



# The Present and Future of Korea Clinical Trials

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KoNECT

Korea National Enterprise  
for Clinical Trials,

# START WITH KOREA

The Best Destination for  
Global Clinical Trials





# Contents



1. Introduction of KoNECT & Korea Clinical Trials
2. KoNECT Approaches for Global Collaboration including NE Asia development
3. Future





## KoNECT and Korea Clinical Trial Activities

# What KoNECT Do

*Korea National Enterprise for Clinical Trials*



- Build world-class **clinical trial capacity** in Korea
- **Collaborate with Korea's clinical trial enterprise** of Korea across government, academics, industry and patients.
- Provide **extensive training and certification** programs for clinical trial professionals and CROs
- **Support domestic companies** and CROs: Consultation and Clinical development forums
- Collaborate with **global partners and sponsors** for MRCT and serve as **one-stop shop for clinical trials** in Korea.
- Develop **data-driven approach** in clinical trials

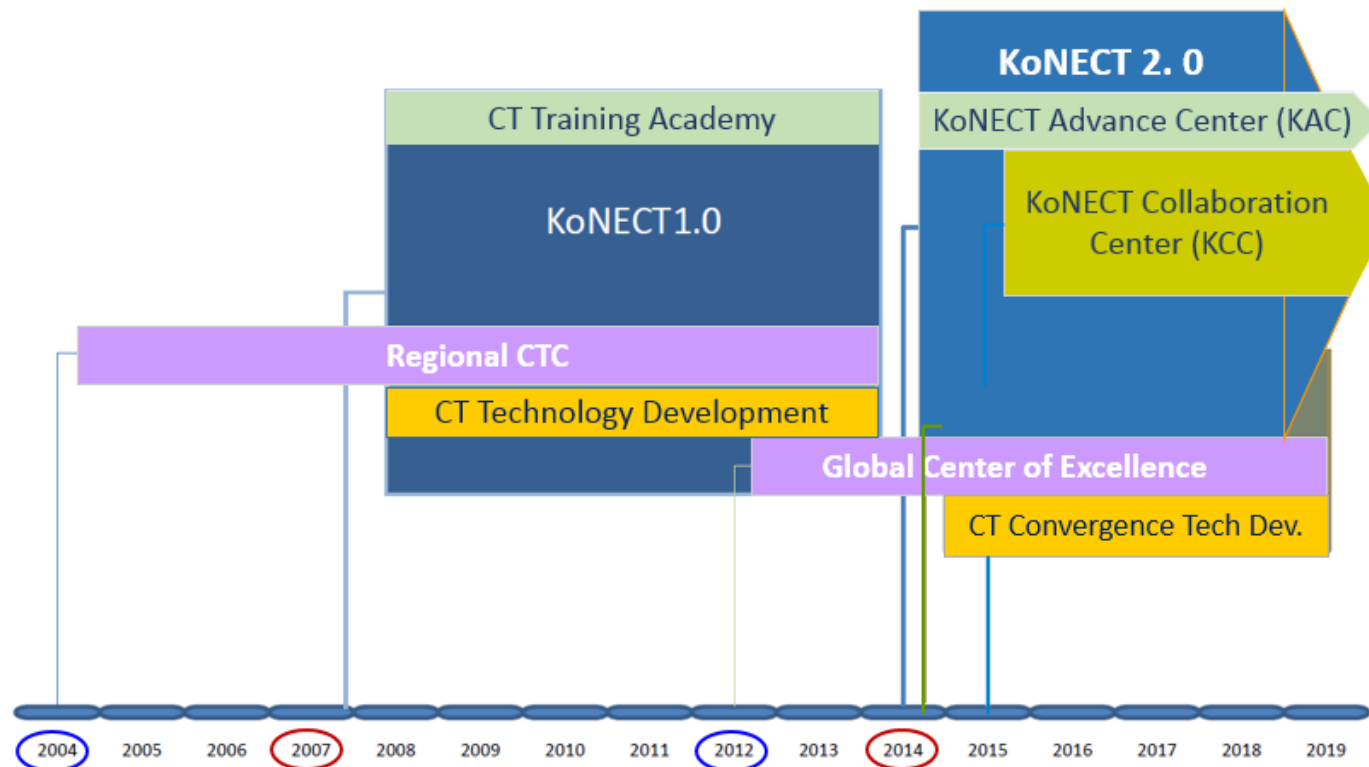
# Korea, A Competitive Edge in Clinical Trial

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- Favorable demographics
- Westernized disease pattern with Asian genetics
- World-class infrastructure & medical care
- Faster study start-up time
- Site excellence with faster enrollment and ethical/clinical standards for world-class quality data
- Accumulated experience in Global/Asian studies
- Increasing use of health insurance claim and EMR big data in clinical trials
- Government (MOHW) initiatives for clinical trial excellence
  - ✓ Regional Clinical Trial Center Program (2004 ~ 2014)
  - ✓ KoNECT (2007~)
  - ✓ Global Center of Excellence of Clinical Trials (GCE) and Convergence Technologies for CT Program (2012~2019)

# Chronology of Korea Clinical Trial Capacity Building Initiatives

- A 15-years journey to **Quality and Efficiency** to build credibility in clinical trial capacity and to help patients through KoNECT.
- Focus on academic centers with hospitals.
- The journey is ongoing.



# Seoul, The Top City in Clinical Trials @ ClinicalTrials.gov

No	2014		2015		2016		2017		2018	
	Total City	Site	Total City	Site	Total City	Site	Total City	Site	Total City	Site
	7,517	58,253	7,683	58,438	5,746	44,797	5,363	46,415	5,482	50,336
	City	%	City	%	City	%	City	%	City	%
1	Seoul	1.06	Houston	1.03	Houston	1.16	Seoul	1.40	Seoul	1.18
2	Houston	0.91	Seoul	1.03	New York	1.00	Houston	1.00	Houston	1.11
3	New York	0.81	New York	0.92	Seoul	0.98	New York	0.98	Madrid	0.93
4	London	0.79	London	0.73	Boston	0.94	Madrid	0.84	New York	0.90
5	Boston	0.73	Madrid	0.71	Miami	0.81	Boston	0.81	Miami	0.82
6	Berlin	0.72	Miami	0.70	Madrid	0.76	London	0.80	London	0.80
7	Los Angeles	0.72	Boston	0.68	Barcelona	0.75	Miami	0.73	Boston	0.76
8	Madrid	0.66	Barcelona	0.68	London	0.74	Barcelona	0.71	Barcelona	0.72
9	Miami	0.65	Berlin	0.67	San Antonio	0.71	Beijing	0.64	San Antonio	0.70
10	Barcelona	0.61	San Antonio	0.61	Dallas	0.64	Los Angeles	0.62	Beijing	0.64
11	Chicago	0.57	Los Angeles	0.60	Philadelphia	0.63	Dallas	0.58	Los Angeles	0.61
12	Dallas	0.51	Chicago	0.57	Los Angeles	0.62	Moscow	0.56	Berlin	0.59
13	Philadelphia	0.51	Philadelphia	0.56	Chicago	0.60	Chicago	0.56	Moscow	0.57
14	Moscow	0.50	Dallas	0.54	Berlin	0.58	Berlin	0.55	Dallas	0.53
15	San Antonio	0.49	Paris	0.49	Beijing	0.53	Philadelphia	0.54	Atlanta	0.51
16	Paris	0.49	Atlanta	0.48	Nashville	0.50	San Antonio	0.53	Philadelphia	0.50
17	Nashville	0.47	Budapest	0.45	Atlanta	0.50	Budapest	0.47	Tampa	0.49
18	Atlanta	0.43	Nashville	0.45	Tampa	0.47	Saint Louis	0.47	Chicago	0.48
19	Birmingham	0.43	Birmingham	0.42	Baltimore	0.45	Atlanta	0.44	Toronto	0.47
20	Toronto	0.42	Toronto	0.41	Seattle	0.45	Nashville	0.43	Nashville	0.46

