other, Software Program Development

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46732 248 Way SE
Enumclaw, WA 98022
Business: 360-802-1075
Fax: 360-802-1076
E-mail: jtaylor@nwclinicalresearch.com
Web Site: www.nwclinicalresearch.com
Contact: Jeffrey Taylor
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment; Training & Education**

NORTHWESTERN UNIVERSITY CLINICAL & TRANSLATIONAL SCIENCES INSTITUTE
750 N Lake Shore Dr 11 Flr
Chicago, IL 60611
Business: 312-503-1709
Fax: 312-503-1505
E-mail: nucats-ed@northwestern.edu
Web Site: www.nucats.northwestern.edu
IRBs; Subject Recruitment; Training & Education

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22287 Mulholland Hwy 91302
Calabasas, CA 91302
Business: 818-348-1543
E-mail: nova-one@sbcglobal.net
Contact: Jon Gilchrist
Laboratory Supplies

NOVELLA CLINICAL
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Morrisville, NC 27560
Business: 919-484-1921
E-mail: info@novellaclinical.com
Web Site: www.novellaclinical.com
Contact: Kristi Robison
Career Recruitment & Staffing; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), **Subject Recruitment**

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5900 Penn Ave
Pittsburgh, PA 15206
Business: 412-363-3300
Fax: 412-362-5783
E-mail: businessdevelopment@novumprs.com
Web Site: www.novumprs.com
Contact: Chris Hendy
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Niche, Phase I-V, **Sites**

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1830 Lefthand Circle
Longmont, CO 80501
Toll-free: 800-574-7374
Business: 303-666-5555
Fax: 303-666-4044
E-mail: mbrown@nspirehealth.com
Web Site: www.nspirehealth.com/clinical
Contact: Michael Brown
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2 The Courtyard Denmark St
Workingham Berkshire RG40 2AZ United Kingdom
Business: 01189-770077
E-mail: info@numerus-ltd.com
Web Site: www.numerus-ltd.com
Contact: Jonathan Alsop
Consulting; Contract Research Services: CT Protocol Design, **CROs:** Medical Device, Niche, Phase I-V, **Information Technology:** Other

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Toll-free: 866-568-8749
Business: 937-310-2270
Fax: 937-310-2275
E-mail: info@nutrixstaffing.net
Web Site: www.nutrixstaffing.com
Contact: Matt Hollingsworth
Career Recruitment & Staffing; Subject Recruitment

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12 W 32 St 5th Flr
New York, NY 10001
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Fax: 212-254-2529
E-mail: contactus@obis.com
Web Site: www.obis.com
Contact: Rick Beasley
Consulting; Information Technology: CTMS, Other, Software Program Development, **Sites; Subject Recruitment; Training & Education**

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Cary, NC 27518
Business: 919-462-8867
Fax: 919-462-9280
E-mail: info@ockham.com
Web Site: www.ockham.com
Contact: Michael Baker
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance

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585 E Swedesford Rd
Wayne, PA 19087
Business: 610-535-6500
Fax: 610-535-6515
E-mail: info@octagonresearch.com
Web Site: www.octagonresearch.com
Contact: Kathleen Bouldin
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Toll-free: 800-290-5766
Business: 484-679-2400
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E-mail: moreinfo@omnicarecr.com
Web Site: www.theoremclinical.com

OMNICOMM SYSTEMS
2101 W Commercial Blvd Ste 3500
Fort Lauderdale, FL 33309
Business: 954-473-1254
Fax: 954-473-1256
E-mail: sjohnson@omnicomm.com
Web Site: www.omnicomm.com
Contact: Steve Johnson
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other

ON ASSIGNMENT
26745 Malibu Hills Rd
Calabasas, CA 91301
Toll-free: 800-313-3779
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Fax: 519-888-0677
E-mail: sales@opentext.com
Web Site: www.opentext.com
Contact: Therese Harris
Information Technology: Other, Software Program Development

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460 Totten Pond Rd
Waltham, MA 02451
Business: 781-547-8416
Fax: 617-621-0065
E-mail: contact@openclinica.com
Web Site: www.openclinica.com
Contact: Rob Rittberg
Information Technology: CTMS, EDC (PDAs, eDiaries), Software Program Development

