

THE GREATS TIMES

The Seoul National University Hospital Clinical Trials Center

Publisher: Yung-Jue Bang, MD, PhD, Director

GREATS&EPICS promotion at the REACTA forum by Dr. Howard Lee



Professor Howard Lee, head of the Department of Global Strategy & Planning, attended the Regional Asian Clinical Trial Annual (REACTA) Forum to promote the Early Phase Integrated Clinic Automation Solution (EPICS) and Seoul National University Hospital Clinical Trials Center (SNUH CTC). EPICS is an

electronic bed-side data capture system developed by SNUH CTC to increase the efficiency of clinical trials performed at SNUH CTC. The REACTA Forum was held on November 26th and 27th, 2015 in the Memorial Hall at Chiba University School of Medicine in Japan.

SNUH CTC officially proved the best infrastructure :Clinical Site Quality Assurance Audit by Celerion

Since September 2013, the SNUH CTC audit has been conducted by the Quality Assurance Department of Celerion, Inc, the biggest early phase CRO in the world. Surviving intense audits and further investigations that followed the audits, SNUH CTC was finally granted an official certificate that assures the high quality of the clinical trials performed at SNUH CTC and its full compliance with Global GCP Industry Standards, ICH E6, US FDA, and other applicable regulatory authority requirements.



Genentech Finally chose SNUH CTC

Genentech
A Member of the Roche Group

Genentech (Roche group) designated SNUH CTC as the first non-oncology core site in Asia. Genentech, an internationally renowned biotechnology company founded in 1976, has thoroughly analyzed and evaluated the capability of SNUH CTC before they reached the conclusion. Based on the agreement, SNUH CTC will be considered first as a candidate site for any clinical studies commissioned by Genentech.

GREATS & EVENTS!

GREATS Consortium gathered for the future



Three GREATS consortium institutes (SNUH, SNUBH, and JBCTC) gathered together to share information on the present condition of the project and to confirm future plans. Designated investigators and administrative office staff convened two meetings and one roundtable discussion. Through various sessions,

the staff and investigators reaffirmed their determination to make this project successful. The GREATS workshop was held at the SNUH Human Resource Development (HRD) Center in Munkyeong, Korea, on January 29th and 30th, 2016.



The 20th Anniversary Commemoration Book “Beyond the First, To the Global Leader”

Established in 1995, Seoul National University Hospital Clinical Trials Center is the first clinical research center in Korea, laying the foundation of Korea's clinical trial environment. SNUH CTC published a history book (image below) to celebrate the 20th anniversary of the center. This book contains the full story of their past from contributors like former center directors and staff to the center's establishment and leadership, particularly in the area of clinical trials in South Korea. This book commemorating their 20th anniversary will be sent to major libraries and network institutes around Korea.

SNUH visits Leading Institutes in Europe



From 24th February, Professor SeungHwan Lee (SNUH CTC) and investigators visited three leading institutes in Europe. The Center for Human Drug Research (CHDR), located in Leiden, Netherlands, is the institution focused on the central nervous system drug evaluation. Prof. SeungHwan Lee gave a presentation titled, “Approaches of SNUH for Efficient Drug Development” targeting trainees at CHDR. Dr. Robert Rissmann (Education director) followed with a discussion with investigators of SNUH and Prof. Lee regarding organizational systems, Human resource education processes, and so on. The core devices, such as Driving simulator, Neurocart™, and Paincart™, were tested firsthand by participants. The next institution they visited was the SGS Global Contract Research Organization (CRO) in Brussels, Ant-

werpen. Dr. Annick van Riel (Director, SGS) discussed the organization’s function and their automated data capturing system. Furthermore, Dr. Steven Remael, a well-experienced investigator in CSF PK/PD, talked about some of the real cases of his CSF research experiences. The meeting was followed by a tour of the facilities like the isolated sound pressure ward. The final destination for the SNUH delegates was the clinical research facility at Guy’s and St. Thomas Hospital in London, England. This particular institute has been strong at investigator-initiated trials (ITT) funded by the National Institute for Health Research (NIHR) in the UK. Director Dr. Phil gave the delegate a guided tour of the facility (cell GMP, MRI for research) after a meeting about revitalizing pharmacology IIT.

The 4th Kitasato—SNUH Joint Symposium (Seoul, Korea) “Special Collaboration is on the way”

On February 22nd, SNUH CTC held the 4th Kitasato-SNUH Joint Symposium under the title “Globalization of Korean Pharmaceutical Industry – Science and Regulation” at the SNUH Biomedical Research Institute (Grand Auditorium) with Kitasato University Clinical Trials Center, Japan. Seven expert speakers were invited to share their various opinions about multi-centers (institutes) and multi-national clinical trials. Approximately 180 participants attended the event and actively suggested diverse feedback. This year was SNUH CTC’s turn to host the annual symposium, which started in 2013. The 5th joint symposium is expected to be held in Japan on 2017.



