



Global Center of Excellence in Early Clinical Trials @ SNUH

**Global Center of Excellence  
in Early Clinical Trials,  
Seoul National University Hospital**

Beyond the first in Korea,  
**Towards a global leader**

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## Greetings

It is my distinct pleasure to welcome you to the Seoul National University Hospital Clinical Trials Center (SNUH CTC).

Since 1997, the SNUH CTC has been leading the development of clinical trials in Korea and contributing to the establishment of Seoul National University Hospital as a world-class research center. In 2004, our center was designated as the first regional clinical trials center, and in 2012, we were awarded with the Global Center of Excellence in Early Clinical Trials (GREATS) by the Ministry of Health and Welfare. In addition, our annual number of conducted clinical trials is on par with the average of the world's leading institutions.

It is our honor to play a pivotal role in the clinical development of new drugs in Korea. We will continue to carry out top-notch clinical trial researches and function as an indispensable institution for the global drug development.

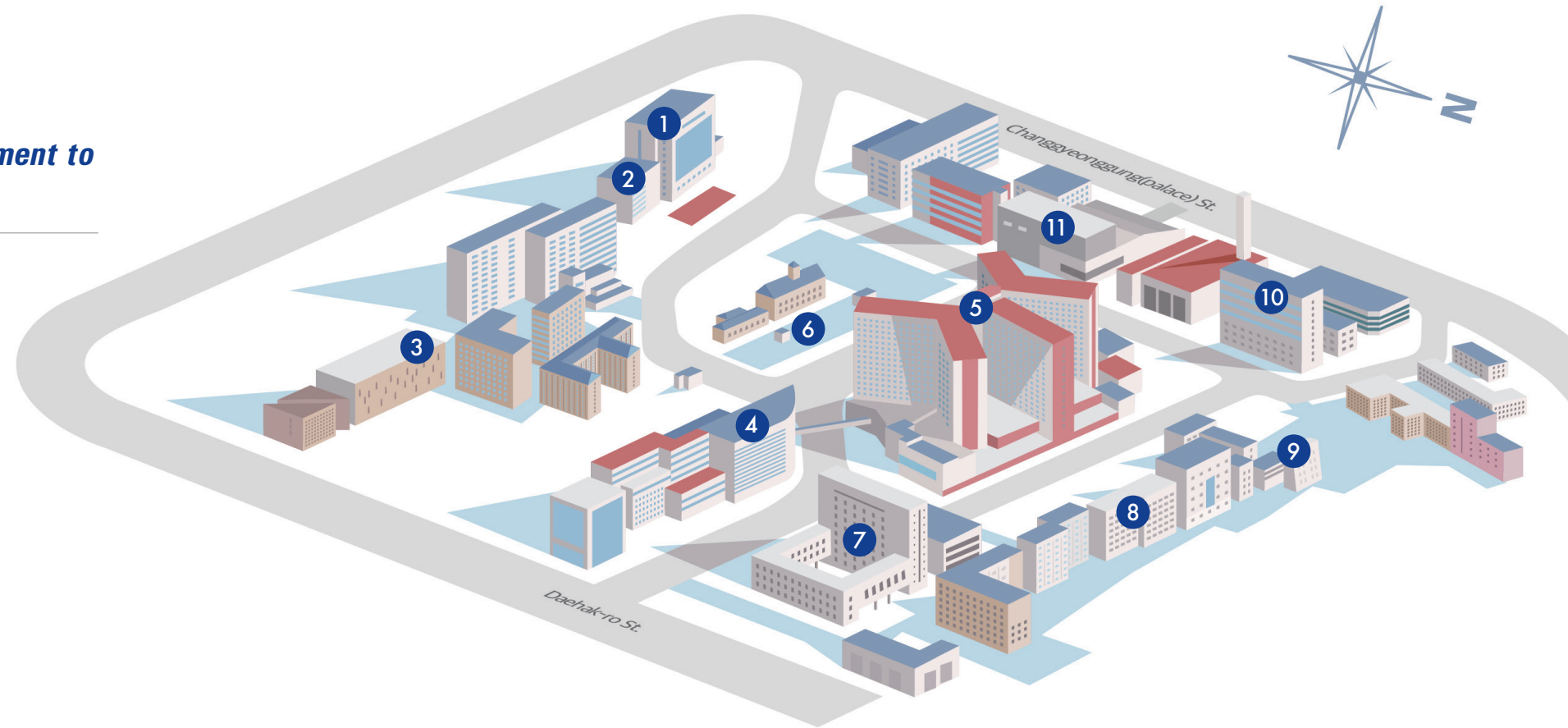
Thank you for your interest and encouragement.

