Making the Business Case for Accreditation

When the Association for the Accreditation of Human Research Protection Programs (AAHRPP) launched in 2001, its first accredited organizations comprised a few market segments. Today, AAHRPP has accredited 138 parent organizations, representing more than 600 entities from almost every type of human research organization.

As the number of accredited organizations continues to grow, the big question is whether the business benefits of accreditation will continue to grow as well.

When representatives from seven non-profit agencies combined in 2001 to create an accreditation program for human subject research, they faced what some viewed as insurmountable challenges.

First, this new accreditor, the Association for the Accreditation of Human Research Protection Programs (AAHRPP), wasn’t the only accreditation option. That same year, the Department of Health and Human Services developed its own accreditation system. As demand for their services continues to grow, medical writers have taken on more responsibility, often performing jobs previously done by statisticians or clinical researchers, and have become an important part of the drug development process.

“Medical writers understand the studies, protocol, data, statistics and what they mean, and are able to interpret the data and write about it in a way that is transparent and easy for anyone who has to review it to understand. Medical writers play a pivotal role in telling the story about a product—if you don’t interpret the data and tell the story effectively, you will not secure approval,” said Melanie Washburn, see Medical Writing on page 8

According to CenterWatch analysis, the medical writing market has more than doubled in size during the past five years, increasing from an estimated $345 million in 2003 to $694 million in 2008.

Medical writers have taken on more responsibility, often performing jobs previously done by statisticians or clinical researchers. They have become an important part of the drug development process.

The medical writing market has grown 15% each year over the past five years, to nearly $700 million, thanks in part to a rise in the volume of work outsourced by drug sponsors hoping to meet regulatory requirements and convert clinical study data into manuscripts for scientific and medical publications.

Demand for medical writing services is rising at a time when many major pharmaceutical companies have cut jobs as part of restructuring plans and when experienced medical writers have left positions in drug companies to work as freelancers. As a result, those doing medical writing on a contract basis, including full-service contract research organizations (CROs), medical communications firms and freelance writers, report strong demand for their services.

As demand for their services continues to grow, medical writers have taken on more responsibility, often performing jobs previously done by statisticians or clinical researchers, and have become an important part of the drug development process.

“Medical writers understand the studies, protocol, data, statistics and what they mean, and are able to interpret the data and write about it in a way that is transparent and easy for anyone who has to review it to understand. Medical writers play a pivotal role in telling the story about a product—if you don’t interpret the data and tell the story effectively, you will not secure approval,” said Melanie Washburn, see Medical Writing on page 8

Inside this issue...

Month in Review .................. 4
CentreStage Europe ............... 5
Grant Opportunities ............... 18

Conditional and Accelerated Approach No Easy Route to Market Success
Eye On: Juvenile Arthritis
In the Pipeline
TrialWatch
Opportunities Underway

Visit http://store.centerwatch.com to learn more about Central and Eastern Europe: Outsourcing Trends and Growth Opportunities in Clinical Trials
Inclinix is an Enrollment CRO with specialized focus on clinical trial recruitment solutions. Our sole focus is to help you meet your enrollment goals, so you can successfully complete your trials. Our recommended sites are proven to enroll three times faster.

Attain your goals with Inclinix.

Visit www.inclinix.com/today to make your enrollment soar.
WHEN YOU NEED TO BE SURE

WINNING IS AN ATTITUDE

Winners leave nothing to chance. Teamwork and experience are key. Selecting the right partner can favorably impact your drug development timelines and decision-making processes. SGS’ Life Science Services has 30 years of experience as a global contract service organization providing integrated solutions from preclinical activities to Phase I-IV trials, Bioanalytical and Quality Control testing. Stay ahead in your business, visit www.sgs.com/CRO

Contact us: lss.info@sgs.com
EU: +33 1 53 78 18 79
USA: +1 877 677 2667
ASIA: +65 9826 2598

SGS Life Science Services
Clinical Research

Couldn’t You Use an Extra $10 to Start the New Year?

Then take our readership survey online.

CenterWatch continually strives to produce the best quality news sources in the clinical trials industry. So we want to know what you think. Please take a moment to fill out our online readership survey and we’ll send you a $10 Visa® Gift Card—just be one of the first 50 respondents* by December 31, 2008 to get yours. As always, your responses will remain confidential.


*Limit one entry per reader.
Month in Review

Editor's Note: These stories appeared last month in CWW eekly. For more information about these articles, please refer to the following CWW eekly issues: Volume 12, Numbers 43-47.

Sponsors

Amidst a company-wide restructuring effort that will cut 550 U.S. sales representatives, Swiss pharmaceutical giant Novartis appointed Joerg Reinhardt to the new post of chief operating officer. In this role, Reinhardt will relieve long-time CEO Daniel Vasella of operational duties to allow Vasella to focus on the drug company's strategic efforts. Merck also announced layoffs after the New Jersey-based company posted a 28% drop in third-quarter net income. The drugmaker plans to cut 7,200 jobs.

Academic

The University of Rochester Medical Center (URMC) broke ground on a new $76.4-million facility that will bring together under one roof resources that help researchers write grants, design clinical trials, recruit participants, collect and evaluate data, and collaborate with industry and other partners. The 200,000-square-foot Clinical and Translational Science Building is part of a $300-million investment that URMC plans to make over the next several years in research, education and clinical care capabilities. The building also will serve as a hub for the Upstate New York Translational Research Network, a consortium of nine institutions that will develop and share clinical research resources.

CROs

In an effort to enter the U.S. clinical trials market, Bulgarian contract research organization (CRO) Associated Medical Group (AMG) has contracted with sales, marketing, and business development services provider AmeriStart to promote the CRO's services to North American pharmaceutical and biotech companies. AMG already conducts phase I to phase III trials in Bulgaria, Austria, Croatia, Bosnia, Serbia, Macedonia, Romania and Turkey.

King of Prussia, Pa.-based MDS Pharma Services has moved its Singapore central laboratory to a larger facility, enabling the CRO to meet the growing needs of its Asia Pacific client base. The new facility, in Marsiling Industrial Park, offers twice its previous capacity for sample storage, processing, and safety testing. MDS Pharma's Asia Pacific operations include central lab facilities in Singapore and Beijing, preclinical operations in Taiwan, and late-stage trial services in Beijing, Malaysia and Australia.

People for the Ethical Treatment of Animals (PETA), which owns 80 shares of Princeton, N.J.-based CRO Covance, has submitted a shareholder resolution calling on Covance to report to stockholders on its progress correcting what the animal rights organization calls "a myriad of violations of the federal Animal Welfare Act." The resolution also calls for the CRO to outline what steps it has taken to preventrecurrences of the violations.

China has seen significant growth in the area of drug research and development in the past few years, and this growth will continue into the fourth quarter of 2008 with the opening of two new preclinical facilities in Shanghai. In October, preclinical contract CRO MPI...
Research opened a 50,000-square-foot building in Shanghai’s Chuansha Economic Park. The new facility, a result of a recently formed joint venture between MPI Research and Shanghai Medicilon, will provide preclinical drug discovery and development services in Asia. Preclinical research powerhouse Charles River Laboratories also plans to expand its global reach with a new 60,000-square-foot facility in Shanghai slated to open in early 2009. Charles River and Shanghai-based Shanghai BioExplorer formed a joint venture last year to create Charles River Preclinical Services Greater China last year. The new facility is the result of this partnership.

In the field of Technology, CRF, a Waltham, Mass.-based provider of electronic Patient Reported Outcomes (ePRO) and data collection solutions, appointed Rachael King as CEO, replacing Pamela McNamara who resigned as chairman and CEO in October. King was formerly CRF’s vice president of European and Asian Operations.

CRF's predecessor, Waltham, Mass.-based eClinical company Phase Forward reported a 23% jump in third quarter revenues to $43 million from $34.9 million in the third quarter of 2007. Non-GAAP net income for the period slid to $5.4 million compared with $6.9 million in the third quarter of 2007. The decline was due primarily to an increase in the company’s tax rate from 10.3% in the third quarter of 2007 to 36.2%, according to president and CEO Bob Weiler.

IRBs

Copernicus Group IRB appointed Bruce Tomason as its new CEO, replacing Copernicus founder and CEO Sharon Hill Price. Price will stay on as senior advisor to the Research Triangle Park, NC-based independent institutional review board (IRB) and will continue to serve on the board of directors. Prior to joining Copernicus, Tomason held positions at Organon, Evans Healthcare and One Call Medical. Tomason also served on the board of directors of several companies, including Pozen, where he served from 1997 to October 2008.

Conditional and Accelerated Approach No Easy Route to Market Success

The accelerated and conditional approval processes are coming under close scrutiny in Europe, raising the possibility of a shake-up in how priority drugs are regulated over the coming months. One casualty could be the randomized clinical trial’s position as the “gold standard” of evidence in assessing drug efficacy.

The U.S. Food and Drug Administration (FDA) pioneered accelerated approval regulation, which offered faster approval for drugs fulfilling unmet clinical needs in treating serious medical conditions. Accelerated approval provided patients with earlier access to promising new treatments. Under the procedure, companies were required to provide further clinical trial data before a conditional authorization could become permanent. In slowly progressing conditions such as cancer, this often requires the use of a surrogate endpoint, rather than a conventional clinical outcome.

The accelerated approval regulation was part of a package of measures that enabled the FDA to halve the time needed to authorize priority drugs in the decade following its enactment. But both industry and patient representatives have complained about the difficulties in achieving the intended goals of this system, particularly in rare conditions with small patient populations. They have highlighted a number of practical problems that have caused the necessary confirmatory studies to take longer than anticipated.

The European Union had the opportunity to learn from the U.S. experience when it introduced its own plans for “accelerated” and “conditional” approval under the revised pharmaceutical regulations of 2005.

The EU’s accelerated approval process is similar to the fast-track system developed by the FDA. It requires the relevant European Medicines Agency (EMEA) committee to give approval within 150 days if the applicant can demonstrate that a drug meets unmet clinical needs or is a significant improvement on the treatments currently available.

The conditional approval process applies to products aimed at the treatment, prevention or diagnosis of seriously debilitating or life-threatening diseases, as well as those used in emergency situations in response to
public health threats and for orphan medicines. It should only be used in situations where the public health benefits outweigh the inherent risks of reduced data and requires the applicant company to carry out further studies to provide comprehensive clinical data.

There is a good deal of crossover between the accelerated and conditional systems. To ensure early availability of its Isentress treatment for HIV infection, Merck Sharp & Dohme (the U.K. subsidiary of Merck & Co.) submitted and received approval using both routes in 2007. It was one of three drugs approved through the conditional process last year, the same number as in 2006. In addition, two products went through the accelerated approval process in each of those years.

Early experience in comparing the U.S. and EU systems shows they are similar, but not the same. There are differences in the kind of data that the two authorities like to see, particularly in the oncology area, according to Gwenan White, a spokesperson for GlaxoSmithKline, which has submitted its metastatic breast cancer treatment Tyverb (Tykerb in the U.S.) or lapatinib for approval on both sides of the Atlantic.

U.S. regulators generally like to receive confirmatory data indicating time to progression of disease, whereas their European counterparts prefer data showing overall survival. Nevertheless, when evaluating Tyverb after it had already been through the U.S. system, the EMEA was prepared to accept data intended to satisfy the FDA's criteria.

“From our point of view, the fact that the EMEA will make exceptions when it recognizes that a product has a positive risk-benefit profile is obviously a good thing,” White explained.

No Easy Route to Market via Conditional Approval

However, GSK was dismayed by the subsequent decision by the UK National Institute for Health and Clinical Excellence (NICE) to block the drug’s use in National Health Service hospitals following a negative health technology assessment (HTA). GSK insists that it is impossible to provide the sort of cost-benefit analysis on which NICE bases its decisions when patients are in end-stage disease. GSK has a right of appeal, and the agency was due to make a final decision at a meeting on November 19.

This demonstration that approval through the EU’s centralized process will not guarantee an easy route to market for conditionally approved drugs came as no surprise to Dr. Richard Tiner, medical director of the Association of the British Pharmaceutical Industry (ABPI), the UK trade association. At the 15th International Conference on Pharmaceutical Medicine, held in Amsterdam in September, he noted the dangers of a disconnect between the centralized procedure and national HTAs.

Although the cost-benefit issue has only arisen so far in the UK, there is potential for similar disagreements in other EU states. Marketing authorization in the UK will normally mean that its doctors are free to prescribe the drug, unless it is assessed and rejected by NICE. In other countries, the license holder has to agree on a price for the medicine with the relevant authorities before it goes on sale. These negotiations can be difficult over relatively mainstream products, let alone the sort of high-cost products intended for narrow patient populations considered in the conditional licensing process. Could these discussions cause significant delays? Quite possibly, Tiner says.

Despite this inauspicious start, Tiner believes that NICE involvement in the authorization of drugs with a conditional license could be beneficial, provided that these economic issues are aired earlier. The 2006 Cooksey report, commissioned by the UK Government to identify ways of stimulating pharmaceutical R&D in that country, suggested that sponsors and NICE discuss the clinical and economic evidence required for authorization before a drug enters phase III trials. The ABPI backs this approach, noting that it gives companies a chance to tackle cost-benefit issues at the time in the drug development process that they are best able to address them.

Expanding the range of products that can be dealt with under conditional licensing arrangements was another important issue addressed by Cooksey. But, because these products are authorized through the centralized process, any changes in the rules would require EU-wide agreement—and that is only likely to be reached if the current arrangements prove successful.

Tiner fears that the fledgling European system may run into the same problems as the FDA process, and companies may have difficulty recruiting enough subjects to provide confirmatory data on efficacy within the timetable demanded by the EMEA.

“If you are a patient with the particular condition for which the medicine has been given its conditional license, then why would you want to take part in a phase III trial?” Tiner asked. “If the only way you are going to get that medicine is to join a trial, then you will accept that you may be given the older control treatment. But if you are suffering from a chronic or life-threatening condition and a new treatment is given a license and becomes freely available, then you will do everything you can to get hold of it.”
Randomized Controlled Trials No Longer “Gold Standard”?  

