The current status and policy of early stage clinical trials in Korea

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1. Introduction

Because many participants are already familiar with the status of clinical trial activity in Korea, as the first part of my talk, I will present a brief update of recent activity and the current global position of Korean clinical trial, especially focusing on early stage clinical trial activity. As a second part, I will talk about our recent policy for improving global competency for clinical trials.

2. Clinical trials in Korea and previous efforts to improve clinical trial infrastructure

Clinical trial activity in Korea has been rapidly grown (Fig. 1) through the government initiative to support regional clinical trial centers started from year 2004. In 2008, the total number of clinical trials approved by KFDA (Korea Food and Drug Administration) in Korea reached over 400. We had more than 200 multinational clinical trials in 2008. However, after the global economic crisis, clinical trial activity in Korea has stagnated. Last year (2010), we had total 439 clinical trials received CTA (clinical trial authorization) from KFDA. Among them, 210 trials were global trials.

Regional Clinical Trials Centers (RCTCs) program was initiated by the Ministry of Health and Welfare (MOHW) from 2004. In the year of 2007, two more support programs were added to set up educational or training programs for clinical trial related professionals and to support development

Fig. 1　Clinical trials approved by KFDA

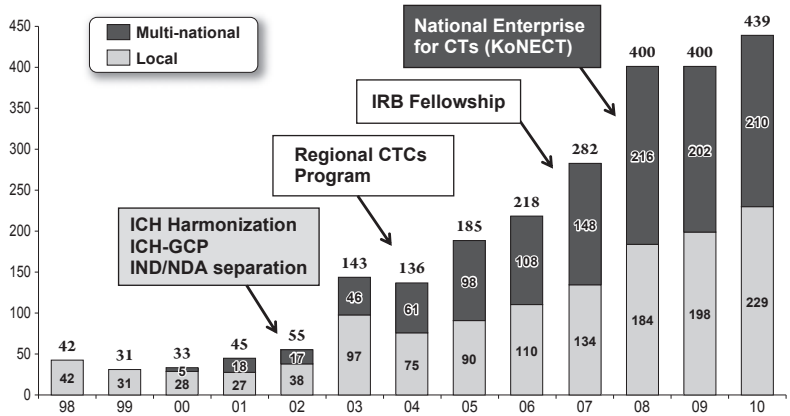

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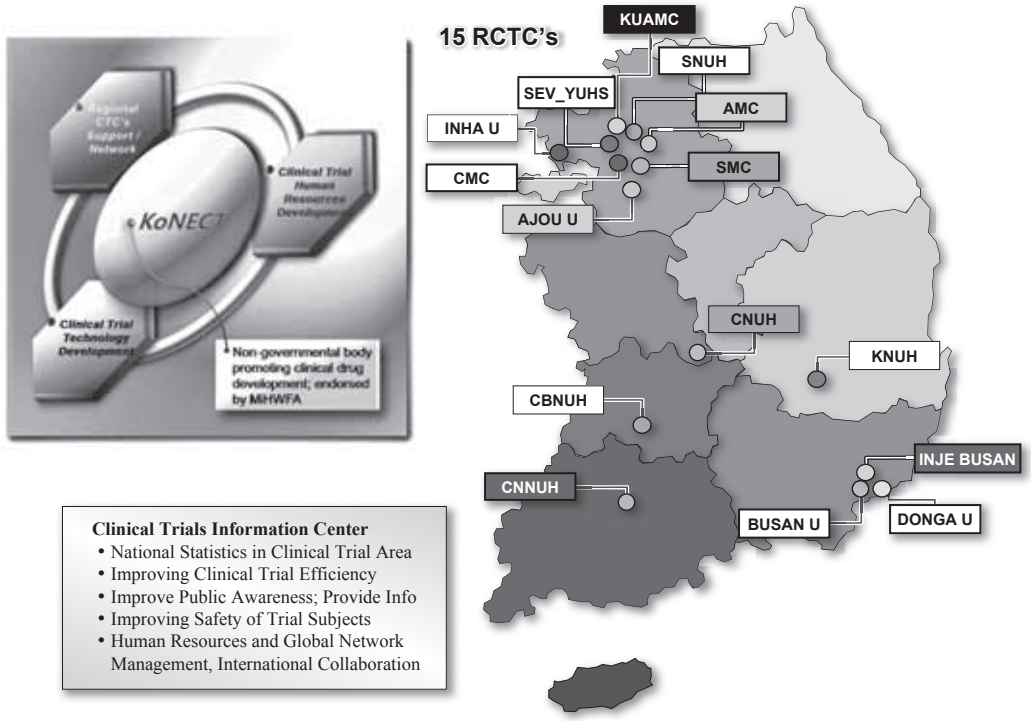
Fig. 2　Initiatives by MOHW (2004 -): KoNECT (2007 -)



