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THE GREATS TIMES

The Seoul National University Hospital Clinical Trials Center

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

KoNECT-SNUH International Symposium

KoNECT-SNUH International Symposium on 'Application of Microdosing Technologies in Clinical Drug Development and Translational Studies' was held on January 23, 2014 in the auditorium at the Biomedical Research Institute of SNUH.

As the microdosing is still a fairly new concept even to those who are in the field of clinical trials, nine speakers including six domestic and three foreign experts were invited to provide informative lectures to the audience. The symposium began with welcome remarks by Sang-Goo Shin (KoNECT) and Yung-Jue Bang (SNUH CTC) and continued with three sessions.

For the first session, "Introduction to AMS Technology," Won-Sik Lee (Pfizer Korea) served as a chairperson, and Byung-Yong Yu (KIST), Sang Soo Hah (Kyung Hee University), and Young Shin (Chungnam National University) gave presentations to explain basic principles and application of the accelerator mass spectrometry (AMS), one of most common methods to conduct a microdose analysis. With a brief introduction of the session by Sang Hong Baek (Catholic University of Korea), the second session on "Application of AMS Technology to Translational and Clinical Research" started. It continued with three foreign speakers, Stephan Dueker (Eckert & Ziegler, USA), Wouter Vaes (TNO, the Netherlands), and Yuji Kumagai (Kitasato University East Hospital, Japan) to explain various ways of applying AMS to clinical research. Jae Won Lee (Hanwha Dream Pharma) was the chairperson of the last session on "Microdosing for Early Clinical Drug Development." From the last session, attendees had chances to see different perspectives of pharmaceutical industry, regulatory authority, and clinical research institution on microdosing studies through presentations by Se-Woong Oh (Yuhan Research Institute), Younjoo Park (MFDA), and Howard Lee (SNUH).

This joint symposium by KoNECT and SNUH provide opportunities to audiences to learn and exchange views on this new concept in clinical research, microdosing. About 250 professionals gathered to hear informative presentations.

Efficient Clinical Trials of Newly-developed Foreign Drugs

On Tuesday October 29, 2013, invitees from the government agencies, hospitals, global pharmaceutical companies, and CROs gathered at the Lotte Hotel in Seoul, Korea to attend an exclusive seminar sponsored by the Ministry of Food and Drug Safety (MFDA) and GREATS. The seminar began with congratulatory messages by Myung-jung Kim (Director of Pharmaceutical Safety Bureau, MFDA) and Dr. Yung-Jue Bang (Director of Seoul National University Hospital CTC). After all attendees briefly introduced themselves, the seminar continued with the first speaker, Mee-ryung Ahn (Deputy Director of Drug Evaluation Department, MFDA), sharing her own experience of reviewing proposed clinical trials and opinions on how to avoid some common mistakes for the review. Before the second speaker, JiHyun Lee (CR Manager of Global Clinical Operation, Jassen Korea), presented the regulatory system in other Asian countries for clinical trials of foreign newly-developed drugs, Jason Huang (Global Clinical Operation Manager of Korea and Taiwan, Jassen Taiwan) introduced the system in Taiwan in details. Two more guest speakers, Jeanie Kim (Clinical Research Physician, Boehringer Ingelheim) and Ji Young Lee (Director of Clinical Operation, ICON Clinical Research), were invited to give presentations on successes and failures of early clinical trials in Korea and possible ways to improve the regulatory system for more efficient clinical trials in Korea. Suggestions to the government agency and the pharmaceutical companies in order to achieve more efficient early clinical trials in Korea were presented by Kyung-Sang Yu (Professor, Seoul National University Hospital) and Seock-Ah Im (Professor, Seoul National University Hospital) followed by a fruitful discussion to share the views of invitees further.

This informative exclusive seminar is becoming a tradition as many attendees look forward for the third exclusive seminar which may be held in the beginning of next year.

UPCOMING EVENTS!

2nd Annual Kitasato-SNUH Joint Symposium

- ◊ Date: February 14, 2014 (Friday)
- ◊ Time: 11:00 — 18:-00
- ◊ Place: Auditorium, SNUH Children's Hospital
- ◊ Topics: Promoting Quality Pan-Asian Clinical Trials
- ◊ Contact: Sujin Rhee (sujinrhee@snuh.org)

Medical Device Symposium

- ◊ Date: February 14, 2014 (Friday)
- ◊ Time: 14:00 — 18:00
- ◊ Place: Suh Seung Hwan Hall (2nd floor of Cancer Hospital at SNUH)
- ◊ Topics: Collaboration between the Schools of Medicine and Engineering for medical device
- ◊ Contact: Jonghee Lee (jongheelee@snuh.ac.kr)

Director's Corner

Professor Yung-Jue Bang was invited to speak at 2014 American Society of Clinical Oncology – Gastrointestinal Cancers Symposium, which took place from January 16 to January 18 in San Francisco, CA, USA. He gave a presentation titled, "Metastatic Disease Treatment: Implications of Disease Biology," during "General Session 2: Gastric Cancer-Etiology, Development, and Implications for Therapy."

KyungHee University Medical Center

Professors from the Clinical Trial Center at Kyung Hee University Medical Center visited GREATS on October 17, 2013. In June 2013, CTC at Kyung Hee University Medical Center was designated by the Korean Ministry of Health and Welfare as a part of 'Oriental Clinical Infrastructure Support Project' securing about 5 million dollar research funding over a period of 5 years.

The meeting began with an introductory presentation by Dr. Howard Lee followed by the center tour. After walking through the facilities, Jung-Mi Baik, Director of QI Department at GREATS, shared the educational and training system within the center.