Tiner’s solution to this conundrum is to slaughter “the sacred cow” of medicines regulations by rejecting randomized controlled trials as the only basis for assessing a drug’s efficacy. He would like confirmatory studies on drugs given conditional licensing to be based on real life data from routine clinical use. 

He acknowledges that interpreting data collected from such a poorly controlled environment would present significant problems. But, as when conducting meta-analyses of conventional trials carried out under entirely different protocols, it is possible for the statisticians to make sense of “dirty data,” Tiner points out. Certainly, there would no longer be concerns about the slow pace of patient recruitment; the great strength of the European central licensing procedure is that it offers immediate access to a potential pool of 500 million patients across the 27 member states. 

Key to the success of this sort of project would be a patient registry recording every detail of the patient’s health status, treatment and response, Tiner said. This resource could probably be based on one of the electronic patient record systems already under development in most EU member states. As a condition of their receiving the drug, patients must agree to be included in the registry and to continue providing information long after treatment has ended. Tiner sees few difficulties in getting such agreements because patients eligible to receive conditionally approved drugs have serious diseases such as cancer, and they and their families are typically willing to help other patients. 

Tiner is not alone in expressing doubts about the position of randomized controlled trials as the gold standard of evidence in assessing drug efficacy. In a recent lecture at the Royal College of Physicians in London, NICE chairman Sir Michael Rawlins highlighted some of the limitations of randomized controlled trials and called for greater weight to be placed on the results of observational studies. 

Randomized controlled trials are often carried out on specific types of patients for a relatively short period of time. But, in clinical practice, the treatment will be used on a much greater variety of patients, many of whom suffer from other medical conditions, and for a much longer time period, Rawlins said. 

“There is a presumption that, in general, the benefits shown in a [randomized controlled trial] can be extrapolated to a wide population. But there is abundant evidence to show that the harmfulness of an intervention is often missed in [randomized controlled trials],” he said. 

Switching over to a new model for collecting and analyzing data on drug safety clearly presents tremendous challenges, especially for those developing the software necessary to gather and process data from each EU state, Tiner noted. “But there is phenomenal potential in such an approach. You would be able to see what is happening in real life and in real time, and if there is a safety problem with a drug, then it would be possible to intervene much earlier.”

—John Bonner
Medical Writing
continued from page 1

Bruno, Ph.D., vice president of regulatory affairs at Kendle. “Their role is really quite pivotal.”

Market Remains Strong

According to CenterWatch analysis, the medical writing market has more than doubled in size during the past five years, increasing from an estimated $345 million in 2003 to $694 million in 2008. In addition, a 2005 CenterWatch Vendor & Outsourcing Survey found that medical writing was the fourth most frequently contracted service from CROs, following monitoring, data management and drug supply management. The same survey reported that 41% of respondents used outsourced medical writing services.

A membership survey conducted in April by the American Medical Writers Association (AMWA) also indicates a robust medical writing market. When asked about the economic prospects for their work, 56% of respondents said they expected their income from medical writing to be higher this year than last, while another 29% expected their income to stay the same. Among freelance medical writers, 42% expected business to be better this year than last, 35% thought it would be the same, and 24% believed their business would be worse.

A third of hiring managers who responded to the AMWA survey said they expect to have larger staffs this year than last, while half of the managers expected steady staffing levels. Another 16% of hiring managers said they anticipated having a smaller staff this year.

CROs report that demand for medical writing services has increased both as part of full-service outsourcing agreements, where the medical writing team produces documents such as protocols and clinical study reports as part of the bundled service for a project, and also for stand-alone medical writing work, such as preparing regulatory documents required in the drug approval process.

“As CRO work across all phases has increased, we’ve seen our work increase as well,” said Mark Dudley, Ph.D., senior director and head of Global Medical Writing at Quintiles. “As the projections for CRO business grows, ours will grow right along with that.”

In addition to the rise in demand for regulatory medical writing, another growth area involves converting data from clinical trials or post-marketing studies into manuscripts in order to publish scientific and clinical findings. Some companies, such as Envision Pharma, a medical and scientific communications company that was acquired by United BioSource Corporation (UBC) in April, specialize in this type of medical writing.

“Many times, companies may not have the resources to develop the publications in-house,” said Thomas Gedney, senior medical writer and editor in the Scientific Solutions division of Envision Pharma. “Our specialization is in bringing people together to work on a publication, to bring it from draft to draft, to take the revisions forward, and then to help provide the knowledge and expertise around various publication guidelines, authorship criteria and journal specifications for styling and submissions.”

Demand for Outsourced Services Increasing

The volume of medical writing has increased in recent years as regulatory authorities require an ever growing amount of documentation during the drug development process. Concerns about clinical trial transparency, and charges that some pharmaceutical companies have suppressed negative study results, have contributed to this tougher regulatory environment. The Food and Drug Administration Amendments Act (FDAAA), for example, which took effect earlier this year, establishes stringent requirements for clinical trial registration and results reporting, a function that fits within the medical writing skill set. “Under ICH [International Conference on Harmonisation] guidance, under transparency rules like FDAAA, and under publication requirements under ICMJE [the International Committee of Medical Journal Editors], you can’t just publish your positive studies. You’ve got to publish everything. That also tends to increase the volume of work that needs to be done,” said Art Gertel, vice president of Strategic
Regulatory Consulting, Medical Writing and Quality Assurance, at Beardsworth Consulting Group.

This greater demand for medical writing services comes at a time when many major pharmaceutical companies, facing economic pressure from expiring patents and emptier product pipelines, have drastically cut jobs. Nearly all of the largest pharmaceutical companies have announced restructuring plans that will eliminate tens of thousands of jobs (Merck recently eliminated 12% of its workforce). This has resulted in an increase in outsourcing R&D activities. “The pharma industry, as well as many other industries, is under a lot of pressure these days to reduce their costs and find other ways to still get the work done that must be done. Outsourcing medical writing is one of the avenues for that,” said Kendle’s Bruno.

Despite the massive layoffs, someone needs to perform the medical writing work, said Beardsworth’s Gertel. “When you are a publicly held company, you have to generate applications for marketing licensure to regulatory authorities. Even if you decide to jettison products from your development pipeline, you still have regulatory obligations to file documents. If a study is withdrawn, you still have to write a safety report or an abbreviated study report or some sort of reckoning of what the risk/benefit was for subjects exposed to your therapeutic intervention. The work doesn’t go away. And if you are reducing your internal forces, one would logically think that you have to go somewhere to get it,” he said.

At the same time the volume of required documents has increased, the industry has seen a trend toward fewer available in-house medical writers. In the 1990s, when technology began to allow writers to work from home, many experienced medical writers began leaving large pharmaceutical companies to establish freelance writing businesses.

The 2008 AMWA survey found that freelance writers comprise the largest percentage of its members; a total of 34% reported they were self-employed. The survey also found that 19% of AMWA members work for pharmaceutical or biotechnology companies, 9% are employed by communications firms that produce regulatory and manuscript documents for the drug industry, 7% of members work for a university or medical school while another 6% write for CROs.

“Once you’ve got 10 to 20 years experience as a medical writer, you can do pretty well and command your own schedule as a freelancer. The really experienced medical writers tend to go off on their own and hang up a shingle, leaving experienced people in-house for pharma companies to rely on. That’s one reason to outsource,” said Beardsworth’s Gertel, who formerly directed the Medical Communications Department at Schering-Plough.

Linda Fossati Wood, RN, MPH, president of Westford, Mass.-based MedWrite, a contract regulatory-writing business, said medical writing lends itself to a freelance business. “There tends to be an ebb and flow in the need for writers within all companies. If you have a permanent staff, there may be times when you don’t have enough work and so you have too many writers. Freelancers are able to fill in and help out when companies have a large submission and suddenly need a greater number of people for a short period of time. That’s why there tends to be a good-sized freelance market in writing,” she said.

**Outsourcing Models for Medical Writing Mixed**

Pharmaceutical and biotechnology companies use a mix of business models to meet medical writing needs. Many large pharmaceutical companies that once had large in-house departments of medical writers are downsizing their medical writing teams due to internal restructuring plans. Other drug sponsors, however, that may have more products coming through the pipeline, continue to advertise for new writers.

Even large pharmaceutical companies with in-house staffs routinely rely on contract medical writers during peak periods; some employ a hybrid approach where regulatory work will be completed in-house, but manuscript and publications work is outsourced. Many smaller pharmaceutical and biotechnology companies, which lack the resources to employ in-house writers, may employ a few senior medical editors to oversee outsourcing efforts and then employ outside contractors for the bulk of their medical writing work.

During the past 18 months, major CROs see Medical Writing on page 10
have seen an increase in pharmaceutical companies requesting a functional service provider (FSP) agreement for medical writing teams, a trend expected to continue as drug sponsors reduce in-house staff and look to outsource an increasing amount of medical writing work. “I’ve seen more and more requests for what are often referred to as functional service provider relationships, where you have a bank of medical writers that work exclusively for a particular customer,” said Kendle’s Bruno. “They work in the customer’s electronic systems or their document management system, they write according to their standards, they sit on their project teams along with other members of the customer’s project team, and sometimes they go to the actual company and work there for certain periods of time at critical points during the writing process.”

Quintiles also reports an increase in requests for dedicated writing teams under some type of FSP agreement. “We’re definitely looking at those to see if that is a viable way of providing medical writing resources for some companies. They are asking for us to provide writers for them full-time. Whether that is a good model to use, or if we should look at unit-based pricing by the study, depends on the amount of guaranteed work,” said Dudley. “It can be an advantage to both parties since we know that we are getting a guaranteed amount of work, and it’s easier for us to look at the number of writers that we need. It’s also better for the provider since they are being asked to forecast their needs so that they can better budget.”

Beardsworth uses a preferred-provider model that allows the CRO to buy back the services of its dedicated medical writers during a drug sponsor’s slow periods. Under this arrangement, Beardsworth dedicates the agreed-upon number of staff to the pharmaceutical or biotechnology company; the writers must be available to the client at all times. However, if the client isn’t using the writers fully, the CRO has the option of buying back their services for other projects.

“We can use them in any way we want just as long as when the client rings the bell, they are available to them. That’s part of the deal,” said Beardsworth’s Gertel.

Another model employed by some organizations involves staff placement where the CRO or other vendor hires freelance medical writers, assumes benefit payments and tax liabilities under Internal Revenue Service law, and then places the team onsite at a pharmaceutical or biotechnology company.

As some pharmaceutical companies pursue bottom-line savings in their outsourcing agreements, many have looked to India for medical writing services as a way to meet development goals. Many large pharmaceutical companies have set up dedicated medical writing departments in India, where the cost of clinical research activities can be reduced anywhere between 35% and 50%.

Global CROs are exploring similar strategies.

Quintiles, for example, is in the planning stages to potentially have a medical writing group in Quintiles India and is assessing candidates for medical writing positions. According to Dudley, the group would complement Quintiles’ data management and statistics group in India to assist in sales to Indian pharma and as an additional resource for the CRO’s global medical writing group.

In addition, several India-based CROs and medical writing companies are positioning themselves to become players in western markets. The Mumbai-based medical communications firm Cactus Communications, for example, just opened an office in Memphis, Tenn., in order to compete for business in North America.

“I’ve spoken with a number of people who represent the medical writing departments in major pharma companies,” said Beardsworth’s Gertel. “They were told by mandate that they had to go to India for medical writing and establish a medical writing presence in India.”

At the moment, results in outsourcing medical writing to India have been mixed. Many pharmaceutical executives have reported that the upfront costs and the learning curve and costs involved in having more experienced staff rewrite some documents produced by Indian writers have resulted in either a zero balance or higher cost. While many industry experts believe that the quality of medical writing from India eventually will improve, the cost of services in the emerging economy also is on
the rise. Some believe that India will ultimately become another resource for medical writers, but outsourcing medical writing work to India may not result in huge savings of time and money.

“lt will be interesting to see if there are other emerging economies that will supplant India. If you look at what other countries have as a basis the English language and a significant number of post-graduates educated in the sciences, there aren’t that many out there,” said Beardsworth’s Gertel. “You may start to see partnerships established among service providers in medical writing where CROs that have a U.S. base may annex an India-based medical writing department. They can essentially hire them as staff, but pay them at a lower salary. It’s an evolving situation.”

As pharmaceutical companies increasingly contract medical writing work to outside vendors—whether they contract work to a large company or many individual writers or they outsource work to domestic writers or those overseas—they must assess the effectiveness of their outsourcing strategy.

“There is a general sense that if a company can’t do something in-house, all you have to do is spend money and send it outside and you can get it done faster because they can throw as many people at it as they want. A problem with that is there are points at which more bodies does not help and often hurts because it takes a certain amount of time to analyze data and understand it,” said Robert J. Bonk, Ph.D., author of the book “Medical Writing in Drug Development: A Practical Guide for Pharmaceutical Research” and associate professor of professional writing at Widener University in Chester, Pa. “For example, if you had 20 laboratory tests, you can’t have 20 writers each analyzing one test and writing it because you need to look at all the tests together. That is an extreme example, but I think there is a point at which you need a limited number of people who really understand the program.”

**Growing Field**

Membership in the AMWA, the organization that sets industry standards for medical writers, has increased 14% during the past four years to nearly 5,700 members in the United States, Canada and 26 other countries. These rising membership numbers reflect steady growth in the medical writing field as the volume of work increases and medical writers are given greater responsibilities.

In another indication of growth in the medical writing field, about two dozen colleges and universities have established either certificate or degree programs in medical or scientific communication in recent years. There also has been an increase in the number of organizations involved with publications-related issues, such as the International Society for Medical Publication Professionals (ISMPP) and The International Publication Planning Association (TIPPA).

“The reasons why the profession is continuing to grow are quality, cost and timelines,” said Sue Hudson, immediate past president of AMWA and owner of Medical Writing Associates of Simi Valley, Calif. “People who can organize information and communicate effectively will produce a better product. Because medical writers are generally paid less than physicians and scientists, they can lower project costs. Finally, medical writers can work faster because they’re dedicated specialists—writing is their primary function. The world seems to know that medical writers are here to stay.”

