

# GLOBAL Clinical Research SUMMIT 2013

*Innovative, Integrative &  
Personalized Care Approach*

**October 1-2, 2013**  
Hotel Inter-Burgo, Daegu, Korea

human  
safety  
global  
clinical  
monitoring  
innovation  
ethics  
sustainable  
research  
medicine

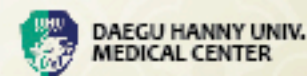
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Center for Integrative Medicine  
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Harvard Univ. MRCT, Georgetown Univ. Medical Center, WIRB-Copernicus Group, PRIM&R  
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Fudan Univ. Shanghai Cancer Center, Jiangsu Province Hospital

# Invitation

## 안녕하십니까?

현대는 글로벌 시대로 모든 지역과 국가간의 거리는 더욱더 가까워지고 있고, 보건의료산업도 글로벌 시대와 발맞추어 발전하고 있습니다. 혁신의료, 첨단의료, 통합의료, 연구중심병원과 같은 다각적 접근으로의 의료상황에 대한 시각의 전환은 새롭게 표준화되고, 질적으로 우수한 의료기술에 바탕을 둔 개별맞춤의료의 방향으로 나아가고 있습니다.

새로운 의료기술 (의약품, 의료기기, 복합제제 등)에 대한 임상연구는 지난 10여년간 국내외 임상시험을 활성화 시켰을 뿐만 아니라, 전문인력의 양성, 다학제 간의 연구 및 연구인프라를 구축하여 왔습니다. 글로벌 시대에 들어선 국·내외 상황은 임상연구에 대한 총괄적 거버넌스 체제를 구축하여, 안전과 행복의 시대를 여는 데 강조점을 두고 있습니다.

그러므로, 본 "GLOBAL Clinical Research SUMMIT 2013" 국제대회는 임상연구의 거버넌스 체제를 구축하는데 필요한 이슈, 전략, 추진방향 등을 글로벌 관점에서 논의하는 자리입니다. 전반적인 논의를 국제적인 규제와 관점에 비추어 국내여건을 바라보고, 연구의 올바른 책임감 있는 전개를 위해, 연구대상자의 안전을 위한 "IRB / HRPP", 부작용 및 이상반응을 평가하고 안전하고 유효한 임상연구를 지향하기 위한 "DMC / DSMB" WOKRSHOP이 동시에 열리게 됩니다.

특히 IRB / HRPP WORKSHOP은 미국 WIRB-Copernicus, PRIM&R과 공동으로 열리게 되며 (국내 최초), 글로벌 임상연구를 주도하는 Harvard Univ. MRCT와 더불어 DMC / DSMB과정을 열게 되어 (미국 이외의 지역 최초) 더욱더 심도 있는 자리가 되리라 여겨집니다.

많은 관심과 참석을 부탁드립니다.



대회조직위원장  
(전) 보건복지부 차관  
(재) 통합의료진흥원 이사장 손건익

Mr. Sohn Gun Yik  
Chair of CIMI  
Former Vice Minister of Ministry of  
Korean Health and Welfare



대회상임고문  
(전) 새누리당 원내대표  
국회의원 이한구

Lee Hahn-Koo  
Former Floor Leader of  
Ruling Party, Saenuri  
National Assembly Member

## Greetings from Daegu, Korea!

In today's globalized world, the distance between the regions and nations is ever decreasing. In pace with the global era, the healthcare industry is also evolving. Diversified approaches to healthcare such as innovative, state-of-the-art, and integrated healthcare services and research-focused hospitals have changed the way we see our medical environment that is steering more and more toward personalized and customized services based on newly standardized high-quality medical technologies.

Clinical research on new medical technologies (medicine and medical supplies, equipment, combination drugs) have not only stimulated clinical testing in Korea and overseas during the past decade, but also contributed to fostering and training professionals, promoting multidisciplinary research, and creating an infrastructure for continued studies. With the advent of the age of globalization, focus has moved on both at home and abroad to establishing a comprehensive system of governance for clinical research and opening an era of safety and happiness.

The GLOBAL Clinical Research SUMMIT 2013 will be an occasion to discuss about the issues, strategies, and directions related to establishing a system of governance for clinical research from a global point of view. Participants will be able to reflect on their local conditions from an international perspective based on international regulations. Workshops on IRB / HRPP for conducting responsible and proper research and respecting and promoting the safety of research subjects and DMC / DSMB for evaluating side effects and abnormal reactions and promoting safe and effective clinical studies will also be held.

