

SpineMark and Wooridul Hospital of Korea Team up to Create Spine Centers in Asia

Moving toward its goal of adding 10 international research sites to its growing network of spine centers, San Diego, Calif.-based research organization SpineMark has partnered with Wooridul Hospital of Korea and set its sights across Asia.

The international alliance will include establishing a contract research organization (CRO) to help set up and manage centers in Korea, China, Singapore, Japan, India and Abu Dhabi.

"Since 2005, we have been working steadily toward it. We wanted to have 10 or more centers abroad to complement our work in the U.S. We truly want to create the first global

network of spine centers with research entities in medical education," said Marcy Rogers, M.Ed., president and CEO of SpineMark.

Rogers added that the partnership also gives Wooridul Hospital "strength in the Far East" by using SpineMark's resources and client base. "Their interest in collaborating in other areas and the unique contributions they bring to the field made it a great fit for us," Rogers added.

Wooridul Hospital is located in Seoul and has a reputation of excellence. The hospital was founded in 1992 and has 108 spinal surgeons who also treat patients in

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TranSenda, Microsoft Get Together with CTMS

TranSenda International launched Office-Smart Clinical Trial Manager, a clinical trial management system (CTMS) that addresses the need to unify study software with the 2007 Microsoft Office System.

Clinical trial professionals are often frustrated with the inefficiencies surrounding study software that does not work with their Microsoft Office software, according to Robert Webber, president and chief executive officer at TranSenda.

With the introduction of TranSenda's Office-Smart Clinical Trial Manager, clinical trial professionals can now take advantage

of the widely supported Microsoft Office system. TranSenda, located in Bellevue, Wash., is a partner of Microsoft.

Founded in 1998, TranSenda has 34 employees, including 14 located in the Ukraine. Three years ago, the company began focusing on the CTMS market. Microsoft's life sciences group has grown to 900 people and \$1 billion in annual sales.

The CTMS market is fragmented and is currently about \$300 million and growing in the mid-teens annually, according to company officials. Microsoft and TranSenda officials spoke with *CWWeekly* at the recent DIA Annual Meeting in Boston.

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**Industry Briefs****CROs**

- Port Jefferson, N.Y.-based CRO **Symbio** opened a new 62-bed phase I unit in collaboration with **Saint Anthony Memorial Hospital** in Michigan City, Indiana. The unit, a 45-minute drive from Chicago, borders Illinois and Michigan in the northwest corner of Indiana. Symbio stated it will use the facility to run bioequivalence studies for the generics industry.
- **PRA** relocated its Berlin office to a larger and more central facility to allow for an increase in headcount from the acquisition of **Pharmacon** in 2007. As with the old facility, the new office will support both early and clinical development operations. It is also the headquarters for the company's early stage work in Central and Eastern Europe. PRA also has a office in Mannheim that provides project management and clinical monitoring services. "The expanded offices in Berlin, from where we coordinate our trials in Central Europe, are designed to support this fast growing business," says John Horkulak, vice president of early development services in Central and Eastern Europe for PRA.

Technology

- Warrendale, Pa.-based medical device and imaging company, **MEDRAD** reported it will save \$150,000 by using CoSign, the

digital signature product from San Francisco, Calif.-based technology company **ARX**. MEDRAD stated it could now generate, sign and send the "field service reports" it requires as per U.S. Food and Drug Administration (FDA) regulations. The companies stated that a specific company process that took two weeks to complete, now takes about 60 seconds with CoSign. ARX noted it works with three large CROs and named ClinPhone as one of its eClinical clients. "The cost of CoSign will pay for itself in just three months, and allows more time for our field reps to concentrate on work, not paperwork," says Angela Gasper, IT project manager at MEDRAD.