As the medical writing field has grown, so has the role of medical writers in the drug development process.

“One of our roles is to try to put the results of the clinical studies into a story that can tell what happened with the drug; that is in the clinical study report and the submission documents. We have taken that role over from the clinical people or the biostatisticians, who have done this before we did,” said Quintiles’ Dudley. “Medical writers have to be able to interpret scientific data and statistics and to be able to put that information into a paragraph, rather than just numbers on a table. An important part of what we do is integrate the various parts—the efficacy and the safety data—into a story that tells how the drug behaved in a particular trial.”

When they are brought in at the beginning of a development program or study, medical writers can help streamline the process by helping companies plan for documents, offer insight about what type of data may be needed, and even suggest
Seamless drug development. At Medpace, one of the industry’s most experienced and therapeutically focused clinical trial management teams takes your compound from protocol to study report without the costly detours of extended enrollment timelines or disruptive protocol amendments. Medpace experts have a wealth of experience – as investigators, sponsors and regulatory officials – bringing a multi-dimensional approach to the challenges of clinical development. Not just getting the critical data you need for submission, but putting it in perspective for approval. That’s the advantage of focus.
what type of efficacy measure could be used for the type of disease being studied.

“Certainly from the beginning of either an entire development program or a particular study, it’s important to outline the content and format and the data that are going to be included in the protocol, which is the best place to start. But at the end of the day, you want to ensure you are gathering the right kind of data so that your product labeling truly reflects the information you gather,” said Kendle’s Bruno. “A combination of early involvement by medical writers in the protocol development and creation of a shell of the study report with the kinds of information that will be discussed helps set the stage for our customers to think very analytically along with the writers about what other data to gather. At the end of the day, our customers want to be able to make certain claims about their products. What data do we need to gather? What do we need to be getting in the protocol, how do we explain that in the clinical study report, and how do we explain that further in the risk/benefits section of the NDA [New Drug Application]? Getting medical writers involved early is very important.”

As pharmaceutical companies outsource an increasing amount of their clinical work to Asia, medical writers also find themselves helping non-native English-speaking investigators, statisticians and bench scientists present their data in documents clearly. Another important role that medical writers routinely fill but that isn’t always acknowledged is quality assurance. “Certainly companies have quality departments and quality control, but when a medical writer is working with information from a clinician or a statistician, if things don’t make sense to the medical writer, then chances are it may not make sense to someone else or there could possibly be a flaw somewhere that wasn’t caught. They often serve that role of going back and seeking clarification on points,” Bonk said.

Medical writers also check the reliability of references, make sure manuscripts have internal consistency and double-check data in manuscripts against the source documentation, said AWMA president Cindy Hamilton, PharmD, principal of the Virginia-based Hamilton House, a medical writing business that specializes in helping authors prepare manuscripts for publications. “We try to provide a lot of quality control that might not happen otherwise,” she said.

**Looking Ahead**

As long as regulatory authorities continue to require an increasing amount of documentation as part of the drug approval process, industry experts believe the demand for medical writing will continue to grow. Yet the role of medical writers is often undervalued and misunderstood, as highlighted by recent controversies concerning ghost-writing for scientific publications. One of the challenges facing the profession involves education about medical writers contributions to both the development of new drugs and disseminating information about the products after clinical trials are completed. “It’s definitely a field that is here to stay,” said Envision Pharma’s Gedney. “The biggest challenge will be the recognition that a highly skilled communicator is part of the clinical publication team in the same way as highly skilled statisticians or the people who design the clinical trials. All of these folks lend a level of expertise.”

— Karyn Korieth
Veterans Affairs (VA) and the National Committee for Quality Assurance (NCQA) created an accreditation program for VA hospitals that eventually became the Partnership for Human Research Protection (PHRP). Although backed by leaders from some of the nation’s top universities, teaching hospitals, institutional review boards (IRBs) and patient and disease advocacy programs, AARPP didn’t have the advantages of PHRP’s VA contract.

Perhaps of more concern, however, was that accreditation was completely voluntary, so, although most research organizations viewed accreditation as valuable, they weren’t required to seek it. The new accreditor faced two big questions: How will two accreditors survive in a relatively small market and will any but the largest, most forward-thinking research organizations invest the time and money needed to achieve accreditation?

Fast forward to today and AARPP is not only surviving but thriving. Rather than struggling to prove its viability, AARPP is increasingly recognized as the seal of approval in human subject research, and the 2005 dissolution of PHRP has only increased AARPP’s influence.

When AARPP launched, its first accredited organizations comprised several market segments (e.g., teaching hospitals, universities, and IRBs) based on the association’s founding members. Today, those markets have expanded and grown to include 138 parent organizations, representing more than 600 entities from almost every type of human research organization.

Universities and Teaching Hospitals

AARPP accreditation in academia was a natural fit early on because many of AARPP’s founding members were leaders of universities, medical schools and teaching hospitals.

Of the 138 AARPP-accredited organizations today, 49 are universities. Almost one-third of the country’s medical schools and nearly 40% of the clinical research-intensive universities are AARPP-accredited, according to AARPP president and CEO Marjorie Speers. Based on the number of these organizations that have committed to seeking accreditation in the coming years, Speers estimates that by the end of 2010, almost 80% of eligible universities will have completed the accreditation process.

“If you talk to most universities today, most of them feel the need to get accredited because they see that this is the way of the future and they want to be part of this group. Certainly among the universities, peer pressure is driving this process now as much as anything,” Speers explained.

Mid-size universities that conduct behavioral and social science research are among the academic institutions that are now feeling that peer pressure, Speers said. She estimates that there are 300 mid-size universities eligible for accreditation, several of which are already in the process of applying. This segment of academia is expected to be a growth area for AARPP, especially as more and more mid-size universities become accredited.

Teaching hospitals earn accreditation in one of two ways: either as part of an affiliation with an accredited university or by seeking accreditation independently. To date, AARPP has accredited 16 independent teaching hospitals. When combined with the

<table>
<thead>
<tr>
<th>Active Protocols</th>
<th>2009 Application Fee</th>
<th>Active Protocols</th>
<th>2009 Application Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0 *</td>
<td>$6,400</td>
<td>Level 9</td>
<td>3,501 - 4,000</td>
</tr>
<tr>
<td>Level 1</td>
<td>1-100</td>
<td>Level 10</td>
<td>4,001 - 4,500</td>
</tr>
<tr>
<td>Level 2</td>
<td>101-500</td>
<td>Level 11</td>
<td>4,501 - 5,000</td>
</tr>
<tr>
<td>Level 3</td>
<td>501-1,000</td>
<td>Level 12</td>
<td>5,001 - 5,500</td>
</tr>
<tr>
<td>Level 4</td>
<td>1,001-1,500</td>
<td>Level 13</td>
<td>5,501 - 6,000</td>
</tr>
<tr>
<td>Level 5</td>
<td>1,501 - 2,000</td>
<td>Level 14</td>
<td>6,001 - 6,500</td>
</tr>
<tr>
<td>Level 6</td>
<td>2,001 - 2,500</td>
<td>Level 15</td>
<td>6,501 - 7,000</td>
</tr>
<tr>
<td>Level 7</td>
<td>2,501 - 3,000</td>
<td>Level 16</td>
<td>7,001+</td>
</tr>
<tr>
<td>Level 8</td>
<td>3,001 - 3,500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Organization that relies entirely on the services of one or more external IRBs that are accredited by AARPP. Source: AARPP 2008

Industry Reports
number of teaching hospitals that are accredited through a university, Speers estimates that AAHRPP has accredited 60% of the hospitals conducting research, and she expects to see that number grow in the future.

**Community Hospitals**

Another market in which AAHRPP hopes to grow is community hospitals, which are often smaller and therefore lack the resources necessary to pursue accreditation.

Newton-Wellesley Hospital (NWH) in Newton, Mass., was one of the first community hospitals to seek accreditation, and it was one of the first 14 organizations of any type to be accredited by AAHRPP. Although accreditation was relatively new (especially for smaller community hospitals), NWH executives saw it as a business necessity if they wanted to compete with bigger research programs.

“We wanted to make sure that, as we were growing our program, we were growing it in a way that was going to protect our human subjects,” said Hope Violette, manager of NWH’s Office of Research. “We wanted to assure ourselves, we wanted to assure our investigators, we wanted to assure our sponsors that even though we aren’t large in terms of numbers we certainly have the infrastructure to provide the same protections as a larger program.”

NWH’s application process took almost 18 months to complete. Much of that time was spent completing AAHRPP’s required self-evaluation, a process in which organizations are encouraged to find—and fix—organizational shortcomings.

“We looked for big gaps first, and, once we thought we got some of those things resolved and had systems in place to address those, we went back and went standard by standard by standard through the process,” Violette said.

This step-by-step self evaluation (also required as part of AAHRPP’s triennial reaccreditation process) is one of accreditation’s biggest benefits, Violette said, because it provides organizations with a systematic method for reviewing policies and procedures on a periodic basis—a review that might not otherwise occur if not required by AAHRPP.

Accreditation gives NWH a slight advantage when dealing with clinical trial sponsors, Violette said, an advantage that is especially important as a smaller organization.

“I don’t know that we’re at the point yet where the sponsors are just going to the accredited organizations and not going to other organizations … But I do know the other way around, when the sponsor comes to us, they are pleased by the fact that we’re an accredited organization, and I do think it holds some weight,” Violette said.

**Independent IRBs**

To earn AAHRPP accreditation, a research institution must use only accredited institutional review boards (IRBs) or be able to demonstrate that the IRBs they use meet all the standards of an accredited IRB. This is fairly simple for universities or teaching hospitals, which often have their own IRBs, but independent research sites or contract research organizations (CROs) usually work with numerous independent, or central, IRBs, many of which may not be accredited.

To these organizations, the process of seeking accreditation and switching all their work over to the handful of accredited IRBs may be overwhelming or prohibitive—unless more independent IRBs become accredited. Therefore, increasing the number of accredited independent IRBs was one of AAHRPP’s earliest strategic goals.

Speers estimates that there are approximately 35 independent IRBs (a number that she said changes almost daily), nine of which are accredited. AAHRPP’s eventual goal is to accredit 80% of the country’s independent IRBs.

Wellesley, Mass.-based New England Institutional Review Board (NEIRB) and Columbia, Md.-based Chesapeake Research Review (CRRI) were among the first independent IRBs to be accredited by AAHRPP.

Although only one other IRB (Western IRB in Olympia, Wash.) had achieved AAHRPP accreditation in 2003, the CEO of NEIRB at that time saw accreditation as an opportunity to improve the IRB’s processes, said NEIRB director of operations Erin Bowers. A number of programs and procedures now in place at NEIRB resulted from the process of pursuing AAHRPP accreditation.

see AAHRPP on page 16
“Before 2003, we didn’t have a site-visiting program, so if we thought a site was out of compliance, we didn’t have any ability to actually go there and see what was going on,” Bowers said. “We implemented a nationwide program where we can go check out compliance at sites. That was required for us [by AAHRPP].”

CRRI, accredited in 2004, was one of the only independent IRBs to seek and achieve both AAHRPP and PHRP accreditation. Although a stringent believer in the safety and quality assurance benefits of an accreditation program, CRRI founder and CEO Dr. Felix Kihn-Maung-Gyi said organizations like his have only just begun to see the business benefits of accreditation.

“Whereas five years ago, I think most folks were saying, ‘We’re not interested because it doesn’t translate to increased business opportunities,’ I think today they are starting to realize that there may be better business opportunities if they are accredited,” Gyi said.

CROs and Private Research Sites

CRRI saw one of those business opportunities come to light in 2006 when it partnered with Montreal-based contract research organization (CRO) ethica Clinical Research to deliver ethics review services to both Canada and the United States.

ethica is the only CRO to be AAHRPP-accredited, but others are going through the application process, according to Speers. AAHRPP’s ultimate goal is to have 80% of CROs be accredited.

“If you focus on who in the research enterprise potentially poses the most risk to research subjects—who has the greatest influence over research subjects—it would be independent IRBs because they review so much of the research for industry and it would be CROs because CROs are managing so much of the research.”

In September, AAHRPP accredited its first independent investigative research facility, HOPE Research Institute of Arizona. As the first private research site to be accredited, HOPE undertook a challenging year and a half process of documenting procedures and reorganizing relationships with IRBs, according to HOPE’s managing partner Patricia Adams.

“We do 40 to 50 trials at any given time, and we were using a number of IRBs that weren’t AAHRPP-accredited. We had to evolve our studies and, as we started new studies up, encourage our sponsors to use only accredited IRBs,” Adams said.

Speers believes the accreditation process for CROs and independent research facilities will get easier as more organizations go through it and as more independent IRBs achieve accreditation.

Government Agencies

Although the U.S. government doesn’t require all human research programs to be accredited, it does require accreditation for all the medical centers within the Department of Veterans Affairs. The dissolution of PHRP opened the door for AAHRPP to move in and accredit those medical centers.

Of the 93 VA medical centers that are separately eligible for accreditation, all have applied and undergone site visits, and, to date, 57 have achieved accreditation. (None have been denied, but some are still undergoing the process.) The National Institutes of

<table>
<thead>
<tr>
<th>Active Protocols</th>
<th>2009 Application Fee</th>
<th>Active Protocols</th>
<th>2009 Application Fee</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 0</td>
<td>*</td>
<td>Level 9</td>
<td>3,501 - 4,000</td>
</tr>
<tr>
<td>Level 1</td>
<td>1-100</td>
<td>Level 10</td>
<td>4,001 - 4,500</td>
</tr>
<tr>
<td>Level 2</td>
<td>101-500</td>
<td>Level 11</td>
<td>4,501 - 5,000</td>
</tr>
<tr>
<td>Level 3</td>
<td>501-1,000</td>
<td>Level 12</td>
<td>5,001 - 5,500</td>
</tr>
<tr>
<td>Level 4</td>
<td>1,001-1,500</td>
<td>Level 13</td>
<td>5,501 - 6,000</td>
</tr>
<tr>
<td>Level 5</td>
<td>1,501 - 2,000</td>
<td>Level 14</td>
<td>6,001 - 6,500</td>
</tr>
<tr>
<td>Level 6</td>
<td>2,001 - 2,500</td>
<td>Level 15</td>
<td>6,501 - 7,000</td>
</tr>
<tr>
<td>Level 7</td>
<td>2,501 - 3,000</td>
<td>Level 16</td>
<td>7,001+</td>
</tr>
<tr>
<td>Level 8</td>
<td>3,001 - 3,500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Organization that relies entirely on the services of one or more external IRBs that are accredited by AAHRPP. Source: AAHRPP
Health and the Centers for Disease Control, both part of the Department of Health and Human Services, are undergoing the accreditation process now, as are the national laboratories of the Department of Energy (one national laboratory is already accredited).