**In-Jin Jang**  
Director, Clinical Trials Center

# History

*A comprehensive translational research environment to accelerate and enhance medical research*

- ① Samsung Cancer Research Building
- ② Biomedical Center for Animal Resource Development
- ③ Center for Medical Research Innovation
- ④ Children's Hospital (Pediatric Clinical Trials Center)
- ⑤ Main Hospital
- ⑥ Daehan Center
- ⑦ SNU College of Medicine (Research Building)
- ⑧ Medical Science Building
- ⑨ Non-Human Primate Research Center
- ⑩ Biomedical Research Institute (Clinical Trials Center)
- ⑪ Cancer Hospital (Cancer Clinical Trials Center)



1997 | 1999 | 2001 | 2003 | 2005 | 2007 | 2009 | 2011 | 2013 | 2015 | 2017

**May 1997**

Established as a CTC



**Dec 2004**

Designated as the Regional CTC by the Korean Ministry of Health and Welfare (KMHW)



**Feb 2007**

Facility renovation



**Jun 2007**

Selected as the Medical Device CTC by the Ministry of Food and Drug Safety (MFDS)

**April 2008**

Designated as the Center for Advanced Course for Pharmaceutical Medicine by the KMHW

**Mar 2011**

Establishment of the Cancer CTC



**Jan 2012**

Establishment of the Pediatric CTC



**Nov 2012**

Awarded as the Global Center of Excellence in Early Clinical Trials (GREATS) by the KMHW

**Sep 2017**

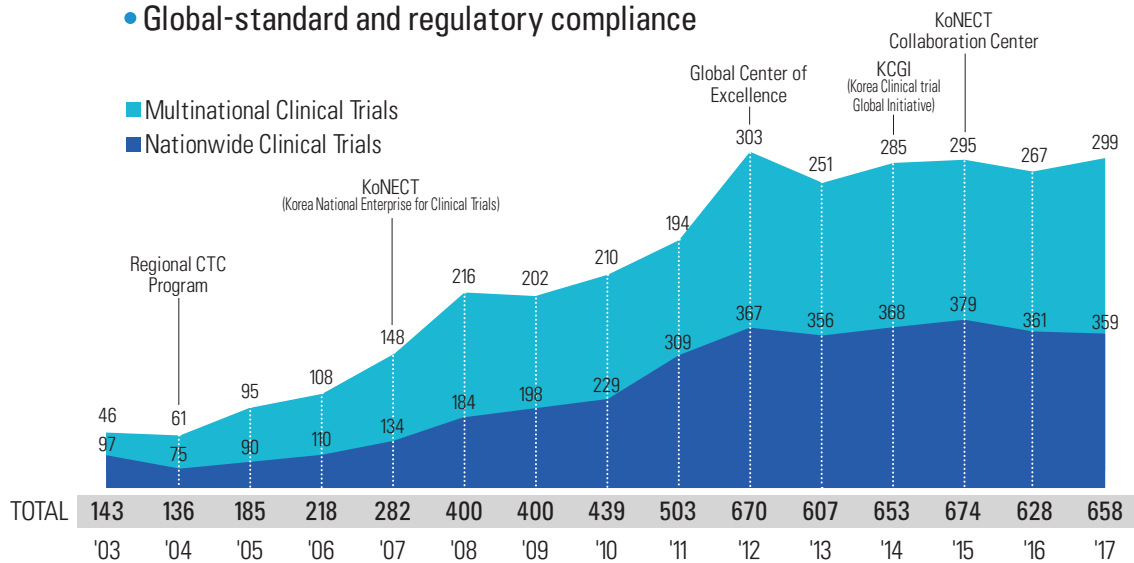
Completion of the expansion project





# Why Choose Korea for Clinical Trials?

- Strong government support in clinical trials
- National Health Insurance covers 98% of the Korean population
- CTCs are affiliated with university hospitals – diverse patient pool and rapid patient recruitment
- Global-standard and regulatory compliance