- Cambridge, Mass.-based open source clinical software company **Akaza Research**—makers of EDC system OpenClinica—has established a joint-partnership with **Conecta**, an Italian consulting firm that specializes in open source products. The goal of the partnership is to introduce and market OpenClinica to the Italian clinical trials industry. Akaza stated OpenClinica was in use at a World Health Organization study at the Disability Italian Network in the Tuscany Region. It is also being implemented at the Regional Health Care Authority in Friuli-Venezia Giulia.

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Features (continued from page 1)

SpineMark

other parts of Korea such as Busan, Gimpo Airport and Daegu.

“SpineMark’s model of offering physicians and device companies the oversight and support needed to conduct clinical trials under one umbrella will allow us to further our R&D efforts on a global level,” said Jihoon Jeong, M.D., director of research and international business at Wooridul Hospital.

SpineMark partners with hospitals and clinical sites and assists them in setting up state-of-the-art spine research sites. These centers may also offer services in spine disease prevention, diagnosis, testing, treatment and rehabilitation. These centers—now numbered at 35 in the U.S.—would then be included in SpineMark’s network of clinical sites.

The expansion into the Asian market is client-driven. The majority of SpineMark’s

clients are medical device companies, many of which are looking to expand their studies globally. The company has a target goal of running between 10 and 20 trials at each site

The partnership with Wooridul Hospital is the first step to expand SpineMark centers across the globe. The company has a particular interest in areas such as Japan and China, but also sees newer emerging markets—such as Abu Dhabi—as completely untapped.

“Abu Dhabi, like China, is the next new frontier. Not just for economic reasons, but for clinical reasons. You are seeing major universities like Harvard, Princeton and Johns Hopkins all going in to set up satellite sites there. There is an enormous amount of money there and a strong need for this type of research,” said Rogers.

In addition, the joint venture plans to create a medical education center in Singapore to train investigators in the latest spine research

and care. These would be similar to SpineMark’s existing Medical Conference Center at Texas Back Institute in Plano, Texas.

To coordinate its global expansion plans, the company stated it will most likely set up an international office in either Korea or Singapore to act as its Asian hub of operations.

Under the agreement, medical device companies will be able to contract with SpineMark and Wooridul to gain access to their network of research sites.

Once the SpineMark International Medical Advisory Board, chaired by Dr. Rudolf Bertagnoli, has approved a prospective study, the SRO will begin enrolling patients under SpineMark’s CRO Management (SCROM), a wholly owned subsidiary of SpineMark and the nation’s only clinical research organization dedicated to spine.

TranSenda

“When conducting clinical trials, life sciences professionals often struggle with toggling in and out of different systems to input their data and there’s an ongoing challenge of knowing which spreadsheet is the ‘single version of the truth,’” said Michael Naimoli, U.S. life sciences industry director, Microsoft. “TranSenda’s Office-Smart Clinical Trial Manager addresses these problems with an Office Business Application that allows professionals to work from their familiar Microsoft

Office environments, while workflows are seamlessly assigned in the background. This not only simplifies clinical trials information management, but also amplifies the impact of people within their organizations.”

Clinical trial professionals can experience a work environment in which their study software works in harmony with their familiar Microsoft Office software. Users can leverage Office tools such as Microsoft Office, Excel and Office Outlook within the regulated environment of a clinical trial management system. Mismatched data from workaround spread-

sheets that are outside of the clinical trial management software system can become a thing of the past.

According to Microsoft, Office-Smart Trial Manager will be particularly useful for multi-site trials and global trials. While on the road, a clinical research associate (CRA) can access managed Microsoft Office Word documents such as the latest standard operating procedures (SOPs), create site visit reports, and even trigger workflow for an approval process. A CRA can handle it through Microsoft Outlook while traveling to a site.

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Profile: Investigative Site

Sarkis Clinical Trials Gainesville, Fla.

An interview with Elias H. Sarkis, M.D., principal investigator, and Jorge Franceschi, director of operations

How and why was Sarkis Clinical Trials founded?