“The one department that is not accredited is the Department of Defense,” Speers said. “We’re hoping that they will come on board and seek accreditation over the next couple of years.”

Room to Grow

Although Speers is pleased with AAHRPP’s progress to date, she says there are still market segments in which to grow.

Opportunities for growth beyond the United States remain to be seen. AAHRPP has accredited one organization each in Canada, Singapore and Korea, and Speers says the association is working in a number of other countries in Asia, Europe and South America.

“With the exception of Canada, the attraction to AAHRPP [for institutions outside the United States] is that AAHRPP accredits a foreign institution according to the U.S. regulations as well as to any in-country code. A number of institutions want to attract industry sponsors to their institution, and AAHRPP is a very good way for them to show that they can meet the U.S. standards for conducting research,” Speers said.

One state department of health—in Florida—has achieved AAHRPP accreditation, and Speers sees state government agencies as a critical market for AAHRPP’s growth.

“It’s important for state health departments to get accredited because they generally perform research on vulnerable populations—people of lower income or lower educational achievement…I think it’s really important for state health departments to have good protection programs in place,” Speers said.

Another potential market segment for accreditation is sponsors, but pharmaceutical companies have been slow to seek accreditation for their own research. One sponsor is currently in the process of applying for accreditation, Speers said, and she expects to see others.

Industry leaders such as Hope Violette at Newton Wellesley Hospital say sponsors still have much to learn about AAHRPP accreditation and what it really means.

“[Sponsors] don’t understand the difference between the whole program is accredited versus just the IRB. Most of them really do believe that it’s just your IRB that is accredited and they don’t understand the scope of accreditation. We’re making progress, but I think we have a ways to go in terms of the sponsors really understanding what that means,” she said.

Looking Ahead

Regardless of how many organizations say accreditation is a good idea, the fact remains that it is voluntary and it takes valuable resources. Conducting the initial self-evaluation required to apply for accreditation can take a significant amount of time—anywhere from a few months to two years—and, according to the AAHRPP web site, application fees start at $6,900—a number that goes up depending on the size and complexity of the human research protection program. That price doesn’t include the annual accreditation fee that organizations must pay once they are accredited or the time involved in seeking initial accreditation, submitting the required annual reports, and applying for re-accreditation every three years.

“Until we really see a demonstration from the part of the sponsors seeking only accredited organizations, I think smaller research groups are going to have a hard time justifying return on investment based solely on mission and value statements as opposed to true dollars and enhanced revenues. I think that that’s where the real crux is: What makes [accreditation] valuable for a small organization other than to have that stamp of good-housekeeping approval?” said CRRI’s Gyi.

AAHRPP highlights several benefits to AAHRPP accreditation, including partnership and marketing opportunities, competitive advantages and improved performance in FDA audits, but accredited organizations themselves say they’ve seen more of the internal benefits of accreditation—benefits that can’t always be seen in revenue statements.

As the number of accredited organizations continues to grow, the big question is whether the business benefits of accreditation will continue to grow, as well.

— Molly Rowe
Juvenile arthritis (JA), which is any type of arthritis or arthritis-related condition in young people under 18 years of age, affects approximately 294,000 children in the United States, according to the Arthritis Foundation. Typical symptoms are joint pain, swelling, tenderness and stiffness, which must be confirmed by physical examination. Ultimately, JA may progress to cause restricted range of motion, contracture, damage, deformity and/or altered growth of affected joints.

Polyarticular juvenile rheumatoid arthritis (JRA) is more common in girls and usually affects at least five joints, particularly the knees, wrists and ankles. Other forms of JA are juvenile idiopathic arthritis (JIA), with a similar joint distribution but with involvement of only four or fewer joints. JIA is sometimes accompanied by uveitis (eye inflammation), especially in young girls with positive anti-nuclear antibodies (ANA).

Systemic onset JRA or JIA may be associated with high, spiking fevers, rash on chest or thighs, and arthritis in the small joints. Because of their systemic nature, outcomes are poor and these conditions often respond poorly to treatment. Other forms of JA include the juvenile spondyloarthropathies involving the spine and legs, juvenile psoriatic arthritis, juvenile dermatomyositis and juvenile systemic lupus erythematosus.

Diagnosis of JA is based on history and examination, as well as laboratory markers of inflammation and often imaging procedures such as joint X-rays, ultrasound, CT scan and/or MRI scan. Most forms of JA should be managed by a pediatric rheumatologist, with treatment goals including control of joint inflammation and swelling, pain relief, preventing joint damage and optimizing functional abilities.

In addition to pharmacotherapy, exercise, physical and occupational therapy, patient education, eye and dental care, and proper nutrition may be helpful.

To help manage pain and inflammation, nonsteroidal anti-inflammatory drugs (NSAIDs) are the first line of therapy, with oral or intra-articular corticosteroids sometimes needed for refractory inflammation. However, these manage only the symptoms and do not affect disease progression.

Because JA is a disorder of the immune system, treatments are being developed that inhibit tumor necrosis factor (TNF) or other immune system proteins known as cytokines, which mediate inflammation. When TNF inhibition is ineffective, another approach is to target other cytokines such as interleukin-1 (IL-1). The pathophysiology of JIA in particular may involve IL-1.

Currently available formulations of cytokine inhibitors must be administered subcutaneously or intravenously. To reduce joint inflammation and help prevent bone and cartilage damage, methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs) may be used, although adverse events are a concern, particularly in the pediatric population.

CenterWatch has identified a pipeline of 11 drugs in various stages of development for JA. Not surprisingly, given the autoimmune basis of JA, most of these are monoclonal antibodies or other immune system modulators.

Etanercept, in phase IV development by Amgen, is a fully human anti-TNF-alpha protein that binds to and deactivates some TNF-alpha molecules before they can initiate an inflammatory cascade. It is FDA-approved for symptom control in moderately to severely active polyarticular JIA in patients at least two years of age. However, serious infections, including bacterial sepsis and tuberculosis, requiring hospitalization or leading to death have been reported in patients treated with etanercept.

Another anti-TNF-alpha agent, in phase III testing by Abbott/Eisai, is adalimumab. This self-injectable recombinant human monoclonal antibody can help relieve the signs and symptoms of moderate to severe polyarticular JIA. It should be used only in children at least four years of age, either alone or with methotrexate or other drugs. As with etanercept, serious, sometimes fatal, infections may occur with use of adalimumab. Other serious adverse events may include lymphoma, non-melanoma skin cancer, serious allergic reaction, nervous system disease, hematological disease, heart failure or immune reactions including lupus-like syndrome.

Centocor's version of an anti-TNF-alpha monoclonal antibody, which was first in its class, is infliximab, in phase III testing for JA and in phase II/III testing for juvenile spondyloarthropathies. Clinical trials in more than 900,000 patients during the past 15 years have shown that this drug is safe and effective for adult forms of arthritis as well as in Crohn's disease. However, adverse events are similar to those reported with etanercept and adalimumab.

Another type of injectable humanized monoclonal antibody is tocilizumab, in phase III development for JA by Roche/Chugai. This antibody affects the immune response by targeting the anti-interleukin-6 receptor, with demonstrated safety and efficacy in patients with rheumatoid arthritis refractory to methotrexate.

Amgen is developing an intravenously
injected, recombinant, nonglycosylated form of human anti-interleukin-1 (IL-1) receptor known as anakinra, currently in phase II/III trials. Studies in adult rheumatoid arthritis (RA) suggest that patients who fail to respond to anti-TNF therapy may respond to IL-1 inhibition. In adults, anakinra is indicated to reduce signs and symptoms and to slow the progression of joint damage in patients with moderately to severely active RA unresponsive to treatment with one or more DMARDs.

Anakinra can be used as monotherapy or combined with DMARDs other than TNF-blocking agents. Like other immune system modulators, it has been linked to serious infections. Other adverse effects may include injection-site reactions, worsening of RA, headache and flu-like symptoms.

Rilonacept, in phase II testing by Regeneron, is a fusion protein IL-1 antagonist that acts as a high affinity ligand trap, binding to and neutralizing IL-1 before it can attach to cell-surface receptors and trigger inflammation.

Canakinumab is a subcutaneously administered, fully human anti-IL1 beta monoclonal antibody in phase I/II trials by Novartis. Early trials suggest that canakinumab can rapidly achieve at least 50% control of symptoms in more than half of children with systemic JIA. Treatment was well-tolerated, with upper respiratory tract infection being the most frequently reported adverse event.

Italfarmaco is in phase II development of ITF-2357, an orally administered anti-inflammatory agent that suppresses inflammatory cytokines including TNF and IL-1, thereby quenching immune system reactions. It also brings about apoptosis, or programmed cell death, making it potentially useful in cancer therapy. The mechanisms of action of this hydroxamic acid derivative include inhibiting the expression of B1 kinin receptors and histone deacetylase.

Sulfasalazine, which also reduces synthesis of inflammatory mediators and inflammatory cytokines, is a derivative of 5-acetylsalicylic acid. It is FDA-approved for ulcerative colitis, which is also an autoimmune disorder, and it is in phase I testing for JA by Pfizer. The drug should not be given to patients with intestinal or urinary obstruction or those with porphyria, and it should be used only with caution in patients with liver or kidney damage or blood disorders.

Because one of the complications of JA may be altered joint growth resulting in short stature, human growth hormone may be an interesting approach to treatment. Pfizer is in phase III trials with genotropin, a recombinantly produced somatotropin with an amino acid sequence identical to that of human growth hormone.

Injectable genotropin is FDA-approved to treat growth failure in other conditions, and treatment to date of more than 60,000 children with these conditions has shown that it is safe and effective. Side effects may include injection site reactions, changes in body composition, headache, blood in the urine, hypothyroidism and mildly increased blood sugar.

Like other disorders associated with abnormal immune system hyperactivity, JA may respond to immune system modulators. Most of these are monoclonal antibodies acting to suppress inflammatory cytokines. Because of their effects on the immune system, however, they can be associated with potentially dangerous adverse events such as tuberculosis, other serious infections and lymphoma. Especially in young people, careful monitoring is warranted to determine long-term complications of immunologically active agents.

—Laurie Barclay, M.D.
## In the Pipeline: Juvenile Arthritis

<table>
<thead>
<tr>
<th>Drug</th>
<th>Company</th>
<th>Contact</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Pfizer</td>
<td>(212) 733-2323 <a href="http://www.pfizer.com">www.pfizer.com</a></td>
<td>a 5-ASA derivative; reduces the synthesis of inflammatory mediators and inflammatory cytokines</td>
</tr>
<tr>
<td><strong>Phase I/II</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>canakinumab</td>
<td>Novartis</td>
<td>(862) 778-8300 <a href="http://www.novartis.com">www.novartis.com</a></td>
<td>a fully human anti-IL1 beta antibody</td>
</tr>
<tr>
<td><strong>Phase II</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ITF-2357</td>
<td>Italfarmaco</td>
<td>+39 2 64 43 2300 <a href="http://www.italfarmaco.com">www.italfarmaco.com</a></td>
<td>an orally available apoptosis-inducing cytokine suppressive anti-inflammatory agent and hydroxamic acid derivative that inhibits the expression of B1 kinin receptors and histone deacetylase</td>
</tr>
<tr>
<td>rilonacept</td>
<td>Regeneron</td>
<td>(914) 345-7400 <a href="http://www.regeneron.com">www.regeneron.com</a></td>
<td>a protein IL-1 antagonist that acts as a high affinity ligand trap</td>
</tr>
<tr>
<td><strong>Phase II/III</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>anakinra</td>
<td>Amgen</td>
<td>(805) 447-1000 <a href="http://www.amgen.com">www.amgen.com</a></td>
<td>an intravenous recombinant, nonglycosylated form of human interleukin-1 receptor antagonist</td>
</tr>
<tr>
<td>infliximab</td>
<td>Schering Plough</td>
<td>(908) 298-4000 <a href="http://www.schering-plough.com">www.schering-plough.com</a></td>
<td>an anti-TNF alpha monoclonal antibody; for juvenile spondyloarthropathies</td>
</tr>
<tr>
<td><strong>Phase III</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>adalimumab</td>
<td>Abbott/Eisai</td>
<td>(847) 582-2000 <a href="http://www.abbott.com">www.abbott.com</a></td>
<td>a self-injectable recombinant human monoclonal antibody that binds to and neutralizes TNF-alpha</td>
</tr>
<tr>
<td>infliximab</td>
<td>Centocor</td>
<td>(610) 651-6000 <a href="http://www.centocor.com">www.centocor.com</a></td>
<td>an anti-TNF alpha monoclonal antibody</td>
</tr>
<tr>
<td>genotropin</td>
<td>Pfizer</td>
<td>(212) 733-2323 <a href="http://www.pfizer.com">www.pfizer.com</a></td>
<td>a recombinantly produced somatropin with an amino acid sequence identical to that of human growth hormone</td>
</tr>
<tr>
<td>tocilizumab</td>
<td>Roche/Chugai</td>
<td>+41-61-688 1111 <a href="http://www.roche.com">www.roche.com</a></td>
<td>an injectable humanized anti-interleukin-6 receptor monoclonal antibody.</td>
</tr>
<tr>
<td><strong>Phase IV</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etanercept</td>
<td>Amgen</td>
<td>(805) 447-1000 <a href="http://www.amgen.com">www.amgen.com</a></td>
<td>a fully human anti-TNF receptor</td>
</tr>
</tbody>
</table>

*Note: If you would like further information on any drug listed above, or to review our comprehensive database of drugs in development, please visit www.centerwatch.com.*
TrialWatch

TrialWatch is designed to help sponsors and CROs identify a pool of investigators for their upcoming trials. Each sponsor that is listed here has confirmed that it will be actively selecting sites during the next few weeks and would like to receive inquiries from investigative sites. Sponsors and CROs that would like to use this service should contact the CenterWatch Customer Support Team at Trialwatch@centerwatch.com. Visit our website at www.centerwatch.com/professional/trialwatch.html to use TrialWatch online.