of new technology for clinical trials. These support programs were endorsed to KoNECT (Korea National Enterprise for Clinical Trials), a newly established academic based organization, for more flexible and efficient management. Last year (2010). KoNECT selected the last two Regional Clinical Trial Centers. Currently Korea established 15 regional clinical trial centers nationwide. Eight regional clinical trial centers in Seoul metropolitan area and 3 RCTCs in Busan region (Fig. 2).

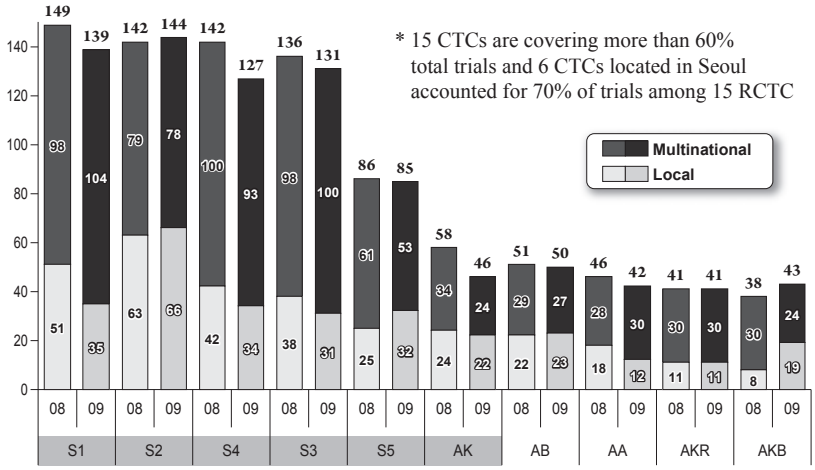
3. Clinical trials in major university hospitals of Korea

Fifteen regional clinical trial centers in Korea are serving as the core sites covering more than 60 percent of total clinical trials conducted in Korea. And especially, 6 major university hospitals located in Seoul are doing major roles (Fig. 3). One problem of clinical trials area in Korea is that industry sponsored trials are too much concentrated in Seoul metropolitan area. It is one of the issues Korea has to solve for future growth.

4. Global position of major Asian countries including Korea in clinical trial sector

Before talking about the current global position of Korea in clinical trial, I would like to briefly show some data on industry-funded trials from clinicaltrials.gov database. Although the database cannot be complete sources, it's very informative to understand the trend of clinical trial activities in the world. The clinical trial activity in the world was continuously growing with about 10 percent per year until 2007. However, owing to global economic crisis, the clinical activity in the world is

Fig. 3 Clinical trials in major hospitals (10) of Korea, 2009



declining from year 2008. The declining rate of protocol number newly registered to the database is about 10 percent per year. The reduction in clinical trial sites is even more dramatic, about 20 percent per year. During last 2 years, the number of trial sites in whole world declined about 40 percent.

Looking over the trend of clinical trial activities in the Asian region (Fig. 4), Korea, China and India are also showing steadily growing activity from the year 2005. The global ranking of clinical trial activity in year of 2010, China, India and Korea shows quite competitive around 13-15th. But if we look at the number of trial sites after 2008, the numbers of sites are stagnated to almost same number in those countries. This means that in the Asian region, these countries are stably conducting clinical trial activity. Relatively, in other countries or other regions, the number of clinical trial sites is getting down. As the results, the rank of Asian countries is going up. How about Japanese situation? If you're looking at the number of Japanese clinical trial sites from year 2008 to year 2010, there's a dramatic increase. This is somewhat good sign of reactivation of clinical trials in Japan.