Notes: [www.clinicaltrials.gov](http://www.clinicaltrials.gov) | Registered in 2018 | Download 2.Jan.2019 | **Industry Sponsored** | Total Protocol & Site (Single/Multinational) | Intervention type(Biological/Drug) | KoNECT



# Global Site Ranking in Oncology Trials

- Four Korean sites are listed on world top 10 oncology clinical trial sites

Rank	Hospital	Number of Studies Past 5 Years	Country
1	University of Texas – MD Anderson	1,025	US
2	Dana-Farber Cancer Institute	661	US
3	Seoul National University	658	Korea
4	Massachusetts General Hospital	630	US
5	Memorial Sloan-Kettering Cancer	621	US
6	Asan Medical Center	595	Korea
7	Samsung Medical Center	563	Korea
8	Hospital Universitari Vall d'Hebron	541	Spain
9	Mayo Clinic	461	US
10	Yonsei University Severance	442	Korea

*These Korean hospitals, like others in this ranking, have a designated infrastructure to support large volume of clinical trials*



- *High volume patient access*
- *Medical sophistication and research interests*
- *Molecular testing /scientific innovation & investment*
- *“Technology positive”*

Source: Citeline Site Trove (as of Feb 1<sup>st</sup> 2016)

am INC Research

# Densely Built Hospitals with Big Patient Pool and World Class Facility (Top 15)

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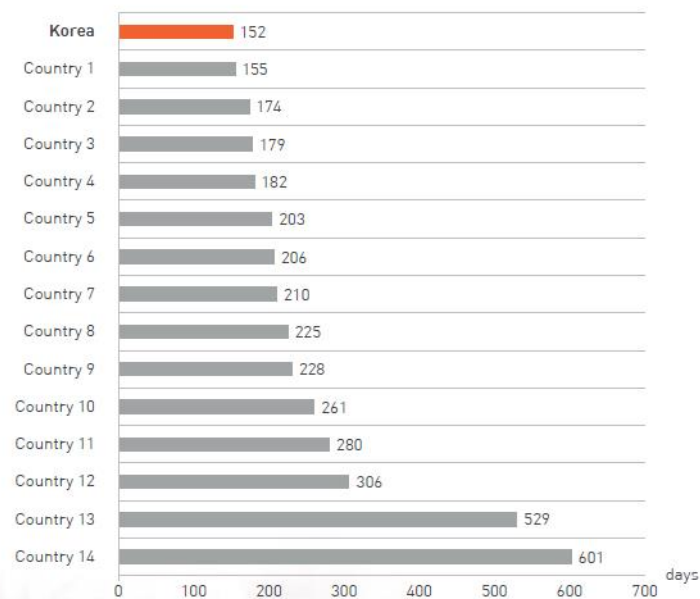
Hospital	Location	No. of beds
Seoul Asan Hospital	Seoul	2,704
Yonsei Severance Hospital	Seoul	2,471
Seoul National University Hospital	Seoul	1,786
Samsung Medical Center	Seoul	1,869
Seoul St. Mary Hospital	Seoul	1,356
Korea University Hospital, Anam	Seoul	1,051
Korea University Hospital, Guro	Seoul	1,074
Gacheon Univ. Gil Medical Center	GeoyngGi	1,400
Aju University Hospital	GeoyngGi	1,179
Seoul National University Hospital, Bundang	GeoyngGi	1,309
Pusan National University Hospital	Busan	1,310
Pusan National University Hospital, Yangsan	Busan	1,173
Chungnam National University Hospital	Jeola	1,353
Chonbuk National University Hospital	Jeola	1,104
Chonnam National Unviersity Hospital	Jeola	1,028

# Faster Study Start-up

## ■ Study Start Up

The study start-up (SSU) process is frequently noted as one of the most cumbersome and costly bottlenecks present in clinical research. Major milestones in the process include site selection and initiation, contract and budget execution, and other activities occurring prior to enrollment of the first patient.

Korea has shown more competitive SSU timelines than other countries.



Protocol to Study Start-Up in Countries\* for a Top 10 R&D Pharma. Company

\*Top 15 countries based on number of study sites

Source: KoNECT

# IRB/EC

## : International Accreditation of Major Hospitals

	SNUH	SNUH Bundang	Chonbuk	AMC	Ajou	Severance	Catholic	Inha	Inje Baik
<b>FERCAP</b>	√		√	√	√		√	√	√
<b>AAHRPP</b>	√	√		√		√			
	Dong-A	Chungnam	SMC	Korea	KyungPook National	Gachon	Cha	Chonnam	
<b>FERCAP</b>	√	√		√	√	√	√	√	
<b>AAHRPP</b>			√						



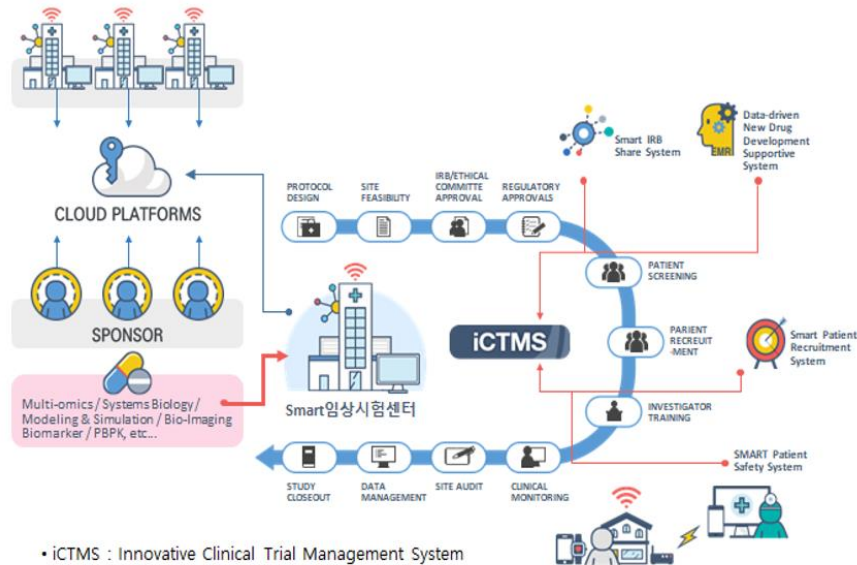
The Association for the  
Accreditation of **Human  
Research Protection  
Programs**



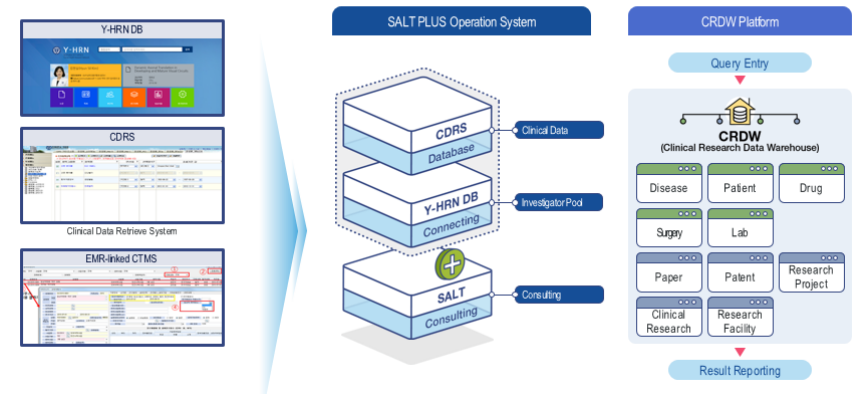
Forum for **Ethical Review  
Committees** in the Asian and  
Western Pacific Region (FERCAP)



