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ASIA EDITION

# Asia wide CRO round-up-Annual BSA CRO survey

October 11, 2015 | Analysis | By BioSpectrum Bureau

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**CHINA:**
**Registered Ongoing Clinical Trial: 6501**
Ã?Â¢Ã¢â??Â¬Ã?Â¢ China issued new guidelines for clinical research companies to conduct trial in China that include submission of dossier filed anywhere for CFDA review, inspection of non-chinese sites and thorough inspection and credibility of clinical research investigators.

Ã?Â¢Ã¢â??Â¬Ã?Â¢ WuXi Pharma Tech collaborated with Foundation Medicine to provide genomic profiling to biopharma companies conducting clinical trials in China

Ã?Â¢Ã¢â??Â¬Ã?Â¢ WuXi PharmaTech inked deal with gene therapy expert, ReGenX Bio, to hammer out a manufacturing process for the company's potential one-time treatments. Under the deal, WuXi is lending its expertise in biologics manufacturing to help ReGenX establish a production process for treatments that use a safe human virus to insert corrective genes into the body

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Sihuan Pharmaceuticals inked a deal with Covance that would provide clinical and research services to develop Sihuan's product pipeline of cardiovascular, metabolic and infectious diseases, oncology and urology. As per the deal, Sihuan will be provided with drug development and regulatory expertise, in efforts to achieve dual or multiple filings for regulatory approvals such as investigational new drug (IND) applications and new drug applications (NDA) in China and internationally

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Sydney-based CRO, Novotech, expanded its Hong Kong operations with permanent office to meet the increasing demand in the research market. With its new operation, Novotech is focusing on Phase I trials in Hong Kong, partnering with local universities to host early-stage studies on in-development drugs

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**KOREA**

**Registered Ongoing Clinical Trial: 6483**

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Korea is now recognized as a global clinical trial hub in Asia as the government offers a variety of incentives to support the country's biotechnology and clinical trial industries

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Korea established Korea National Enterprise for Clinical Trials to advance standards, promote training and collaboration, forge industry partnerships and build an advanced clinical trial infrastructure

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Korea Drug Development Fund (KDDF) was launched with a budget of USD1 billion to help transform the country into a global leader for the development of new drugs

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Celerion expanded its clinical operations in Korea through partnership with Seoul National University Hospital (SNUH)

Ã?Â¢Ã¢â??Â¬Ã?Â¢ AstraZeneca signed a memorandum of understanding (MOU) with the Korea Health Industry Development Institute (KHIDI) to establish an Oncology Research Programme to provide support for 12 early-stage translational research projects by Korean investigators' in the field of oncology

**AUSTRALIA**

**Registered Ongoing Clinical Trial: 4801**

Ã?Â¢Ã¢â??Â¬Ã?Â¢ National Health and Medical Research Council (NHMRC) has developed an initiative to recognize clinical trial sites, including public and private hospitals and other organizations to carry out high quality clinical trials in a timely, transparent and efficient manner

Ã?Â¢Ã¢â??Â¬Ã?Â¢ NHMRC has developed a Good Practice Process for the site assessment and site authorisation phases of clinical trials research governance

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Department of Industry and Science has commissioned Swinburne University to develop an accredited course to be delivered to hospital staff who oversee clinical trials, and researchers who submit clinical trials applications to assist in improving the timeliness of clinical trial applications

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Indian CRO GVK BIO collaborated with the Australia-based clinical stage biopharmaceutical company, Akaal Pharma, for the scale-up of its novel topical AKP-11 ointment to support Phase II clinical study in psoriasis

**TAIWAN**

**Registered Ongoing Clinical Trial: 4062**

Ã?Â¢Ã¢â??Â¬Ã?Â¢ China and Taiwan made a significant partership by allowing new drug clinical trials to be conducted and launched to both the market simultaneously

Ã?Â¢Ã¢â??Â¬Ã?Â¢ China and Taiwan agreed to recognize Good Clinical Practice (GCP) certified clinical trials agencies on each side, including National Taiwan University Hospital, the Taipei Veterans General Hospital, the Tri-Service General Hospital and Taipei Chang Gung Memorial Hospital in Taiwan, and the Peking Union Medical College Hospital, the Affiliated Hospital of Peking University, Ruijin Hospital (Shanghai Jiao Tong University School of Medicine) and Zhongshan Hospital Fudan University in the mainland side

Ã?Â¢Ã¢â??Â¬Ã?Â¢ The two countries agreed to recognize the hospitals' medical trials data to be integrate with each other's resources in order to reduce duplicated research

Ã?Â¢Ã¢â??Â¬Ã?Â¢ National Taiwan University Hospital Clinical Trial Center is running 607 clinical trials, including 43 Phase I clinical trials

Ã?Â¢Ã¢â??Â¬Ã?Â¢ National Taiwan University Hospital partnered with Novartis to establish the R&D centre in Taiwan

**INDIA**

**Registered Ongoing Clinical Trial: 2688**

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Indian conglomerate Piramal sold off its CRO business to Indoco Remedies
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Quest Life Sciences received a notice of concern from World Health Organisation for critical lapses and deviations from standards in its clinical trials of HIV drugs. The WHO's prequalification team had visited the Chennai-based Contract Research Organisation (CRO) Quest's facilities in October 2014 and inspected the clinical trial of Lamivudine, Zidovudine and Nevirapine, a combination of drugs for treating HIV patients. Reportedly, the team observed lack of data integrity in clinical trial records, failures in protection of subject safety, inadequate quality assurance
GLOBAL
Registered Ongoing Clinical Trial: 196811
Ã?Â¢Ã¢â??Â¬Ã?Â¢ US-based Parexel expanded its global Clinical Logistics Services (CLS) capabilities with the establishment of a new distribution centre in Singapore and expansion of the firm's facility in the US
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Northern Ireland-based Almac Group established regional hubs in Singapore and to address the growing need to conduct clinical trials in Asia
Ã?Â¢Ã¢â??Â¬Ã?Â¢ Irish CRO giant Icon inked a deal with to Cancer Genetics, to offer biotech and pharmaceutical clients' access to ICON Laboratory Services' global central laboratory experience combined with Cancer Genetic's expertise in oncology testing and genomic assay development. Under the agreement, Icon will integrate Cancer Genetics' lab tests into its oncology services, which span the clinical development process

Ã?Â¢Ã¢â??Â¬Ã?Â¢ BBK Worldwide, a leading clinical trial marketing firm, appointed Mr Toshio Mori as managing director of operations, Japan. Mr Mori will lead business development and help drive sales and marketing in Japan

Ã?Â¢Ã¢â??Â¬Ã?Â¢ As part of its restructuring program, CRO giant Parexel announced plans to shed about 850 jobs over the next year, roughly 5 percent of its total workforce, in an effort to cut costs as it lowers its financial expectations for the quarter. Parexel has about 17,440 workers worldwide. The company, headquartered in Boston, is cutting into its payroll in an effort to save between $20 million and $30 million a year.

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Specialty CRO DaVita Clinical Research, which handles outsourced trials for the kidney care giant, is expanding its European presence, bringing in global experts to extend its network of R&D sites. The CRO has added outposts in Germany, Poland and Portugal to its group of recognized sites, allowing it to conduct worldwide, late-stage clinical trials on a once-impossible scale

Ã?Â¢Ã¢â??Â¬Ã?Â¢ Covance has joined forces with Novartis to develop new ways to help drug developers quickly integrate and analyze huge swaths of study data. Under the collaboration, Covance will step in to help expand the Novartis Institutes for Biomedical Research's (NIBR) existing clinical data warehouse, which already houses results from hundreds of studies