

# THE GREATS TIMES

The Seoul National University Hospital Clinical Trials Center

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

## [Director's Corner] Professor Yung-Jue Bang

### SNUH CTC's Successful Performances on Global sponsored Trials

#### Gastric Cancer: Results from the GOLD Trial

Yung-Jue Bang, MD, PhD, of Seoul National University Hospital, discusses phase III study findings on olaparib and paclitaxel in patients with advanced gastric cancer who have progressed following first-line therapy.

Recorded October 10, 2016

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Oncology Education.com - The Education Resource for Oncology Professionals (October 7 -11 2016). Olaparib, in combination with paclitaxel, in patients with advanced gastric cancer who have progressed following first-line therapy. Phase III GOLD study: As a part of the 2016 ESMO congress (Copenhagen, Denmark) activity, Professor

Bang participated as a leading investigator for ESMO (European Society for Medical Oncology) with an interview for the GOLD trial. This interview was posted at the ASCO Post Newsreels as well. This is one of the prominent data among GI cancer at the ESMO 2016.

Please see the video here :[http://www.ascopost.com/videos/2016-](http://www.ascopost.com/videos/2016-esmo-congress/yung-jue-bang-md-phd-on-gastric-cancer-results-from-the-gold-trial/)

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ESMO is the leading European professional organization, committed to advancing the specialty of medical oncology and promoting a multidisciplinary approach to cancer treatment and care founded in 1975.

### Greetings to all!

We are nearing the end of another year, filled with splendid opportunities and vigorous efforts to upgrade the quality of clinical trials, not only at SNUH, but worldwide as well. I hope you have sweet memories that were made at SNUH CTC, through your work and your team. To make every moment with us special in the coming year we promise to continue doing our best. I wish you a very Happy New Year.

Prof. Yung-Jue Bang Director, SNUH CTC



Merry Christmas

# Roche-imCORE summit: Leading Network Started for New Way for Cancer



## SITE ALLIANCE MANAGERS MEETING

Thursday, September 15<sup>th</sup>, 2016



imCORE (the global cancer immunotherapy Centers of Research Excellence) is a global network of basic and clinical scientists from 21 leading academic research institutions in cancer immunotherapy who work together with scientists from Roche and Genentech (a member of the Roche group in the United States) with the goal of developing potential cures for people with cancer.

imCORE™ merges networks around the globe to accelerate cancer immunotherapy research and development to transform cancer treatment. This group consists of world-renowned hospitals (institutes), including Dana-Farber and Johns Hopkins. Prof. Do Youn Oh (Medical Oncology, Internal Medicine Dept.) has been assigned as a site alliance manager (SAM) for this group. Professor Oh participated in the 2<sup>nd</sup> annual imCORE network SAM F2F meeting held at Roche Basel headquarters on September 14<sup>th</sup>-15<sup>th</sup>.

Roche will invest up to 100 million Swiss Francs to support basic and clinical research collaboration within the imCore Network.

## Hopeful Step of Alzheimer's Disease Drug Development



On October 25<sup>th</sup>, SNUHCTC signed an MOU with Medifron DBT Co., Ltd, which focuses on Alzheimer's disease and neuropathic pain treatment. The two parties have laid the foundation for a comprehensive mutual research collabora-

tion on clinical trials for Alzheimer's disease. We expect the successful clinical trials to be conducted through various communication in the future. SNUH and Medifron is now conducting phase I study and phase II study will be performed through this collaboration. Two parties will cooperate to develop the drug that will originally treat the disease by inhibiting the beta amyloid aggregation and blocking the beta amyloid toxicity.

Medifron has experience in licensing out and researching with Germany, Switzerland, and NIH, and is currently undergoing a Phase I clinical trial with a joint research and development agreement with a domestic pharmaceutical company.

