

## AstraZeneca Invests \$100M in R&D in China

**A**straZeneca plans to invest \$100 million in R&D in China in the next three years. The pharmaceutical company plans to focus on the benefit and value of innovative medicines for Chinese patients.

With its \$100 million investment in China, AstraZeneca, already one of the most heavily invested of big pharma in China, will establish the AstraZeneca Innovation Centre China. The company has initiated a comprehensive search for an appropriate location for the Innovation Centre, which will be operational by the end of 2009. The center will focus on

translational science by developing knowledge about Chinese patients, biomarkers and genetics. The initial therapeutic area for the Innovation Centre will be cancer, which is a major cause of death in China.

In addition, AstraZeneca will expand its clinical research capabilities and is looking this year to increase the number of scientific collaborations with local Chinese organizations. AstraZeneca recently signed a deal worth \$14 million with Wuxi Pharmatech for compound collection synthesis and has an existing collaboration with Shanghai Jiao Tong University on the

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## Averion Expands Operations to Europe

**F**ramingham, Mass.-based Averion, a contract research organization (CRO), has expanded into Europe through the creation of Averion GmbH, a new wholly-owned subsidiary based in Germany.

Averion also appointed John Shillingford, Ph.D, as president of Averion GmbH. Shillingford has most recently held positions overseeing clinical operations and project management responsibilities at PRA International and IMFORM GmbH.

"We are very excited to have John joining us and leading Averion's expansion into Europe," said Philip Lavin, Ph.D, president and chief executive officer of Averion. "This will enable Averion to better serve our USA clients seeking to conduct clinical

trials using European sites and to serve the ever expanding European marketplace in pharmaceuticals, biotechnology and medical devices. John brings a unique combination of exceptional management and operations credentials."

Shillingford will oversee the operations of Averion GmbH, including recruiting new European clients as well as running trials for Averion's existing North American customers.

Averion GmbH will work to develop relationships with European clients as well as run European studies for existing North American clients.

The new subsidiary will offer Averion's full range of services, including: auditing,

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**Industry Briefs****CROs**

■ **Covance** has acquired substantially all of the assets of **Signet Laboratories**, for \$8.95 million. Signet, based in Dedham, Mass., is a provider of monoclonal antibodies used in the research of cancer, infectious disease and neurodegenerative disease. "These new service offerings will allow us to tap into commercial opportunities in the pharmaceutical and clinical diagnostics markets. We look forward to integrating these new products and services in our drug development portfolio, and in particular with our industry leading preclinical and central laboratory services," said Joe Herring, Covance's chairman and chief executive officer.

■ **TKL Research**, formerly headquartered in Paramus, N.J., has expanded and relocated its corporate headquarters to Rochelle Park, N.J. TKL's executive offices and all of its major administrative functions in support of its clinical trials division, clinical site division and recruitment management division have moved to this new location. The company doubled its office space. The Paramus location will continue to operate as the primary clinical site for the clinical site division, which includes its four New York metropolitan sites.

■ **Clinilabs'** new 24,400-square-foot clinical trial facility was opened in New York City. The new facility will feature more than 100

staff including clinical researchers experienced in all phases of human clinical trials, nursing and technology staff.

■ The first phase of **Charles River Laboratories'** new Shrewsbury expansion site is on target to open in January 2007. Upon completion of the first phase of construction, 400 employees will move from the company's Worcester, Mass. facility to the new Shrewsbury site.

**Technology**

■ **Medidata Solutions**, a provider of electronic clinical data capture, management and reporting solutions, has expanded its customer support services through the addition of a new data center and with the appointment of **Louis Gilbert** as vice president of information technology. Medidata has also entered into a strategic partnership with **C3i**, a consulting and services company that specializes in helping life sciences organizations advance customer management effectiveness.

**Personnel**

■ **Kforce** has promoted **Kelli Henry** to associate director of clinical operations for Kforce Clinical Research Staffing. She is responsible for supporting clinical operations initiatives and program management and delivery, as well as business development and marketing support.