5. World top 30 cities in clinical trials

Which cities in the world are getting active in clinical trials (Fig. 5)? Here I've listed the top 30 cities in the world. Actually, from 2005 until 2009, almost all of the top 30 cities were from the United States or EU countries. Only Moscow and Seoul were listed in the top 30 cities. Seoul was ranked the 4th city in the world in 2009. However, we can see a very interesting finding in the data in 2010. We can see 4 big cities from Asia in the top 30 cities, Tokyo, Osaka, and Beijing newly listed in the top 30 cities conducting clinical trial activity. Actually last year (2010), Seoul was ranked as second city just behind of Berlin. Tokyo was ranked 6th in the world. Actually, the number of trial sites has been quite increasing in Tokyo area. Osaka was ranked 21st and Beijing in 29th. In early 2000s, there has been a marked decline in activity in Western Europe. It seems like that US clinical trial activity start to be going down. It seems to be very promising sign for the future activation and growing role of East Asian countries in global clinical drug development.

Fig. 4　Clinical trials activities (ISTs only, rank as no. of sites)

	2005			2006			2007			2008			2009			2010		
1	US	41,030	47.85%	US	37,106	43.54%	US	35,573	40.69%	US	46,649	39.48%	US	34,884	36.91%	US	26,020	33.48%
2	Germany	4,791	5.59%	Germany	5,679	6.66%	Germany	11,841	13.55%	France	13,057	11.05%	Germany	8,107	8.58%	Germany	8,423	10.84%
3	Canada	4,503	5.25%	France	4,434	5.20%	France	3,420	3.91%	Germany	8,477	7.17%	France	7,744	8.19%	France	7,968	10.25%
4	France	3,950	4.61%	Canada	3,942	4.63%	Canada	2,856	3.27%	Japan	4,023	3.40%	Canada	2,894	3.06%	Japan	4,610	5.93%
5	Italy	2,575	3.00%	UK	2,607	3.06%	Spain	2,348	2.69%	Canada	3,862	3.27%	Spain	2,771	2.93%	Canada	2,718	3.50%
6	UK	2,530	2.95%	Spain	2,375	2.79%	Italy	2,154	2.46%	Spain	3,146	2.66%	Belgium	2,676	2.83%	Spain	1,805	2.32%
7	Spain	2,177	2.54%	Italy	2,000	2.35%	UK	2,146	2.45%	Italy	2,774	2.35%	Japan	2,674	2.83%	Italy	1,772	2.28%
8	Netherlands	1,758	2.05%	Japan	1,715	2.01%	Japan	2,022	2.31%	UK	2,709	2.29%	Italy	2,463	2.61%	Czech republic	1,654	2.13%
9	Japan	1,683	1.96%	Poland	1,646	1.93%	Russia	1,793	2.05%	Russia	2,152	1.82%	UK	2,386	2.52%	UK	1,544	1.99%
10	Australia	1,599	1.86%	Russia	1,559	1.83%	Poland	1,741	1.99%	Poland	1,995	1.69%	Poland	2,177	2.30%	Russia	1,534	1.97%