## GREATS Events

### #1 New Look of Cancer Clinical Trials Center of SNUH



On 29<sup>th</sup> September, the Cancer Clinical Trials Center celebrated their refurbishment. Five tables and long chairs have been placed at the entrance of the center for patients and CRCs for use while consulting about procedures. Four benches have also been set up next to the pharmacy for patients waiting for their medications. Prof. Chang Suk Suh (President&CEO, SNUH), Prof. Tae-Yoo Kim (President, SNU Cancer Hospital), and Prof. Yung-Jue Bang (President, SNUH BRI) attended the ceremony to listen to the briefing and to see the project's completion. Professor Suh (President&&CEO, SNUH) thanked everyone for their efforts to improve the environment and to elevate the wellbeing of patients who are involved to the trials.

### #2 The 4<sup>th</sup> Microdosing International Symposium



The 4th Microdosing International Symposium was held on November 11<sup>th</sup> from 9am to 5pm at the Children's Hospital and Seosunghwan Hall of the Cancer Hospital. During the morning symposium, there were four presentations and an in-depth discussion on the future prospects on the theme 'On the use of AMS technology in drug development', and Dr. Graeme Young from GSK presented the plenary lecture about 'AMS enabled clinical studies in GSK: Past, Present and Future'.

Dr. Young is now associated at Drug Metabolism and Pharmacokinetics, GlaxoSmithKline Research and Development Ltd. Currently chair of the Global Bioanalysis Consortium team on AMS.

Through afternoon workshop, there were five

talks on the practical issues (facility & regulatory) in the afternoon. About 150 people attended the morning symposium and took lectures about BioAMS technology trends and future strategies. Approximately 80 people attended the afternoon workshop, used valuable discussion time with the panels, and listened to presentations on technology composition strategies through analysis of actual research cases. One of the participants from the pharmaceutical company said, "It was very beneficial to share tips and traps of the technology through actual research analysis. I think it will be very helpful for future research."



### #3 Round-table Conference for Local & Global Sponsors

#### SNUH strives to listen to the industry voices for better environment



On September 22nd and November 8th with global companies, Prof. Dong-Wan Kim SNUHCTC invited local and global pharmaceutical companies and CRO to announce the center's current status of development over the past year and to hear detailed opinions about conducting clinical trials with SNUH CTC. In the first meeting with local companies we introduced the role of SNUHCTC in drug development, with a local company's and our own developed program for clinical trial data management, followed by a session for collecting comments. At the meeting

gave a talk about recent trends in oncology trials followed by Prof. Seung-Hwan Lee speaking on the theme of general changes at the center. In addition, we took the time to gather improvement requirements and suggestions from the sponsors so we can comprehensively check difficulties in clinical trials. SNUHCTC will review the opinions gathered at the meeting and actively reflect on them to improve the environment thoroughly.

#### #4 The 2<sup>nd</sup> KIC (KoNECT International Conference)

SNUH participated second international conference from November 2<sup>nd</sup> to 3<sup>rd</sup> thrown by KoNECT (Korean National Enterprise for Clinical Trials) . Also, Prof. Yung-Jue Bang (Director, SNUHCTC), Prof. Howard Lee, and Prof. Seung Hwan Lee introduced the center's system related to GREATS and project management.

#### #5 Korean Business Seminar for Future Collaboration (Tokyo, Japan)

The Korean Business Seminar was held at the Conrad Hotel in Tokyo, Japan, on December 2<sup>nd</sup>, sponsored by KOTRA and KoNECT . SNUH CTC participated as a specialized institute among the clinical trial industry in Korea



If you would like to visit us, please contact:

Theresa Choi +82 2 2072 1684, [tchoi85@snuh.org](mailto:tchoi85@snuh.org)

# Introducing Seoul National University Bundang Hospital CTC

## Healthcare Innovation Park (HIP) expects to become Multiplayer!



Healthcare Innovation Park (HIP) opened in April as the first hospital in Korea to launch a healthcare research complex that links hospitals, municipalities, universities, and industries. HIP specializes in five areas: medical devices, healthcare ICT, human genome, nanomedicine, and regenerative medicine. HIP aims to fulfil various sectors, such as employment creation effects, global biotechnology companies, infrastructure inflows, and new research models. HIP's goal is to build a foundation for the growth of the industrialization of medical research at an international level. At the end of July, the HIP website was opened (<https://hip.snubh.org/>) to establish a pathway for promoting research collaboration between hospitals and industry to accelerate the project.