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Business: 407-240-7878
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Web Site: www.ocrc.net
Contact: Thomas Marbury
Sites

OSMOS CLINICAL RESEARCH
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South San Francisco, CA 94080
Business: 415-979-9492
Fax: 415-901-0304
E-mail: infoplease@osmos.us
Web Site: www.osmos.us
Contact: Diana Fowler
Career Recruitment & Staffing; Contract Research Services: CT Protocol Design, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Medical Device, Niche, Phase I-V, **Subject Recruitment; Training & Education**

OSNET
1919 Hwy A1A Ste 305
Indian Harbour Beach, FL 32937
Business: 321-773-7119
Fax: 866-828-6892
E-mail: concisereport@earthlink.net
Web Site: www.osnet.org
Sites; Subject Recruitment

OUTCOME
201 Broadway 5th Flr
Cambridge, MA 02139
Toll-free: 888-526-6700
Business: 617-621-1600
Fax: 617-621-1620
E-mail: info@outcome.com
Web Site: www.outcome.com
Contact: Kristin Gould
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** EDC (PDAs, eDiaries), IVRS, **Subject Recruitment**

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San Ramon, CA 94583
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Fax: 925-804-6552
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Web Site: www.outsystems.com
Information Technology: Software Program Development

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4880 Havana St Ste 100
Denver, CO 80239
Business: 866-413-1855
E-mail: infor@ovclinical.com
Web Site: www.ovclinical.com
Contact: Gizelle Baker
Career Recruitment & Staffing; CROs: Niche

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Web Site: www.oxrx.com
Contact: Jan Steiner
Contract Research Services: CT Protocol Design, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** Phase I-V

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Web Site: www.paladinmedical.com
Contact: Elaine Duncan

PALM BEACH CRO
400 Columbia Dr Ste 111
West Palm Beach, FL 33409-1948
Business: 561-200-3344
Fax: 561-828-8157
E-mail: info@palmbeachcro.com
Web Site: www.palmbeachcro.com
Contact: Arthur Simon
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Niche, Phase I-V

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9685 Research Dr
Irvine, CA 92618
Toll-free: 800-6-PARAGON
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Fax: 949-224-2811
E-mail: cwest@parabio.com
Web Site: www.parabio.com
Contact: Clareece West
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other, **Subject Recruitment**

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Web Site: www.paragonmeetings.com
Contact: Christopher Diehl

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Web Site: www.parexel.com
Contact: Sean McIntosh
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PATHEON
4721 Emperor Blvd Ste 200
Durham, NC 27703-8580
Business: 919-226-3200
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Contact: Larry Risen
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Contact: Annie Garvey

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E-mail: julie.churchthomas@pcmtrials.com
Web Site: www.pcmtrials.com
Contact: Julie Church-Thomas
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Web Site: www.perceptive.com
Contact: Kathleen Pomykola
Information Technology: CTMS, EDC (PDAs, eDiaries), IVRS, Other, **Laboratories:** Imaging, **Subject Recruitment**

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32 Case St
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Toll-free: 800-848-8481
Business: 315-826-3600
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Web Site: www.perfexonline.com
Contact: Irene Gauthiar
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Houston, TX 77060
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Fax: 713-559-7901
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Web Site: www.pharm-olam.com
Contact: Eric Rupprath
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, **Subject Recruitment**

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Web Site: www.pharmamedica.com
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Arlington, VA 22209
Business: 703-276-0178
Fax: 703-276-0069
E-mail: customer_service@peri.org
Web Site: www.peri.org
Contract Research Services: CT Protocol Design, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Phase I-V, **IRBs; Laboratories:** Bioanalytical, Biomarkers, Cardiovascular-ECG, **Subject Recruitment; Training & Education**

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Nottingham NG11 6JS United Kingdom
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Contact: Rachel Bacon
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Web Site: www.pharmanet-i3.com
Contact: Anne-Marie Hess
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Web Site: imp.pierrel-research.com
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PHARMASEEK
8476 Greenway Blvd Ste 210
Middleton, WI 53562
Business: 608-664-9000
Fax: 608-662-4176
E-mail: lmarks@pharmaseek.com
Web Site: www.pharmaseek.com
Contact: Lisa Marks