11	Belgium	1,422	1.66%	Netherlands	1,391	1.63%	Belgium	1,670	1.91%	Belgium	1,815	1.54%	Russia	2,138	2.26%	Belgium	1,392	1.79%
12	Poland	1,318	1.54%	Australia	1,360	1.60%	Australia	1,337	1.53%	India	1,560	1.32%	Australia	1,340	1.42%	Poland	1,276	1.64%
13	Sweden	1,227	1.43%	Belgium	1,350	1.58%	Netherlands	1,084	1.24%	Czech republic	1,509	1.28%	India	1,323	1.40%	Korea	1,145	1.47%
14	Denmark	934	1.09%	Brazil	1,071	1.26%	India	1,029	1.18%	Australia	1,483	1.26%	Korea	1,222	1.29%	China	1,078	1.39%
15	Russia	911	1.06%	Argentina	1,036	1.22%	Hungary	983	1.12%	Netherlands	1,419	1.20%	Hungary	1,122	1.19%	India	961	1.24%
16	Czech republic	900	1.05%	Czech republic	1,022	1.20%	Czech republic	947	1.08%	Korea	1,400	1.18%	China	1,091	1.15%	Australia	866	1.11%
17	South africa	804	0.94%	India	996	1.17%	Brazil	849	0.97%	Brazil	1,236	1.05%	Netherlands	1,040	1.10%	Romania	831	1.07%
18	Norway	756	0.88%	Hungary	834	0.98%	Argentina	751	0.86%	Hungary	1,146	0.97%	Romania	983	1.04%	Hungary	819	1.05%
19	Hungary	750	0.87%	Austria	812	0.95%	Korea	748	0.86%	China	1,125	0.95%	Czech republic	971	1.03%	Brazil	678	0.87%
20	Brazil	690	0.80%	Sweden	803	0.94%	Ukraine	748	0.86%	Romania	1,063	0.90%	Brazil	866	0.92%	Ukraine	666	0.86%
21	Finland	649	0.76%	Mexico	790	0.93%	China	745	0.85%	Sweden	1,060	0.90%	Sweden	837	0.89%	Sweden	645	0.83%
22	Mexico	591	0.69%	Korea	753	0.88%	Sweden	729	0.83%	Austria	937	0.79%	Austria	801	0.85%	Slovakia	619	0.80%
23	Argentina	587	0.68%	South africa	744	0.87%	Austria	683	0.78%	Argentina	924	0.78%	Mexico	769	0.81%	Austria	615	0.79%
24	India	550	0.64%	Ukraine	703	0.82%	Mexico	650	0.74%	Mexico	841	0.71%	Slovakia	716	0.76%	Netherlands	601	0.77%
25	Switzerland	481	0.56%	Israel	686	0.80%	Israel	605	0.69%	South africa	799	0.68%	South africa	695	0.74%	Mexico	567	0.73%
26	Austria	478	0.56%	China	666	0.78%	South africa	589	0.67%	Ukraine	783	0.66%	Ukraine	670	0.71%	Greece	539	0.69%
27	Israel	411	0.48%	Denmark	549	0.64%	Romania	536	0.61%	Israel	783	0.66%	Israel	669	0.71%	Israel	482	0.62%
28	Greece	390	0.45%	Romania	467	0.55%	Denmark	506	0.58%	Denmark	744	0.63%	Argentina	625	0.66%	Turkey	438	0.56%
29	China	370	0.43%	Finland	420	0.49%	Taiwan	502	0.57%	Slovakia	674	0.57%	Switzerland	620	0.66%	Argentina	422	0.54%
30	Korea	358	0.42%	Switzerland	410	0.48%	Finland	463	0.53%	Greece	573	0.48%	Taiwan	545	0.58%	Taiwan	392	0.50%