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## AstraZeneca

genetics of schizophrenia. "With China's rapid economic growth and increasing demand for better healthcare, China has become one of the most important emerging markets for AstraZeneca and will be important to our future success," stated David Brennan, chief executive officer of AstraZeneca. "We fully support China's national focus on innovation by substantially increasing our R&D investment, both in financial terms and in terms of scientific collaboration. AstraZeneca welcomes and supports the Chinese government's continuing policy to recognize investment in knowledge transfer and R&D innovation by strengthening IP [intellectual property] protection, and ensuring timely market access for Chinese patients to innovative products, at prices which recognize the value of innovation."

AstraZeneca has built a network of

marketing and sales offices, a manufacturing site and clinical research unit in China. AstraZeneca, which now has 2,200 employees locally, was the first multinational pharmaceutical company to include China as an area for large-scale international multicenter trials and establish a clinical research center there.

Dr. Ross Horsburgh, regional medical director, Asia Pacific Region for AstraZeneca, told CenterWatch recently that the AstraZeneca model has undergone change in China, which reflects the way China is seen in the marketplace now versus only five years ago. "We were expecting the ACRU [AstraZeneca Clinical Research Unit] to need to be there for five years as a standalone unit, which is an unusual model for us. It was an emerging market model we were using. What we've done now just in April [2005] is integrated and we have one large R&D unit now in China serving both China market needs but also

regulatory studies, local phase IV work but also doing global trial work. This is a more efficient model and it's now a model that makes China consistent with major European markets like Germany and the U.K. Back in 2001 to have predicted that in April 2005 we were going to be ready to step to this new developed market model that we have at AstraZeneca, people would not have believed it. It's a big change," he said.

To further demonstrate its commitment to being "In China, For China," AstraZeneca is partnering with government organizations and industry associations to develop academic and management knowledge among medical professionals and hospital executives. AstraZeneca has also initiated a number of programs on disease education and public health.

## Averion

biometrics, monitoring, project management, compliance and validation, database development, data management, data monitoring and clinical endpoint committees, medical monitoring, medical writing, metrics consulting, pharmacovigilance, program planning/study design and

regulatory consulting.

IMFORM, where Shillingford had been general manager, recently sold to Premier Research Group, a UK-based CRO, for about 7 million euros.

The acquisition doubled the size of Premier to about 350 employees. IMFORM was founded in 1991 and has 144 employees with offices in the Czech and Slovak

Republics, Poland, Hungary, Romania, Bulgaria, Russia, Ukraine, Austria and the UK, and operations in 25 European countries. Two years ago, Premier had 160 employees and \$19 million in annual revenue when it was combined with CRC Development in the UK.

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## Profile: Contract Research Organization

### iGate Clinical Research (iGate CR), Mumbai, India; Pittsburgh, Pa.

An interview with Vasudeo Ginde, founder and managing director

#### What is iGate CR's background?

I worked with Lilly from 1993 until 1997, then I started my own CRO, DiagnoSearch. It was one of the first CROs to launch in India. In 2003, iGate, a \$300 million Nasdaq-listed corporation, made two acquisitions—Pittsburgh Clinical Research Network, a site management organization, and the majority of DiagnoSearch—and created iGate Clinical Research. We are the only CRO in the country that is end-to-end. We have three major components—biostatistics and data management; clinical research operation, which ranges from inputs to protocol writing, investigator selection to conducting the entire study; and a central lab. Today, our lab is accredited by the College of American Pathologists. There are six labs in India that have this distinction. We are the only one among the six that is dedicated for clinical trials.

#### What else differentiates iGate CR from other CROs in India?

From the Indian standpoint, it's the track record. More than 50 of our 67 clinical trials have been for global databases. CROs are pretty much starting up every month, and many do not have as much background, training and experience as they

should have. Also, there is a lot of concern about employee retention in India. Fortunately, in the last nine-plus years of our business, we've only lost five employees. We can offer a sponsor company the same team they worked with five years ago. We also have a U.S. office, so a Western client can reach someone during U.S. business hours who's knowledgeable about the progress of their study. And, we offer contracting for U.S. companies so that they can contract with a U.S. entity.

