

Novotech forges new partnerships in South Korea

By John W Mitchell

July has been a big month for **Novotech** in South Korea. The Australian-based CRO that operates in 13 countries made two announcements aimed at furthering its presence in one of the hottest CRO markets in the Asia-Pacific region.

On July 19 Novotech announced that they launched a new site management organization (SMO) in South Korea. And on July 26 the company announced that it signed a Memorandum of Understanding (MOU) with South Korea's SCI-Consortium (SCIC) of Clinical Trial Centers and its representative hospital, **Severance Hospital, Yonsei University Health System**.

The SCIC network consists of four leading South Korean hospitals with clinical trial access to 1,500 investigators and more than seven million patients a year. There are currently 30,000 active patients in clinical studies in the network.

"We continue to view South Korea as a leading clinical trial destination," John Moller, M.D. CEO at Novotech told **CenterWatch**.

According to Moller, there are three reasons for this assessment. He cited the country's population size and concentration. Seoul, he noted, is the second largest and one of the most modern metropolitan cities in the world, with a population of 26 million people.

The country also has an excellent clinical trial infrastructure. South Korean hospitals

have the latest equipment, technology and infrastructure, as well a sophisticated patient database to recruit trial participants. And finally, he added, South Korea has a supportive regulatory environment provided by its clinical trial institutions.

This SMO was launched in response to an unmet need in South Korea—a new legislative change was presented in 2016 to allow for SMOs to support sites in the country.

"Site management organizations are quite common in the U.S., EU and Japan, and are an effective platform for principal investigators and sites to participate in clinical trials," said Dr. Moller. "We currently operate a SMO in Taiwan and, given our depth of experience in South Korea, we are well placed to serve the Korean market."

Novotech is currently undertaking a "large number" of clinical trials in South Korea. Dr. Moeller said the company is in advanced discussions to introduce its new SMO support for some of these trials.

"Most of Novotech's clients are U.S. and European biotechs undertaking cutting-edge research, and clinical trials allow South Korean patients to access innovative therapies that may not be on the market for many years," he said.

He also said that another reason for the company's decision to launch the new SMO business in South Korean was to address a

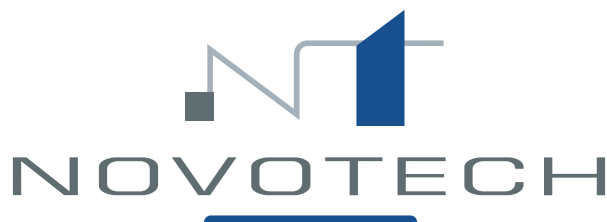
long-standing vulnerability in the clinical trial model. Traditionally, site coordinators (SCs) are hired by principal investigators on a trial-by-trial basis.

"This provides SCs with limited job security and can result in a high level of SC turnover," explained Dr. Moller. "The spillover of this unpredictability can negatively affect site feasibility, patient recruitment timelines and site management."

By providing an outsourced platform, Novotech believes it can better support all the parties involved in the clinical trial process. The new SMO business will provide SCs with training and scheduled employment. This, in turn, assures Principal investigators with a quality SC talent pool. Moller said that the company's Management Associates would provide an increased level of support to sponsors, clinical trial sites management, and ethics committees.

Novotech's ambitions for South Korea are supported by independent data. According to a July report published in *The Korea Herald*, clinical trials conducted by pharmaceutical companies were up 2.19% in the first half of the year, which is a slight increase from 2.08% in 2016. During the same period, according to the article, global clinical trials dropped 22.5%, with a 40% decline in tests by U.S. pharmaceutical companies.

A March 2017 **Frost and Sullivan** report found that clinical trials costs in Asia are 30 to 40% lower than in the U.S. and Europe. And in a recent announcement, Novotech made reference to the lower costs in the country due to a decision by the **South Korean National Health Insurance Program** that outlined



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plans to cover the cost of standard of care for patients participating in clinical trials.

“The decision to reimburse the standard of care for patients in clinical trials could translate to a 24-35% difference in cost for sponsors.

This potential difference significantly enhances South Korea’s attractiveness as a clinical trial destination,” said Novotech Executive Director for Asia Operations Yooni Kim, Ph.D. “For spon-

sors considering Asia for their next clinical trial, South Korea will be able to present yet another convincing reason for being a key country of choice—with globally competitive patient standard of care costs.”

Under the terms of the SCIC MOU last week, Severance Hospital, as the representative, will provide professional and medical advice to Novotech for clinical trials con-

ducted at the network’s four hospitals. This will include feasibility, Principal Investigator selection and assistance with patient recruitment. Novotech will also assist in promoting the clinical research capabilities of the SCIC internationally.

Both parties have agreed to continue expanding the future scope of the collaboration. 