

Parexel Acquires Taiwan-based CRO APEX Clinical Research

Waltham, Mass.-based contract research organization (CRO) Parexel International purchased APEX Clinical Research, a CRO based in Taiwan with operations throughout the Asia-Pacific region.

The company paid \$50.9 million in cash for the remaining 20.3 million shares of APEX. The newly acquired company will become a wholly owned subsidiary and will be called Parexel APEX International. Parexel had already purchased a minority interest in the CRO in April 2003. The CRO has a staff of about 350 and 13 offices throughout the region.

"They were a good partner because they were familiar with doing things in an ICH com-

pliant manner. They understood the regulatory requirements and the dynamics of the various countries. So having that local knowledge is just very important," said Mark Goldberg, M.D., president of clinical research services and Perceptive Informatics at Parexel.

Since Parexel had worked with APEX in the last few years on a number of projects, it was able to introduce its own project management standard operating procedures and expertise gradually. Working with APEX also gave Parexel an opportunity to learn more about the region and the CRO's abilities there. According to Goldberg, it

page 4

DSG Takes on EDC, Randomization and Supply Integration

DSG has replaced the need to use an interactive voice response system (IVRS) for complex randomization to obtain drug kit numbers, thus cutting out a third technology vendor.

By using eSourcing on a tablet PC and DSG's eCaseLink EDC system, site investigators were able to record patient information in real time and receive randomized and blinded kit numbers for drugs already shipped from the sponsor. This also eliminated the need to reconcile the IVRS data with a site's main trial management system. Automated emails and alerts were sent out for everything from product supply, data

verification to serious adverse events.

"Customers drove this innovation. The clients know the tangible cost of a separate IVR system and the actual resources it takes to set them up. They know working with another vendor adds a whole other layer of management, integration and reconciliation," said Tony Varano, founder and chief executive officer of DSG.

The catalyst for the integration of DSG's EDC system with patient randomization was Sirion Therapeutics, a biotech client that approached the company to help shave costs and improve efficiency. The two companies

page 4

Averion sells clinical staffing services unit...2

Pivotal Research Centers 2007 revenues decrease...2

Company Profile... 5

An interview with Kathleen Ashenfelter, director, operations and development **Cu-Tech**

Drug & Device Pipeline News... 6

CenterWatch has identified 29 drugs and devices that have entered new trial phase this week.

Trial Results... 8

CenterWatch reports on results for nine drugs. Visit www.centerwatch.com for real-time updates on drugs in clinical trials.

Biotech Review... 10

Biotech briefs from *Bioworld Today*.

Features (continued from page 1)

Parexel

became apparent that it was time to take full ownership of the company.

"Ultimately, clients are looking for fully integrated solutions and I think clients are much more comfortable when there aren't subcontractor relationships that are built into the model, which was the way we had to work initially," Goldberg said.

APEX, which stands for Achievement through Passion and EXecution, was founded in 1999 by Albert Liou and offers trial services in China, Hong Kong, India, Taiwan, Singapore, Indonesia, South Korea, Malaysia, Thailand, the Philippines, New Zealand and Australia. Liou

will become corporate vice president and general manager of Parexel APEX.

"The clinical trials industry is really only now starting to emerge in this region and we believe the time is right to put the stake more firmly in the ground," Josef von Rickenbach, chief executive officer for Parexel, stated during an analyst call.

He added that having a strong presence in the region could "tip the balance between winning or losing a particular contract" because of the push by sponsors to conduct studies in these regions. Rickenbach said that the timing of the acquisition was also important because of a lack of CROs in that region and that, given APEX's reputation, there were other companies

looking to buy the CRO at the same time.

Parexel has had a presence in Australia for some time. It gained a foothold in India in June with the opening of a data management office in Hyderabad, India. Parexel already operated an 86-bed, phase I unit in Ahmedabad—through a joint venture with the CRO Synchron.

Meanwhile, Parexel upped its financial guidance for the first quarter of 2008, partly because of the APEX purchase. It stated the impact of the acquisition is expected to contribute approximately \$1 million in service revenue. Over the full 2008 fiscal year, APEX is expected to bring in \$14 to \$17 million in revenue.

DSG

collaborated on the project and customized a solution that worked.

"So what we did was take out one layer of contact by working directly with Sirion's packaging company. Once the supply went to the site, a study coordinator could use eCaseLink to verify the kits and use the tablet PC throughout the study for not only collecting trial data but for patient randomization," said Suzanne Lamerand, vice president, clinical data management at DSG.

As a former data manager, Lamerand recalled reconciling data with the external IVRS

vendor was often "tedious, cumbersome and often overlooked." Historically, data managers had to reconcile from paper reports which could become onerous for a several hundred patient study. Lamerand added that at the end of the trial there would inevitably be a patient that was given the wrong kit.

"Most of the time what happens is that a study coordinator receives a randomized kit number over the phone and jots down the number on a piece of paper or in their source notes. So you can envision how if the phone voice said '1234' and they jotted down '1243' and they didn't enter that information into an EDC system right away it could be days, weeks

or months before they know they have handed out the wrong kit," said Lamerand.

With DSG's solution the sponsor becomes aware of problems instantly; however, because the system has removed the possibility of transcription errors, those kinds of issues are much less likely to occur.

DSG won the Society for Clinical Data Management's (SCDM) Data Driven Innovation Award for the integrated solution at the organization's 2007 fall meeting in Chicago. The award was contingent upon successful completion of real clinical trials with the system; DSH and Sirion have already performed six. Four other finalists competed for the award.



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