ES: In 1997, one of our nurse practitioners at Sarkis Family Psychiatry, our group psychiatry practice, was interested in clinical trials. I didn't know much about clinical trials at the time, but after we discussed it, we decided to conduct two phase II clinical trials. Afterward, I conducted exit interviews with the 20 people who had participated in those trials. I was amazed to discover that every single one of the subjects spoke very positively about the experience and all were happy to have participated, regardless of whether or not they received benefits from the study drugs. They all emphasized that they were very glad that they had been able to speak to me, the nurse practitioner and other staff members at each study visit. They said they had learned a lot about their condition and potential medications. It was such an overwhelmingly positive response that I decided that we should conduct more clinical trials.

I established Sarkis Clinical Trials in 1997. As a legal entity, it is part of the psychiatry practice, but it has its own budget. It also is in a separate facility that is only 50 feet away from our group practice. So if a potential subject is identified at the practice, it is a short walk to the building where we conduct our clinical trials. We have conducted phase II through IV clinical trials, mostly in CNS [central nervous system] studies

and in other areas where I have experience, such as migraine and fibromyalgia. We have also worked in phase I, by collaborating with another facility and using their inpatient unit.

It's been exciting to be at the forefront of clinical research and knowledge. We are providing a great service to the community—many people don't have access to specialized care, particularly mental health treatment. If a person qualifies for a clinical trial, they get a thorough evaluation, the study drug and follow-up care, and I think that helps everybody concerned. Our number of active clinical trials jumped when we hired Jorge.

JF: When I was hired in 2002, my primary responsibility was business development. When I first got here, the site specialized in pediatric ADHD [attention deficit hyperactivity disorder] clinical trials. After I started, we started expanding into other areas of psychiatry. We started conducting adult ADHD trials and trials for anxiety, bipolar, autism and other areas. When I first started we had about five trials and since then we average around 20.

What differentiates Sarkis Clinical Trials from other sites?

ES: What differentiates us is the quality of our physicians and the fact that we are determined

Year founded: 1997
PIs: 3
CRCs: 5
Avg. # of active trials per year: 20
Contact: Jorge Franceschi
Tel: (352) 333-0094
Email: Jorge@ehsfamily.com
Web site: www.sarkisclinicaltrials.com

to provide high quality information. At almost every visit, the subject is seen by a physician who is a board certified psychiatrist and additionally board certified in adolescent and child psychiatry. In addition, we have a full-time nurse practitioner who helps coordinate trials, a full-time regulatory person and a staff member dedicated to patient recruitment. Three of our coordinators are certified, and the other two are working toward certification. We also have three rater/psychometricians, one of whom is internationally recognized for her work in ADHD and has published two books on the subject.

JF: One of the most exciting things that we're involved in and that differentiates us from many other sites is our ability to use QEEG [quantitative electroencephalography] in clinical trials. We have a clinician on-site who is certified in QEEG—something that is not typically found at other sites. We just recently completed a trial that examined whether brain activity, as measured by the QEEG, is consistent with clinical diagnosis. More sponsors, government agencies and insurance companies are looking into the use of the QEEG as a diagnostic tool. In addition, the QEEG is being used before dispensing the study drug.

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The QEEG is administered again, and from the resulting brain activity data, it may be determined if a patient will respond to the drug. In one of the trials that Sarkis Clinical Trials is participating in, we are the only private site in the entire study—the rest of the sites are university medical centers.

What are the advantages of being located in Gainesville?

ES: We are very fortunate to be in a university town, so the general attitude here is pro-research. Most everyone in town has a relative who is involved in research at the university in some capacity. In addition, the level of education here is generally higher than the national average, so we have been able to hire the best people.

JF: The primary endpoints in site trials are the ratings scales, and we have a Ph.D. rater and two Master's level raters.

What challenges do you face?