Source: www.clinicaltrials.gov, 2010. 12. 31

Fig. 5　Top 30 cities (ISTs only, rank as no. of sites)

	2005			2006			2007			2008			2009			2010		
1	Houston	674	0.79%	Houston	628	0.74%	Berlin	836	0.96%	Houston	860	0.73%	Houston	710	0.75%	Berlin	764	0.98%
2	New York	673	0.78%	New York	582	0.68%	Houston	776	0.89%	New York	770	0.65%	Berlin	685	0.72%	Seoul	560	0.72%
3	Chicago	580	0.68%	Moscow	517	0.61%	New York	671	0.77%	Berlin	747	0.63%	New York	593	0.63%	Houston	549	0.71%
4	Boston	550	0.64%	Berlin	511	0.60%	Boston	548	0.63%	San Antonio	695	0.59%	Seoul	556	0.59%	New York	441	0.57%
5	Los Angeles	549	0.64%	Chicago	492	0.58%	Chicago	525	0.60%	Philadelphia	638	0.54%	Boston	534	0.57%	Hamburg	415	0.53%
6	Philadelphia	545	0.64%	Philadelphia	484	0.57%	Moscow	523	0.60%	Los Angeles	621	0.53%	Moscow	532	0.56%	Tokyo	372	0.48%
7	Dallas	516	0.60%	Dallas	477	0.56%	San Antonio	506	0.58%	Dallas	619	0.52%	San Antonio	504	0.53%	San Antonio	366	0.47%
8	Atlanta	487	0.57%	Boston	464	0.54%	Dallas	487	0.56%	Boston	591	0.50%	Dallas	473	0.50%	Dallas	360	0.46%
9	San Antonio	463	0.54%	Madrid	442	0.52%	Philadelphia	483	0.55%	Moscow	582	0.49%	Madrid	454	0.48%	Los Angeles	340	0.44%
10	Berlin	448	0.52%	San Antonio	424	0.50%	Los Angeles	472	0.54%	Seoul	573	0.48%	Los Angeles	453	0.48%	Chicago	339	0.44%
11	San Diego	438	0.51%	Los Angeles	420	0.49%	Seoul	423	0.48%	Chicago	567	0.48%	Chicago	422	0.45%	Boston	333	0.43%
12	Toronto	427	0.50%	Barcelona	410	0.48%	Madrid	401	0.46%	San Diego	531	0.45%	Philadelphia	415	0.44%	Moscow	321	0.41%
13	Cincinnati	406	0.47%	Atlanta	391	0.46%	Barcelona	392	0.45%	Atlanta	512	0.43%	San Diego	412	0.44%	Madrid	308	0.40%
14	Montreal	405	0.47%	Baltimore	377	0.44%	Atlanta	384	0.44%	Paris	487	0.41%	Paris	394	0.42%	San Diego	302	0.39%
15	Madrid	400	0.47%	Toronto	374	0.44%	Toronto	363	0.42%	Madrid	484	0.41%	Barcelona	387	0.41%	Miami	287	0.37%
16	Portland	399	0.47%	Miami	358	0.42%	San Diego	347	0.40%	Cincinnati	473	0.40%	Toronto	373	0.39%	Toronto	285	0.37%
17	St. Louis	397	0.46%	San Diego	353	0.41%	Miami	339	0.39%	Miami	471	0.40%	London	365	0.39%	Atlanta	284	0.37%
18	Baltimore	382	0.45%	Montreal	350	0.41%	Cincinnati	335	0.38%	Baltimore	458	0.39%	Baltimore	348	0.37%	Barcelona	282	0.36%
19	Barcelona	379	0.44%	Birmingham	345	0.40%	London	329	0.38%	Barcelona	453	0.38%	Cincinnati	339	0.36%	Philadelphia	280	0.36%
20	Moscow	376	0.44%	Seoul	329	0.39%	Baltimore	326	0.37%	Toronto	432	0.37%	Miami	336	0.36%	London	275	0.35%
21	Birmingham	360	0.42%	Cincinnati	326	0.38%	St. Louis	324	0.37%	Birmingham	431	0.36%	Atlanta	335	0.35%	Osaka	274	0.35%
22	Pittsburgh	359	0.42%	St. Louis	325	0.38%	Paris	314	0.36%	Portland	403	0.34%	Hamburg	317	0.34%	Paris	263	0.34%
23	Indianapolis	351	0.41%	Paris	319	0.37%	Cleveland	308	0.35%	Montreal	386	0.33%	Montreal	314	0.33%	Cincinnati	254	0.33%
24	Rochester	349	0.41%	London	318	0.37%	Rochester	306	0.35%	Phoenix	386	0.33%	Nashville	314	0.33%	Nashville	217	0.28%
25	Paris	349	0.41%	Phoenix	317	0.37%	Hamburg	300	0.34%	Indianapolis	385	0.33%	Phoenix	304	0.32%	Birmingham	212	0.27%
26	Miami	345	0.40%	Cleveland	310	0.36%	Birmingham	298	0.34%	London	380	0.32%	Portland	300	0.32%	Baltimore	208	0.27%
27	Seattle	331	0.39%	Buenos Aires	304	0.36%	Pittsburgh	294	0.34%	Tampa	371	0.31%	Birmingham	282	0.30%	Phoenix	206	0.27%
28	Phoenix	326	0.38%	Portland	302	0.35%	Portland	292	0.33%	St. Louis	363	0.31%	St. Louis	279	0.30%	Montreal	204	0.26%
29	Denver	313	0.37%	Indianapolis	300	0.35%	Nashville	291	0.33%	Rochester	354	0.30%	Rochester	276	0.29%	Beijing	203	0.26%
30	Nashville	311	0.36%	Rochester	295	0.35%	Montreal	286	0.33%	Cleveland	348	0.29%	Budapest	273	0.29%	Rochester	201	0.26%
57	Seoul	205	0.24%															