For investigators, this listing provides pre-qualified leads for clinical grants. Please note: Unless a phone or fax number is given, do not call the sponsor or CRO. Sponsors have provided this information to CenterWatch with the understanding that investigative sites will mail cover letters, CVs and other information about their facilities, staff and patients. Please inform the sponsor or CRO that you learned of the project through CenterWatch.

Investigators—Have you called a sponsor in this issue of TrialWatch and learned that the sponsor is no longer seeking sites? If so, please call (617) 948-5100 or toll free (866) 219-3440, Option #3, to let us know so that we may contact the sponsor and update our listings accordingly.

Multiple Therapeutic Areas

New Leads

Welch Allyn
619 Jordan Road
Skaneateles Falls NY 13153
Name: Karen Czerniel
Email: czernielke@welchallyn.com
Device: Not available
Indications: Device Trials
Speciality: All
Phase: All
Notes: We are seeking sites to perform medical device trials.

Welch Allyn
4619 Jordan Road
Skaneateles Falls NY 13153
Name: Karen Czerniel
Email: czernielke@welchallyn.com
Device: Not available
Indications: Device Trials
Speciality: All
Phase: All
Notes: We are looking for sites/PI's interested in conducting device clinical trials.

Still Seeking Investigators

AstraZeneca
Egide Van Oppemstraat 110
1180 Ukkel Belgium
Name: Ilya De Schepper
Email: ilya.deschepper@astrazeneca.com
Drug name: Not applicable
Indications: All
Speciality: Belgian Investigators/
Phase: All
Notes: Join the Kendle investigator team as we study breakthrough therapeutic agents. Our teams of Investigator professionals play a critical role in the advancement of medical science across the world. Please send an email to investigators@kendle.com to be contacted regarding joining our Investigator team.

Welch Allyn
4619 Jordan Road
Skaneateles Falls NY 13153
Name: Karen Czerniel
Email: czernielke@welchallyn.com
Device: Not available
Indications: Not applicable
Speciality: Multi
Phase: III
Notes: We are looking for sites/PI’s interested in conducting device clinical trials.

Kendle International
1200 Carew Tower,
441 Vine Street
Cincinnati OH 45202
Name: Karen Kempf
Email: kempf.karens@kendle.com
Device: Not applicable
Indications: Any
Speciality: Some key specialities being sought are: Rheumatologists,

Gastroenterologists, Oncologists,
Hematologists, Pediatricians,
Allergists, Acute Neurologists,
Internal Medicine, OB/GYN,
Women’s Health
Phase: I- IV
Notes: Join the Kendle investigator team as we study breakthrough therapeutic agents. Our teams of Investigator professionals play a critical role in the advancement of medical science across the world. Please send an email to investigators@kendle.com to be contacted regarding joining our Investigator team.

Welch Allyn
4619 Jordan Road
Skaneateles Falls NY 13153
Name: Karen Czerniel
Email: czernielke@welchallyn.com
Device: Not available
Indications: Cardiac, pulm onary, neonatology, pediatrics, emergency
Speciality: Device experienced researchers
Phase: Class I & II Device
Notes: Seeking device-experienced/interested clinical researchers for upcoming studies. Class I & II in neonatal, pediatric and adult populations; AMC, hospital and private practice settings.

Cardiology/Vascular Disease

Still Seeking Investigators

ICON Clinical Research
4350 La Jolla Village Dr, Ste 400
San Diego CA 92122
Name: Angelo Evans
Email: angelo.evans@iconplc.com
Drug name: AVE 5026
Indications: VTE Prevention
Speciality: Cardiologists, Pulmonologists, Internists, Family Practioners
Phase: III
Notes: ICON Clinical Research is currently recruiting sites for a phase III clinical study on the safety and efficacy of an investigational drug in the prevention of venous thromboembolism (VTE) in...
Grant Opportunities

Merck & Co. Inc.
351 N. Sumneytown Pike
North Wales PA 19454
Name: Julie Kennedy
Email: julie_kennedy@merck.com
Drug name: Prolipostat
Indications: Hypercholesterolemia
Speciality: Endocrinologist & Diabetologist
Phase: III
Notes: Seeking Indian investigators

Nicholas Piramal India Ltd.
Name: Anjali Sonawane
Email: asonawane@nicholaspiramal.co.in
Drug name: Niyat (Atrovastatin+Niacin)
Indications: Hypercholesterolemia
Speciality: Cardiovascular
Phase: II
Notes: Potential investigators in New York state, with potential IRBs in the same area

Parexel International
Watford Road
HA1 3UJ UK
Name: Jovita Amadi
Email: joveeangel@yahoo.com
Drug name: Prolipostat
Indications: Hypercholesterolemia
Speciality: Cardiovascular
Phase: II
Notes: Potential investigators in New York state, with potential IRBs in the same area

Tasly Pharmaceuticals, Inc.
One Research Court, Suite 450-54
Rockville MD 20850
Name: Jason Guo
Email: jxguo@gmail.com
Drug name: T89
Indications: Prevention of occurrence of stable angina
Speciality: PI specializing in cardiovascular disease (angina), in a hospital, university, or medical research centers
Phase: II/IIb
Notes: 2-herb drug for chronic stable angina. Open, 500mg, baseline-controlled. 40 patients. Patients take T89, stop long term nitrate, reduce current anti-angina to 50% on day 0, and to 0% on day 28 if justified, free to use on-demand nitrate as needed. Exercise treadmill testing on days -14, 0, 28 & 56. Emergency Medicine

Still Seeking Investigators

Wyeth
Ctra,N-I, KM. 23 Desvio Algete, km1. 28700
S. Sebastian de los reyes
Madrid Spain
Name: Luisa Rodriguez Pose
Email: rodrigl4@wyeth.com
Drug name: Sitagliptin phosphate
Indications: Type 2 Diabetes Mellitus in moderate and severe renal insufficiency; Type 2 Diabetes Mellitus in End Stage Renal Disease
Speciality: Endocrinologist & Diabetologist
Phase: III
Notes: When responding, please specify which of the two studies you’re interested in. The first study involves patients 30-years-old and above with T2DM who are on dialysis for at least 6 months with uncontrolled HbA1c. In both studies, patients are either off their AHA therapy or currently on oral AHA therapy. Patients on insulin are excluded. Enrollment period is until end of 4Q 2008.

Endocrinology

New Leads

SMO Clinical Research India Pvt. Ltd.
335, 14th Main, Sadashivnagar, RMV Extension,
Bangalore 80 INDIA
Name: Guru Murthy
Email: gurumurthy@smo-india.com
Drug name: Not available
Indications: Diabetes Mellitus Type 2
Speciality: Endocrinologist & Diabetologist
Phase: III

Still Seeking Investigators

AlthoTech Pharmaceutical Inc.
310 Glen Manor Dr. W.
Toronto Ontario M4E 2X7 Canada
Name: Peter Tomlinson
Email: althotech@rogers.com
Drug name: ATPI-C01
Indications: Treatment of ischemic and neuropathic foot ulcers
Speciality: Clinical diabetologist; clinical dermatologist
Phase: I
Notes: ATPI-C01 is a patented intralethal formulation of EGF for treating diabetic foot ulcers. Treatment effective in end-stage DFU sized from 1-80cm², where the amputation is the only available choice.

Biodel
6 Christopher Columbus Ave.
Danbury CT 06810
Email: clinicaltrials@biodel.com
Drug name: Not available

Indications: Diabetes
Speciality: Endocrinology
Phase: III

Merck & Co., Inc.
126 East Lincoln Ave., Maildrop RY34-A104
Rahway NJ 07065
Name: Catherine Anderson
Email: catherine_anderson@merck.com
Drug name: Sitagliptin phosphate
Indications: Two studies: 1. Type 2 Diabetes Mellitus in moderate and severe renal insufficiency; 2. Type 2 Diabetes Mellitus in End Stage Renal Disease
Speciality: Nephrology, Endocrinology
Phase: III
Notes: When responding, please specify which of the two studies you’re interested in. The first study involves patients 30-years-old and above with T2DM who are on dialysis for at least 6 months with uncontrolled HbA1c. In both studies, patients are either off their AHA therapy or currently on oral AHA therapy. Patients on insulin are excluded. Enrollment period is until end of 4Q 2008.

Sanofi Aventis
Great Valley
Malvern PA
Name: Allen
Email: allen.anyabolu@sanofi-aven-tis.com
Drug name: SSRI80575
Indications: Diabetic peripheral neuropathy
Speciality: Neurology, endocrinology
Phase: Iib
Notes: The sites will be required to perform 4 skin biopsies, (2)Nerve Conduction Studies (NCS), Total Neuropathy Scores, and capsaicin placement and removal. In addition, there is a central ECG and laboratory, and central vendors for the biopsy evaluations and the NCS.

Gastroenterology

New Leads

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Dr.
Los Angeles CA 90045
Name: Roland Strickland
Email: roland.strickland@siemens.com
Drug name: Not available
Indications: Celiac Disease determination
Speciality: Gastroenterologist
Phase: Not applicable
Notes: Seeking PI/trial sites for collection / testing of serum samples from celiac disease patients. Samples will be used for validation of immunoassays for Anti-Gliadin IgA/IgG and Anti-tTg IgA antibodies.

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Dr.
Los Angeles CA 90045
Name: Roland Strickland
Email: roland.strickland@siemens.com
Drug name: Not available
Indications: Celiac Disease determination
Speciality: Gastroenterologist
Phase: Not applicable
Notes: Seeking PI/trial sites for collection / testing of serum samples from celiac disease patients. Samples will be used for validation of immunoassays for Anti-Gliadin IgA/IgG and Anti-tTg IgA antibodies.

Still Seeking Investigators

Alba Therapeutics
800 W. Baltimore Street, Suite 400
Baltimore MD 21201
Name: Kate Huber
Email: khuber@albatherapeutics.com
Drug name: Larazotide acetate
Indications: Celiac Disease determination
Speciality: Gastroenterologist
Phase: Not applicable
Notes: A randomized, double-blind, placebo controlled trial to study the efficacy of larazotide acetate in treating active Celiac Disease

ProMedDx, LLC
10 Commerce Way
Norton MA 02766
Name: Marion M. Santa Ines
Email: marion@promeddx.com
Drug name: Not applicable
Indications: Non-Viral Liver Disease
Speciality: Gastroenterology, Hepatology
Phase: Not applicable
Notes: This study is designed to collect a small volume of whole blood from individuals diagnosed with a non-viral liver disease. Only one study visit will be required. The only risks to subjects are those associated with a routine blood draw. Demographics and medical history are required on a CRF.

Geriatrics

ClinSmart LLC
3000 Cabot Blvd West, Suite 200
Name: Saptarshi Bandyopadhyay
Email: sbandyo@stattrade.com
Drug name: Not available
Indications: Anti-Inflammatory
Speciality: Geriatric Pharmacokinetics
Phase: I
Notes: Looking for a skilled and experienced site willing to conduct Geriatric Pharmacokinetic study with well-known NSAID compound. Must have large pool of elderly (>65 years old) as well as healthy adult volunteers (18-65 years). This is a food-effect pharmacokinetic study.

Still Seeking Investigators

Immunodiagnostics

Investigator Location Services, Inc.
1280 Bison St.
Suite B9-543
Newport Beach CA 92660
Name: Joe Bollert, PhD
Email: jbollert@invlocate.com
Drug name: Not available
Indications: Pediatric HIV
Speciality: Pediatric HIV
Phase: II
Notes: >18 with ITP, with or without prior splenectomy-plt levels <150%D7109/L for >6 mos, an adequate course of at least one standard tx, plts <30x109/L at entry and on one other occasion 1 week apart within the past mo (Phase I only: plt count >10x109/L at entry), and bldg assessment score 0 or 1.

Immunology/Infectious Disease

Infectious Disease

OraSure Technologies, Inc
220 East First Street
Bethlehem PA 18015
Name: Nicole Oshodi
Email: oosho@orasure.com
Drug name: OraQuick Advance HIV 1/2 Antibody Test

Grant Opportunities
Grant Opportunities

Indications: To determine if certain unrelated medical conditions can potentially influence the sensitivity and specificity of OraQuick Advance

Speciality: Infectious Disease, Oncology targeted Human T-Cell Leukemia Virus patients, Hepatitis B Virus patient

Phase: II

Notes: Investigation of the influence of Unrelated Medical Conditions on the sensitivity and Specificity of the OraQuick Advance HIV 1/2 Antibody test. To determine if certain unrelated medical conditions can potentially influence the sensitivity and specificity of OraQuick Advance.

**Kendle International**

Research Park, 1011 Ashes Drive

Wilmington DE 28405

Name: Anne Baldwin

Email: Baldwin.AnneM@kendle.com

Drug name: Not available

Indications: HIV

Speciality: Immunology/Infectious Disease

Phase: II

Notes: Currently seeking Investigators for a clinical study designed to collect a small volume of whole blood from individuals diagnosed with Hep C. Only 1 study visit is required. The only risks involved are those associated with a routine blood draw. Specimens are to be submitted with a completed CRF.