#### What challenges do you face?

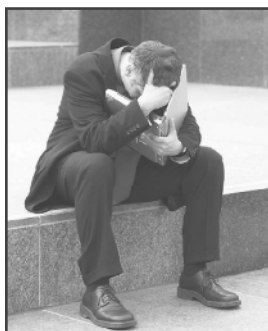
The first challenge is that even the big pharma that come to India start small. India has big potential, but these companies new to the country don't want to go by the success of the companies that came here before them. They want to start all over again. Second is that India needs to take the initiative of capacity building for every stakeholder—CRO staffs, ethics committees, the regulatory agency and investigators. With investigators, there seems to be a tendency for all of us in India to go back to the same ones because of their experience in doing clinical research. Instead, we should be investing in newer and newer investigators because India has 17,000 doctors graduating every year. Pharma companies con-

**Year founded:** 1997  
**Employees:** 60  
**Active trials:** 17  
**Contact:** Lisa Cohn  
**Telephone:** 412-490-9608  
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tribute to that challenge because every time they come to us or to another CRO, they say they want investigators who are trained and experienced in GCP trials. So you end up going to the same investigators again. One recommendation is that for any given trial, if you need 10 investigators, you probably should have five or six who are experienced and get four or five who are new. As a CRO, we make sure that the quality standards are just the same.

#### What are iGate CR's plans for growth?

In April, iGate Clinical Research had 60 employees and by August, we will have 120. We are scaling up in terms of infrastructure also. Currently, in Mumbai, we have a 10,000-square-foot office. We are moving to a facility this month that is 30,000 square feet. We have steadily invested over time and we continue to invest. For 2006 we will be investing as much as \$2 million or even more if we need to, to make sure that we have a scaled up operation in terms of people and competence.



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## Drug & Device Pipeline News

Company	Drug/Device	Therapeutic Area	Status	Sponsor Info
Inspire	epinastine	seasonal allergic rhinitis	IND filing planned; phase II trials planned enrolling 700 subjects	(919) 941-9777 www.inspirepharm.com
CytImmune	CYT-6091	advanced cancers	Phase I trials planned enrolling 42 subjects	(240)-864-2796 www.cytimmune.com
Poinard (NeoRx)	picoplatin	prostate cancer	Phase I/II trials initiated	(206) 281-7001 www.poinard.com
PowderMed	prophylactic DNA vaccine	influenza	Phase II trials planned	+44 018 6550 1500 www.powdermed.com
NeoPharm	LE-SN38	colorectal cancer	Phase II trials initiated enrolling 54 subjects	(847) 887-0800 www.neopharm.com
CuraGen	velafermin	oral mucositis	Phase II trials initiated enrolling 400 subjects across 40 U.S. sites	(203) 481-1104 www.curagen.com
Amarillo Biosciences	oral interferon	influenza	Clinical trials planned enrolling 200 subjects	(806) 376 1741 www.amarbio.com
Crucell	H9N2 virosomal vaccine	avian influenza	Clinical trials initiated enrolling 560 subjects	+31(0) 71 5248701 www.crucell.com
Debiopharm	Sanvar	esophageal variceal bleeding	Phase III trials planned in the U.S.	+41 (0) 21 321 0111 www.debiopharm.com
Novelos	NOV-002	lung cancer	Phase III trials planned enrolling 840 subjects across 100 sites	(617) 244-1616 www.novelos.com
Javelin Pharmaceuticals	Dyloject (diclofenac)	postoperative pain	Phase III trials initiated enrolling 360 subjects in the U.S.	(617) 349-4500 www.javelinpharmaceuticals.com
Ista Pharmaceuticals	Xibrom (bromfenac)	cataract surgery pain	Two phase III trials initiated enrolling 350 subjects	(949) 788-6000 www.istavision.com
Regeneron	IL-1 Trap	CIAS1-associated periodic syndromes	Fast Track status granted by the FDA	(914) 345-7400 www.regeneron.com
Point Therapeutics	talabostat	non-small cell lung cancer	Fast Track status granted by the FDA	(617) 933-2130 www.pther.com
Intercell	JEV vaccine	Japanese encephalitis prevention	BLA submission planned	+43 1 20620 0 www.intercell.com
Cell Therapeutics	Xyotax (paclitaxel poliglumex)	lung cancer	NDA submission planned	(206) 282-7100 www.cticseattle.com
Cardiome/Astellas	RSD1235	atrial fibrillation	NDA refused	(604) 677-6905 www.cardiome.com
CollaGenex	Oracea (doxycycline)	rosacea	FDA approved	(215) 579-7388 www.collagenex.com
Merck/Oka	Zostavax	shingles prevention	FDA approved	(908) 423-1000 www.merck.com