The New SNUH CTC is Coming!

Seoul National University Hospital Clinical Trials Center (SNUH CTC) set the renovation plan that would take the environment to the next level. The operating system will be more efficient and more easy to perform. The general facilities, such as ward and pharmacy, will be approximately doubled to increase the overall capability. The construction would be gradually done according to the plan by the end of 2016.

SNUH CTC insist you to visit new center once its done.

If you would like to visit us, please contact Global Strategy Planning associate, Theresa Choi for visit request. Please refer to the contact information below.



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Here I come DIA 2016!



Seoul National University Hospital Clinical Trials Center (SNUH CTC) will attend DIA2016, Philadelphia, USA as an exhibitor. Please visit us at the booth and have informative time to share opinions. See you at Philadelphia!

Director's Corner! Prof. Yung-Jue Bang, Director of SNUH CTC

ASCO Exclusive Coverage (August 2015)

- Paper by director - Bang YJ, Im SA, Lee KW, Cho JY, Song EK, Lee KH, Kim YH, Park JO, Chun HG, Zang DY, Fielding A, Rowbottom J, Hodgson D, O'Connor MJ, Yin X, and Kim WH. J Clin Oncol. 2015 Nov 20;33 (33):3858-65(PAPER TITLE) ASCO (American Society of Clinical Oncology) selected the paper by Professor Yung Jue Bang (Director, SNUH CTC) regarding translational research with AstraZeneca. The research was intended to be a collaboration from the design through to the multi-institutes performance nationwide. Through this study, combination therapy of paclitaxel and olaparib, a PARP inhibitor, (olaparib/paclitaxel) showed greater overall survival benefit compared to paclitaxel alone therapy in patients with metastatic gastric cancer with low ataxia telangiectasia mutated (ATM) expression. Based on these results, olaparib is being investigated in the GOLD (Phase 3) study. It is a representative case of the rapid translation in new drug development from

preclinical stage to the phase 3 stage. It is also the first study to demonstrate the possibility of the ATM as a biomarker for the selection of the subjects who are indicated for PARP inhibitor. As a result, ASCO gave this paper exclusive coverage in their August 2015 edition and the Journal of Clinical Oncology (JCO) also chose this article to be presented at the meeting.

Director's Corner! Prof. Yung-Jue Bang , Director of SNUH CTC

“The Scientist of the year”



- ◆ On December 10th 2015, Professor Yung Jue Bang (Director, SNUH CTC) received “The Scientist of the year award” presented by Korea Science Reporters Association, who announced Professor Bang as the winner based on his contribution to building an infrastructure for oncology and general clinical trials

1st INC Research Best Institute



- ◆ INC Research Best Institute - On 22 October, 2015, INC Research awarded Professor Yung-Jue Bang with a Clinical Research Site Recognition Award on behalf of the Seoul National University Hospital (SNUH). The award was presented by representatives of INC Research including Clare Grace, Vice President, Site and Patient Access; Siew Lee Goh, Associate Director, Clinical Operations; and Eun Jihn Roh, Director, Clinical Operations. This award was presented in recognition of the outstanding commitment and support of Oncology clinical trials by Professor Bang and his team. It also recognizes the value that SNUH, Prof. Bang, and his team bring as partners in the clinical research process. INC presented the awards based on nominations of its clinical study teams of outstanding investigational site partners. The nominations for the INC Clinical Research Site Award consider a number of factors including but not limited to study start-up timelines; enrollment rates; regulatory compliance; protocol adherence; appropriate source documentation and CRFs; and highly engaged investigators and site staff. Prof. Bang's team was nominated for the Site Recognition Award based on the following feedback from the INC clinical study teams:

- Prof. Bang and his team at the SNUH site have shown outstanding performance in the INC studies he has performed.
- Prof. Bang has shown great collaboration with the INC team, who highly respect his expertise in Oncology and clinical trials.
- Through participation in many studies, Prof. Bang has enabled many patients to have greater access to novel treatments and the opportunity to contribute to their development.
- Prof. Bang is always very supportive, responsive, and a great help to the INC team, providing very timely responses with detailed explanations and rationale that supports our development of new protocols and feedback to sponsor organizations.

INC Research introduced the Clinical Research Site Recognition Awards Program in 2014 to reinforce their commitment to sites and to provide a visible reminder and outward sign of their appreciation to those sites identified by INC Team Members as exceptional partners in the clinical development process. To date, the program has recognized approximately 200 sites globally.

Introducing Seoul National University Bundang Hospital CTC!