**MedImmune, LLC**

One MedImmune Way

Gaithersburg MD 20878

Name: Mark Eickhoff

Email: eickhoffm@medimmune.com

Drug name: MEDI-559

Indications: RSV Vaccine

Speciality: Pediatrics, Infectious Disease

Phase: I/IIa

Notes: Central or Local IRB. Access to -70 non-frost free freezer or willingness to acquire one. Ability or willingness to utilize snap freezing procedures using liquid nitrogen or a dry ice, ethanol bath. Experience with pediatric vaccine trials a plus

**Merck & Co. Inc.**

351 N. Sumneytown Pike

North Wales PA 19454

Name: Julie Kennedy

Email: julie_kennedy@merck.com

Drug name: V212

Indications: Prevention of Herpes Zoster and Herpes Zoster-Related Complications in Immunocompromised Individuals

Speciality: Infectious Disease Physicians

Phase: I

Notes: Currently enrolling Immunocompromised Subjects with Hematologic Malignancies (leukemia, lymphoma, multiple myeloma), Solid Tumor Malignancies (breast, colon, lung) and Hematopoietic Cell Transplant (allogeneic and autologous)

**ProMedDx, LLC**

10 Commerce Way

Norton MA 02766

Name: Marion M. Santa Ines

Email: marion@promeddx.com

Drug name: Not available

Indications: Hepatitis C

Speciality: Hepatology

Phase: Not applicable

Notes: We are seeking Investigators for a clinical study designed to collect a small volume of whole blood from individuals diagnosed with Hep C. Only 1 study visit is required. The only risks to subjects are those associated with a routine blood draw. Specimens are to be submitted with a completed CRF.

**MedImmune, LLC**

One MedImmune Way

Gaithersburg MD 20878

Name: Mark Eickhoff

Email: eickhoffm@medimmune.com

Drug name: MEDI-559

Indications: RSV Vaccine

Speciality: Pediatrics, Infectious Disease

Phase: I/IIa

Notes: Central or Local IRB. Access to -70 non-frost free freezer or willingness to acquire one. Ability or willingness to utilize snap freezing procedures using liquid nitrogen or a dry ice, ethanol bath. Experience with pediatric vaccine trials a plus

**Merck & Co. Inc.**

351 N. Sumneytown Pike

North Wales PA 19454

Name: Julie Kennedy

Email: julie_kennedy@merck.com

Drug name: V212

Indications: Prevention of Herpes Zoster and Herpes Zoster-Related Complications in Immunocompromised Individuals

Speciality: Infectious Disease Physicians

Phase: I

Notes: Currently enrolling Immunocompromised Subjects with Hematologic Malignancies (leukemia, lymphoma, multiple myeloma), Solid Tumor Malignancies (breast, colon, lung) and Hematopoietic Cell Transplant (allogeneic and autologous)

**PAREXEL**

2520 Meridian Pkwy

Durham NC 27713

Name: Alissa Carmona

Email: alissa.carmona@parexel.com

Drug name: Not available

Indications: Severe sepsis

Speciality: Critical care

Phase: II

**Merck & Co. Inc.**

351 N. Sumneytown Pike

North Wales PA 19454

Name: Julie Kennedy

Email: julie_kennedy@merck.com

Drug name: V212

Indications: Prevention of S. aureus infection 90 days post full mid-sternotomy

Speciality: Cardiothoracic surgeons, or research-experienced MDs with active collaborations with cardiothoracic surgeons

Phase: IIb

Notes: Experience with pediatric vaccine trials a plus

**Merck & Co. Inc.**

351 N. Sumneytown Pike

North Wales PA 19454

Name: Julie Kennedy

Email: julie_kennedy@merck.com

Drug name: V212

Indications: Prevention of S. aureus infection 90 days post full mid-sternotomy

Speciality: Cardiothoracic surgeons, or research-experienced MDs with active collaborations with cardiothoracic surgeons

Phase: IIb

Notes: Experience with pediatric vaccine trials a plus

**Schering-Plough Corp.**

19 Ridge Lake Drive

Manning SC 29102

Name: Rosalind Jones

Email: rosalind.jones@spcorp.com

Drug name: Not available

Indications: HIV, Oncology

Speciality: Hematology, Oncology

Phase: unknown

**Nephrology**

**Still Seeking Investigators**

**1st International Research Centers**

Hospital Punta Pacifica, floor 2, cons 204

Name: Diana Agudelo

Email: icrdiana@gmail.com

Drug name: Not available

Indications: Immunology

Speciality: Immunology

Phase: I, II, III, IV

**Genocea**

161 First Street, Suite 2C

Cambridge 02142

Name: Henry W. Calderon

Email: henry.calderon@genocea.com

Drug name: Not available

Indications: Infectious Diseases/ STDs

Speciality: Infectious disease; Ob/Gyn; Pre-clinical

Phase: Pre-clinical

**Schering-Plough Corp.**

19 Ridge Lake Drive

Manning SC 29102

Name: Rosalind Jones

Email: rosalind.jones@spcorp.com

Drug name: Not available

Indications: HIV, Oncology

Speciality: Hematology, Oncology

Phase: unknown

**Advanced Magnetics, Inc.**

Clinical Trials Dept.

61 Mooney Street

Cambridge MA 02138
Name: Carrie Delaney  
Email: cde-laney@advancedmagnetics.com  
Drug name: Ferumoxytol  
Indications: Anemia  
Speciality: Nephrology  
Phase: III  
Notes: Multicenter study

Atlantic Research Group  
125 South Augusta Street, Suite 3000  
Staunton VA 24401  
Name: Paul Bishop  
Email: pbishop-op@atlanticresearchgroup.com  
Drug name: Not available  
Indications: Intradialytic hypotension  
Speciality: Nephrology clinics, dialysis centers  
Phase: II  
Notes: We are seeking sites interested in participating in a Phase II clinical study on ESRD patients with intradialytic hypotension.

Name: Hope McPherson  
Email: hmcperson@medsource.com  
Drug name: Not available  
Indications: Renal Adenocarcinoma  
Speciality: Nephrology, Oncology  
Phase: III  
Notes: I am looking for investigators who might be interested in participating in a Phase III Vaccine study for patients with Renal Cell Adenocarcinoma. This is a great drug with a wonderful safety profile. Please let me know if any of your sites might be interested in more information.

Name: Catherine Anderson  
Email: catherine_anderson@merck.com  
Drug name: Sitagliptin phosphate  
Indications: Two diabetes: 1. Type 2 Diabetes Mellitus in moderate and severe renal insufficiency; 2. Type 2 Diabetes Mellitus in End Stage Renal Disease  
Speciality: Nephrology, Endocrinology  
Phase: III  
Notes: When responding, please specify which of the two studies you're interested in. The first study involves patients 30-years-old and above with T2DM with moderate or severe renal insufficiency and uncontrolled HbA1c. The second study involves patients 30-years-old and above with T2DM who are on dialysis for at least 6 months with uncontrolled HbA1c. In both studies, patients are either off their AHA therapy or currently on oral AHA therapy. Patients on insulin are excluded. Enrollment period is until end of 4Q 2008.

Novo Nordisk  
Krogsh jvej 53 9E  
Name: Christian Born Djurhuus  
Email: cbdj@novonordisk.com  
Drug name: Norditropin  
Indications: Low Serum Albumin in Dialysis  
Speciality: Nephrology - Hemodialysis  
Phase: 3a  
Notes: Patients on Hemodialysis with s. albumin <40g/L (4.0 g/dL) MHD (spKt/V >=1.20).

Recruiting in: US, Argentina, Australia, Brazil, Canada, Czech Republic, Denmark, France, Germany, Hungary, India, Israel, Italy, New Zealand, Poland, Portugal, Russia, South Africa, Spain, Sweden, Turkey, and UK.

Name: John Hogan  
Email: jhogan@clinsys.com  
Drug name: Not available  
Indications: Diabetic Peripheral Neuropathy  
Speciality: Diabetic Peripheral Neuropathy  
Phase: I-III

Neurology

Still Seeking Investigators

Clinsys Clinical Research  
8540 Colonnade Center Dr.  
Ste 501  
Raleigh NC 27615  
Name: Aaron Latta  
Email: alatta@clinsyscro.com  
Drug name: Not available  
Indications: Alzheimer’s  
Speciality: Alzheimer’s  
Phase: I-IV  
Notes: Looking for Alzheimer’s sites for potential studies.

Clinsys Clinical Research  
8540 Colonnade Center Dr.  
Ste 501  
Raleigh NC 27615  
Name: Aaron Latta  
Email: alatta@clinsyscro.com  
Drug name: Not available  
Indications: Parkinson’s Disease  
Speciality: Parkinson’s Disease  
Phase: I-IV  
Notes: Looking for sites for potential Parkinson’s studies.

Clinsys Clinical Research Inc.  
One Crossroads Drive  
Building A, Second Floor  
Bedminster NJ 07921  
Name: John Hogan  
Email: jhogan@clinsys.com  
Drug name: Not available  
Indications: Diabetic Peripheral Neuropathy  
Speciality: Diabetic Peripheral Neuropathy  
Phase: I-III

Ethicon, Inc.  
PO Box 151  
Route 22 West  
Somerville NJ 08876  
Name: Sonya Littlejohn  
Email: sllittlej@its.jnj.com  
Drug name: Not available  
Indications: Fibrin Sealant (Human)  
Speciality: Neurology  
Phase: II/III

Ovation Pharmaceuticals, Inc.  
Four Parkway North, Suite 200
Deerfield IL 60015
Name: Carmen Miceli
Email: Cmichel@OvationPharma.com
Drug name: Anti-epilepsy drug
Indications: Pediatric and adult patients with active epilepsy
Speciality: Neurologists with in-patient phase
Phase: III
Notes: We are looking for investigators who have conducted or are conducting studies for Tardive Diskinesia, Drug Induced Movement Disorder or Schizophrenia. The PI's can be international, but we prefer North America.

PrecisionMed
132 N. Acacia Ave
Malvern PA
Name: Carole Marks
Email: carolemarks@precisionmed.com
Drug name: No Drug
Indications: Probable Alzheimer's Disease or Mild Cognitive Impairment
Speciality: Neurology, Psychiatry
Phase: Biological Sample Collection
Notes: This is a long term follow-up of subjects with Mild Alzheimer’s Disease or Mild Cognitive Impairment. Subjects are seen every 6 months and have a blood draw, spinal tap, and rating scales. Any medications are allowed.

Sanofi Aventis
Great Valley
Malvern PA
Name: Allen
Email: allen.anyabolu@sanofi-aventis.com
Drug name: SSR180575
Indications: Diabetic peripheral neuropathy
Speciality: Neurology, endocrinology
Phase: III
Notes: The sites will be required to perform 4 skin biopsies, (2)Nerve Conduction Studies (NCS), Total Neuropathy Scores, and capsaicin placement and removal. In addition, there is a central ECG and laboratory, and central vendors for the biopsy evaluations and the NCS.

Schering-Plough
2000 Galloping Hill Road
Mailstop K-15-3-3113
Kenilworth NJ 07033
Name: Bohang Chen, MD
Email: bohang.chen@spcorp.com
Drug name: SCH
Indications: Movement Disorders
Speciality: Tardive Dyskinesia, Drug Induced
Notes: The comparator in this trial is Alox. Patients will be allowed to participate in up to 4 treatment cycles and do not have to be chemotherapy naïve.

OB/Gyn
Still Seeking Investigators
ICON Clinical Research
525 West Monroe,
Suite 1000
Chicago IL 60661
Name: Jill Franczyk
Email: Jill.Franczyk@iconplc.com
Drug name: Not applicable
Indications: Iron Deficiency Anemia in Women
Speciality: OB/GYN, Internal Medicine, Family Medicine
Phase: III
Notes: The objective of this Phase 3 study is to confirm the safety and efficacy of BIOVAXID, an autologous tumor derived idiotype vaccine, as measured by prolongation of disease-free survival of patients with follicular (NHL) during their first complete remission induced by PACE. Seeking several investigative sites in US, Canada and Mexico. Sites must be willing to use only PACE for remission induction. No CHOP-R or Rituxin permitted. Patient-specific vaccine manufactured from biopsy materials.

Siemens Healthcare Diagnostics Inc.
5210 Pacific Concourse Dr.
Los Angeles CA 90045
Name: Roland Strickland
Email: roland.strickland@siemens.com
Drug name: Not applicable
Indications: In vitro detection of Epstein-Barr Virus (EBV) infection
Speciality: Infectious Disease
Phase: Data Collection Trial
Notes: Seeking sites for prospective or retrospective collection of patient sera positive for EBV VCA IgM, VCA IgG and EBNA IgG. Samples will be used to validate Siemens’ assays in support of FDA 510(k) submission.

Oncology
Still Seeking Investigators
A.P. Pharma Inc.
123 Saginaw Drive
Redwood City CA 94063
Name: Erin O’Boyle
Email: eoboyle@appharma.com
Drug name: AFF530; TEG-POE polymer Based Formulation Containing 2% Granisetron
Notes: The objective of this Phase 3 study is to confirm the safety and efficacy of BIOVAXID, an autologous tumor derived idiotype vaccine, as measured by prolongation of disease-free survival of patients with follicular (NHL) during their first complete remission induced by PACE. Seeking several investigative sites in US, Canada and Mexico. Sites must be willing to use only PACE for remission induction. No CHOP-R or Rituxin permitted. Patient-specific vaccine manufactured from biopsy materials.

Accentia Biopharmaceuticals Inc.
450 Park Avenue, South 12th Floor
New York NY 10016
Name: William Calhoun, MS
Email: WCalhoun@analyticalintl.com
Drug name: BioVaxid
Indications: Follicular, Non-Hodgkin’s Lymphoma
Speciality: Immunology; Hematology; Oncology
Phase: III
Notes: The objective of this Phase 3 study is to confirm the safety and efficacy of BIOVAXID, an autologous tumor derived idiotype vaccine, as measured by prolongation of disease-free survival of patients with follicular (NHL) during their first complete remission induced by PACE. Seeking several investigative sites in US, Canada and Mexico. Sites must be willing to use only PACE for remission induction. No CHOP-R or Rituxin permitted. Patient-specific vaccine manufactured from biopsy materials.