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## Trial Results

### Infectious Diseases

- **PowderMed** reported positive results of a phase I trial of their **prophylactic DNA vaccine**, for the treatment of influenza, in the journal *Vaccine*. Trial data yielded evidence of immunogenicity, with the highest trial dose eliciting seroprotective antibody responses. The level of this response for the highest dose was sufficient to meet EU CPMP immune response approvability criteria at 21 days, and all three doses met EU CPMP criteria at 56 days. This single ascending dose study enrolled 36 healthy volunteers, who received one of three doses of the vaccine (1 mcg, 2 mcg or 4 mcg).
- **Vical** reported positive results of a phase I trial of its investigational **West Nile Virus (WNV) vaccine**, at the American Society of Gene Therapy (ASGT) 2006 Annual Meeting in Baltimore. Results from the study demonstrated a positive safety profile, with no serious adverse events reported and a positive tolerability profile. Further, all subjects treated to date achieved neutralizing antibody WNV-specific responses following a three-month vaccination schedule; a number of subjects achieved neutralizing antibody response following two doses. This open-label study had treated 11 healthy volunteers to date at the NIH Clinical Center; subjects received 4 mg of the vaccine once monthly for three months.

### Ophthalmology

- **Acuity Pharmaceuticals** issued positive results of its phase II C.A.R.E. trial of **bevasiranib (Cand5)**, for the treatment of wet age-related macular degeneration (AMD), at the ASGT annual meeting. Top line data indicated a positive safety profile, with no serious adverse events reported and a positive overall tolerability profile. Preliminary response was noted in several measures, including near vision, lesion size (CNV) and time to rescue. All doses of the drug produced evidence of efficacy; the magnitude of response was seen to be dose related. This randomized, double-blind study enrolled 129 patients with serious disease across 28 sites in the U.S., who received one of three doses of the drug.

### Cardiovascular

- **Millennium Pharmaceuticals** reported positive results of a phase II trial of **MLN1202**, for the prevention of atherosclerotic cardiovascular disease. Preliminary data indicated that the drug met its primary efficacy endpoint, significantly reducing levels of C-Reactive Protein (CRP, an inflammatory biomarker) for several months following a single-dose of the drug, compared to placebo ( $p=0.0275$ ). No serious adverse events were reported. This randomized, placebo-controlled study enrolled 108 patients

with elevated CRP levels who were at high risk for atherosclerosis. Subjects received a single dose of the drug or placebo, and were then followed for several months. Additional results from this study were expected at upcoming major medical meetings.

### Neurology

- **Biogen Idec** and **Fumapharm** issued positive results of a phase II trial of **BG-12**, for the treatment of relapsed/remitting multiple sclerosis (MS), at the European Neurological Society annual meeting in Lausanne, Switzerland. This double-blind, placebo-controlled, dose-ranging study enrolled 257 patients across sites in 10 European countries. Subjects received one of three doses of the drug (120 mg, 360 mg, or 720 mg) or placebo daily for six months. Trial data indicated that the highest investigational dose produced a 69% reduction in the mean number of gadolinium-enhancing lesions on monthly observations for weeks 12-24, compared to placebo. The dose also produced a 48% reduction in newly enlarging T2-hyperintense lesions, and a non-significant, positive-trending 32% reduction in relapse rate. The two lower trial doses did not produce significantly superior efficacy to placebo. No incidence of opportunistic infections was noted.



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# Biotech Review

## From *BioWorld Today*

- **Illumina** pulled down net proceeds of about \$83.6 million through a public offering of 3.5 million shares of common stock at \$25.50 per share and aims to use the money partly to boost diagnostics work. "You can see the direction we're going by the DeCode deal we announced [last] Monday," said Jay Flatley, president and CEO of San Diego-based Illumina. With DeCode Genetics, of Reykjavik, Iceland, Illumina plans to co-develop and commercialize DNA-based diagnostic tests in several major disease areas, including heart attack, diabetes and breast cancer.
- Every scientist doing a long-term study wonders whether his or her conclusions would be different if the experiment had lasted longer. And a brief communication published in the April 27 issue of *Nature* said that for the side effects of X-SCID gene therapy, the answer is yes. But clinical researchers remain skeptical, with some alleging that the paper was rushed to publication. In 2000, the successful treatment of babies suffering from x-linked severe combined immunodeficiency disorder (X-SCID) was hailed as gene therapy's first triumph. But subsequently, for some of those children, the cure turned out to be as bad as the disease: To date, three of 14 patients have developed leukemia after the therapy. One of the children died. While not scrapping gene therapy trials altogether, the FDA

has recommended that only patients for whom conventional therapy has failed be treated with gene therapy.