Growth of Korea's CTA Approvals and Government Initiatives  
Source: Ministry of Food and Drug Safety (MFDS)

US	12,096
Germany	3,214
UK	2,952
Canada	2,577
Spain	2,427
France	2,404
Korea	2,120
Italy	1,866
Belgium	1,724
Australia	1,627
Japan	1,585

Number of Industry-Sponsored Interventional Drug Trials in Top10 Countries, 2011-2016  
Source: KoNECT's analysis of ClinicalTrials.gov data

Korea	2,120
Australia	1,627
Japan	1,585
China	1,448
Taiwan	926
New Zealand	458
India	386
Thailand	382
Singapore	381
Hong Kong	318

Number of Industry-Sponsored Drug Trials in Asia Pacific, 2011-2016  
Source: KoNECT's analysis of ClinicalTrials.gov data

# Seoul National University Hospital

## SNUH provides

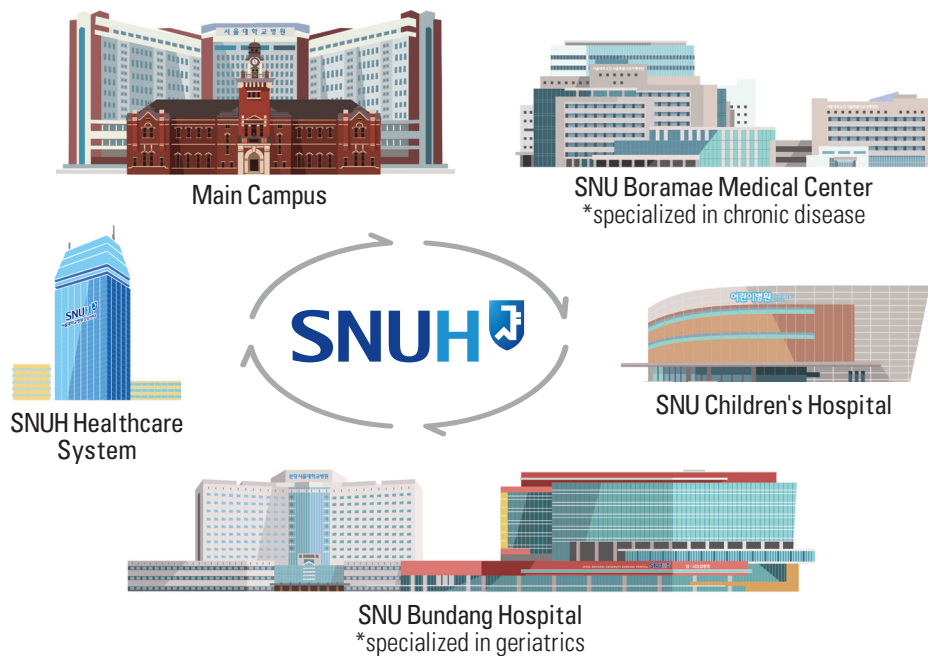
- World-class medical service
- No.1 in patient satisfaction
- Extensive patient population served within the network
- Advanced translational research infrastructure