Dept. of Clinical Pharmacology & Therapeutics of SNUBH



Pharmacokinetics/Pharmacodynamics

Pharmacokinetics, Safety, and Tolerability of Metformin in Healthy Elderly Subjects

Kyungho Jang MD¹, Hyewon Chung MD¹, Jang-soo Yoon MD¹, Seol-Joo Moon MD¹, Seo Hyun Yoon PhD¹, Kyung-Sang Yu MD, PhD¹, Kwangil Kim MD, PhD² and Jae-Yong Chung MD, PhD^{3,*}

Article first published online: 22 FEB 2016
DOI: 10.1002/jcph.699
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Issue

The Journal of Clinical Pharmacology
Early View (Online Version of Record published before inclusion in an issue)

Seoul National University Bundang Hospital Clinical Trials Center (SNUBH CTC) published a clinical study on the elderly subjects in the Journal of Clinical Pharmacology on Dec 2015. SNUBH CTC Phase I Unit enrolled 12 healthy elderly subjects aged 65-85 years and investigated the pharmacokinetics and pharmacodynamics of metformin compared to 20 younger healthy volunteers. The systemic exposure to metformin was significantly increased in the elderly subjects, who exhibited 1.7- and 2.0-times higher average Cmax

and AUC than the younger subjects, respectively ($P < 0.01$). However, the glucose lowering effects, defined by relative glucose level changes from baseline after metformin administrations, tended to be lower in the elderly subjects. This study is important because it was the first to show the plasma concentrations and the glucose-lowering effects of metformin in elderly Asian subjects. SNUBH CTC has an outstanding infrastructure and a large elderly subject pool to efficiently support geriatric early phase clinical trials.

Extra Information of SNUBH - Facility Expansion is done



Despite the short period of time the organization has been in operation, SNUBH CTC has shown a rapid growth in the field with top-ranked investigators and has become a well-respected center in Korea. Through its facility expansion in March

2014, SNUBH CTC has moved towards its goal of building infrastructure at global level. Also, by promoting its strength in the elderly medical care, it increased its value as a senior specialized hospital.



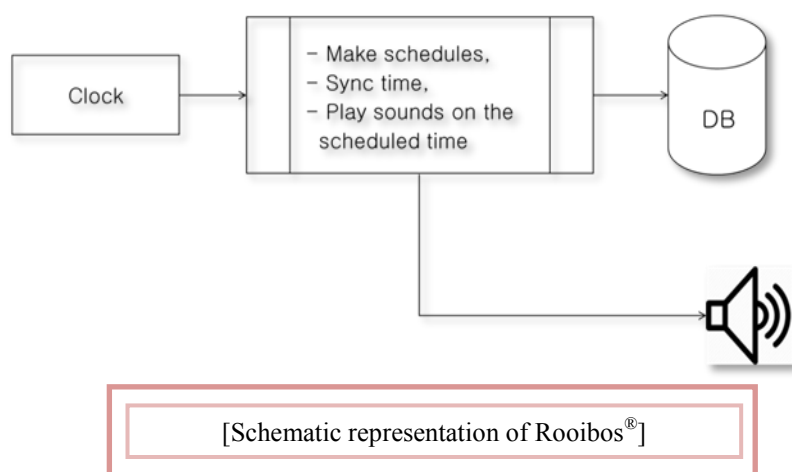
분당서울대학교병원 임상시험센터
SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL CLINICAL TRIALS CENTER

Introducing Chonbuk University Hospital Global Center of Excellence!

Chonbuk National University Hospital Global Center of Excellence in Early Clinical Trials (CUH Global Center) has performed various pharmaceutical drug clinical trials including botanical drugs. They have 62 beds with a centralized monitoring system; high-tech research facilities and equipment; and clinical researchers experienced with clinical trials. They have sought continuous change and innovation in order to become a global leader of the sci-

entific and systematic clinical trials. The CUH Global Center achieved 11 clinical trial IND approvals in 2013, 20 clinical trial IND approvals in 2014, and 21 clinical trial IND approvals in 2015 for phase I studies in healthy subjects. They performed the largest number of clinical trials for phase I studies in healthy subjects in Korea last year. The CUH Global Center also performed bioequivalence tests in 50 rheumatic patients taking Azathioprine according to

Good Clinical Practice (GCP). To help the performance of these studies, they developed a subject broadcasting software program (Rooibos®) to efficiently manage the times of dosing, blood draw, and meals. By broadcasting the subject number at the scheduled time, this software allows the CUH Global Center to improve the accuracy of clinical trials and decrease researcher workload while conducting clinical trials.



In addition, the CUH Global Center also supports professional training for researchers. In March 2016, the CUH Global Center will conduct Clinical Data Interchange Standard Consortium (CDISC)

public training (SDTM, CDASH). They expect to apply international standard clinical data management and analysis by data types and analysis models in which CDISC is applied.

Extra Information of CUH - Research Infrastructure



By establishing a new Clinical Research Support Center, CUH CTC has created a sophisticated clinical trial system that comprises of 60 clinical beds, 8 outpatient clinics, and 8 monitoring rooms fully dedicated to clinical research.