# Smart CT Support System and Data-Driven Approaches in Hospitals for Faster and Safer Trials



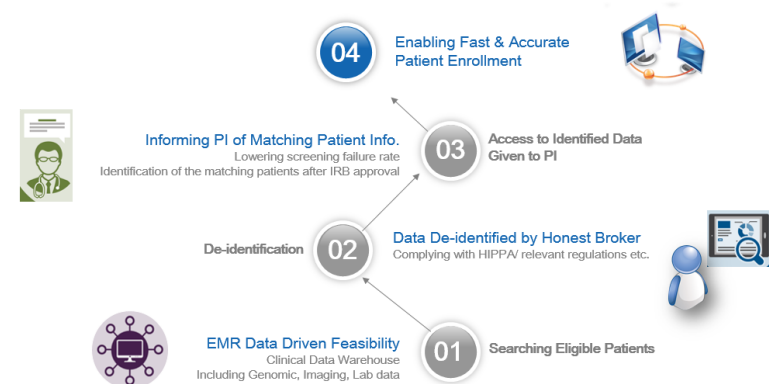
New Drug Consultancy by Clinical Development Supportive System Development based on Hospital Big Data



## Data Driven Feasibility & Patient Enrollment

### Real Time notice system of ER Visit by a subject

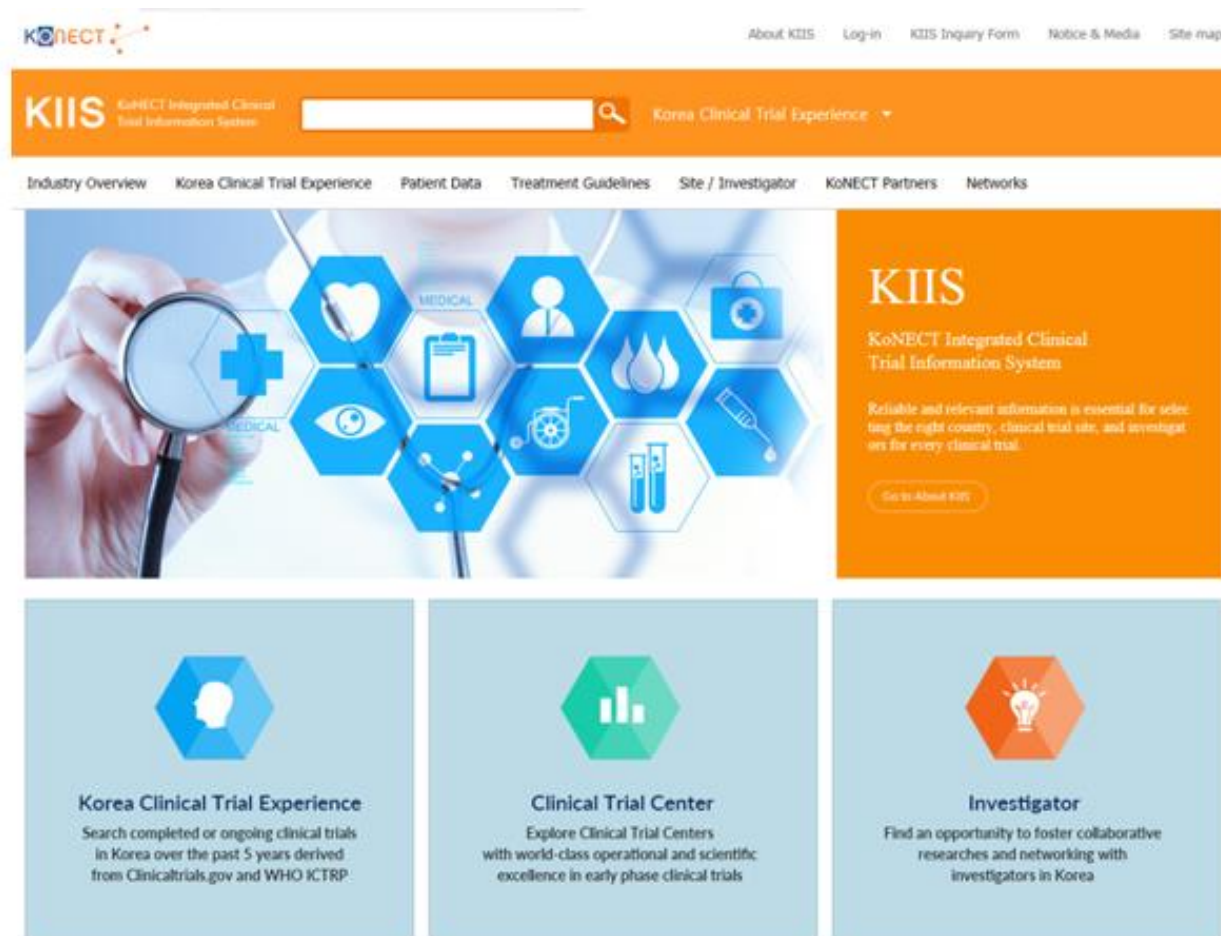
Immediate action to adverse events during CT



# KIIS, Korea Clinical Trial Information Hub @KoNECT

## KoNECT Integrated clinical trial Information System (KIIS)

<http://kiis.konect.or.kr>



The screenshot displays the homepage of the KIIS website. At the top, there is a navigation bar with links for 'About KIIS', 'Log-in', 'KIIS Inquiry Form', 'Notice & Media', and 'Site map'. Below this is a prominent orange header containing the 'KIIS' logo, the text 'KoNECT Integrated Clinical Trial Information System', a search bar, and the phrase 'Korea Clinical Trial Experience'. A secondary navigation bar lists categories: 'Industry Overview', 'Korea Clinical Trial Experience', 'Patient Data', 'Treatment Guidelines', 'Site / Investigator', 'KoNECT Partners', and 'Networks'. The main content area features a large banner with a stethoscope and medical icons, alongside a text block that describes KIIS as a reliable source for clinical trial information. Below the banner are three light blue boxes, each with an icon and a title: 'Korea Clinical Trial Experience' (search icon), 'Clinical Trial Center' (building icon), and 'Investigator' (lightbulb icon). Each box contains a brief description of the service or resource.

**KIIS**  
KoNECT Integrated Clinical Trial Information System

Korea Clinical Trial Experience

Industry Overview | Korea Clinical Trial Experience | Patient Data | Treatment Guidelines | Site / Investigator | KoNECT Partners | Networks

**KIIS**  
KoNECT Integrated Clinical Trial Information System

Reliable and relevant information is essential for selecting the right country, clinical trial site, and investigators for every clinical trial.

