

Celerion Korea Office Opened in SNUH!

Celerion, a world-renowned Contract Research Organization, established its first presence in Asia through its Korean office opened on March 3, 2014. Celerion Korea office is located on the first floor of the Biomedical Research Institute at Seoul National University Hospital (SNUH), where the Clinical Trials Center is also housed.

Celerion first visited Korea few years ago exploring opportunities to expand its business in Asia. Since Korea has shown a remarkable growth in the global clinical trials market over the past 10 years, it has become the most potential place for Celerion to establish its presence in the Asia Pacific region. Also, strong government support to develop a world-class infrastructure for clinical trials through funding and resources provided by Korea National Enterprise for Clinical Trials (KoNECT) contributed to the decision Celerion made to open Celerion Korea.

In search of a perfect location, Celerion has visited many clinical trials centers in Korea including the Global Center of Excellence in Early Clinical Trials at SNUH or GREATS. GREATS had many



desirable qualities that Celerion had been looking for, including enthusiastic and well-trained investigators and research staff, a huge patient pool, research environment, and etc. Moreover, through continuous meetings between key members of Celerion and SNUH CTC, it was clear that focus and goals of Celerion and SNUH CTC align very well. Since Celerion is primarily focused on early clinical research on a global level, an access to a large subject pool with multi-ethnic background that could be provided by SNUH was mandatory. On the other hand, as a leading early clinical trial center, GREATS was

in need of Celerion's ability to bring in more global drug development studies, particularly at the early phase.

Professor Yung-Jue Bang MD PhD, President of the Biomedical Research Institute at SNUH and Director of the SNUH Clinical Trials Center, stated, "it is an honor for us to partner with Celerion, a global leader in early clinical research. The partnership enables us to participate more actively in global drug development programs as well as supporting the early clinical research needs for the emerging Korean drug discovery industry."

"We are pleased to have a presence in South Korea through our partnership with Seoul National University Hospital," said Susan Thornton PhD., President and CEO at Celerion. "They are highly respected institution and among the global leaders in the conduct of quality medical research. Collectively, we are in a solid position to successfully conduct and analyze complex clinical pharmacology studies involving patients with access to specialized equipment."

More early clinical trials are expected to be performed in Korea through Celerion Korea. It also will provide opportunities to many domestic pharmaceutical companies and clinical trials centers to improve and show their abilities in developing new drugs to the global player. Also, the partnership with Celerion is a welcoming fruit of the concerted approach that the Korean government initiated and has led for many years to upgrade the infrastructure for clinical trials in Korea. Celerion Korea Office will be a new chapter for SNUH and Celerion benefiting both parties for future collaborations that could have taken many different forms.

Kitasato University Hospital – GREATS Joint Symposium



The Second Annual Kitasato University Hospital – Seoul National University Hospital (GREATS) Joint Symposium on 'Promoting Quality Pan-Asian Clinical Trials' was held on February 14, 2014, in the auditorium 1 at the Children's Hospital of SNUH.

This symposium meant more than just gathering important professionals from each country together to share information. The first joint symposium between Kitasato University Hospital and SNUH took place in Japan last year. It has been then becoming a tradition to build relationship between the two institutions. Members of both institutions believed that finding ways to strengthen collaboration and connections between countries in Asia is important in order to increase the quality of clinical trials performed in Pan-Asia. Therefore, many members from GREATS and its consortium institutes such as Seoul National University Bundang Hospital and Chonbuk National University Hospital were invited to the first symposium in Japan. This year, many leading figures from Kitasato University Hospital were invited in return to attend the second symposium.

This second joint symposium covered many interesting topics including the role of regulators in promoting multi-national clinical trials and the best governance options for the clinical trials center. Particularly, such presentations as perceptions of clinical trial

participants and the difference between Japanese and Korean by Dr. Ock-Joo Kim, Director of the Center for Human Research Protection at SNUH, and Ryosuke Koizumi, Clinical Research Coordinator at Kitasato University East Hospital, grabbed audience's attention. Their presentations offered the audience opportunities to hear the volunteers' side of stories that most of healthy volunteers are male in their 20s who are single with no children. Through the surveys conducted for the presentations, the audience could learn that many volunteers participate in clinical trials for the financial rewards since they would reconsider the participation if there are no financial rewards. Moreover, the surveys also revealed that many of volunteers acquire information through websites.

