

# THE GREATS TIMES

The Seoul National University Hospital Clinical Trials Center

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

## Congratulations, SNUH CTC!!

### SNUH CTC's 20th Anniversary Symposium 'The Past, Present, and Future of Clinical Trials in Korea'



The 20<sup>th</sup> anniversary Symposium of Seoul National University Hospital Clinical Trials Center (SNUH CTC, Prof. Yung-Jue Bang, Director) took place on September 17, 2015. Leading researchers and clinical experts were a part of the symposium, which was titled 'The Past, Present, and Future of Clinical Trials in Korea'. Participants shared their opinion on how to analyze the past and current situations of Korea's clinical trials. They also discussed designing future development plans. The symposium was conducted in two

parts, including presentations by Dr. Deborah Chee (President, KoNECT), Prof. Kyung-Sang Yu (SNUH), Prof. Dong-Wan Kim (SNUH) and Prof. Rae Woong Park (Ajou University Hospital).

The center also thanked all those who had dedicated their time to the center for several years. Another official event was held to commemorate the establishment of the Investigational Product Management System (IPMS/RFID System) and Early Phase Integrated Clinic Automation Solution

(EPICS). Both systems were developed by SNUH CTC for accurate and efficient clinical trial environment. SNUH CTC expects to significantly increase the quality of the trial performed by Seoul National University Hospital.





## The 3<sup>rd</sup> Microdosing International Symposium 'Frontiers in Microtracing for Clinical & Diagnostic Development'



SNUH CTC held the 3<sup>rd</sup> Microdosing International Symposium as part of 'The GREATS Week' series (Four events were conducted as SNUH CTC's Week to commemorate the 20th anniversary from September 16 to 18) Eight speakers including Prof. Howard Lee (SNUH) shared their knowledge and latest information about microtracing technology to domestic pharmaceutical companies and research institutes. The event saw

the participation of more than 100 attendees. The morning seminar dealt with current status and cases such as that applied to the development of new drugs and study examples using microtracers. The afternoon workshop began after the lunch break. The workshop focused on microtracer studies conducted in western countries, which will lead to presenting a blueprint for the future.

## Best Environment for Clinical Trials and Researches



Novartis Korea and Seoul National University Hospital (SNUH) has signed an agreement for the 'observational clinical research support' on July 15 at the Biomedical Research Institute. 20 people attended the event, including Professor Byung-Hee Oh (President, Seoul National University Hospital) and Brian Gladsden (CEO, Novartis Korea) alongside agency officials for the signing ceremony. They discussed about the future cooperation between both parties and shared information. Through this agreement, SNUH and Novartis Korea planned to collaborate on exchanging research information and data, knowledge and study experience sharing, workforce exchanging and training programs. Professor Byung-Hee Oh expressed his strong interest in more active cooperation and collaboration between Novartis and SNUH.

## UPCOMING EVENTS!

<Celerion Korea—SNUH CTC Symposium> *Innovation in Early Clinical Research*

\*Date: December 8th 2015 \*Venue: Biomedical Research Institute, Grand Auditorium (1F)

# Splendid Achievement of SNUH & SNUH CTC



## #1 Magnolia Medal for Prof. Byung-Hee Oh

Professor Byung-Hee Oh (President, Seoul National University Hospital) was honored with the Magnolia Medal (Order of Civil Merit) on July 24 by the Ministry of Education. He was appreciated for his work on the globalization of Korean medical education through international hospital consigned operations and overseas staff training support system. The contract includes operating Sheikh Khalifa Specialty Hospital (SKSH) (UAE, Ras Al Khaimah) worth 1 trillion KRW (1 billion USD) for five years. Also Korea's excellent medical technology was recognized through international medical staff training programs with 220 people from 38 countries, including Mongolia.



## #2 No.1 City & Site

Seoul ranked the No.1 City for performing clinical trials two years in a row (2013, 2014), based on the US National Institutes of Health (NIH). Professor Yung-Jue Bang (Director of SNUH CTC) said, "Seoul National University Hospital and its clinical trial infrastructure is well-stocked with the support of the government, which has enabled a much faster patient enrollment. Also many multinational companies commended SNUH for its quality in clinical trial performance. The data shows that SNUH CTC got the first place in a number of clinical studies as a single site at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NIH). In addition, SNUH CTC was ranked the No.1 site based on patient enrollment rate among 30 sites around the world, two years in a row for big CRO study.

## #3 New Page of Automated System for Clinical Trials

The official launching ceremony of the Seoul National University Hospital Clinic Trials Center EPICS (Early Phase Integrated Clinic Automation Solution) and the pharmacy RFID System was held on September 17. Videos describing the operational status report were then shared along with detailed changes to help the professors and staff members understand them. EPICS is Korea's first automation system for early clinical trials' data capture that SNUH CTC will use for the early clinical trial process, which has been intensively evaluated and validated. Professor Yung-Jue Bang (Director of SNUH CTC) said that those IT systems will help SNUH CTC maintain the highest quality of the clinical trials.



