

THE GREATS TIMES

The Seoul National University Hospital Clinical Trials Center

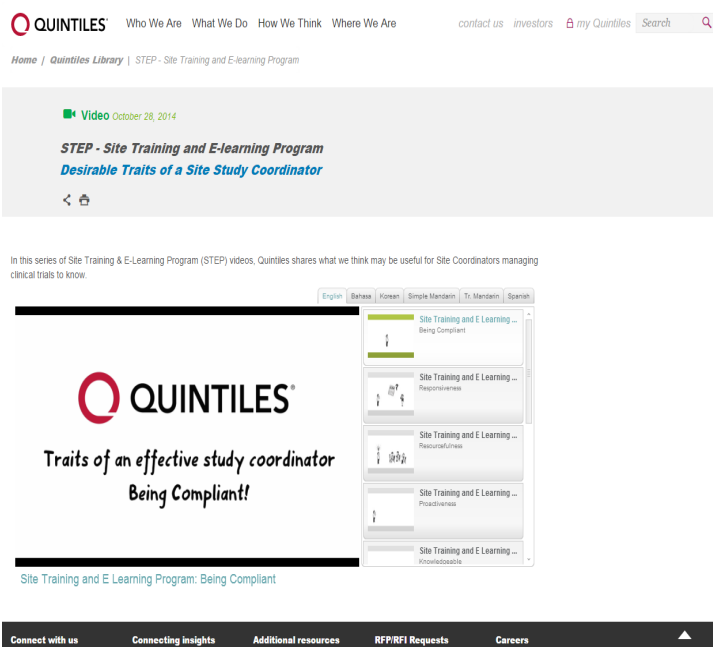
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SNUH CTC-QUINTILES Collaboration

Seoul National University Hospital Clinical Trials Center (hereafter, SNUH CTC) Phase I – CRO (Contract Research Organization): Quintiles collaborated to create an online program called ‘STEP-Site Training and E-learning Program’. This program contains a series of video clips that has desirable traits of a site study coordinator such as ‘Resourcefulness’, ‘Building rapport’ etc. There are 10 video clips with 9 separate traits, one in each video, followed by 1 organized conclusion video. Five of them were mostly done by Asian sites, while

rest of the videos were completed by sites around the world.

Many professors at SNUH CTC participated by pitching in ideas. Sharing what we think may be useful for site coordinators managing clinical trials to know. To provide these essential guidelines in an efficient manner, Quintiles had prepared each video in 5 different languages including English, Korean, Chinese (2versions) and Spanish. This program is currently uploaded to our YouTube channel and on the Quintiles website.



See more detail at:

<http://www.quintiles.com/library/videos/step-site-training-and-elearning-program>

SNUH CTC shown in Sanofi Newsletter

In the 4th quarter newsletter of Sanofi S.A that has its head office in France, Seoul National University Hospital Clinical Trials Center (hereafter, SNUH CTC) was presented as core site of Asia. SNUH CTC had been a long-term

partner of Sanofi R&D, supporting important portfolios such as PCSK9, Lixisenatide and Sarilumab.

It was the opportunity to promote our facilities, followed by overall information of the center. This

newsletter had introduced SNUH CTC values to the world. We have constantly strived to elevate the quality of studies based on our core values. This article shows important information related to the quality and efficiency of SNUH CTC, such as internation-

al accreditation issued by AAHRPP and SIDCER/ FERCAP. Along with this, an English newsletter, ‘The GREATS Times’, would be sent out to professionals of pharmaceutical companies and CROs around the globe on a quarterly basis.

SEOUL NATIONAL UNIVERSITY HOSPITAL CLINICAL TRIALS CENTER – SEOUL - KOREA



Seoul National University Hospital has been a long-term partner of Sanofi R&D, supporting important portfolios such as PCSK9, Lixisenatide and Sarilumab.