Study participants always play a critical role in clinical trials so it is important to understand their needs to promote the overall quality of studies. The content of presentations by Dr. Kim and Mr. Koizumi provided the audience with a brief description of the needs of volunteers and several tips to increase the efficiency of communication with them. Now it is the audience's turn to think about how to improve the environment for volunteers in clinical trials while keeping them safe. This informative symposium is expected to be held again next year in Japan with a different set of challenging topics.



GREATS will be at DIA 2014!

Like last year's DIA in Boston, GREATS team will attend this year's DIA as exhibitors so please feel free to come by and say hello!

- ◇ What? DIA 50th Annual Meeting
- ◇ When? June 16 - June 19, 2014
- ◇ Where? San Diego Convention Center, San Diego, CA, USA

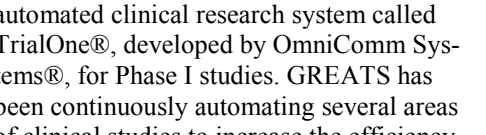
If you would like to have a meeting or receive any information ahead, please feel free to contact Sujin Rhee (+82 2 2072 0255 or sujinrhee@snuh.org).

We are looking forward to meeting you there!

=Industry News=

On February 11, 2014, the Ministry of Food and Drug Safety (MFDS) of Korea released a statistical overview of clinical trials approved in 2013. According to the statistics released, Seoul National University Hospital ranked the first in conducting the highest number of clinical trials in 2013 within Korea. It also ranked the top in the number of investigator initiated trials approved by MFDS in the same year. Clinical trials sponsored by domestic pharmaceutical companies increased in 2013 by 9.1 percent despite global economic recession. This increasing trend has been continued for the last 4 years. The overview by MFDS has shown that Novartis and Ildong as the multinational and domestic pharmaceutical companies with the highest number of clinical trials approved in the last year.

Automated Clinical Research System on Its Way!



GREATS has decided to implement a new automated clinical research system called TrialOne®, developed by OmniComm Systems®, for Phase I studies. GREATS has been continuously automating several areas of clinical studies to increase the efficiency and quality standards, but this new system will definitely bring a breakthrough to the situation.

GREATS has been in need of efficient management of data collection for high quality

early phase clinical trials. To this end, GREATS has carefully evaluated some off-the-shelf programs, and has done two mock studies to compare the pros and cons of the competing software programs currently available on the market. TrialOne® is expected to maximize the efficiency in the areas of subject recruitment, study data capture, sample tracking, reporting, data management, and integration with laboratory and medical monitoring equipment. Also, the new automated clinical research system has embedded strong foreign language support functionality, which is indispensable for performing global studies.

"This new system will automate many study activities enabling more streamlined work flows," says Yung-Jue Bang, M.D., Ph.D., Director of SNUH CTC. "It will greatly improve our research environment and help us get a step closer to our goal of becoming an international leader of early clinical trials."

GREATS signed five year agreement with OmniComm Systems® for TrialOne®, the leading automated clinical research system for early phase clinical trials.

MOU with Sekisui Med and DCK Consulting

On April 28, 2014, Dr. Shin-ichi Ninomiya (Board Director, Sekisui Medical Co., LTD) and Mr. Toru Washino (Manager, Pharma & Research Business) with Dr. Dong-Chool Kim (President, DCK Consulting) and his staff visited Seoul National University Hospital CTC attend Memorandum of Understanding (MOU) Signing Ceremony. The MOU between Sekisui Medical, DCK Consulting, and Seoul National University Hospital was intended to promote the use of the microdosing technology based on the Accelerator Mass Spectrometry for drug development clinical studies, particularly for early phase.

increase the success rate of the drug development program.

Recently, GREATS has successfully conducted a microdosing study, that measured the absolute bioavailability of an orally administered drug, which is the first of its kind in Korea. GREATS is planning to provide different types of microdosing study services to pharmaceutical companies based on the clinical platform built through this experience. Therefore, MOU with Sekisui Medical and DCK Consulting is expected to play a key role in performing more microdosing studies within GREATS.