Cephalon, Inc.
CCRI
Children's Hospital of Philadelphia
3535 Market St., Suite 1200
Philadelphia PA 19104
Name: Eileen Dorsey
Phone: (215) 590-1295
Email: dorseye@email.chop.edu
Drug name: Not applicable
Indications: Pediatric breakthrough pain
Speciality: Pediatric oncology
Phase: II

Chiltern
2111 Palomar Airport Rd.
Carlsbad CA 92110
Name: Anjo Sanchez
Email: anjo.sanchez@chiltern.com
Drug name: Not applicable
Indications: Advanced esophageal cancer
Speciality: Oncology clinics with endoscopy
units or esophageal centers

Phase: II

Chonjisan Ltd.
2804, Bangbae2-Dong, Seocho-Gu
Seoul South Korea
Name: Bae Joon Sook
Email: gungde2@hanmail.net
Drug name: Not available
Indications: Cervical cancer
Speciality: Oncology

Phase: IIa

Delcath Systems
1100 Summer Street
Stamford CT 06905
Name: Dr. Samuel Herschkowitz
Phone: (718) 624-6277
Email: docsam.rm@yahoo.com
Drug name: Melphalan
Indications: Cancer (melanoma)
Speciality: Oncology, Interventional radiology
Phase: III
Notes: Delivery system for the isolated hepatic arterial infusion of chemotherapy to patients with metastatic liver tumors.

Endocyte, Inc.
3000 Kent Avenue, Suite A1-100
West Lafayette IN 47906
Name: David Morgenstern
Email: dmorgenstern@endocyte.com
Drug name: EC145
Indications: Platinum-resistant ovarian cancer
Speciality: Medical Oncology, Gynecologic Oncology
Phase: II
Notes: Endocyte is seeking investigators for a multicenter, randomized study in women with platinum-resistant ovarian cancer. This study will evaluate a combination of standard therapy + EC145 versus standard therapy alone.

GenVec, Inc.
65 West Watkins Mill Road
Gaithersburg MD 20878
Name: Yolanda Caraballo
Phone: (301) 944-1176
Email: ycaraballo@genvec.com
Drug name: TNFerade
Indications: Pancreatic Cancer
Speciality: Oncology
Phase: II/III
Notes: Please contact us for additional information to participate in this study.

ICON Clinical Research Canada Inc.
7405 Transcanada Hwy, Suite 300
St. Laurent QC H4T 1Z2 Canada
Name: Stefan Milenkov
Email: milenkows@iconcan.com
Drug name: Not available
Indications: Non-small cell lung cancer (NSCLC)
Speciality: Oncology
Phase: II

Javelin Pharmaceuticals
125 CambridgePark Drive
Cambridge MA 02140
Name: Jennifer Burg
Email: clinicaltrials@javelinpharma.com
Drug name: Intranasal Ketamine
Indications: Breakthrough pain in cancer patients
Speciality: Anesthesia; Pain Management; Oncology
Phase: III

Light BioScience
933 First Colonial Rd. Suite 204
Virginia Beach VA 23454
Name: Susan Kaplan, PhD
Email: susan@lightbioscience.com
Device: Gentlewaves
Indications: Radiation dermatitis in breast cancer treatment
Speciality: Radiation oncologist treating breast cancer patients
Phase: II or III (new indication)
Notes: Phase II or III trial of a new treatment to be used to decrease the incidence and severity of radiation dermatitis in patients being treated with radiation therapy for breast cancer.

MedSource
16902 El Camino Real
Houston TX 77058
Name: Hope McPherson
Email: hmcperson@medsource.com
Drug name: Not available
Indications: Renal Adenocarcinoma
Speciality: Nephrology, Oncology
Phase: III
Notes: I am looking for investigators who might be interested in participating in a Phase III Vaccine study for patients with Renal Cell Adenocarcinoma. This is a great drug with a wonderful safety profile. Please let me know if any of your sites might be interested in more information.

Pharmaceuticals
999 East Arques Avenue
Sunnyvale CA 94085
Name: Priscilla Horn
Email: PHorn@pcyc.com
Drug name: Xcytrin (Motexafin Gadolinium) Injection
Indications: Non-Small Cell Lung Cancer
Speciality: Medical Oncology
Phase: II
Notes: Randomized Phase II study of Motexafin Gadolinium as second line treatment of unresected locally advanced (Stage IIIIB) or metastatic non-small cell lung cancer. Do not respond if you are a CRO or SMO.

PPD
3900 Paramount Parkway
Morrisville NC 27560
Name: Peidi Gu
Email: peidi.gu@rtp.ppd.com
Drug name: Not available
Indications: CTM; head & neck cancer therapy
Speciality: Oncology
Phase: I and II

Sanofi Aventis
9 Great Valley Parkway
Malvern PA 19355
Name: Peter O’Neill
Email: peter.onell@sanofi-aventis.com
Drug name: Larotaxel (XR9881)
Indications: Urinary Bladder Cancer
Speciality: Oncology
Phase: III
Notes: This is an ongoing, randomized,
open-label, multi-center study comparing the efficacy and safety of Larotaxel + cisplatin to gemcitabine + cisplatin in the first line treatment of locally advanced/metastatic urothelial tract or bladder cancer. The primary objective is to compare overall survival.

**Schering-Plough**
2015 Galloping Hill Road
Kenilworth NJ 07033
Name: Siu-Long Yao
Email: siu-long.yao@spcorp.com
Drug name: Not available
Indications: Cancer
Specialty: Oncologist or physician experienced with oncology trials
Phase: I
Notes: We are interested in sites that can utilize central IRBs and have experience with Phase I trials.

**Schering-Plough Corp.**
19 Ridge Lake Drive
Manning SC 29102
Name: Rosalind Jones
Email: rosalind.jones@spcorp.com
Drug name: Not available
Indications: HIV, Oncology
Specialty: HIV, breast, ovarian, prostate, renal cancers, lymphoma, leukemia and lung cancers
Phase: unknown

**Seattle Genetics**
21823 30th Drive SE
Bothell WA 98021
Name: Dr. Eric Sievers
Email: e sievers@seagen.com
Drug name: SGN-30
Indications: Cutaneous ALCCL (Anaplastic Large Cell Lymphoma)
Specialty: Hematologist Oncologist
Phase: II/III
Notes: This is a rare form of lymphoma. We would be interested in contacting research sites even if they only see 1-3 cases per year.

**Tragara Pharmaceuticals, Inc.**
10955 Sorrento Vista Parkway, Suite 120
San Diego CA 92130
Name: Deborah Jezior
Email: djezior@tragarapharma.com
Drug name: Apricoxib
Indications: Breast cancer and Non-small cell lung cancer (NSCLC)
Specialty: Oncology
Phase: II
Notes: An oral investigational drug given in combination with erlotinib for NSCLC and capecitabine/lapatinib for breast cancer.

**Vical Incorporated**
10390 Pacific Center Court
San Diego CA 92121
Name: Linda Strause, PhD
Email: istrause@vical.com
Drug name: Allovectin-7
Indications: Metastatic Melanoma
Specialty: Medical Oncologist
Phase: III
Notes: This is a head-to-head superiority trial of Allovectin-7 vs. first line chemotherapy in metastatic melanoma patients where surgery is not a curative option. This trial will enroll 375 patients, randomized 2:1 to Allovectin-7. Please contact Vical at melanoma@vical.com or call (877) 343-6389.

**Wyeth Research**
Gretchen Patrick
Phone: (617) 665-8648
Email: patricg2@wyeth.com
Drug name: Not available
Indications: Metastatic Breast Cancer
Specialty: Oncology
Phase: III
Notes: Potential investigators needed to participate in a Phase III Metastatic Breast Cancer study in the salvage population.

**Ophthalmology**

**Still Seeking Investigators**

**Appian International Research, Inc.**
8701 Mallard Creek Road, Suite 112
Charlotte NC 28262
Name: Kimberly Slusher
Email: investigators@appianresearch.com
Drug name: 003-3105-01
Indications: Dry Eye Syndrome (Keratoconjunctivitis Sicca)
Specialty: Ophthalmology
Phase: III
Notes: Appian International Research is currently seeking experienced investigators for an upcoming clinical trial in dry eye syndrome. Please document relevant experience in your response, including indications, treatment, dates of participation and screening/enrollment numbers.

**Rx Development Resources**
3104 Cherry Palm Drive
Suite 260
Tampa FL 33619
Name: Penny Cobb
Email: pcobb@rxdevres.com
Drug name: Not available
Indications: Adenovirus/conjunctivitis
Specialty: Ophthalmology; Infectious disease
Phase: II
Notes: Please contact me as soon as possible if you feel your site could potentially enroll 4-5 subjects in a 3 month period.

**Rx Development Resources**
3110 Cherry Palm Drive
Suite 350
Tampa FL 33619
Name: Penny Cobb
Email: pcobb@rxdevres.com
Drug name: Not available
Indications: Adenovirus/conjunctivitis
Specialty: Ophthalmology; Infectious disease
Phase: II
Notes: We are currently seeking potential retinal research sites that have a MP-1 MicroPerimeter and a HRA II. At least one piece is required to be considered as a potential site.

**Otolaryngology**

**Still Seeking Investigators**

**Alcon Research, Ltd**
6201 South Freeway, TC-40
Fort Worth TX 76134
Name: Sally F. Beezley
Email: sally.beezley@alconlabs.com
Drug name: Not available
Indications: Acute Otitis Media with Tympanostomy Tube (AOMT)
Specialty: Ear Nose and Throat (ENT) or Pediatrician
Phase: III
Notes: Must have access to the following equipment: Vacuum suctioning, tympanometry, and audiology. No placebo arm in study; all active treatment.
Pain Management

Still Seeking Investigators

Javelin Pharmaceuticals
125 CambridgePark Drive
Cambridge MA 02140

Name: Jennifer Burg
Email: clinicaltrials@javelinpharma.com
Drug name: Intranasal Ketamine
Indications: Breakthrough pain in cancer patients
Speciality: Anesthesia; Pain Management; Oncology
Phase: III
Notes: Investigator must have access to Hologic DEXA and/or Peapd. Anthropometrics will be monitored for this study. In addition, two blood draws, at approximately 3 and 6 months of age will be required.

Pediatrics/Neonatology

New Leads

Investigator Location Services, Inc.
1280 B ison St.
Suite B 9-543
Newport Beach CA 92660

Name: Joe Bollert, PhD
Email: jbollert@invlocate.com
Drug name: Not available
Indications: Pediatric HIV
Speciality: HIV, Infectious Disease, Pediatric Infectious Disease
Phase: II
Notes: Experience w ith healthy volunteers

MedImmune
One MedImmune Way
Gaithersburg MD 20878

Name: Joe Coffie
Email: coffiej@medimmune.com
Drug name: MEDI 559
Indications: Pediatric RSV
Speciality: Pediatricians
Phase: I/IIA
Notes: Protocol: MI-CP147, a Phase 1/2a, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety, Tolerability, Immunogenicity, and Viral Shedding of MEDI-559, a Live Attenuated Intranasal Vaccine Against Respiratory Syncytial Virus in Healthy 1 to <12 Month-Old Children

Still Seeking Investigators

Biosolve
638 Via Cristina
Newbury Park CA 91320

Name: Andrea Friedman
Email: biosolve@adelphia.net
Drug name: Infant formula
Indications: Infant nutrition
Speciality: Investigator with access to a population of healthy infants followed from 3 months to a year. Infants may be breastfed or formula fed; either exclusively, or mixed.
Phase: II/III
Notes: Looking for a skilled and experienced site willing to conduct Geriatric Pharmacokinetic study with well-known NSAID compound. Must have large pool of elderly (>65 years old) as well as healthy adult volunteers (18-65 years). This is a food-effect pharmacokinetic study.

Genentech
1 DNA way
South San Francisco CA

Name: Carlos Navarrete
Email: carlosn@gene.com
Drug name: Not available
Indications: Oncology
Speciality: Phase I trial unit
Phase: I
Notes: We’re looking for phase I oncology units in the US.

Johnson & Johnson PRD

Name: Yvonne Tan
Phone: (800) 362-6345 x74060
Email: ytan@gcous.jnj.com
Drug name: Not available
Indications: Healthy volunteers
Speciality: Experience w ith healthy volunteers
Phase: I
Notes: Very interested in seeking centers/CROs on the West Coast that run phase I healthy-volunteer studies, preferably in Southern California.

Merck & Co., Inc.
351 N Sumneytown Pike
North Wales PA 19454

Name: Julie Kennedy
Email: julie_kennedy@merck.com
Drug name: V212
Indications: Prevention of Herpes Zoster and Herpes Zoster-Related Complications in Immunocompromised Individuals
Speciality: Oncologists, Hematologists, Infectious Disease Physicians
Phase: I
Notes: Currently enrolling Immunocompromised Subjects with Hematologic Malignancies (leukemia, lymphoma, multiple myeloma), Solid Tumor Malignancies (breast, colon, lung) and Hematopoietic Cell Transplant (allogeneic and autologous)

Schering-Plough
2015 Galloping Hill Road

Notes: Looking for a skilled and experienced site willing to conduct Geriatric Pharmacokinetic study

CenterWatch
December 2008
29
Grant Opportunities

Kenilworth NJ 07033
Name: Siu-Long Yao
Email: siu-long.yao@ spcorp.com
Drug name: Not available
Indications: Cancer
Speciality: Oncologist or physician experienced with oncology trials
Phase: I
Notes: We are interested in sites that can utilize central IRBs and have experience with Phase 1 trials.

Podiatry

Still Seeking Investigators

Clinsys Clinical Research Inc.
28 Federal Street
Blackstone MA 01504
Name: John Hogan
Email: jhogan@clinsyscro.com
Drug name: Not available
Indications: Bunionectomy
Speciality: Podiatrists, Foot and Ankle Surgeons, Orthopedic Surgeons
Phase: I-III

Psychiatry/Psychology

Still Seeking Investigators

Appian Services, LLC
10107 White Cascade Drive
Charlotte NC 28269
Name: Grier Harris, PharmD
Email: tghjr@bellsouth.net
Drug name: Not available
Indications: Cocaine abuse and addiction
Speciality: Psychology
Phase: II
Notes: Study: new agent for cocaine addiction. Population: adults with established history of cocaine use. Enrollment goal is 60, to complete a minimum of 40. Study duration: 14-16 weeks. Total of 34-40 visits. Target enrollment period is 6 months.