[Go to About KIIS](#)

**Korea Clinical Trial Experience**  
Search completed or ongoing clinical trials in Korea over the past 5 years derived from Clinicaltrials.gov and WHO ICTRP

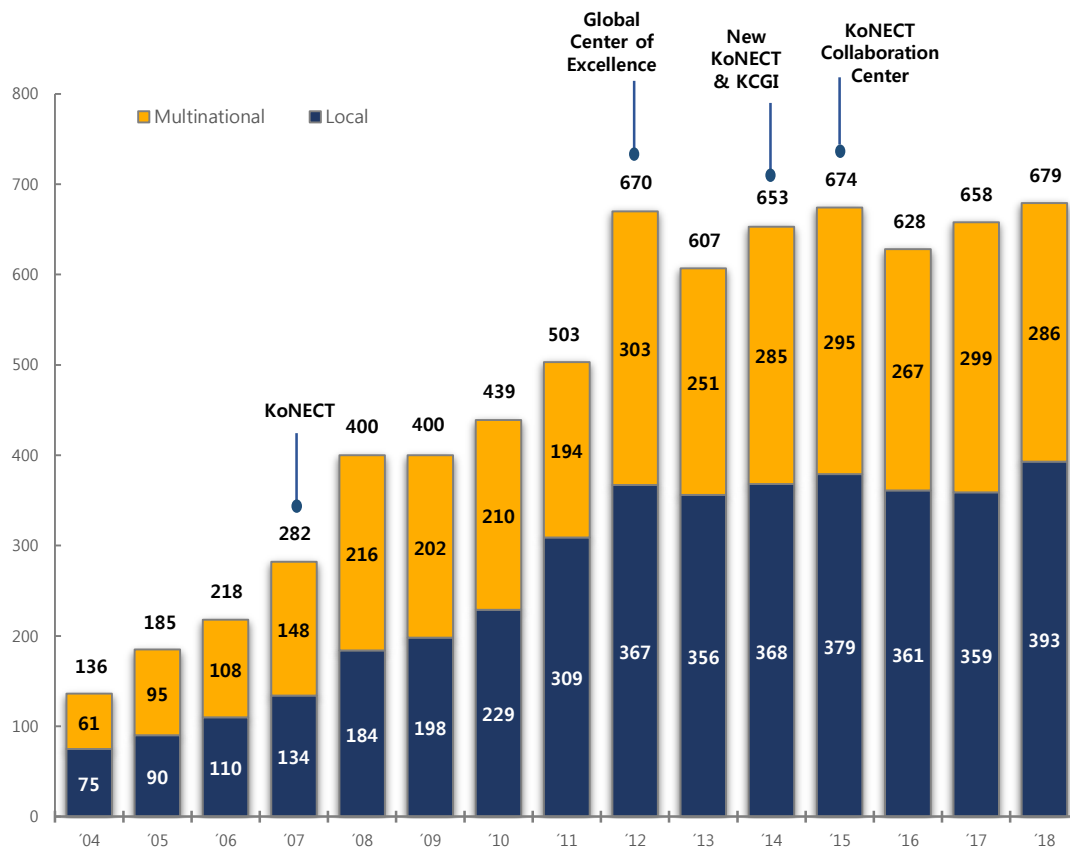
**Clinical Trial Center**  
Explore Clinical Trial Centers with world-class operational and scientific excellence in early phase clinical trials

**Investigator**  
Find an opportunity to foster collaborative researches and networking with investigators in Korea

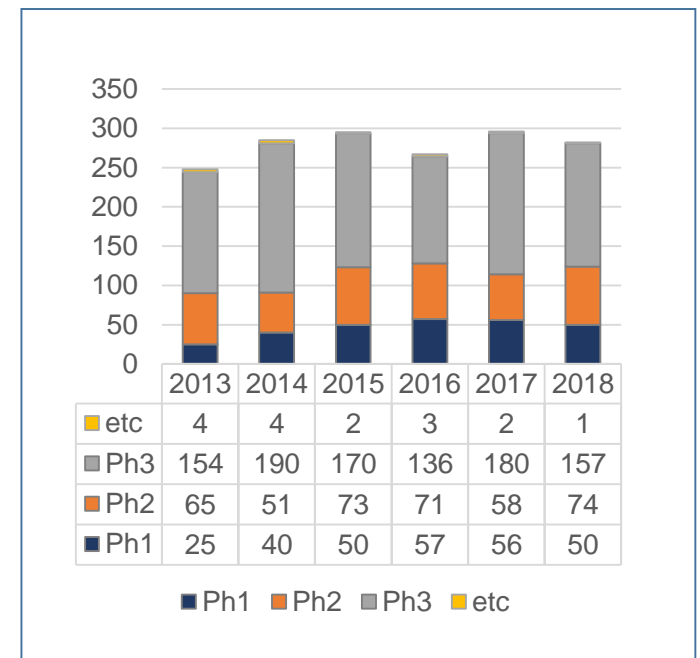
# Growth of Korea Clinical Trials 2004-2018

## 2018 MFDS(Korean Ministry of Food and Drug Safety) IND Approval Status

- 1) Local: Conducting clinical trials only in Korea
- 2) Multinational: Conducting clinical trials in several countries including Korea