ES: Some protocols are a little bit more challenging to enroll for because they are not subject-friendly. For example, a pediatric clinical trial may have a lot of blood draws, which is difficult for some children. Another protocol might have many

visits. Some protocols ask for subjects to fill out rating scales. In the case of ADHD or manic subjects, it can be difficult for them to focus long enough to complete the scales. Sometimes less is more—many studies only need one primary and one secondary endpoint measure. The less information you ask for, the better the quality of information.

How has clinical research conduct changed in the past 10 years?

ES: It's become somewhat more challenging. Reimbursement isn't as good as it used to be, and the requirements are a bit more complicated. Some medication trials that we're involved with now are not studying totally innovative medications. They're me-too medications, and that makes it more difficult to recruit for those trials. It's a lot easier to recruit for a clinical trial of an innovative medication, rather than one that is already on the market and being prescribed off-label already to the study population.


We have had very good responses to a couple of autism trials. However, for the last autism trial we conducted, we were using a compound that is already on the market. A lot of pediatricians in the city were already using that compound, so all of my private practice autism patients with aggression either already had a trial with

that compound or were currently taking that compound. Because of the town that we're in, people are always looking for the best and the latest drug. It was very difficult to recruit for that trial. Sometimes the research gets behind the practice and that can be a bit frustrating.

What are your plans for growth?

JF: We are planning to diversify the kinds of studies we conduct. We have a board certified family medicine physician who is going to be starting with us in a few months. We are going to go beyond CNS and conduct clinical trials in areas such as hypertension, hyperlipidemia, diabetes, asthma and allergies. We already have the infrastructure and the SOPs [standard operating procedures]. We are going to apply the same know-how and practice in a new specialty. The staff are excited about working in a new area. We are hoping that in the next year we will be conducting between five and 10 general medicine studies in addition to our standard 20 CNS studies.

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Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
SGX Pharmaceuticals	SGX393	chronic myelogenous leukemia	IND submitted to the FDA	(858) 558-4850 www.sgxpathma.com
Quark Pharmaceuticals	DGFi	delayed graft function in kidney transplants	IND approved by the FDA; phase I/II trials planned	(510) 402-4020 www.quarkpharma.com
Taiwan Liposome Company	Lipotecan	cancer	IND approved by the FDA; phase I trials planned	(650) 872-8816 www.tlcbio.com
Novartis	PTH134	postmenopausal osteoporosis	Phase I trials initiated in Switzerland	+41 61 324 11 11 www.novartis.com
Protherics	Angiotensin Therapeutic Vaccine	hypertension	Phase IIa trials initiated enrolling 124 subjects in the UK	+44 (0)1928 518000 www.protherics.com
NeuroSearch	ACR325	Parkinson's disease	Phase II trials planned	+45 4460 8000 www.neurosearch.com
Affymax	Hematide	anemia/chronic renal failure/dialysis	Phase II trials initiated enrolling 120 subjects in Russia	(650) 812-8700 www.affymax.com
Catalyst Pharmaceutical	CPP-109	methamphetamine addiction	Phase II trials initiated enrolling 180 subjects in the U.S.	(305) 529-2522 www.catalystpharma.com
MediciNova	MN-221	asthma	Phase II trials initiated enrolling up to 25 subjects in the U.S.	(858) 373-1500 www.medicinova.com
MethylGene	MGCD0103	myelodysplastic syndromes	Phase II trials initiated enrolling 180 subjects in North America and Europe	(514) 337-3333 www.methylgene.com
Peregrine	bavituximab	non-small cell lung cancer	Phase II trials initiated enrolling up to 70 subjects in India	(714) 508-6000 www.peregrineinc.com
Sinovac	influenza vaccine	influenza	Phase II trials initiated enrolling 350 subjects in China	+86-10-82890088, x 871 www.sinovac.com
Thallion Pharmaceuticals	TLN-232	melanoma	Phase II trials initiated enrolling 49 subjects in Canada	(514) 940-3600 www.thallion.com
Ardea	RDEA806	HIV	Phase IIb trials planned internationally	(760) 602-8422 www.ardeabio.com
Repros Therapeutics	Androxal	hypogonadism	Phase IIb trials initiated enrolling 24 subjects in New York	(281) 719-3400 www.reprosr.com
AcruX	Testosterone MD-Lotion	hypogonadism	Phase III trials initiated enrolling 150 subjects in the US, Europe and Australia	+61 3 8379 0100 www.acruX.com
Alkermes	Vivitrol	opioid dependence	Phase III trials initiated enrolling 200 subjects in Russia	(617) 494-0171 www.alkermes.com