## SNUBH Celebrates 10<sup>th</sup> Anniversary of pre-clinical trials center



연번	시각	주제
1	13:30-14:00	Opening Ceremony
2	14:00-14:30	Keynote: The Future of Pre-clinical Research
3	14:30-15:00	Panel Discussion: Challenges and Opportunities in Pre-clinical Research
4	15:00-15:30	Workshop: Emerging Technologies in Pre-clinical Research
5	15:30-16:00	Panel Discussion: Regulatory and Ethical Considerations
6	16:00-16:30	Workshop: Data Analysis and Reporting in Pre-clinical Research
7	16:30-17:00	Panel Discussion: The Role of Pre-clinical Research in Drug Development
8	17:00-17:30	Workshop: Quality Control and Assurance in Pre-clinical Research
9	17:30-18:00	Panel Discussion: The Impact of Pre-clinical Research on Patient Care
10	18:00-18:30	Workshop: Collaborative Research Models
11	18:30-19:00	Panel Discussion: The Role of Pre-clinical Research in Biotechnology
12	19:00-19:30	Workshop: Emerging Technologies in Biotechnology
13	19:30-20:00	Panel Discussion: The Role of Pre-clinical Research in Regenerative Medicine
14	20:00-20:30	Workshop: Emerging Technologies in Regenerative Medicine
15	20:30-21:00	Panel Discussion: The Role of Pre-clinical Research in Nanomedicine
16	21:00-21:30	Workshop: Emerging Technologies in Nanomedicine
17	21:30-22:00	Panel Discussion: The Role of Pre-clinical Research in Medical Devices
18	22:00-22:30	Workshop: Emerging Technologies in Medical Devices
19	22:30-23:00	Panel Discussion: The Role of Pre-clinical Research in Healthcare ICT
20	23:00-23:30	Workshop: Emerging Technologies in Healthcare ICT
21	23:30-24:00	Panel Discussion: The Role of Pre-clinical Research in Human Genome Research
22	24:00-24:30	Workshop: Emerging Technologies in Human Genome Research

The pre-clinical trial center of Seoul National University Bundang Hospital celebrated its 10<sup>th</sup> anniversary this year and held a commemorating symposium on the 25<sup>th</sup> of November. Pre-clinical trials center was opened on 8<sup>th</sup> November, 2006 to provide high-quality preclinical experimental services to meet the diverse needs of researchers and has grown steadily. In order to become a world-class infrastructure and facility, the center is preparing for renovation, which will be completed by 2018. The center will move to the Healthcare Innovation Park (HIP) and will be approximately 4,960m<sup>2</sup> (1.2ac) in size