### No. of multinational trials

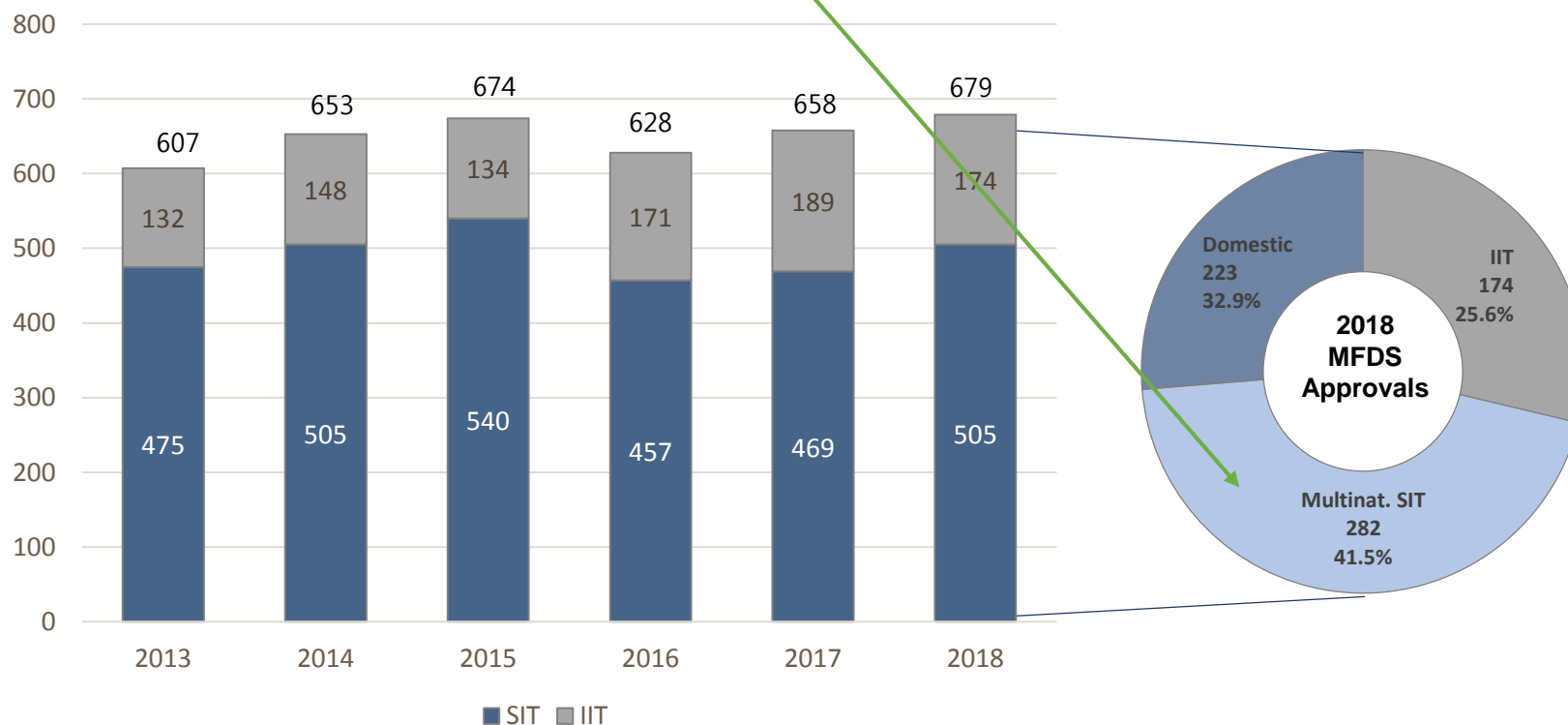


Source: MFDS 2019 media release. Modified by KoNECT

# Clinical Trial Authorization in Korea by MFDS

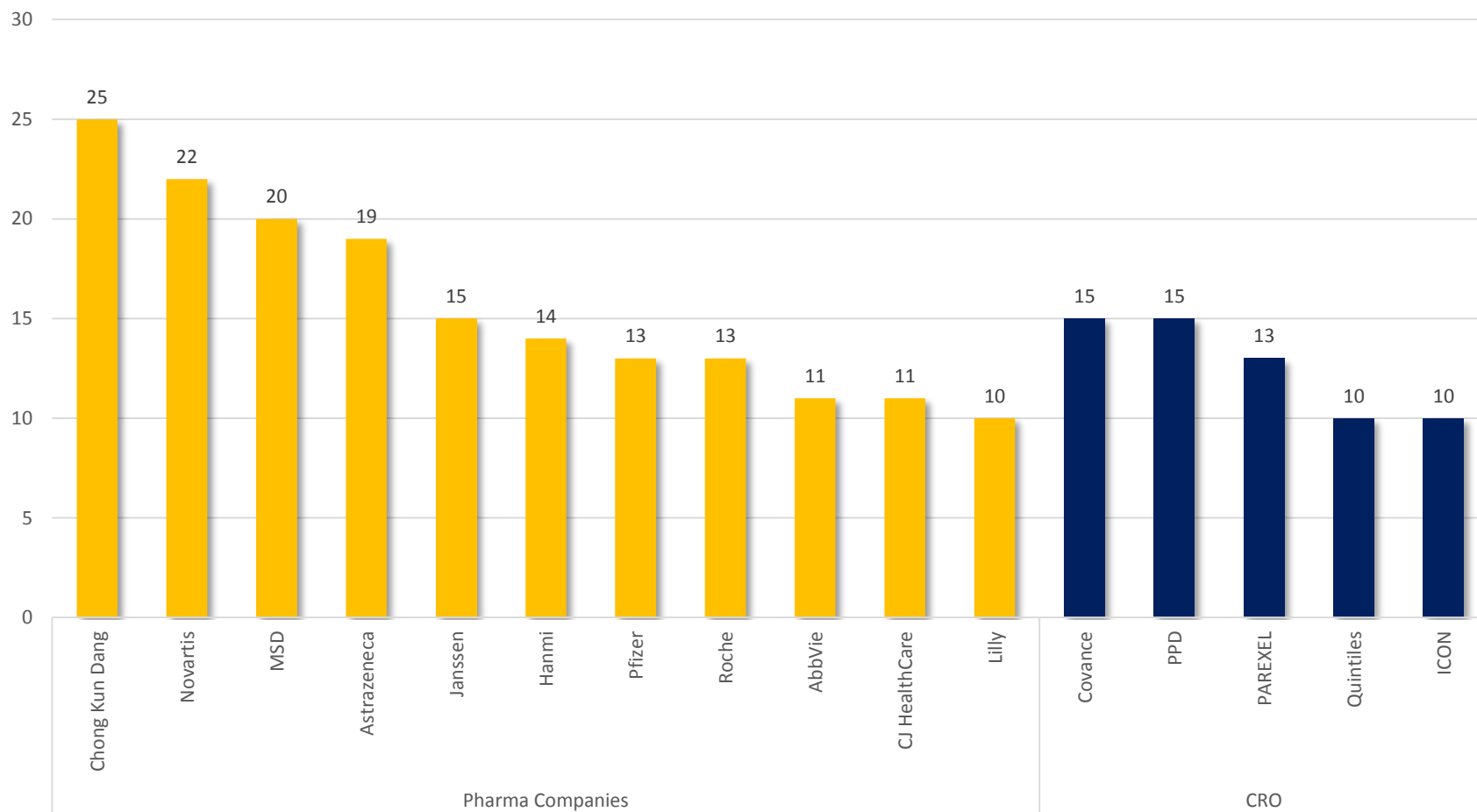
## 19 Approvals for Japanese companies

- ✓ Astellas 6
- ✓ Daiichi Sankyo 6
- ✓ Taiho Oncology 2



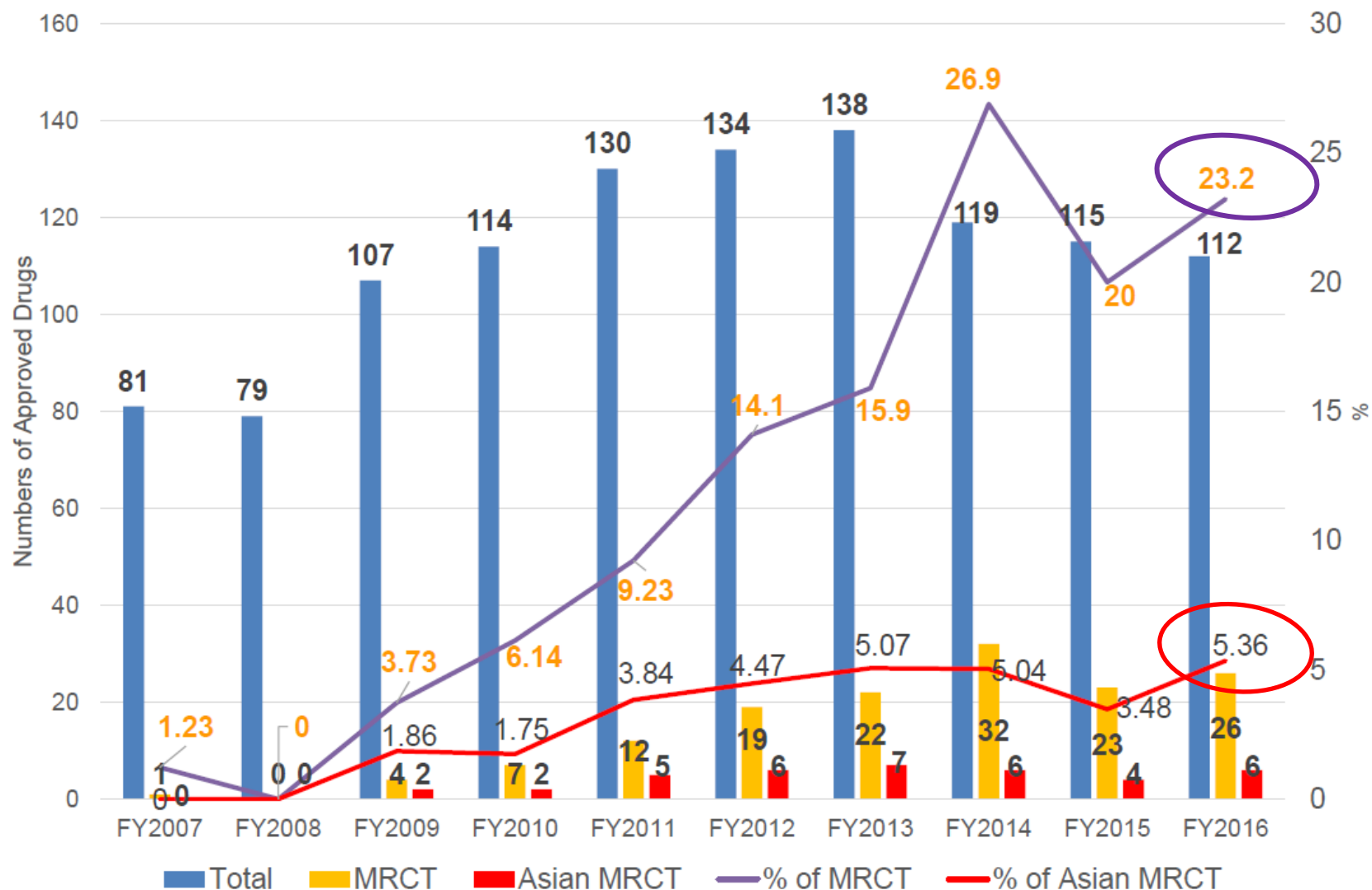


# MFDS IND Approvals by Sponsor 2018



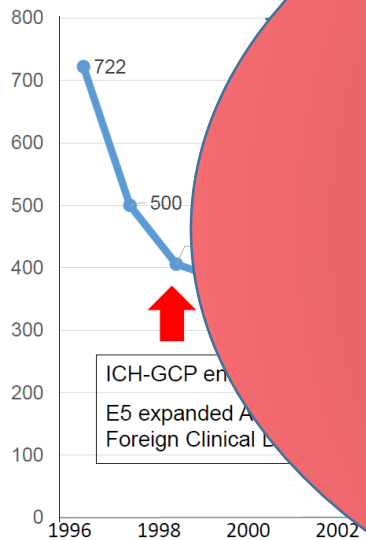
Source: MFDS Database 2018, Analyzed by KoNECT

# Trends of new drug application based on MRCTs in Japan

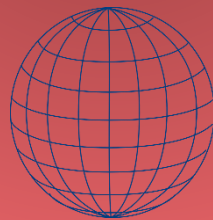


Toshi Tominaga, PMDA 2017

CT Notification Japan's M



NOT ONLY FOR PATIENTS BUT  
ALSO FOR INDUSTRY THAT  
TARGETS **GLOBAL** !



E17 (MRCT)

E5  
(Bridging)

E6 (GCP)



ugs Approved in

1,111 days

Foreign  
trial  
(n = 13)

No efficacy/  
safety  
trial (n = 5)

Clinical development strategy



# 2

## Approaches of KoNECT for Global Collaboration in CT



# Supporting your clinical Trials in Korea

## One-Stop Shop for Your Clinical Trials in Korea

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# Ask Us, Data-Driven Feasibility Using National Big Data



## Patient Pool

· Patient distribution data derived from HIRA\*

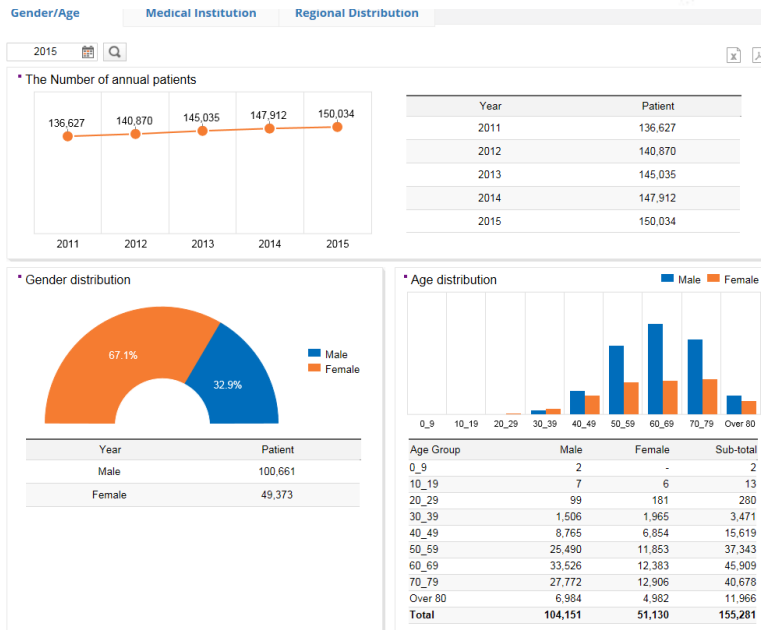
\* HIRA; the national Health Insurance Review and Assessment database



## Number of annual patients

## Clinical Department

## Regional Distribution



City	Patient	%
Songpa-gu	5,116	15.4
Jongno-gu	5,013	15.1
Seodaemun-gu	3,520	10.6
Gangnam-gu	3,374	10.2
Seocho-gu	1,847	5.6
Gangdong-gu	1,539	4.6
Dongdaemun-gu	1,471	4.4
Guro-gu	1,321	4.0
Dongjak-gu	1,196	3.6
Yeongdeungpo-gu	1,191	3.6
Nowon-gu	1,158	3.5
Yangcheon-gu	1,153	3.5
Seongdong-gu	880	2.6
Seongbuk-gu	810	2.4
Jungnang-gu	502	1.5
Gwangjin-gu	473	1.4
Eunpyeong-gu	416	1.3
Dobong-gu	410	1.2
Gangseo-gu	388	1.2
Jung-gu	388	1.2