PHARMASEEK COS
8476 Greenway Blvd Ste 210
Middleton, WI 53562
Business: 608-664-9000 Ext 2238
Fax: 608-662-4176
E-mail: agarvey@pharmaseek.com
Web Site: www.pharmaseek.com
Contact: Annie Garvey
Contract Research Services: Negotiating Budgets/Contracts, **Sites; Subject Recruitment**

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789 Sherman St Ste 310
Denver, CO 80203
Business: 800-383-6610
E-mail: sales@pharmatech.com
Web Site: www.pharmatech.com
Contact: Rob Bohacs
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Niche, Phase I-V, **Sites; Subject Recruitment**

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Hillsborough, NJ 08844
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Fax: 908-359-2299
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Web Site: www.pharmatrials.info
Contact: Jerry Piotrowski
CROs: General, Phase I-V

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Web Site: www.phlexglobal.com
Contact: Karen Redding
Career Recruitment & Staffing; CROs: General, Medical Device, Niche, Phase I-V, **Information Technology:** Other, **Training & Education**

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831 Parkview Dr N
El Segundo, CA 90245
Business: 310-338-0400
Fax: 310-338-0801
E-mail: johnbrayman@phoenixsoftware.com
Web Site: www.phoenixsoftware.com
Contact: John Brayman
Contract Research Services: CRF Design, Data Collection, Data Monitoring, **Information Technology:** CTMS, EDC (PDAs, eDiaries), Software Program Development

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Toll-free: 877-246-2007
Business: 773-628-1567
Fax: 773-278-2935
E-mail: phonescreen@researchsite.net
Web Site: www.phonescreen.com
Contact: Karen Johnson
Contract Research Services: Data Collection, **Information Technology:** IVRS, Other, **Subject Recruitment**

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Boston, MA 02129
Toll-free: 877-360-2901
Business: 617-973-1600
Fax: 617-973-1601
E-mail: info@phtcorp.com
Web Site: www.phtcorp.com
Contact: Nick Randazzo
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Fax: 609-242-4347
E-mail: info@placemart.com
Web Site: www.placemart.com
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200 Commonwealth Ct Ste 101
Cary, NC 27511
Business: 919-463-0003
Fax: 919-463-0004
E-mail: info@polarisconsultants.com
Web Site: www.polarisconsultants.com
Contact: Celine Clive
Consulting; Contract Research Services: Medical Writing, **Training & Education**

POPSI CUBE
Clinical Services
6 rue Jean Pierre Timbaud, Le Campus A1 sud
Montigny Le Bretonneux 78180 France
Business: 33-1-80905080
Fax: 33-1-80905089
E-mail: contact@popsicube.fr
Web Site: www.popsicube.fr
Contact: Fabrice Beauchene
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development

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Wilmington, NC 28401-3331
Toll-free: 800-948-8002
Business: 910-251-0081
Fax: 910-762-5820
E-mail: randy.buckwalter@ppdi.com
Web Site: www.ppdi.com
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Pharmacovigilance, **CROs:** General, Medical Device, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Software Program Development, **Laboratories:** Bioanalytical, Biomarkers, Central, **Subject Recruitment**
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PPH PLUS GMBH & CO.KG
Altenhoeferallee 3
Frankfurt am Main 60438 Germany
Business: 49-69-5870035-0
Fax: 49-69-5870035-29
E-mail: info@pph-plus.com
Web Site: www.pph-plus.com
Contact: Johanna Schenk
Consulting; Contract Research Services: CT Protocol Design, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** Niche, Phase I-V, **Training & Education**

PRA
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Raleigh, NC 27612
Business: 919-786-8200
Fax: 919-786-8201
E-mail: endpoints@praintl.com
Web Site: www.praintl.com
Contact: Roger Boutin
Contract Research Services: CT Protocol Design, Data Collection, Health Metrics, Medical Writing, Pharmacovigilance, **CROs:** General, Phase I-V, **Laboratories:** Bioanalytical, **Sites; Subject Recruitment**
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Fargo, ND 58104
Business: 701-461-8202
E-mail: cheryl.brammer@pracs.com
Web Site: www.pracs.com
Contact: Cheryl Brammer
CROs: General, Medical Device, Niche, Phase I-V, **Laboratories:** Bioanalytical, Central, **Laboratory Supplies**