Professor Yung-Jue Bang (Director, SNUH CTC)



RFID(Radio-Frequency Identification) for SNUH CTC Pharmacy

SNUH CTC implemented the nation's 1st pharmacy inventory managing program named 'RFID (Radio Frequency Identification)', developed by our center. This program will increase the efficiency and accuracy of dispensing prescription. The prescription related data for clinical trials which used to be manually handled will now be done using electronic data managing automation system controls in real time. By using this system, we can prevent errors that might occur while managing and dispensing drugs. The RFID tag (RFID code) that carries

information such as product number, serial number and expiry date will be attached to every single investigational product container. International standards like 21CFR part11 (U.S) and national guideline of MFDS followed by CSV (Computer System Validation) have been thoroughly applied to be actively uses for global sponsored trials. "We may elevate overall quality and competitiveness of Korea's clinical trials by managing this program efficiently" said Prof. Yung-Jue Bang, director of SNUH CTC.

Clinical Trials Subject Recruitment Website

SNUH CTC has built the nation's 1st website for clinical trial subject recruitment, snuhclinicaltrials.com. This website had been granted by IRB (Institutional Review Board) to secure the safety and rights of the subject. Any one interested in participating in clinical trials can approach us easily through the website and search possible studies by age, gender and BMI etc. This website is prepared in various languages, including Korean, English, Chinese and Japanese to make it easy for foreign residents to use. SNUH CTC expects this website to become the foundation for more active multi-ethnic group studies.



New Start of SNUH - CMI (Center for Medical Innovation)



Seoul National University is about to launch new roadmap by presenting Center for Medical Innovation (CMI). The plan is to build the infrastructure of 'Open Innovation Platform' for industry, academia and institute collaborations. Along with that, governance, sustainable research, support system and research capability



optimization plan will be applied for this new Korean R&D business model. The center would be ready by the first quarter of this year.

Become Greats through *GREATS*

In the last edition of 2014 of Asia Pacific Biotech News (hereafter, APBN), GREATS (Global Center of Excellence in Early Clinical Trials at SNUH)-a government-funded project specializing in early phase clinical trials-had received a favorable review by editors. This article explains how SNUH CTC has made Korea the hub of clinical trials, what SNUH CTC had done through GREATS, along with an overview of the center, a general introduction of the center and overall capabilities that are based on strong leadership. GREATS has created a clinical trials infrastructure of global standards and has built and expanded close relationships with many domestic and overseas pharmaceutical companies, CROs, and academic insti-

tutes. Other key strengths that only SNUH CTC had established such as a business unit, the Global Strategy and Planning (GSP) and subject recruitment team

that is in action under GSP are also discussed. GSP is responsible for promoting SNUH CTC to global biopharmaceutical companies and CROs and managing

pre-study activities between sponsors and investigators. This team assists us to get the best results from sponsors' perspectives for both sides.

SNUH CTC will continue to strive towards its ultimate goal of becoming one of the top early clinical trial centers in the world with high quality IT programs along with the GREATS' passionate leaders who are very likely to be an indispensable part of global drug development in the near future.

About APBN APBN is a monthly magazine that offers comprehensive reports in pharmaceutical, healthcare, food and agriculture in the Asia-Pacific region and is read by professionals around Asia and the globe.

Become Greats through *GREATS*



Dr. Howard Lee
Head of the Clinical Trials Center, Seoul National University Hospital, Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine.

Introduction

Around 15 years ago, Korea probably was not the first choice for many global pharmaceutical companies and Contract Research Organizations (CROs) when it came to choosing a site for clinical trials. In the early 2000s, the annual number of clinical trials approved by the Korea Food and Drug Administration, the Korean regulatory agency in charge of drug marketing approval, was less than fifty. However, the number started to grow rapidly as the Korean government began funding for programs promoting clinical trials. With the creation of the Korea National Enterprise for Clinical Trials (KONECT), a government-funded organization that promotes clinical trials in Korea, the number increased to 670 by 2012. Now, Korea has become the hub of clinical trials not only in Asia, but also in the world.