# Korea, A Strategic Phase 1 Site for Your Global /Asian Development

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- Strategy of **multi-ethnic phase I** studies including Korean, Japanese, Chinese and Caucasian subjects.
- Early Asian PK data generation in Asian before your planning for simultaneous development in an efficient way.
- Efficient multiethnic clinical trials using single center.

## A Company's Success Case

- A global pharma conducted 12 multiethnic phase 1 studies in SNUH since 2010.
- One product is under NDA submission in Japan.
- Three products are part of global development studies in Japan.
- A program under Japanese NDA in June 2018 (2 months difference from US submission).
- The rest of the products' development were discontinued by the company

# Experience in multi-ethnic phase I studies

## SNUH Experience


Study Year	Sponsor	Study population (N)			
		Chinese	Japanese	Caucasian	Korean
2010	Global Pharma	36	37	0	0
2011	Global Pharma	27	25	8	0
	Global Pharma	24	24	0	0
2012	Global Pharma	40	40	0	0
	Global Pharma	18	0	18	0
2013	Domestic Pharma	0	0	25	56
	Global Pharma	36	36	25	0
	Global Pharma	33	32	0	0
	Global Pharma	32	32	0	0
	Domestic Pharma	0	16	16	24
2014	Global Pharma	32	32	0	0
	Global Pharma	40	40	0	0
2015	Global Pharma	12	0	0	0
2016	Global Pharma	0	0	48	72
2017	Global Pharma	24	24	0	0
	Global Pharma	24	0	0	0




# Accelerating Global Clinical Development with Asian Investigators Groups (IIT/ SIT)

## To fulfil unmet medical needs in cancer patients especially in Asia

- Work with Asia/Korea collaborative study groups.
- For earlier translation and POC for new targets and molecules.
- MRCT strategy as ICH E 17 in place

 Prof. In-Jin Jang  
SNH, Korea




 Prof. Yuji Kumagai  
Kitasato University, Japan



 Prof. Jae Gook Shin  
Inje University, Korea



 Prof. Hiroshi Watanabe  
Hamamatsu University, Japan



## 1. Asia Gastric Cancer Investigator Network:

An ad-hoc network with 6 countries by KoNECT for gastric cancer study planning and execution.