## SNUH at a Glance

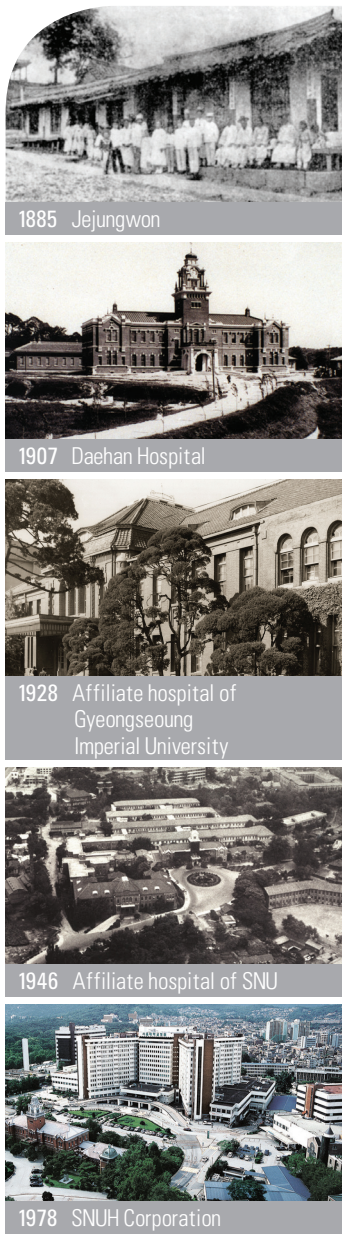
Beds	1,778
Doctors	1,390
No. of outpatients / year	2,256,180
No. of inpatients / year	609,545
No. of surgeries / year	40,380

As of Dec. 2017

## SNUH & Branch Hospitals



## SNUH History



# Clinical Trials Center

## Mission

Through state-of-the-art clinical trials, we create knowledge that changes the standard of care to improve human health around the globe

## Vision 2022

The world's leading early clinical trials center

## Core Values



### Guiding

GREATS guides you through the maze of successful clinical trial projects.



### Respectful

GREATS is respectful of your unique clinical trial needs.



### Ethical

GREATS is ethical in every conduct of its clinical trial business; it always puts human rights first.



### Adept

GREATS works skillfully to get the job done.



### Trustworthy

GREATS is reliable, responsible, and can be trusted completely.



### Sustainable

GREATS provides you with a sustainable clinical trials infrastructure.



## Services We Provide

### Phase I studies

- First-in-Human
- PK/PD bridging
- Bioequivalence
- Multi-ethnic PK/PD
- Food-drug interaction
- Drug-drug interaction
- Special population
- Bioanalysis & Biomarker

### Phase II studies

### Phase III studies

### Phase IV & Postmarketing

### Clinical Pharmacology Service

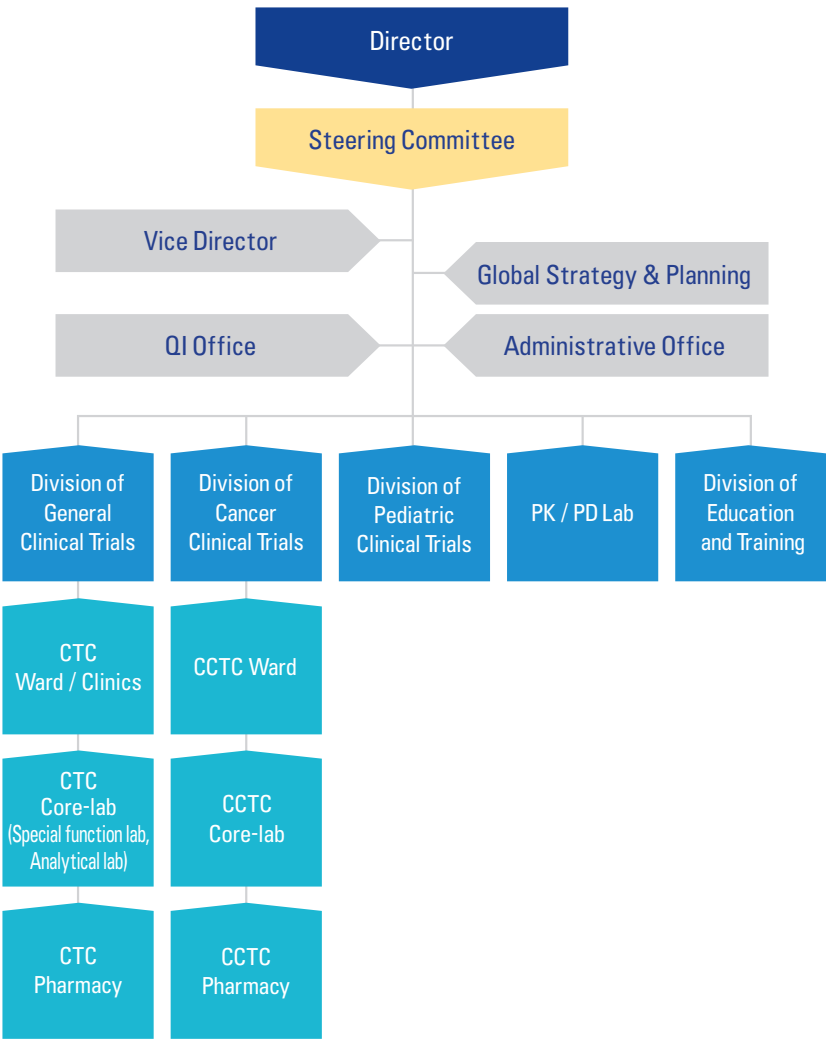
- Data analysis
- Clinical Study Reports
- Pharmacometrics
- Evaluation of exposure-relationship