**If you would like to visit us, please contact:**

**Theresa Choi**

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



## New Stage of Personalized Cancer Treatment



Seoul National University Cancer Hospital (Tae Yoo Kim, President) held a symposium on October 23 at the CMI SeoSeongHwan Research hall for commemorating the official opening of 'Personalized Cancer Medicine Center'. The topic was 'Clinical Implementation of Precision Oncology: Challenges and Solutions' and was discussed by 300 people. Professor Tae-Yoo Kim, president of cancer hospital said, "Since the paradigm shift is rapid these days, we wish to have the opportunity to exchange related professionals' experiences and insight on implementation of precision oncology". Seoul National University Cancer Hospital put to practical use the personalized cancer medicine center since April 2015. The center strives to develop new technology of bi-marker diagnostics, which can effectively verify genetic changes of carcinogenicity and new targeted agents for the next level of personalized cancer treatment.

## For the Next Step of Clinical Trials



The GREATS consortium (Seoul National University Hospital, Seoul National University Bundang Hospital and Chonbuk National University Hospital Clinical Trials Center) held a joint symposium on October 22, 2015 with various participants in the clinical research field at SNUBH CTC auditorium. The symposium was arranged to discuss the direction to aim for the future IT technology applied clinical trials and to introduce successful cases utilizing IT clinical care. Professor Jong-Seok Lee (Seoul National University Bundang Hospital Clinical Trials Center Director) said, 'Attention and expansion at clinical trials using IT technology would change various parts of researches in the near future.'

## Introducing Seoul National University Bundang Hospital CTC!



Seoul National University Bundang Hospital Clinical Trials Center(SNUBH CTC, Pf.Jong-Seok Lee,Director) and C & R Research(CEO MoonTae Yoon) signed a MOU for mutual co-operation at SNUBH conference room on August 10, 2015. The strategic partnership is to share the core competencies and resources for smooth support to both organizations. The process may turn out leverage effect that would

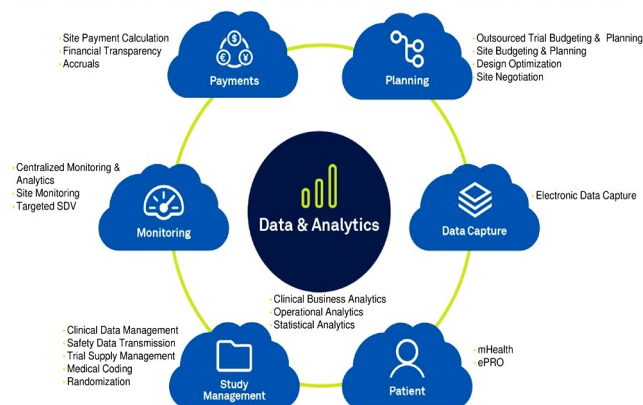
particularly attract international trials actively. Through the MOU, both organizations expect to enable successful implementation of cooperative clinical trials, drug researches and various pathophysiological studies. The contract term includes mutual exchange of research personnel, research facilities and administrative support.

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## Introducing Chonbuk National University Hospital CTC!

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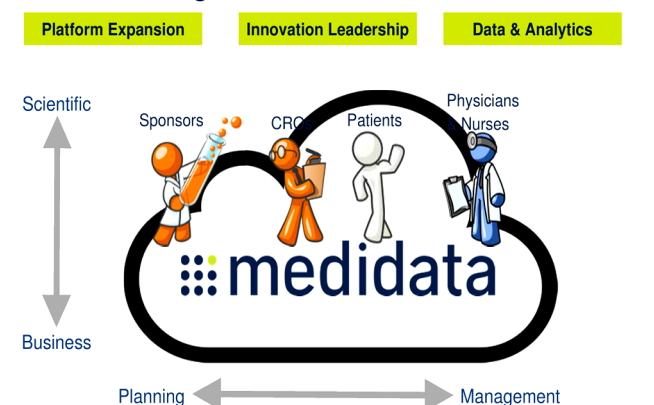
### The Medidata Clinical Cloud: EDC to Platform



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### Better working environment for all stakeholders



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To assure reliability and increase efficiency of clinical trials, use of CDMS (Clinical Data Management system) has been on the rise every year in domestic and overseas. Sponsors have demanded higher accuracy, and reliability of clinical trials data than before. Accordingly, the company has adopted Medidata Rave system, the leading cloud Electronic data capture (EDC) system, to manage clinical trials data and pass the integrity data to

sponsor. It has improved work-efficiency in the whole process from distribution to recovery by implementing eCRF instead of paper CRF. It supports real time audit/monitoring of eCRF Data, electronic signature of investigator, various statistics and analysis of Data. So the company is expecting a big leap about ensuring integrity and accuracy of data on Clinical Trials data management.

**CUH** 임상시험  
글로벌 선도센터  
전북대학교병원