- FDA have agreed on a special protocol assessment for a phase III trial of its chemotherapy-enhancing drug, CoFactor, expected to start this quarter. At the same time, the San Diego-based firm withdrew plans for a public offering, citing adverse market conditions. **Adventrx** filed a prospectus earlier this month, planning to sell 15.5 million shares. The share price had not yet been determined, but based on the May 12 closing price of \$4.84, the company had estimated net proceeds of \$69 million for general corporate purposes, including clinical and preclinical development. "The market has taken a downturn on recent negative news, in general," said Andrea Lynn, director of marketing at Adventrx, "and we just felt it wasn't the right time." She added that the decision is not expected to affect the upcoming CoFactor pivotal trial, and she could not estimate costs for the study.
- **U3 Pharma AG** raised 27 million euros (U.S. \$34.7 million) to accelerate development of its pipeline of targeted therapies, designed to modulate signal transduction pathways in cancer. The company, which now has raised about 42 million euros since its foundation in 2001, aims to move

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its lead product, U-1287, a human antibody that targets a membrane-bound receptor tyrosine kinase, into clinical development within the next 12 months, Chief Business Officer Edward Stuart said.

- The SEC last week issued plans to relieve the burden placed on small public companies by the Sarbanes-Oxley Act, at the same time lawmakers here introduced a bill aimed at a legislative fix. Both represent positive developments for the biotech industry. There has been a barrage of complaints on the costs of compliance with one part of the law, Section 404, which principally deals with internal and external auditing requirements, and lately some weighty reports have seconded those charges. In particular, companies with little to no revenue have found themselves paying large fees for testing internal controls in order to comply with Sarbanes-Oxley's Section 404, and in a notable statement, the SEC said it would consider reform proposals scaled to the individual circumstances.

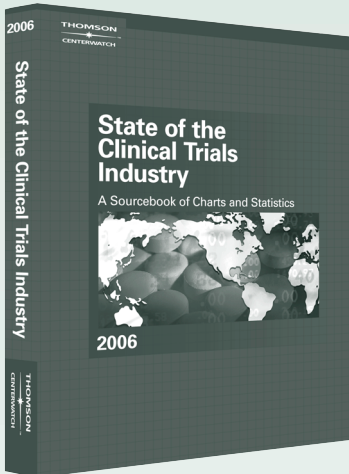


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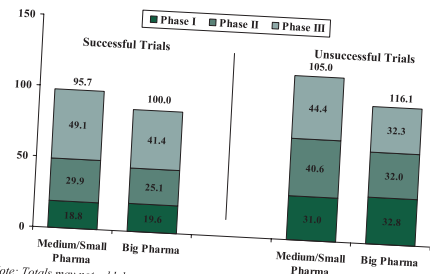
United States



## Average Clinical Development Time

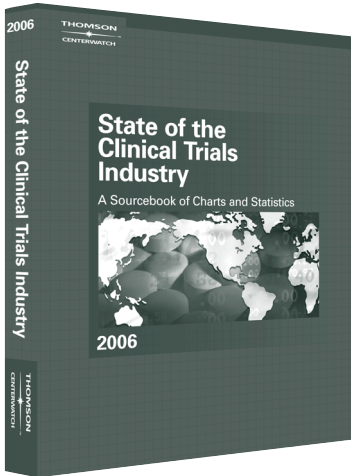
Mean Total Time by Company Size and Phase, All TAs

Mean Total Development Time in Months



Note: Totals may not add due to rounding

Source: Thomson CenterWatch Analysis, 2005; RA Abrantes-Metz, et al., FTC Bureau of Economics, 2004



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