The workshops promise to be particularly rewarding as the IRB / HRPP Workshop will be co-organized with WIRB-Copernicus and PRIM&R for the first time in Korea while the DMC / DSMB Workshop will be held, for the first time outside of the U.S., with MRCT of Harvard University, the global leader in clinical research.

We expect that the GLOBAL Clinical Research SUMMIT 2013 will be an exceptional opportunity for all participants to gain deeper insight and knowledge in the field of clinical research, and look forward to your active interest and participation.

# Program

## October 1, 2013 (Certificate of Attendance)

08:30-09:30	Registration	
09:30-10:00	Opening Remark Opening Ceremony <b>Welcoming Address &amp; Congratulatory Address</b> <ul style="list-style-type: none"><li>• Chin Young (Minister, KMOHW)</li><li>• Jang Byung-Won (Vice Minister, MFDS)</li><li>• Kim Bum-II (Mayor, Daegu Metropolitan City)</li></ul>	Fr. Chae Young-Hee (Chancellor of Medical Affairs in Daegu Archi) <i>Moderator:</i> Kim Ho Gak (Director General of SUMMIT) <ul style="list-style-type: none"><li>• Lee Hahn-Koo (National Assembly Member, former floor leader of ruling party, Saenuri)</li><li>• Sohn Gun Yik (Chair, CIMI / President of SUMMIT, former Vice Minister of KMOHW)</li></ul>
10:00-10:10	Distinguished Professor Announcement MOU Ceremony	Dr. Stephen Rosenfeld Renewal MOU with WIRB-Copernicus Group
<b>Keynote Address</b>		
10:10-10:50	Governance for Global Clinical Research - Issues and Strategy, Infrastructure and Challenge	Dr. Barbara Bierer (Professor, Harvard Univ. Medical School)
<b>Session 1 Challenge for Globalization as Frontier and Pioneer</b>		
10:50-11:10	Korea Challenge for Global Frontier	Mr. Park Inseok (Director general, KMOHW)
11:10-11:30	CIM Challenge to Global Unique Model as Pioneer	Dr. Stephen Rosenfeld (Board Chair, Quorum IRB, SACHRP / USHHS)
11:30-11:50	Meeting the challenges of globalized research on innovative and integrative products	Dr. Stuart Horowitz (President, WIRB-Copernicus Group)
11:50-12:00	Q&A	
12:00-13:00	Lunch	Invited by Minister of KMOHW
<b>Session 2 Enhancement of Infrastructure for Global Clinical Research</b>		
13:00-13:40	Responsibility in Global Clinical Research	Dr. Jeremy Sugarman (Director, PRIM&R)
13:40-14:00	Clinical Research Infrastructure of Korea	Dr. Dong Ho Lee (Chair, KDDF)
14:00-14:30	IRB / HRPP perspective in Global Clinical Research	Dr. Melody Lin (Deputy Director, OHRP/ DHHS USA)
14:30-14:50	MFDS Strategy and View for Globalization	Dr. Kim Jung Mi (Director general, MFDS)
14:50-15:10	Coffee Break	
<b>Session 3 Qualified, Systematic Global Clinical Research</b>		
15:10-15:40	Building Trust and Quality improvement in Global Clinical Research	Dr. Marjorie Speers (President, AAHRPP)
15:40-16:10	Global Regulatory view for Qualified Approach	Dr. David Forster (Chief Compliance Officer, WIRB-Copernicus Group)
16:10-16:30	Management of Integrity in Global Clinical Research	Dr. Joe Massaro (Professor, Boston Univ. / Harvard MRCT)
16:30-16:50	Empowerment and Sharing Knowledge for Global Clinical Research	Dr. Jeffrey Cooper (Vice President, WIRB-Copernicus Group)
16:50-17:10	Where to find successful Global Research in the Era of Change?	Dr. David Borosky (Director, PRIM&R)
17:10-17:30	Efforts to Global Standardized and Harmonized System on IRB / HRPP	Dr. Choi Hyun Il (Vice President, KAIRB)