Since the research funding from the government contributed GREATS to become a leading Clinical Trial Center in Korea, this meeting provided GREATS an opportunity to share its own know-how and thoughts regarding the development of clinical trial center.

Master Clinical Trial Agreement with Sanofi

On October 6, 2013, Sanofi and Seoul National University Hospital signed a Master Clinical Trial Agreement and a Master Confidentiality Agreement. As a result, clinical trials sponsored by Sanofi are expected to be handled according to the work order attached to the master agreement. Also, in cases of pre-assessment or feasibility, no individual confidential agreement will be required since it can be replaced by sending the first contact email with a disclaimer about the Master Confidentiality Agreement between two institutions.

The Master Clinical Trial Agreement shall be effective for 5 years until October 6, 2018 and the Master of Confidentiality Agreement shall be effective for two more years expiring on October 6, 2020. These signed agreements will allow both institutions to collaborate more efficiently in future clinical trials and feasibility.

The Seventh SNUH Medical Device Symposium

On October 11, 2013, Seoul National University Hospital held its 7th Medical Device Symposium, "Everyone can develop a medical device," in the auditorium located on the first floor of the Biomedical Institute Building.

Dr. Seung-June Oh, the Head of Medical Device Clinical Trials Unit at Seoul National University Hospital, was the host of this seminar. He started off the seminar by mentioning that most of expensive medical devices are imported from abroad even though they are utilized every day. He believed that developing new medical device must be a part of clinical trial processes if those devices are essential in daily operations. Also, in his opinion, Seoul National University Hospital is offering very advanced clinical trials based on the strong motivation and passion of investigators but it can be boosted further with the development of medical devices. Therefore, he wanted to provide the audience with some useful information on that matter through this seminar.

This seminar was based on the assumption that although many people are interested in developing medical device, many people take passive attitudes due to lack of necessary information. During the seminar, a survey was conducted and the result of surveys confirmed with the assumption. Therefore, after the congratulatory message by Yung-Jue Bang, 10 speakers presented informative contents regarding examples, processes, supports, and funding of medical device improvement. This seminar provided an opportunity for attendees to take a step forward towards improving medical device.

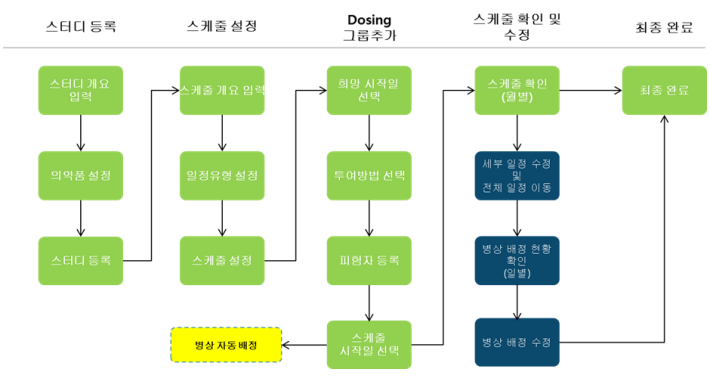
GREATS Going Towards Future

GREATS is in the process of adopting a new clinical trial management system, LabPas, which is designed to reduce errors by minimizing human involvement in the process. This customized system is developed by Oracle and will be delivered and processed through Indigo Consulting and a software company called Techsol. LabPas will cover different stages of clinical trials from study setup to study closure.

When new clinical trial plan is ready to be launched, LabPas will assist setting up the study through planning workflow, scheduling, defining terms for the specific study such as subjects and study drugs, creating bar codes and labels, etc. Once study setup is completed, the system will facilitate volunteer recruitment, screening, and enrollment. Processes for this stage include generating call schedule, planning screening appointments, creating barcode labels for volunteers and sample vessels, and enrolling volunteer as study subject. Through conducting studies including data and sample management, strengths of LabPas will be demonstrated. Different from our old system, study activities will be recorded in real-time. For example, when barcode labels are scanned for sample collection, data will be instantly captured and recorded in the system allowing investigators to track clinical events more easily. Lastly, LabPas will help closing the study by performing study closure tasks, query management, and report generation.

Currently, customizing LabPas system for GREATS has been completed, and pilot study is scheduled to be launched near the end of January 2014. We believe this new system will manage data more efficiently and accurately boosting the quality of studies performed within GREATS.

Bed Management System



GREATS is in the process of adopting a bed management system developed by Devmon automatically assigns beds for patients in order to use the resources more efficiently. Mock studies had already been conducted few times, and the system has been updated with improvements of the weak areas discovered through field tests. It will be adopted for use in the beginning of 2014.

Under the current system, investigators are responsible for managing the timelines of their clinical trial processes including screening status and distributing resources according to the timelines. Then, the investigators need to produce the results of timelines and resources distributions in an excel file and send to other investigators and staff members. As a result, this whole process is done manually leaving the system more susceptible for errors and low flexibility. Also, slow correspondence to the changes will result in slowing down the study processes damaging the quality of the studies.

Since clinical studies are getting more complex involving diversities of ethnicity and gender and different methods of drug intake, flexible and efficient use of resources became critical to the success of clinical trials. Therefore, adopting an automated bed and resources assignment system based on a systematic algorithm was a very important advancement for GREATS to achieve the best quality of clinical trials. This system will optimize its schedule through the efficient use of resources and minimization of errors. Also, complicated studies will be built more systematically allowing GREATS to deal with different types and larger sizes of clinical trials.

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