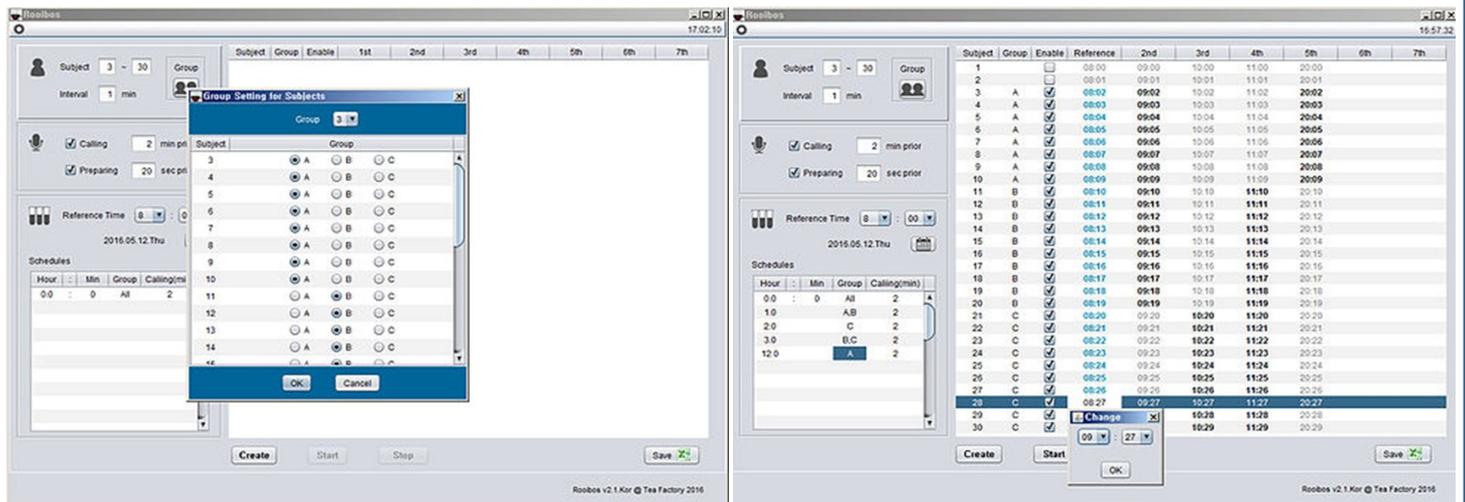


분당서울대학교병원 임상시험센터  
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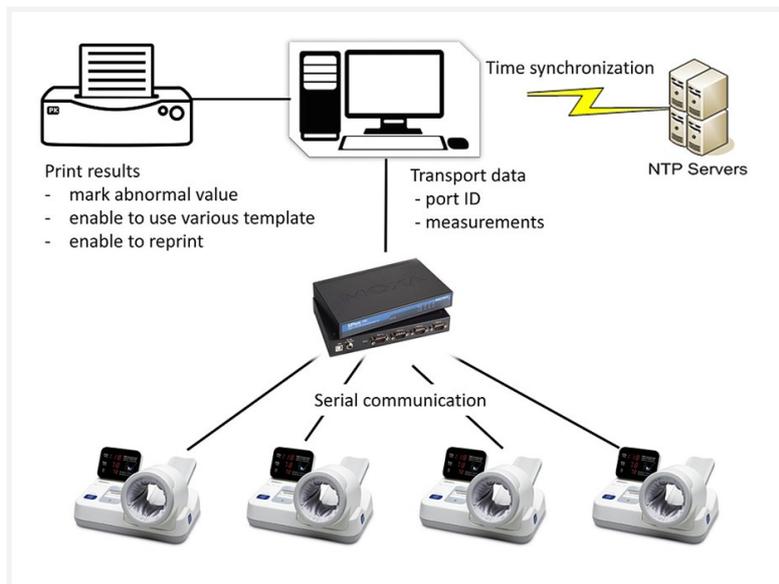
# Introducing Chonbuk University Hospital Global Center of Excellence!

## CUH reaches to the Next Level of Clinical Trials

Chonbuk National University Hospital has established a separate organization (clinical pharmacology center) focusing on early phase clinical trials (Min-Gul Kim, center director). Based on this system, the general clinical trials for patients will be performed at clinical trials centers, and clinical pharmacology studies done with healthy volunteers will be carried out at clinical pharmacology centers. CUH CTC expects to enable more specialized and efficient research. We are working to minimize errors and reduce workload by developing various software in-house. Rooibos™ is actively being used in phase 1 clinical trials as an automatic subject calling system; this was published in the in September 2016 ‘Translational and Clinical Pharmacology’ journal. In addition, a pharmacokinetic evaluation program (Hibiscus™) for early clinical trials and a trial device management program (Green™) are under development, which will greatly contribute to the efficiency of early clinical trials. We also signed an MOU with StarTech Science, LLC in September 2016 to co-develop the clinical trial management system (CTMS). In October we signed an agreement with the Korea Information Technology Research Institute (KITRI) to train professional manpower in clinical trials data management. This project will be very helpful for educating experts in data analysis and visualization using the R method, which is current trend.



### Rooibos™



### Green™