## 2. Asia Clinical Trial Pharmacology Network:

Korea-Japan–(Taiwan)

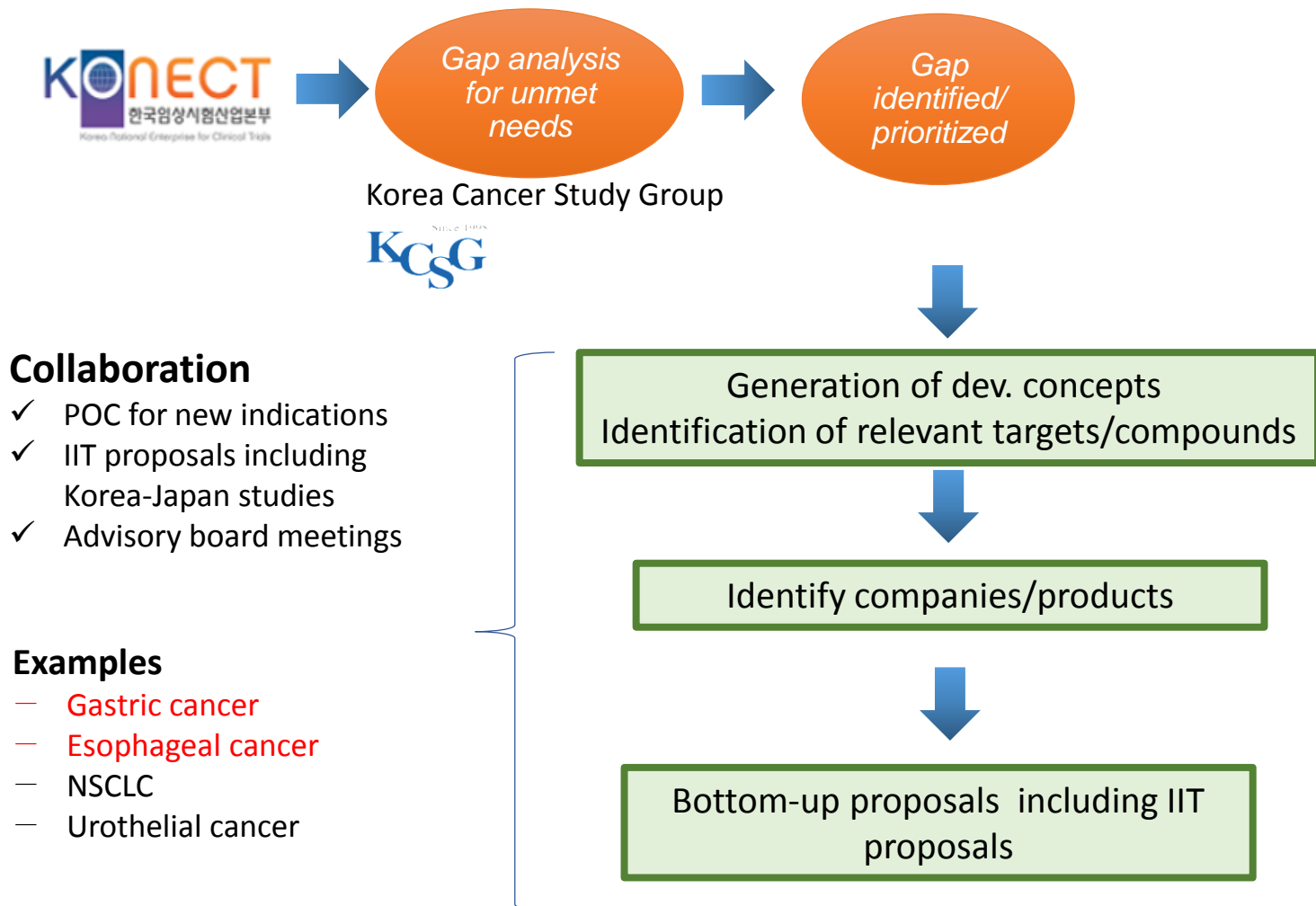
## 3. Korea Cancer Study Group (KCSG)

The largest cooperative study group in Korea

## 4. KCSG-JCOG Collaboration --Ongoing

# Bridging Companies and Investigators Groups Beyond Patient Recruitment

## Fulfilling Regional/Global Unmet Medical Needs – Oncology Model



# Support Foreign SMEs in Need of Collaborators for Asian Development - Oncology Model



with profiles of;

1. Oncology product
2. Aspiration of (simultaneous) global development but with limited experience in Asia or Korea
3. No presence in Asia/Korea and looking for local experts or partners

Review pipelines and development programs



Identify collaborators



- Connection with sites and investigators
  - Advisory board Meeting
  - Local CROs

## Examples

- Head & Neck Cancer for a Japanese company
- Gastric cancer for an American company

SME: Small to Medium Enterprise

# The 5<sup>th</sup> KoNECT International Conference (KIC)

Sep 17-19, 2019, Hotel Conrad, Seoul Korea

- *The Largest International Event on Clinical Trials in Asia with Recent Clinical Development Topics*
- *4 workshops, 2 Plenary and 14 break-out sessions*

<http://www.konectintconference.org>

About Conference

Registration

Scientific Program


Exhibition

Partnering

Accommodation

General Information

News



**2019 KoNECT-MOHW-MFDS  
INTERNATIONAL CONFERENCE**  
September 18<sup>th</sup> (Wed) - 19<sup>th</sup> (Thu), 2019  
[ Pre-Workshop 17<sup>th</sup> (Tue) ]  
Conrad Seoul, Korea

Accelerating Clinical Development, Bringing Hope to Patients

SUPPORTED BY  
대한민국  
Ministry of Health  
and Welfare

Program Details

Register Now

Exhibition

Partnering System



3

**Future**

# Korea Unveils 5-Year Roadmap To Nurture Domestic Industry

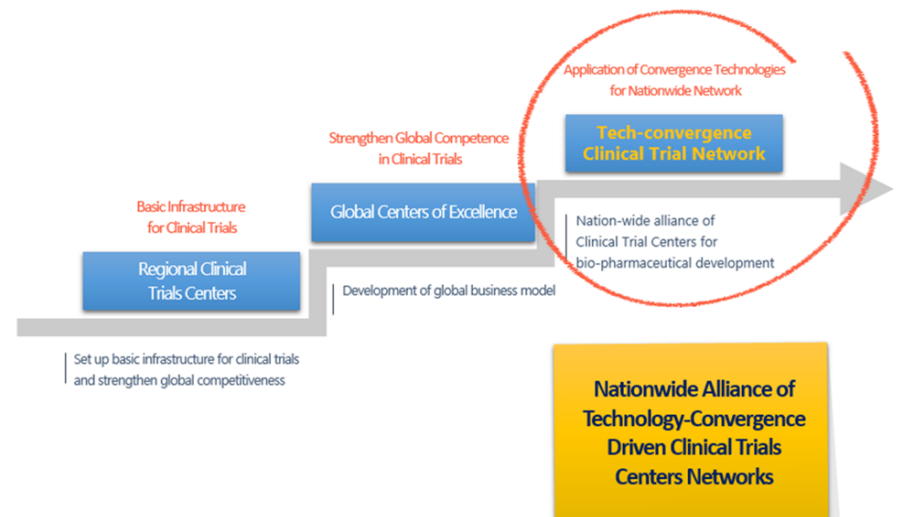
05:53 EST 27 Dec 2017 | SCRIP

South Korea's five-year blueprint to nurture the pharma industry outlines a string of measures including plans to set up smart...