### Methodology

- Modeling & Simulation
- Biomarker
- Pharmaco-genomics
- Metabolomics
- Microdosing



## Organization





# Facility



## Phase I Unit

- Total of 79 fully-monitored beds (65 beds & 14 couches)
- 3 specialized wards
- Injection room
- Volunteer lounge

## Out-patient Clinics – 12 rooms

- Screening room
- Soundproof room
- Temperature and humidity controlled rooms

## Pharmacy / Core-lab

- Refrigerators and freezers with temperature alarms
- Blood collection and ECG
- Platelet aggregometer and centrifuge

## Others

- PK/PD lab
- Monitoring rooms
- CRC offices
- Data archives





# Cancer Clinical Trials Center



- Since March 2011
- 1st Cancer Clinical Trials Center in Korea
- 10 fully-monitored beds and 20 couches
- Independent research ward, pharmacy, core-lab and monitoring rooms
- Opens 24 hours

# Our Commitment to Quality and Efficiency

## Quality in Science, Ethics and Data Management

- Human Research Protection Program, HRPP
  - An integrated institution-wide program to protect the right, safety and welfare of the research participants
- No critical findings from the Audits and Inspections
  - Audits by the top 20 global pharmaceutical companies and CROs
  - Inspections by MFDS, FDA, PMDA, and EMA
- Accreditation
  - AAHRPP accredited in 2012 and 2015
  - SIDCER / FERCAP accredited in 2006, 2009, 2012, and 2016



- Internal Quality Assurance System (1st subject and IIT monitoring) to ensure quality in clinical trials
- Provide educational programs to all research staffs on GCP and regulation updates

## Efficiency in Electronic Management and IRB Reviews

- IT Implementation
  - Real-time data capture from medical device
  - e-CRF data management
- Institutional Review Board, IRB
  - 8 regular meetings per month
  - 2 weeks for initial review after IRB submission
  - Web-based process tracking system