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Trial Results

Endocrinology

■ **Vivus** reported additional positive results from a phase III trial of **Qnexa** for the treatment of type 2 diabetes. Data are from a subset of subjects with higher cardiovascular risk factors at baseline. This randomized, double-blind, placebo-controlled study, dubbed OB-202, enrolled 206 subjects who underwent a four-week dose escalation period followed by 24 weeks of treatment. Following enrollment, subjects were stratified at randomization for either low HbA1c (7.0-8.0%) or high HbA1c (>8.0-12.0%). The subjects received Qnexa (15 mg phen-termine/100 mg topiramate) or placebo. The primary endpoint was change in glycemic control as reflected by measurements of HbA1c. Secondary endpoints included weight loss and various cardiovascular risk factors. In the Qnexa arm systolic blood pressure was reduced by 11.2 mm Hg from a baseline mean of 138.1 mm Hg, as compared to a reduction of 1.9 mm Hg from a baseline mean of 140.7 mm Hg in the placebo group ($p=0.006$). Diastolic blood pressure was reduced by 7.9 mm Hg from a baseline mean of 83.5 mm Hg in the Qnexa group, as compared to a reduction of 3.3 mm Hg from a baseline mean of 86.3 mm Hg in the placebo group ($p=0.015$). Elevated triglyceride levels were also reduced by 86.9 mg/dL (32%) from baseline as compared to a reduction of 25.3 mg/dL

(8.7%) in the placebo group ($p=0.022$). In addition, fasting plasma glucose in this higher-risk population was reduced by 85.2 mg/dL or 35% from a baseline mean of 245 mg/dL in the Qnexa group as compared with a reduction of 42.2 mg/dL or 17% from a baseline mean of 242.4 mg/dL in the placebo group ($p=0.006$). Additional studies of Qnexa are currently underway.

Neurology

■ **Vanda** released positive results from a phase III trial of **tasimelteon** for the treatment of insomnia. This multi-center, placebo-controlled, randomized trial enrolled 322 subjects with chronic primary insomnia. The subjects received either 20 mg or 50 mg of tasimelteon or placebo over the course of four weeks. The primary endpoint, the immediate and short-term ability (average of Nights 1 and 8) of tasimelteon to improve sleep onset as measured by Latency to Persistent Sleep (LPS) through polysomnography (PSG), was reached. Mean LPS at baseline was 78.8 minutes in the 20 mg group, 76.4 minutes in the 50 mg group, and 78.2 minutes in the placebo group. On Nights 1 and 8 of treatment, mean LPS improved over baseline by 45.0 minutes in the 20mg group ($p<.001$), by 46.4 minutes in the 50mg group ($p<.001$), and by

