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## Month in Review

**Editor's Note:** Full text articles of these stories appeared last month in *CWWeekly*. For more information about these articles, please refer to the following *CWWeekly* issues: Volume 12, Numbers 1-3.

### CROs

Cary, N.C.-based early stage contract research organization (CRO) **Cetero Research** broadened its range of therapeutic area research with the acquisition of San Antonio, Texas-based CRO, **DGD Research**. Financial details were not disclosed. The acquired CRO, which conducts studies in both early- and late-stage trials, was formerly known as Diabetes & Glandular Disease Research Associates. With DGD, Cetero also gains a recently built 80,000-square-foot research unit that has 100 phase I beds. The unit also has 12 dedicated beds for diabetes research, specifically euglycemic and hypoglycemic clamp beds.

Wilmington, N.C.-based patient enrollment contract research organization (CRO) **Inclinix** has raised \$10 million in venture capital from private equity firm **Frontier Capital**. Being a patient recruitment CRO driven by metrics and analytical services, Inclinix needed funds to help develop their technologies. As an entrepreneur capitalist himself and having had interactions with Frontier Capital in the past, Inclinix's president and chief executive officer, J. Tobin Geatz, knew just where to turn. Much of the money raised will be used to further develop and deploy patented technologies that allow many of its services to be automated.

Austin, Texas-based contract research organization (CRO) **ResearchPoint Global** has added a core imaging lab to its joint-venture partnership network with the addition of

**M2S**, a medical data and imaging systems company based in West Lebanon, N.H.

M2S offers clients the ability to manage their imaging data on secure imaging servers that are accessible through web-based platforms. M2S began as Medical Media Systems in 1998. The company changed its name in 2004 to Medical Metrix Solutions and again in 2006 to M2S.

**Quintiles** consolidated its China-based Global Central Laboratories and Clinical Development Services (CDS) businesses into a new, 17,000-square-foot facility in Beijing. The new site is larger than the CRO's original laboratory located at the Peking Union Medical College Hospital (PUMCH). The CDS plans to grow to a staff of more than 60 in the next year. The company stated that by consolidating these businesses it could improve coordination and efficiency for Quintiles' customers "The globalization of clinical research is continuing to increase, and China is just beginning to see the rapid growth we have experienced in India, Australia and throughout Asia Pacific," said Lai Lee Tan, head of the Quintiles' Clinical Operations and general manager in China. Quintiles' laboratories in China are certified by the College of American Pathologists (CAP) and the National Glycohemoglobin Standardization Program (NGSP).

Wilmington, N.C.-based contract research organization (CRO) **PPD** continues revamping its global operations with the appointment of Sebastian Pacios, M.D., hired to lead—as a senior vice president—the CRO's European, Middle East and Africa operations. Pacios has experience running trials in those regions, having served at PRA International as vice president of the company's clinical research and project management in Europe, Africa and Asia-Pacific. Last year, PPD set out to break its phase II-IV operations into four separate terri-

tories: North America; Latin America; Europe, Middle East and Africa; and Asia. PPD has been steadily appointing new leaders to these regions since then.

PPD's move is more evidence of the emphasis CROs are now putting on global expansion, as more sponsors push for overseas trials. 2007 saw significant CRO expansions into emerging markets as companies worked hard to keep up with pharma and biotech.

Cincinnati-based contract research organization (CRO) **Medpace** launched a 50-bed phase I/IIa unit, beginning the company's first foray into the early stage clinical trial outsourcing business. The group, called the Medpace Clinical Pharmacology Unit, will be the company's third subsidiary following Imagepace, a core imaging laboratory, and its central lab, Medpace Reference Laboratories. According to John Wynne, Medpace's executive director of marketing and business development, the phase I unit was created to provide its clients with a full service outsourcing destination that has the ability to conduct studies in hard-to-recruit specialty populations.

**Quintiles** has entered into a recapitalization deal with **Bain Capital LLC** and **3i Group**. JPMorgan Chase's private capital group One Equity Partners (OEP) is selling its previous stake in Quintiles to the "new partnership," which includes chief executive officer Dennis Gillings. According to sources cited by *The Wall Street Journal*, Bain, 3i and Gillings will own a majority of the company, each purchasing equal stakes. No financial details were released. Analysts have valued the deal at about \$3 billion. Other minority players in the partnership include Singapore government firm Temasek Holdings, already an investor in the company. Quintiles stated it will not incur new debt as a result of the transaction. The deal is expected to close in January. OEP, TPG Capital and Gillings originally took the company private in September 2003. "The strength of our capital structure and partnership with these leading global investors underscore our unsurpassed ability to bring innovative solutions to the pharmaceutical and biotech industries. I also want to thank One Equity Partners for their contributions over the past four years," stated Gillings. Some industry observers have

suggested the move may signal a future return to the public market for Quintiles.

## Regulatory

The **Abigail Alliance's** petition for a writ of certiorari in The Supreme Court of the United States was denied on January 14. The question presented was "whether terminally ill patients who lack alternative treatment options have a constitutional right to purchase unapproved investigational drugs that have not been shown to be safe or effective and that have not been authorized for treatment uses by the Food and Drug Administration."

A writ of certiorari is a document which a losing party files with the Supreme Court asking it to review the decision of a lower court. It includes a list of the parties, a statement of the facts of the case, the legal questions presented for review, and arguments as to why the Court should grant the writ. Industry insiders as well as many terminally ill patients believed that if Abigail Alliance had won its suit that it would have wreaked havoc on the drug development process and how it is regulated.

## Revolutionary Public-Private Partnership for Early Phase Trials Established in France

**T**he Centre Hospitalier Universitaire (CHU) de Caen, a university teaching hospital and the largest hospital in the West of France, and Therapharm, a large, private contract research organization founded in 1980, have joined forces to form the first public-private partnership to conduct early phase clinical research in France. The clinical research center is called Centre de Recherche Clinique-Basse Normandie (CRC-BN). The center conducts phase I and II clinical trials that are industry-sponsored, investigator-initiated and government-sponsored.

Antoine Cournot, who is president of Therapharm and spearheaded the partnership, said, "The objective of the clinical research center is to be able to perform early phases, phase I and II, with a high level of international quality but with a professional approach."

The impetus for the unique partnership was to attract more industry-sponsored clinical research to France. Creating a public-private partnership clinical research center in a large hospital has been a dream of Cournot's for 20 years, when he first attempted to establish one in Paris, where Therapharm's head-

quarters are. Ten years ago, when Therapharm moved its phase I unit from Paris to Caen—in close proximity to CHU de Caen—Cournot approached the hospital about his idea. But, it wasn't until 18 months ago that the hospital and Therapharm met for a serious discussion about plans for building CRC-BN.

Each organization brings important assets and expertise to the partnership. CHU de Caen has 1500 beds, 80,000 patient visits per year, a catchment area of 2.4 million people, a technology platform and experienced physician investigators. Therapharm offers decades

see CRC-BN on page 6