**Session 4 Panel Discussion**

17:30-17:50 Invited Panel: Panel Discussion

17:50-18:30 Closing Remark

Break

18:30- Welcoming Dinner Party: Pueri Cantores of Daegu Performance \*Choir / \* Handbell Choir

**October 2, 2013 (Certificate of Completion)**

08:30-09:00 Registration

**Session 1 Approach to Issues specifically for Global Clinical Research**

09:00-09:40 IRB / HRPP- Evidence based practice in Global Environment

Dr.Marjorie Speers (President, AAHRPP)

09:40-10:20 DMC / DSMB: Guidance for Global Clinical Research

Dr.Barbara Bierer (Professor, Harvard Univ. Medical School)

10:20-11:00 How to make a leadership in front of diverse view

Dr.Jeremy Sugarman (Director, PRIM&R)

11:00-11:30 Q&A

11:30-12:30 Lunch

**12:30-17:30 Session 2 Concurrent WORKSHOP**

Title (Subject)	IRB WORKSHOP (Everyone)	DMC / DSMB WORKSHOP (Qualified person only)	CIM WORKSHOP (Invited person only)
Hosted by (CIMI with)	PRIM&R, WCG, OHRP / HHS, USA	Harvard Univ. MRCT	Harvard Zakim Center, China Top5 Hospital, GUMC
Moderator	Dr. Kim Ho Gak	Dr. Shin Im Hee	Dr. Gu Sae Kwang
Schedule	IRB activities: WCG	Role of DMC / DSMB	Harvard Zakim Center research activities
	IRB Chair / members / staff : PRIM&R	Monitoring safety / Efficacy	China TOP5 Hospital research reporting
	Protocol review: Jeffrey Cooper	DSMB functioning in multiregional clinical trials	GUMC research reporting
	ICF review: Melody Lin	Study futility	CIMI past, present, future
	Case study / Group discussion presentation	Case discussions	Group discussion
Certification (CIMI with)	WCG, PRIM&R	Harvard Univ. MRCT	GUMC, Harvard Zakim Center

17:30- Gala Dinner

TBD

# Venue



## 대구국제공항에서 오실 때

- 택시 소요시간 약 10분 (요금: 3,000원 정도)
- 버스 급행 1, 팔공 1 → 아양교역 하차 (환승)  
→ 808, 814 (망우공원에서 하차)

## 역에서 오실 때

- 통대구역
- 택시 소요시간 약 10분 (요금: 3,000원 정도)
  - 버스 156, 814, 708 (망우공원에서 하차)
- 대구역
- 택시 소요시간 약 20분 (요금: 6,000원 정도)
  - 버스 808, 708 (망우공원에서 하차)

## 동대구IC에서 오실 때

- 동대구IC에서 시청방향으로 4km (5분소요)

## 지하철을 이용하실 때

- 지하철 1호선 아양교역 하차  
→ 택시 - 소요시간 약 5분 (요금: 3,500원 정도)
- 지하철 1호선 아양교역 하차  
→ 버스 환승 - 808, 814 (망우공원에서 하차)
- 지하철 2호선 만촌역 하차  
→ 택시 - 소요시간 약 10분 (요금: 3,000원 정도)
- 지하철 2호선 만촌역 하차  
→ 버스 환승 - 849

## 동대구 고속버스 터미널에서 오실 때

- 택시 소요시간 약 10분 (요금: 3,000원 정도)
- 버스 156, 708, 814, 통구1-1 (망우공원에서 하차)

## 경유 버스 노선

- 버스노선  
106, 156, 508, 518, 521, 651, 708, 808, 814, 849, 통구1  
통구1-1, 북구3

From the Daegu Airport Taxi - It takes about 10mins (Fare: about 3,000won)


From the Dongdaegu IC Taxi - It takes about 5mins (Fare: about 2,000won)

From the Station

- Dongdaegu Station: By taxi - It takes about 10mins (Fare: about 3,000won)
- Daegu Station: By taxi - It takes about 20mins (Fare: about 6,000won)

From the Dongdaegu Express Bus Terminal By taxi - It takes about 10mins (Fare: about 3,000won)

※ 행사 및 등록에 관한 자세한 사항은 대회 공식 홈페이지를 참조해 주시기 바랍니다. [www.global-summit.or.kr](http://www.global-summit.or.kr)  
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**CIMI / DCUMC**

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