Pulmonology

Still Seeking Investigators

Amarillo Biosciences, Inc.
4134 Business Park Drive
Amarillo TX 79110-4225
Name: Martin J. Cummins
Email: mcummins@amarbio.com
Drug name: Interferon-alpha lozenges
Indications: Chronic cough in COPD patients
Speciality: Pulmonology
Phase: II
Notes: Investigators are sought that can enroll 10 or more COPD patients in 3 months. Eligible subjects will have a 20-pack-year history of smoking but be current non-smokers. Adults over the age of 40 with COPD of GOLD Stage 1 or higher and history of chronic cough for > 3 months will be eligible.

Forest Laboratories, Inc.
Harborside Financial Center, Plaza V
Jersey City NJ 07311
Name: Jessica Hughes
Email: jessica.hughes@frx.com
Drug name: Not available
Indications: Chronic Obstructive Pulmonary Disease
Speciality: Pulmonology
Phase: II

Pacific Clinical Center
17337 Ventura Blvd., Suite #226
Encino CA 91316
Name: Janet Johnson
Email: pacific_clinical@yahoo.com
Drug name: Not available
Indications: Asthma
Speciality: Pulmonology
Phase: III
Notes: Investigator must be Board certified and located in the Los Angeles area.

Pharmaxis Ltd
2/10 Rodborough Rd
Frenchs Forest NSW 2086 AUSTRALIA
Name: Anna Jaques
Email: anna.jaques@pharmaxis.com.au
Drug name: Inhaled dry powder mannitol
Indications: Bronchiectasis
Speciality: Pulmonology
Phase: III
Notes: We are seeking investigators in USA and Canada for a pivotal RCT to commence Q3 2008. We seek experienced investigators with a pool of non CF bronchiectatics for inclusion in this 6 to 12 month intervention study that examines the mucusactive effect of mannitol compared to placebo.

WMCP
10800 Biscayne Blvd,
Suite 660
Miami FL 33161
Name: Yanetza Camacho
Email: ycamacho@wmcphealth.com
Drug name: Not available
Indications: Asthma
Speciality: Asthma
Phase: II,III

Rheumatology

Still Seeking Investigators

Clinsys Clinical Research Inc.
One Crossroads Drive
Building A, Second Floor
Bedminster NJ 07921
Name: John Hogan
Email: jhogan@clinsyscro.com
Drug name: Not available
Indications: Osteoarthritis
Speciality: Rheumatologists, Neurologists, Geriatric Practitioners
Notes: Phase I-III

Northstar Healthcare Solutions
1028 East Bastanchury Road
Fullerton CA 92831
Name: Peter Frenzel
Email: pfrenzel@northstarhs.com
Drug name: Not available
Indications: Rheumatoid Arthritis
Speciality: Rheumatology
Phase: II
Notes: We will need sites to support 600 patients in the US.

Pacific Clinical Center
17337 Ventura Blvd., Suite #226
Encino CA 91316
Name: Janet Johnson
Email: pacific_clinical@yahoo.com
Drug name: Not available
Indications: Arthritis
Speciality: Rheumatology
Phase: III
Notes: Investigator must be Board certified and located in the Los Angeles area.

Strategic Science & Technologies
58 Charles Street

December 2008
CenterWatch
Cambridge MA 02141
Name: Eric Fossel
Email: efossel@strategicsci.com
Drug name: Transdermal ibuprofen
Indications: Arthritis and pain
Speciality: Any who deal with arthritis, joint or muscle pain
Phase: Pilot
Notes: Our transdermal ibuprofen product is potentially revolutionary as it provides effective localized relief of pain at a much lower total body dose than oral ibuprofen and it avoids the complication of stomach irritation and ulceration.

Anika Therapeutics, Inc.
Clinical Department
236 West Cummings Park
Woburn MA 01801

Name: Clinical Department
Email: clinical@anikatherapeutics.com
Device: Unavailable
Indications: Osteoarthritis
Speciality: Orthopedic surgery
Phase: III
Notes: Anika Therapeutics, Inc. is currently seeking orthopedic surgeons for a Phase III trial of OA. Preference will be given to investigator with prior research experience. Please email current CV and contact information if interested.

Auxilium Pharmaceuticals
40 Valley Stream Parkway
Malvern PA 19355

Name: Brian Walker
Email: bwalker@auxilium.com
Drug name: AA4500
Indications: Dupuytren's Contracture
Speciality: Orthopedic Surgeon; Hand Surgeon
Phase: III
Notes: Auxilium Pharmaceuticals is currently recruiting doctors to participate in a Phase III clinical trial involving patients with Dupuytren's Contracture. This trial is studying an enzyme injection as a non-surgical treatment for patients who have Dupuytren's Contracture for Dupuytren's Disease.

Merck & Co., Inc.
351 N. Sumneytown Pike
UG3CD-60
North Wales PA 19454

Name: Julie Kennedy
Email: julie_kennedy@merck.com
Drug name: V710
Indications: Prevention of S. aureus infection 90 days post full mid-sternotomy
Speciality: Cardiothoracic surgery; or research-experienced MDs with active collaborations with cardiothoracic surgeons
Phase: IIb
Notes: Our transdermal ibuprofen product is potentially revolutionary as it provides effective localized relief of pain at a much lower total body dose than oral ibuprofen and it avoids the complication of stomach irritation and ulceration.

PharmaLinkFHII
1251 NW Maynard Rd #184
Gary NC 27513

Name: Ann Marie Cisneros
Email: acisneros@ereadymonitors.com
Drug name: Not available
Indications: Hernia repair
Speciality: Colon and rectal
Phase: IV
Notes: Seeking vascular surgeons with strong relationships with interventional radiologists to investigate contrast vs. non-contrast angiography (DSA/MRI) in patients with intermittent claudication/PAD. Enrollment to begin July 2008

PPD, Inc.
3900 Paramount Parkway
Morrisville NC 27560

Name: Stuart Byham
Email: stuart.byham@rtp.ppd.com
Drug name: Contrast agent
Indications: Vascular enhanced MRI
Speciality: Vascular surgery; interventional radiology
Phase: II
Notes: Seeking vascular surgeons with strong relationships with interventional radiologists to investigate contrast vs. non-contrast angiography (DSA/MRI) in patients with intermittent claudication/PAD. Enrollment to begin July 2008

SkyePharma Inc.
10450 Science Center Drive
San Diego CA 92121

Name: Marius Ardeleanu, MD
Email: mariusa@skypepharma.com
Device: DepoBupivacaine
Indications: Postoperative analgesia
Speciality: Anorectal surgery
Phase: II
Notes: Looking for suitable clinical site to conduct a dose-ranging study in patients undergoing 2- or 3-column excisional hemorrhoidectomy using Milligan-Morgan or Ferguson-type techniques under general anesthesia, including newer approaches with specialized instruments, such as LigaSure and harmonic scalpel. Need site with large volume of cases to ensure timely enrollment (target enrollment for each site is 10 subjects in 3 months).

Urology

Still Seeking Investigators

Premier Research Group, LTD
489 Switchgrass Court
Bolivia NC 28422

Name: Amy Gutierrez
Email: amy.gutierrez@premier-research.com
Drug name: Not available
Indications: Complicated UTI
Speciality: Infectious Disease, Urology
Phase: II
Notes: We are currently recruiting sites for an in-patient complicated UTI study. We are looking for sites that can enroll 4-5 subjects in a 6 month period. Enrollment is scheduled to begin July 2008.

Spectrum Pharmaceuticals, Inc.
157 Technology Drive
Irvine CA 92602

Name: Shanta Chawla, M.D.
Email: schawla@spectrumpharm.com
Drug name: Not available
Indications: Non invasive bladder cancer
Speciality: Urology
Phase: III
Notes: This study is mainly conducted by urologists.
<table>
<thead>
<tr>
<th>Indication</th>
<th>Sponsor</th>
<th>Drug/Device</th>
<th>Date Planned</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase I</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>non-hematologic malignancies</td>
<td>Pfizer</td>
<td>PF-04554878</td>
<td>November 2008</td>
<td>Plans to enroll 74 subjects with advanced non-hematologic malignancies, in the US</td>
</tr>
<tr>
<td><strong>Phase II</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>rheumatoid arthritis</td>
<td>Arana Therapeutics</td>
<td>ART621</td>
<td>December 2008</td>
<td>Plans to enroll 200 subjects across international sites</td>
</tr>
<tr>
<td>Alzheimer's disease</td>
<td>Ceregene</td>
<td>CERE-110</td>
<td>H1, 2009</td>
<td>Plans to enroll 50 subjects with mild to moderate Alzheimer's disease at multiple clinical trial sites in the U.S.</td>
</tr>
<tr>
<td>thrombosis</td>
<td>Portola Pharmaceuticals</td>
<td>PRT060128</td>
<td>December 2008</td>
<td>Plans to enroll 800 subjects undergoing non-urgent percutaneous coronary interventions, in the US, Canada, Austria, Germany and Poland</td>
</tr>
<tr>
<td><strong>Phase IIb</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>rheumatoid arthritis</td>
<td>Incyte</td>
<td>INCB18424</td>
<td>Q4, 2008</td>
<td>Plans to enroll 280 subjects with RA who are receiving disease modifying therapy but whose disease is not adequately controlled.</td>
</tr>
<tr>
<td>rheumatoid arthritis</td>
<td>Incyte</td>
<td>INCB18424</td>
<td>Q4, 2008</td>
<td>Plans to enroll 140 subjects previously treated with anti-TNF therapies for at least eight weeks.</td>
</tr>
</tbody>
</table>
Medical Intelligence Solutions:

Driving VALUE Through Clinical KNOWLEDGE

Specializing in:
Global Congress Coverage | Clinical Data Analysis | Interactive Knowledge Solutions

Supporting your clinical intelligence requirements

Kevin Farberow, MBA  (609)268-4495  kfarberow@medintelsolutions.com

www.medintelsolutions.com
30% off select CenterWatch publications. But hurry! After 30 days, it’s over!

<table>
<thead>
<tr>
<th>Industry News (new subscriptions only)</th>
<th>Industry Analysis</th>
<th>Training and Education</th>
<th>Standard Operating Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>The CenterWatch Monthly</strong></td>
<td><strong>State of the Clinical Trials Industry (2008)</strong></td>
<td><strong>Becoming a Successful Clinical Research Investigator</strong></td>
<td><strong>Standard Operating Procedures for Good Clinical Practice at the Investigative Site</strong></td>
</tr>
<tr>
<td>Regular price $445</td>
<td>Regular price $699</td>
<td>Regular price $79</td>
<td>Regular price $695</td>
</tr>
<tr>
<td><strong>ONLY $312</strong></td>
<td><strong>ONLY $489</strong></td>
<td><strong>ONLY $55</strong></td>
<td><strong>ONLY $497</strong></td>
</tr>
<tr>
<td><strong>CWWWeekly</strong></td>
<td><strong>Asia-Pacific’s Growing Role in Global Clinical Trials</strong></td>
<td><strong>A Guide to Patient Recruitment and Retention</strong></td>
<td><strong>Policies and Standard Operating Procedures for the Institutional Review Board</strong></td>
</tr>
<tr>
<td>Regular price $275</td>
<td>Regular price $995</td>
<td>Regular price $79</td>
<td>Regular price $1,750</td>
</tr>
<tr>
<td><strong>ONLY $193</strong></td>
<td><strong>ONLY $697</strong></td>
<td><strong>ONLY $55</strong></td>
<td><strong>ONLY $1,225</strong></td>
</tr>
<tr>
<td><strong>Research Practitioner</strong></td>
<td><strong>The Emerging Markets of Clinical Research</strong></td>
<td><strong>Protecting Study Volunteers in Research</strong></td>
<td><strong>Standard Operating Procedures for Good Clinical Practice by Sponsors of Clinical Trials</strong></td>
</tr>
<tr>
<td>(with CE credits)</td>
<td>Regular price $499</td>
<td>Regular price $79</td>
<td>Regular price $4,200</td>
</tr>
<tr>
<td>Regular price $159</td>
<td><strong>ONLY $349</strong></td>
<td><strong>ONLY $55</strong></td>
<td><strong>ONLY $2,940</strong></td>
</tr>
<tr>
<td><strong>ONLY $111</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To take advantage of this limited time offer, please visit [http://store.centerwatch.com](http://store.centerwatch.com) and reference code 6364. Offer ends December 20, 2008.
As a global, therapeutically focused CRO, we understand that you need process to support your clinical development goals. The Trusted Process® is our proven methodology that delivers predictably dependable outcomes.

Meet Bekki Brown, a QualityFinish Specialist. As a Senior Director, she manages internal project teams and external client deliverables from planning and training through the final phase of project delivery. In this phase, the proactive planning and solid execution of the previous phases pays off, as trials glide smoothly toward database lock and analysis. By deploying the right technology and resources over the life of the project, her mission is to offer each of our customers a QualityFinish.

At INC Research, it's all about the process. Our Trusted Process means you experience trial excellence. Minimized risk factors. More informed and confident drug and device development decisions. Learn more about QualityFinish by visiting us online at www.incresearch.com/finish.
Academy & APPI Certification
The Global Standard for Clinical Researchers

‘Certification should become a requirement for clinicians and research nurses before they participate in clinical research/trials.’

– Certified Physician Investigator®

Apply Today! for the March 7 Certification Exams for

CCRA® (Clinical Research Associates)
CCRC® (Clinical Research Coordinators) and
CPI® (Physician Investigators)

Visit Certification at www.acrpn.org/certification for applications.

Certification Exam Application Deadline: January 12, 2009

The Academy & APPI Advantage

• The only provider of distinct certification exams specific to CRAs, CRCs and Physician Investigators.

• The Academy and APPI have certified more than 22,000 clinical research professionals to date, more than any other organisation in the world.

• Certification exam questions are drafted by trained writers with industry experience and passed through a rigorous approval process by expert exam-specific committees.

• Provides clinical research professionals the credentials for demonstrating job-knowledge.