## Set Up Smart Clinical Trial Platform, Stronger Networks

- An advanced, converged, and unified clinical trial system to improve the efficiency and safety of clinical trials significantly.
- Will play integral roles by leveraging the new technologies and data-driven approaches to facilitate faster and safer delivery of world-leading clinical trials
- A nation-wide network to build the consensus and synergy to address unmet needs in clinical trials







## Big Data Science Meets EMR Data to solve Medical Challenges

## Physicians Works with Data Scientists Together to solve Medical Challenges



# National CDM Projects in Korea/ 2018-2022

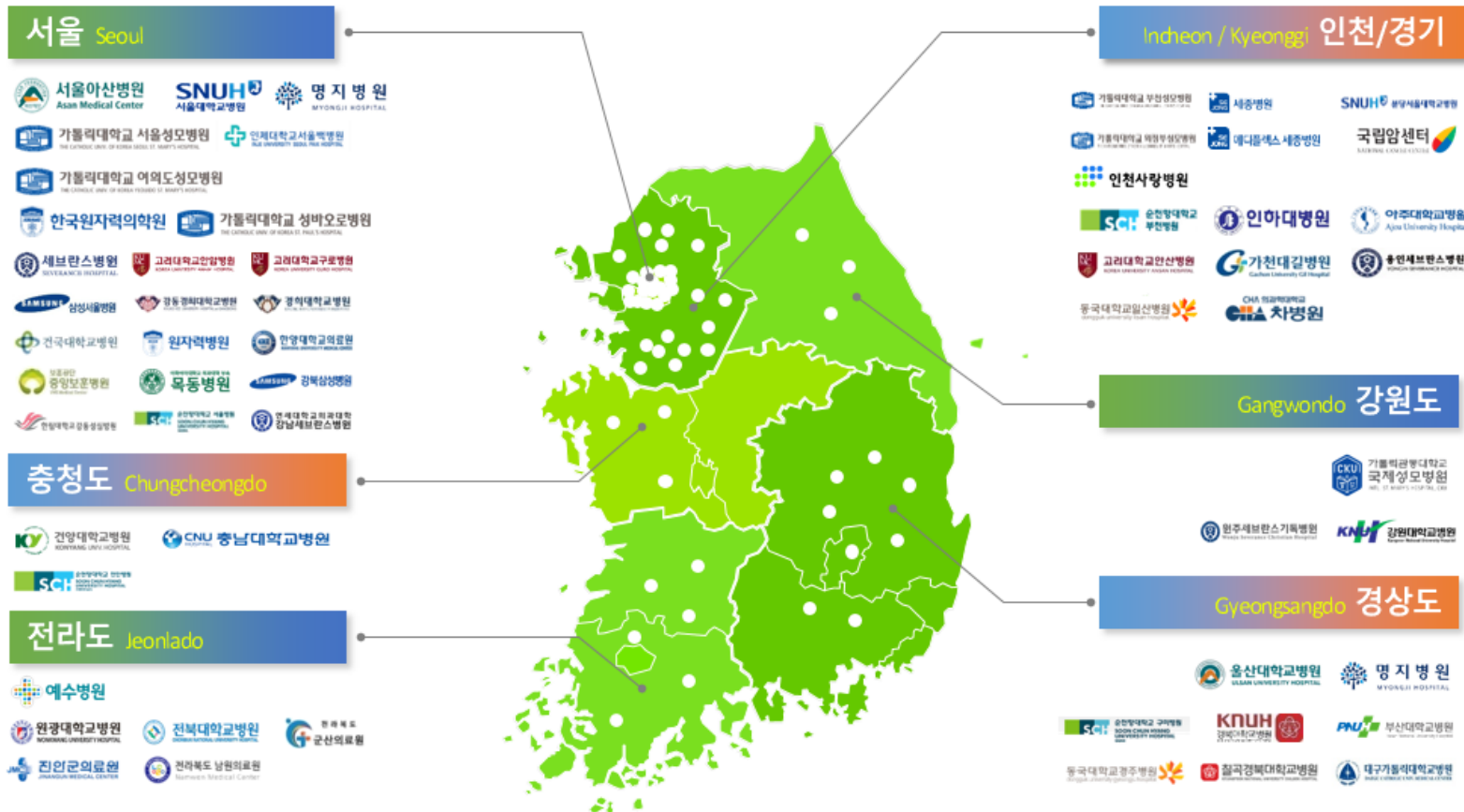


AJOU UNIVERSITY



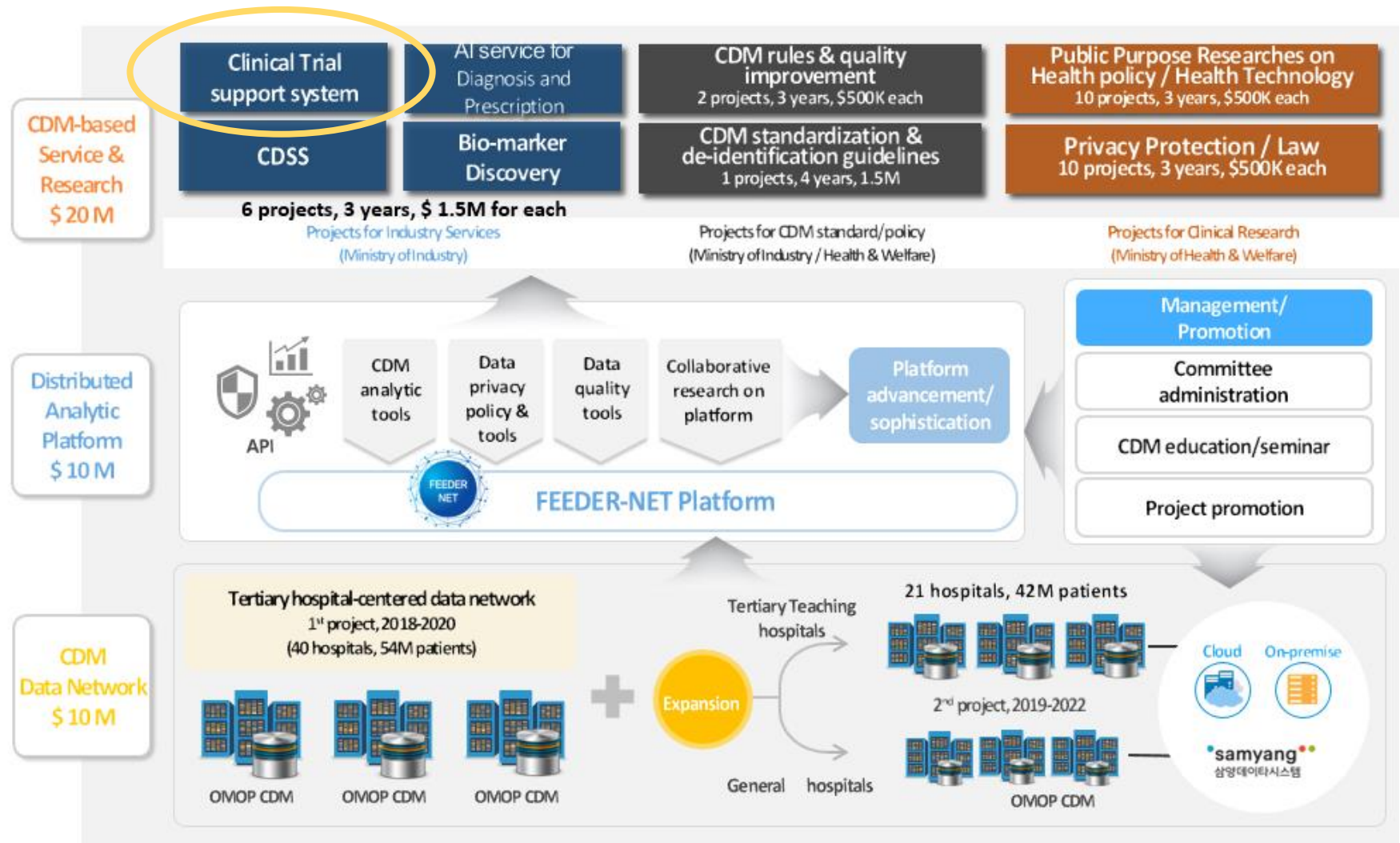
## FEEDER-NET Data Network of 60+ Hospitals, 98M Patients

70% of Tertiary Teaching Hospitals



FEEDER-NET: Federated E-health big Data for Evidence Renovation NETWORK

# National CDM Projects in Korea/ 2018-2022



*Thank you!*



LET'S GO  
GLOBAL  
TOGETHER