Source: www.clinicaltrials.gov, 2010. 12. 31

6. Early phase clinical trial experiences of Korea

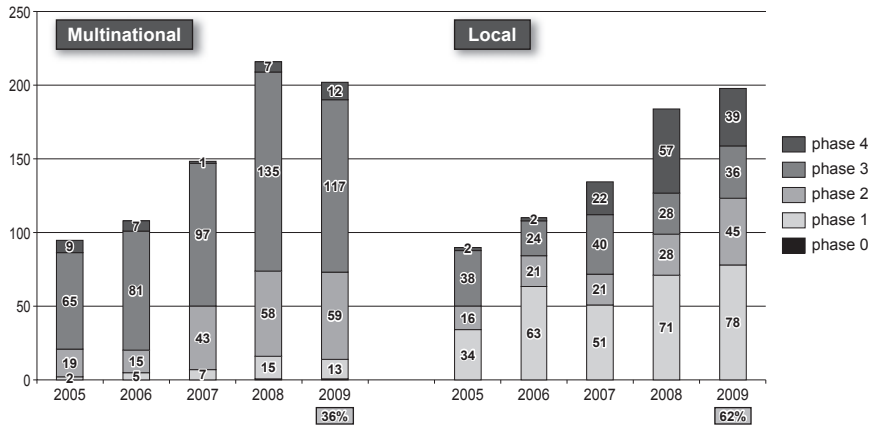
Next, I'd like to briefly talk about early stage clinical trial in Korea (Fig. 6). Actually we have not analyzed last year data yet, so I will just present data until 2009. Before 2007, multinational clinical trials conducted in Korea were almost Phase Ⅲ studies, though there were quite a few Phase Ⅰ, Phase Ⅱa studies. But from year 2008, there was an increasing trend of early phase clinical trials. In the year 2009, the proportion of Phase Ⅰ and Phase Ⅱ trials reached 36 percent.

How about local trials or domestic trials, especially driven by domestic pharmaceutical companies in Korea? A lot of Phase Ⅰ trials has been conducting. But actually these Phase Ⅰ trials are mostly involving new formulations with DDS technology or biosimilar products, requiring some PK, PK-PD or Phase Ⅰc type studies for marketing approval. First-time in man studies from domestic pharmaceutical companies are usually about 5 or 6 per year in Korea.

Looking at the whole picture of total clinical trial activity and comparing the proportion of early phase multinational clinical trials conducted in Korea with western countries. It is still showing emerging country pattern compare to the United States or UK. Recently, many early phase clinical studies for global clinical drug development are off-shoring into Korea, but Phase Ⅰ study still quite limited to oncology area. Phase Ⅱ studies are showing much more diverse pattern in various therapeutic areas, Global Phase Ⅱ studies looks like becoming much more activated in Korea.

How about Phase 0 study experience? Korean FDA doesn't have guidance for exploratory IND study yet. But the KFDA have approved two protocols of Phase 0 study – one in the year 2008, and the other one last year (2010). But the compounds were not agents for therapeutic purpose. Those were the diagnostic agents for PET-imaging category. Until now we do not have any Phase 0 experiences involving therapeutic agents development. Korea shows strong scientific activities in the nuclear medicine field, and we have lot of PET facilities in the country. We have almost 113 PET centers in Korea in fiscal year of 2008, and it's becoming very popular to apply PET/CT in general medical practices. It is the reason why Bayer, a global pharmaceutical company, developed Phase 0 study in Korea.

Fig. 6 Early phase experiences (No. of protocol)



Source: KFDA Data base 2009

7. Policy for improving competency of clinical development, especially focusing early stage

As a second part of my talk, I'd like to briefly mention several policies, and then later, I'll present some movement of Korean government and academia, what we are doing to improve the competency of early stage clinical trial in Korea.

The MOHW and KoNECT are encouraging more close collaboration among academia and drug industries not only for domestic R&D but also for global R&D. Currently, Korean government understands that clinical trial field is one of future knowledge-based technology industry leading bio-and pharmaceutical industries.

8. Global core clinical R&D sites program started to include Asian institutions

Recently, many university hospitals located in Seoul have been establishing close collaborations with some global pharmas and CROs, joining recent strategic initiatives of global pharmas in clinical trials (Fig. 7). GSK (GlaxoSmithKline) actually changed R&D strategy from the centralized to diverse therapeutic area and established a concept of Centers of Excellence in each therapeutic area. Currently, 4 university hospitals located in Seoul are actively collaborating as GSK's Centers of Excellence. In the year 2008, Pfizer started the CORE Research Sites (CRS) program to develop about half of their new pipeline, conducting early phase extrapolating studies through this CRS program. In 2008, 4 big medical university hospitals in Seoul were incorporated as CRS sites of Pfizer, as simultaneously working single consortium. Merck Research Laboratory has recently established a worldwide network especially for developing oncology area. They developed OncoNet program. There are actually 4 university hospitals in Asia working as co-partner in this OncoNet; one in Japan, one in Taiwan and two in Korea. October 2010, Quintiles, leading global CRO, established a strategy similar to the global pharma. They established a new concept called Prime Sites program focusing on early phase trials. Until last year (2010), they selected 8 institutions worldwide, and Seoul National Univer-