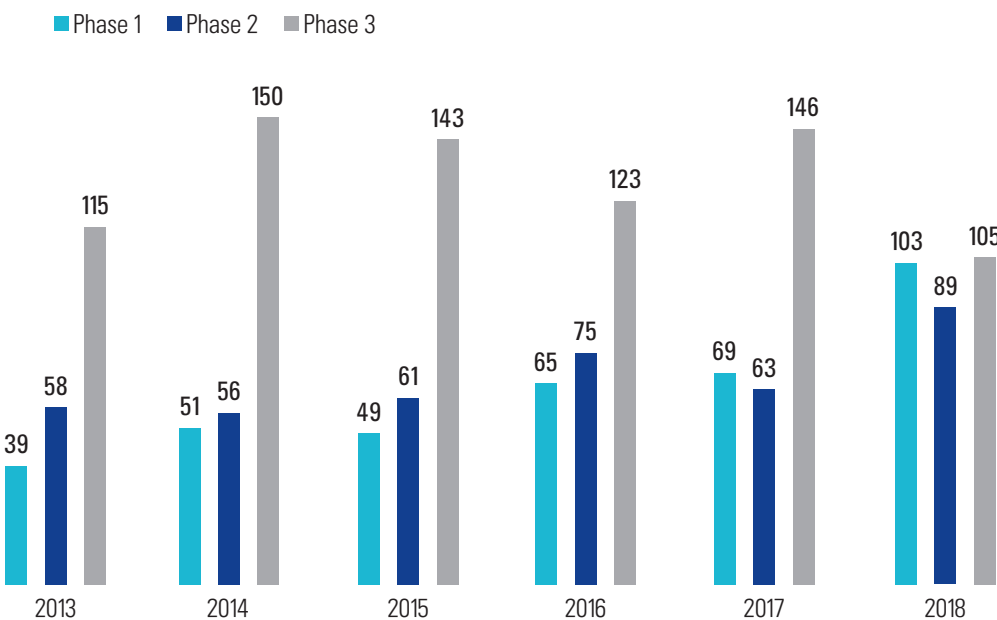
# Pediatric Clinical Trials Center



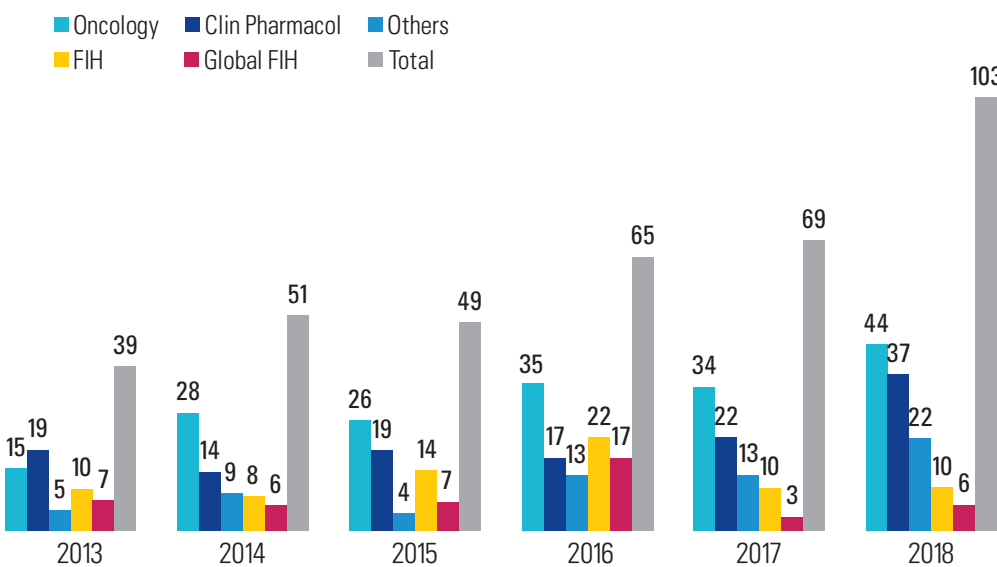
- Since January 2012
- 1st Hospital in Korea to conduct pediatric clinical trials
- Successfully done Phase 1 trial
- Fully-monitored beds and independent core-lab

# Our Experiences with Clinical Trials

Number of Newly Initiated Clinical Trials



Phase I Trials



# Our Leaders

- Jang, In-Jin** Director
- Kim, Dong-Wan** Vice Director / Head, Division of Cancer Clinical Trials
- Lee, Hae-Young** Head, Division of General Clinical Trials
- Kim, Han-Suk** Head, Division of Pediatric Clinical Trials
- Park, Kyung Woo** Head, Global Strategy & Planning
- Yu, Kyung-Sang** Head, PK/PD Lab
- Kwak, Soo Heon** Head, Division of Education and Training
- Lee, SeungHwan** Head, Quality Improvement
- Lee, Howard** Steering Committee
- Lee, Dong Young** Steering Committee
- Park, Ji Won** Steering Committee

- 1. Kim, Han-Suk
- 2. Kwak, Soo Heon
- 3. Park, Kyung Woo
- 4. Yu, Kyung-Sang
- 5. Lee, Hae-Young
- 6. Lee, Howard
- 7. Jang, In-Jin
- 8. Kim, Dong-Wan
- 9. Lee, Dong Young
- 10. Lee, SeungHwan
- 11. Park, Ji Won







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**Towards a global leader**



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