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Indianapolis, IN 46280
Business: 317-275-2870
Fax: 317-844-5698
E-mail: info@praxismi.com
Web Site: www.praxismi.com
Contact: Jamie Morris
Contract Research Services: Pharmacovigilance, **Information Technology:** Software Program Development, **Training & Education**

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San Bruno, CA 94066
Business: 877-519-6001
Fax: 650-351-0349
E-mail: ssingh@prcclinical.com
Web Site: www.prcclinical.com
Contact: Saira Singh
Contract Research Services: CRF Design, CT Protocol Design, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, **Training & Education**

PRC CLINICAL
1111 Bayhill Dr Ste 408
San Francisco, CA 94066
Toll-free: 877-519-6001
Business: 650-262-4230
E-mail: info@prcclinical.com
Web Site: www.prcclinical.com
Contact: Curtis Head
Contract Research Services: CRF Design, CT Protocol Design, Data Monitoring, Negotiating Budgets/Contracts, **CROs:** Niche, Phase I-V, **Other Services & Products; Training & Education**

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Austin, TX 78735
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Contact: Richard Tieken
Contract Research Services: CRF Design, Data Collection, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, Other, Software Program Development

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Philadelphia, PA 19102
Business: 215-282-5500
Fax: 215-282-5528
E-mail: infopremier@premier-research.com
Web Site: www.premier-research.com
Contact: Joe Lindroos
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Web Site: www.premier-research.com
Contact: Juergen Schmidt
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Web Site: www.prisma-cro.com
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Web Site: www.procro.com
Contact: Andrew Zupnick
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Contact: Shannon Stoddard
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Contact: David Bender
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Information Technology: EDC (PDAs, eDiaries), Other, Software Program Development

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Contact: Krinio Palli
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Web Site: www.quanticate.com
Contact: Denise Edmonds
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Web Site: www.qctn.com.au
Contact: Mario Pennisi
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Web Site: www.rcri-inc.com
Contact: Dan Schwartz
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Web Site: www.rentschler-biotechnologie.de

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Web Site: www.therqa.com
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Contact: Tracy Dugan
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Web Site: www.rpsweb.com
Contact: Samir Shah
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Web Site: www.rushcomputer.com
Contact: Joe Korch
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Web Site: www.s-clinica.com
Contact: Temitope Koledoye
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Web Site: www.schiffandcompany.com
Contact: Robert Schiff
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Web Site: www.sgs.com/lifescience
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Web Site: www.simbec.co.uk
Contact: Alan Woodward
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Web Site: www.scdm.org
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Web Site: www.socra.org
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Contact: Elliott Graham
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Contact: Debbie White

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E-mail: info@spartasystems.com
Web Site: www.spartasystems.com
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West Bend, WI 53095
Business: 262-334-6020
Fax: 262-334-6067
E-mail: info@spauldingclinical.com
Web Site: www.spauldingclinical.com
Contact: Amanda Baltz
CROs: General, Niche, Phase I-V, **Laboratories:** Cardiovascular-ECG, Core

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Fax: 201-767-7358
E-mail: sales.spectraclinicalresearch@fmc-na.com
Web Site: www.spectraclinicalresearch.com
Contact: Charles Keyes
Laboratories: Central
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5315 Highgate Dr Ste 202
Durham, NC 27713
Toll-free: 877-966-5347
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Fax: 954-964-8113
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Web Site: www.starlims.com
Information Technology: Other, **Laboratories:** Bioanalytical, Central, Core

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Web Site: www.sticaresinteract.com
Contact: Sylvia Demandewicz
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Web Site: www.suntechmed.com
CROs: Medical Device