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R&D Forum is On Track

제 2회 SNUH R&D Forum:
"R&D Collaboration for Translational Research in Pharmaceuticals and Medical Devices"
DONG-A SOCIO HOLDINGS

날짜: 2014년 11월 28일 (금요일)
시간: 오후 4시
장소: 서울대학교병원 의생명연구원 저서영홀
주최: 서울대학교병원 의생명연구원

Time	Program	Speaker
16:00-16:10	오프닝 인사	
16:10-16:30	내성균 다제내성균 항생제 개발(15분, Q&A 5분)	임현민 이사
16:30-16:50	신약개발 7년 연구용 임상시험(15분, Q&A 5분)	손문호 상무
16:50-17:10	화학성 신약개발 10년 전향물 신약개발(15분, Q&A 5분)	최상진 수련 의 1명
17:10-17:30	영양제 개발(15분, Q&A 5분)	안순환 부장
17:30-17:40	Discussion	
17:40	Closing	

연구중심병원 SNUH
개방과 융합의 Open Innovation

The last quarter was a busy season for SNUH CTC as it kept holding R&D forums with 3 different domestic pharmaceutical companies, including Samyang Biopharm, Dong-a Socio Holdings and ChongKunDang Pharm for further collaboration. These forums allowed sponsors to reveal their newest products and ongoing researches to professors of SNUH CTC. Professors got the chance to give ideas actively to improve overall quality and efficiency of research studies. This R&D forum will be continued through 2015.



Leaders Gathered to Look for Ways to Collaborate

“3rd Korea-Japan Joint Micro-dosing Seminar”

On November 27th, 2014, the 3rd Korea-Japan Joint Micro-dosing Seminar was held at the Biomedical Institute at Seoul National University Hospital. This seminar was held to elevate general understanding of Micro-dosing clinical trials and to discuss how to maximize synergy effects through collaboration be-

tween academia and industries, based on result of ‘¹⁴C radiolabeled compound oral medication bioavailability’ done by SNUH CTC. Professor



Sugiyama Yuichi, Director of RIKEN, who is considered to be the founder of Micro-dosing clinical trials, graced the meeting providing a

dosing study. “This seminar can be a starting point of the future for Micro-dosing study” one of the attendee said.



UPCOMING EVENTS!

- ◆ 4th R&D Forum - April 2015
- ◆ SNU-SNUH Joint Seminar - July 2015

If you would like to visit us, please contact:

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Introducing Seoul National University Bundang Hospital CTC!



On November. 20th. 2014, at Seoul National University Bundang Hospital Clinical Trials Center (SNUBH CTC), a meeting for cooperation of elderly clinical trials was held. This closed discussion was held by key personnel from 3 parties. Mr. Sung-Jun Choi from industry (Boryung Pharm), Professor KuangIl Kim and Professor JaeYong Chung from academia (SNUBH), and HyunYoung Park and SangKi Kim from the government (NIH/MFDS). After presentations, attendees gathered to share their opinions about the present and future prospects of elderly clinical trials. They all agreed to the idea that cooperation of the 3 parties, such as regulatory support of government, proper reward for pharmaceutical companies and constant academic endeavor, will

boost development of elderly clinical trials of Korea. "Since SNUBH is already focusing on Evidence Based therapy of elderly, they will work as the leader to continue this collaboration for the future of elderly clinical trials with a clear vision," said Professor ChongSuk Lee, the director of SNUBH Clinical Trials Center.

Introducing Chonbuk University Hospital Global Center of Excellence!

Chonbuk National University Hospital Clinical Trials Center (JBCTC) has had a total of 30 cases of early phase clinical trials. The number includes 24 clinical pharmacodynamics studies, such as comparative pharmacokinetic study, drug-drug interaction study, food interaction study, pharmacokinetic-pharmacodynamics study, in 2014. JBCTC is one of the few unique centers in the world which specializes in botanical drugs. The center had done 6 new studies, including 3 drug-drug interaction studies (between herbal medicine and synthetic drug). Also JBCTC has begun participating in new herbal medicine developing process under confidentiality agreement with Dong-a ST. As an international promoting activity, JBCTC team visited Las Vegas, USA, to give a presentation of results of 3 research studies, including 'A Population Pharmacokinetic analysis of Zabofoxacin in Patients with Mild to Moderate Community Acquired Bacterial Pneumonia' at ACoP5 (American Conference on Pharmacometrics) which had drawn considerable attention.