Fig. 7 Global core sites program include Asian countries

◆ CORE (Center Of Research Excellence) Research Sites, Pfizer, May 2008

- ◆ Pfizer's new Strategy for Phase II projects : 50% of Phase IIs trials will be conducted at CRS sites (9 countries 12 institution as 2010), **India (2009), Hong Kong (2010)**
- ◆ Korea (as Consortium) : Seoul National, Asan Medical Center, Samsung Medical Center, Yonsei Univ. (2008. 5)

◆ GSK Centers of Excellence (2007)

- ◆ 4 Institutions : Seoul National/Asan/Yonsei/Catholic
- ◆ 2008 : 4 Phase I and 8 Phase II trials

◆ Merck Research Laboratory : OncoNet (June, 2010)

- ◆ 11 countries, 20 centers : (Korea) Seoul Natl', Yonsei, Japan-1, Taiwan-1
- ◆ 4 OncoNet studies in 2010

◆ Quintiles Prime Sites (Oct. 2010)

- ◆ 8th Institutions : **1 in Malaysia, 1 in Korea** ; Seoul Natl' Univ.

sity in Korea and one Malaysian institute were selected as the Prime Sites in Asian region.

This is just one example of global pharmaceutical company's early phase R&D in Asia (Table 1). GSK started early phase clinical study in Asia from 2004. The company is expanding early phase clinical studies in Asian region, especially in Korea, Singapore, Hong Kong, Taiwan and recently, early phase studies in India are growing rapidly.

9. Korea is planning to promote global center of excellence as a post-regional trial center supporting program

Recently, clinical trial activity especially those in early stage in Korea look like growing up well. We made a big stride in Korea to promote clinical trials through the regional clinical trial center support program. But in reality, the supports for six university hospitals were already terminated. This year (2011), 3 more university hospital support programs are expected to be finished. So we are worried about how we can continuously keep the trends of improvements in early stage clinical trial competencies. Currently, KoNECT is planning new program especially to promote real global competency of early phase trials area in major university hospitals. It has been planning as the name of Global Center of Excellence support program with competitive and selective basis. We are trying to consolidate the future program with MOHW as early as possible.

10. Strengthening regulatory competitiveness and streamlining for clinical trial approval by KFDA

Next, I will talk about recent movements inside of KFDA. The KFDA has made many revolutions in terms of CTA review systems and clinical trial oversight mechanisms in Korea. From year 2008, after the agency started the APEC harmonization education center program with ICH-GCG (Global Cooperation Group), they're much eager to make new initiatives, to be globalized and to adopt the ICH guidelines more rapidly. They are also doing more effort to reduce CTA review times. In early 2008, the average CTA review time was about 50 days, but recently CTA review time reduced almost around 30 working days. For more global competi-

Table 1 Centrally co-ordinated early phase studies in Asia by GSK from 2004

Country	No. trials*	Type of sites used	
		Academic	Early Phase Unit
Korea	>10	Y	Y
Singapore	>5 <10	Y	Y
Hong-Kong	<5	Y	Y
Taiwan	2	Y	N
Malaysia	2	Y	N
India	2	Y	N**
Thailand	1	Y	N***
China	1	Y	N

* Numbers includes early phase oncology studies
** Sites evaluated and studies planned in 2010 for HVT
*** Site evaluated, plan to use in the future

Presented in DIA 2010

tiveness, KFDA is starting to make more efficient review system especially for Phase I study; especially for normal volunteer study. They've obliged to reduce their review time to 14 working days, comparable with UK and Canada review system.

Last year (2010), the KFDA published the guideline for joint IRB and mutual recognition mechanism for more efficient IRB process especially for multicenter trials. They've also started to allow submission of English version of the protocol for CTA review. However, the drastic changes cannot be achieved at once. Many reviewers have shifted to reviewing the English version, but there are still some, because of some deficiency in understanding the English protocol, are stick to the Korean translation. But I think it will change rapidly. KFDA is trying to activate pre-consultation system before IND and CTA application. They also have a plan to publish exploratory IND guideline this coming June. And this January, KFDA created a Task Force Committee for Master Planning to make long-range road map for improving future competency in clinical trials in Korea.