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Socinstrasse 57
Basel 4002 Switzerland
Business: 41-61-284-8960
Fax: 41-61-284-8999
E-mail: christian.burri@unibas.ch
Web Site: www.swisstph.ch
Contact: Christian Burri
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Newbury Park, CA 91320
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Contact: Austin Aker
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Contact: Siddharth Jain
Consulting; Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Phase I-V, **Information Technology:** CTMS, **Subject Recruitment**

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Vernon Hills, IL 60061
Toll-free: 866 333-1550
Business: 847-215-0437
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E-mail: info@symphonyclinicalresearch.com
Web Site: www.symphonyclinicalresearch.com
Contact: Nicki Norris
Consulting; Contract Research Services: At-Home Study Services, **CROs:** Niche, **Subject Recruitment; Training & Education**

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Lunga St No: 250
Brasov 500059 Romania
Business: 40-268-510-626
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E-mail: info@syncrotrial.ro
Web Site: www.syncrotrial.ro
Contract Research Services: Data Collection, Data Monitoring, Negotiating Budgets/Contracts, **CROs:** General, Niche

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Business: 760-268-8200
Fax: 760-929-1419
E-mail: contactusgroup@synteracthcr.com
Web Site: www.synteracthcr.com
Contact: Matt Smith
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Web Site: www.syreon.com
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Contact: Todd Grosshandler
Laboratories: Bioanalytical, Biomarkers

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Contact: Nicolette Chin-Shue
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Contact: Vanessa Lee
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Web Site: www.trialformsupport.com
Contact: Daniel Spasic
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Web Site: www.bcw.edu/ccr
Contact: Dennis Devitt
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Fax: 44-1565-732-958
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Web Site: www.thecqacompany.com
Contact: Suzanne Batchelor
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Contact: Joan Butler
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Web Site: www.rdsourcing.com
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Web Site: www.themrn.co.uk
Contact: Stuart Redding
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Knutsford WA16 0AQ United Kingdom
Business: 44-1565-733-772
Fax: 44-1565-732-958
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Web Site: www.theregulatoryaffairscompany.com
Contact: Suzanne Batchelor
Contract Research Services: CRF Design, CT Protocol Design, Data Collection, Data Monitoring, Health Metrics, Medical Writing, Negotiating Budgets/Contracts, Pharmacovigilance, **CROs:** General, Medical Device, Niche, Phase I-V, **Information Technology:** CTMS, EDC (PDAs, eDiaries), IVRS, **IRBs; Subject Recruitment; Training & Education**

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Fax: 866-257-7252
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Web Site: www.theoremclinicalresearch.com
Contact: Sara Davis
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Fax: 858-571-1234
E-mail: bmacy@therapeuticsinc.com
Web Site: www.therapeuticsinc.com
Contact: Bryan Macy
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Contact: Michael Smyth
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Contact: Kathleen Drennan
Subject Recruitment; Training & Education

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Fax: 613-274-3674
E-mail: info@trialstat.com
Web Site: www.trialstat.com
Information Technology: EDC (PDAs, eDiaries)

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Web Site: www.tsg-global.com
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Fax: 484-567-6985
E-mail: info@ttc-llc.com
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Contact: Marie Johnston

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Berkeley, CA 94704-7000
Business: 510-642-4111
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Web Site: www.extension.berkeley.edu/subject/clinical.html
Training & Education

UCSC EXTENSION IN SILICON VALLEY
2505 Augustine Dr Ste 100
Santa Clara, CA 95054
Business: 408-861-3700
E-mail: biosciences@ucsc-extension.edu
Web Site: www.ucsc-extension.edu/biosciences
Contact: Michelle Ragozzino
Training & Education

UNILABS BIOANALYTICAL SOLUTIONS
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Copenhagen O 2100 Denmark
Business: 45-3374-3000
Fax: 45-3374-3030
E-mail: yvonne.lech@unilabs.com
Web Site: www.yorkbio.com
Contact: Yvonne Lech
CROs: Niche, **Laboratories:** Bioanalytical, Biomarkers, **Sites**

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Contact: Arvinder Makkar
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Contact: Fatma Nedjari
Training & Education

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Training & Education

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The Woodlands, TX 77380
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Contact: Peter Casellini
Contract Research Services: Data Monitoring, **CROs:** Niche

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Contact: Jeevan Menon
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Information Technology: IVRS

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