"This MOU is the first step to many microdosing studies that will be conducted in GREATS," said Prof. Yung-Jue Bang, M.D., Ph.D., Director of SNUH CTC. "We are already looking forward to the outcomes that this MOU will bring in next few years," added Dr. Shin-ichi Ninomiya, Board of Director of Sekisui Medical Co., LTD.

Since less than 1/100 of the expected pharmacological dose or less than 100 microgram, whichever is smaller, is involved in the microdosing study, it is known to be very safe. Through microdosing studies, the pharmacokinetics and receptor binding affinity of the drug could be measured at the very early phase of clinical trials, which has been reported to



Jumping into Medical Device Industry to Take the Lead!

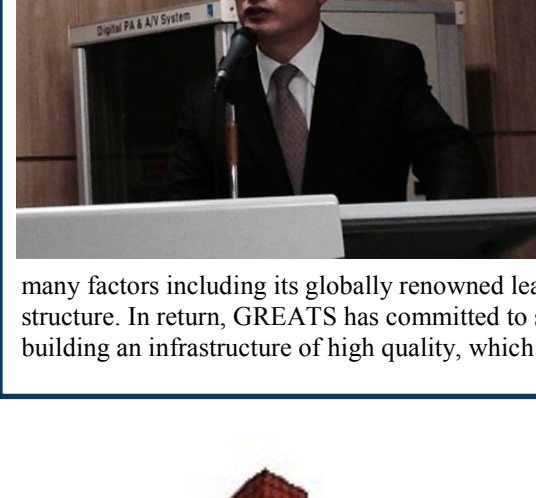
Prof. Byung-Hee Oh, MD, PhD (President & CEO, Seoul National University Hospital) and Dr. Ho-Yong Kim (President, Korea Electrotechnology Research Institute) gathered on April 25, 2014 to sign a Memorandum of Understanding (MOU) to encourage collaboration between the two institutions for the development of medical device and related technologies.

personnel to design infrastructure, joint training and education programs for clinical trials, and etc.

For SNUH, this MOU was the first official agreement to be signed with a research institution focusing on the technology to develop medical device. This meaningful agreement is expected to increase chances of successfully developing medical devices through the consultation with medical professionals, who are in direct contact with patients. Terms and conditions of the MOU include, but are not limited to, the following: shared information on medical device development and study data for the clinical trials, exchange of

The development of medical device used for the diagnosis and treatment of disease is considered a very valuable and promising industry field. Even though the current medical device market is seemed to be controlled only by most developed countries such as the United States and Germany, Prof. Byung-Hee Oh saw its potentials as the market has continuously grown. Under his leadership, which has been well received and supported by senior leaders at SNUH, including Prof. Yung-Jue Bang, MD, PhD (President of the Biomedical Research Institute at SNUH and Director to the SNUH Clinical Trials Center), SNUH has made efforts towards industrializing of medical device and building an infrastructure for clinical trials involving medical device.

GREATS's Performance Impressed the Reviewers at the Second-Year Annual Evaluation



On March 10th, 2014, leaders of Seoul National University Hospital CTC (GREATS) consortiums gathered to give presentations at the annual evaluation meeting for the second year, which is a mandatory step for continuing grant support. Professors Yung-Jue Bang (Director, SNUH CTC), Jongseok Lee (Director, Seoul National University Bundang Hospital CTC), and Min-gul Kim (Chonbuk National University Hospital CTC) went over achievements in 2013 and plans for 2014 for their clinical trials centers and there was Q&A sessions for 8 reviewers. The 2013 annual report was submitted prior to the annual evaluation day allowing them prepare questions for the presenters.

Through a government program called 'Global Center of Excellence in Clinical Trials' supported by the Korea National Enterprise for Clinical Trials (KoNECT), GREATS receives about 2 million US dollars annually from the government for 5 years until 2017. GREATS and its consortiums were qualified for this funding on November 2012 due to many consorts including its globally renowned leaders and the strategic and detailed plans for business development and outstanding infrastructure. In return, GREATS has committed to strengthening its competitive edge to conduct clinical trials in the global market and to building an infrastructure of high quality, which will eventually benefit the biopharmaceutical industry, not only in Korea, but worldwide.