11. Challenges in clinical trial operations of medical institution and new efforts to overcome

As a last part, I present new movements in academic institutions in Korea. Recently big university hospitals are seriously thinking about global competencies in their clinical research activities. So they are moving to implement GCP concepts in all of clinical researches and to meet the industrial needs for the quality of clinical trial in terms of scientific and ethical aspects. They're looking for institutional oversight system to ensure quality of trials and study subject's right & safety. We have a very tight clinical trial inspection program from KFDA, but there is some lack of quality assurance mechanism inside of medical institutions. Several major university hospitals are setting up institutional clinical research governance system to ensure high quality in clinical trials. In Yonsei University and Seoul National University Hospitals, they've set up a Department of Human Subject Protection, and monitoring mechanism for important clinical trials conducting in their university hospitals. Seoul National University Hospital set up the First Patient Monitoring System for major trials. The first-patient data are comprehensively monitored by the quality assurance people of the clinical trial center. It can detect and correct very early for any missing practice of the clinical investigator team or any faults in following clinical trial process.

Medical Institutions are also looking for streamlining of IRB process and clinical trial supporting process at the institution. Recently, the Korean Association of IRBs collaborated with KFDA developing a joint IRB guideline and mutual recognition guidance. They also developed real working joint-IRB in one city in Daegu, which has 4 medical schools and 1 big general hospital. The 5 hospitals in Daegu city made joint-IRB for multicenter protocol review. As one more important event, 5 major university hospitals IRBs in Seoul have started preliminary mutual recognition system for multicenter trials. So, the principal investigator will just submit the protocol to his institutional review board. If that institution's IRB accepts the protocol, the rest of university hospital IRBs can just review the protocol in expedited review process. For robust IRB operation, many university hospitals in Korea are getting international accreditations to ensure the quality of IRB review system. Until last year (2010), 3 university hospitals got AAHRPP (Association for the Accreditation of Human Research Protection Programs) accreditation, and

21 university hospitals got FERCAP (Forum for Ethical Review Committees in the Asian and Western Pacific Region) accreditation (Fig. 8).

As a governmental activity by the MOHW and KAIRB (Korean Association of IRBs) started a national IRB evaluation program for all registered IRBs in Korea from last year (2010). The final goal of the activity is to establish a national accreditation system for IRBs in the country.

Fig. 8 Korean Association of IRBs (2002-)/MOHW, international accreditation

◆ Initially established as a non-governmental organization

◆ Since 2007, MOHW supports KAIRB activities
- Government grants for IRB fellowship training (2 or 6 mo, 10/yr) at Western IRB
- Developing Joint IRB (in DaeGu) & Mutual recognition (5 major in Seoul)
- National IRBs Evaluation since 2010; currently ongoing

◆ International Accreditation (24 as 2010) & **Institutional Research Governance (Major Univ. Hosp's in Seoul)**

Table 1. Accredited institutions and recognized IRBs in Korea[12, 13]

AAHRPP accredited	FERCAP/SIDCER recognized
Samsung Medical Center [2006]	Seoul National University Hospital (SNUH) Institutional Review Board[2006, 2009]
Severance Hospital, Yonsei University College of Medicine [2010]	Asan Medical Centre Institutional Review Board[2006, 2009]
The Catholic University of Korea Catholic Medical Center [2010]	Kangnam St. Mary's Hospital (KSMH) Institutional Review Board[2007]
	Chonnam National University Hospital Institutional Review Board[2007]
	Inje University Busan Paik Hospital (IJUBPH) Institutional Review Board[2007]
	Hallym University Sacred Heart Hospital Institutional Review Board[2008]
	Daegu Cathulic University Medical Center (DCUMC) Institutional Review Board[2008]
	Kyung Hee University Hospital (KHUH) Institutional Review Board[2008]
	Ajou University Hospital Institutional Review Board[2008]
	Inha University Hospital Institutional Review Board[2009]
	Kangbuk Samsung Hospital Institutional Review Board[2009]
	Chungnam National University Hospital Institutional Review Board (CNUH-IRB)[2009]
	International Vaccine Institute (IVI) Institutional Review Board[2009]

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