28.3 minutes in the placebo group. On Nights 22 and 29 of treatment, mean LPS improved by 49.4 minutes in the 20 mg group ($p<.001$), by 45.1 minutes in the 50 mg group ($p=.016$), and by 33.9 minutes in the placebo group. Secondary endpoints were reached as well; including improvements on sleep onset after long-term (average of Nights 22 and 29) use of the compound as well as measures of sleep duration (Total Sleep Time, TST) and sleep maintenance (Wake After Sleep Onset, WASO). On Nights 1 and 8 of treatment, mean TST improved by 51.4 minutes in the 20mg group ($p=.089$), by 52.0 minutes in the 50mg group ($p=.074$), and by 40.0 minutes in the placebo group. On Nights 22 and 29 of treatment, mean TST improved by 60.3 minutes in the 20mg group ($p=.057$), by 48.6 minutes in the 50mg group (not statistically significant), and by 47.4 minutes in the placebo group. WASO times improved as well, however these did not reach statistical significance. On Nights 1 and 8 of treatment, mean WASO improved by 12.2 minutes in the 20mg group, by 14.1 minutes in the 50mg group and by 11.7 minutes in the placebo group. On Nights 22 and 29 of treatment, mean WASO improved by 17.7 minutes in the 20mg group, by 10.2 minutes in the 50mg group and by 20.3 minutes in the placebo group. Based on the results Vanda plans to continue with the development of tasimelteon.



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Biotech Review

From *BioWorld Today*

- Framingham, Mass.-based **GTC Biotherapeutics** and Deerfield, Ill.-based **Ovation Pharmaceuticals** have entered a \$257 million agreement to develop and market ATryn in the U.S., a deal that includes \$3 million up front, and an additional \$2 million expected this year.

The deal with Ovation “closes the gap for 2008 but doesn’t quite give us all the cash we were looking for in 2008,” Thomas E. Newberry, GTC vice president of corporate communications and government relations, said. At the end of the first quarter, GTC’s cash and marketable securities were about \$1 1.7 million, a \$4.1 million decrease compared to the \$15.8 million total at the end of 2007.

GTC’s ATryn has completed phase III clinical trials in the U.S. for patients with a rare disorder called hereditary antithrombin deficiency, or HD, who are undergoing high-risk surgical procedures or childbirth. The company recently initiated a biologics license application filing on a rolling basis.

- Daniel Lawrence and his colleagues from the **University of Michigan** and Sweden’s **Karolinska Institute** reported that the tissue plasminogen activator (tPA)-induced bleeding in stroke patients may be mitigated by using Novartis AG’s imatinib

(Gleevec) in the June 23, 2008, online edition of *Nature Medicine*. Naturally occurring tPA exists both in the blood and the brain. Its role in the blood is to help break up clots. In the brain, however, tPA appears to activate platelet-derived growth factor receptor (PDGFR)-alpha. Its role here is to ensure the blood-brain barrier’s permeability to energy and nutrients when it is active. But during a stroke, Lawrence explained, tPA is up-regulated naturally and treatment with therapeutic tPA (Genentech Inc.’s Activase), the blood-brain barrier may become too permeable with the most extreme consequence being uncontrolled bleeding. In their paper, Lawrence and his colleagues took advantage of the fact that the PDGFR is blocked by Gleevec. They found that mice treated with Gleevec one hour after the induction of an ischemic stroke, had one-third less leakage than controls, and three days later, had brain lesions that were on average one-third smaller than those suffered by controls.

- Two parallel public/private consortia have been set up in the U.S. and Europe to bring together pharma and biotech with regulators, academics, public research funders and patient groups, to work on developing biomarkers in a precompetitive environment. In

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the U.S., the **Biomarkers Consortium** was set up in 2006 with the backing of the NIH, the FDA and the **Centers for Medicare & Medicaid Services**, along with 23 pharma and biotech companies. It is tackling biomarker development along the continuum from discovery to the bedside, focusing on four areas: cancer, inflammation and immunity, neuroscience and metabolic disorders. Proposed programs first are scrutinized for their scientific value before the work program is put in place. To date, four have been approved, three in imaging and one in a biochemical marker. The consortium’s counterpart in Europe, the Innovative Medicines Initiative, involves 26 pharma companies that are putting in time and research valued at €1 billion (U.S.\$1.56 billion) over 10 years. That will be matched by €1 billion from the European Commission, which will be disbursed as grants to academics and small biotechs that partner with pharma on specific peer-reviewed projects.



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