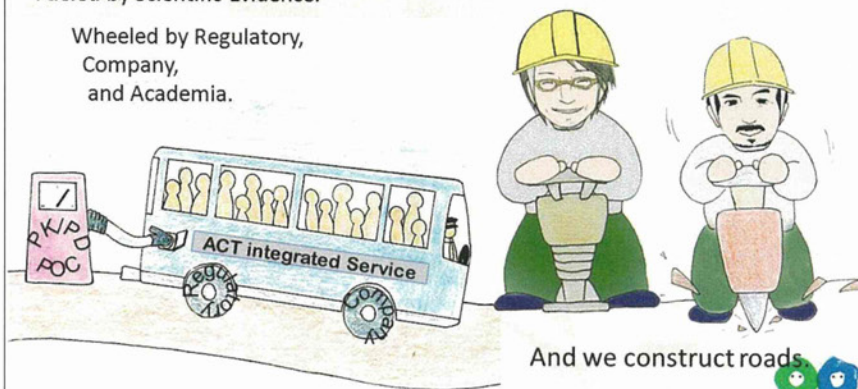


My memorable slide made in 2008.

We are riding on a bus bound for Asian peoples' happiness.

Fueled by Scientific Evidence.

Wheeled by Regulatory, Company, and Academia.



And we construct roads.



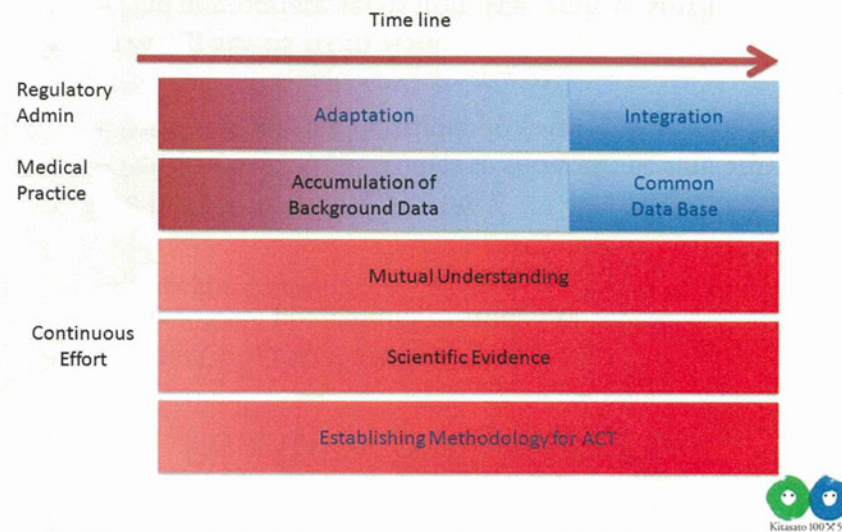
Education for Postgraduate

KCRC is now preparing a course for clinical trial professionals at the postgraduate school

- A course for clinical trial professionals in Asia.
- Lectures in English by experts from various countries through Web.
 - Lectures, quiz, reports etc
 - Schooling in Japan for a week.
- Certification
 - Master degree, diploma



For Asian Clinical Trial



For our Future

- Japan is changing and open to global strategy.
- Japan has abundant experiences and resources for early studies.
- Hope that Japan can contribute to finding appropriate dosage for Asian people.




We provide you with ...

Keys In Tackling Advanced Research Opportunities.




北里大学臨床試験事業本部の設立背景

治験の国際化の遅れ

国内のみで新薬開発が可能であったある意味で幸福な歴史は、種々の要因とあいまって、我が国における治験の国際化を妨げてきた。

現在の隔離された治験の状況は「ガラパゴス化」した得意な状況にある。交配不能になる前に打開策を講じる必要がある。



KitARO
北里大学臨床試験事業本部
Kitasato Academic Research
Organization



北里大学臨床試験事業本部の設立背景

日本におけるARO設立の意義と東アジア共同治験構想



学校法人
北里研究所
THE KITASATO INSTITUTE

アジアから見た日本の臨床試験

- インド – the magnet
 - 韓国 – the runner up
 - 中国 – still in transition
 - 台湾 – already in the mainstream
 - フィリピン、タイ、マレーシア – moving ahead
 - 日本 – in isolation
- 経済力、臨床試験施設数、海外展開製薬企業の数にもかかわらず、日本における国際共同試験数は少ない。

Source: Clinical Trial Magnifier Vol. 1:5 May 2008

治験のガラパゴス化がきたすもの

- ・患者、医師の新薬へのアクセスの遅延。
- ・国内開発能力の低下、国際競争力の低下。
- ・臨床研究の遅れ。日本人におけるエビデンスの欠如。
- ・リスクを低開発国に負わせる南北摩擦。
- ・アジア人における不適正用量の蔓延。

国際誌に掲載された日本の医学研究

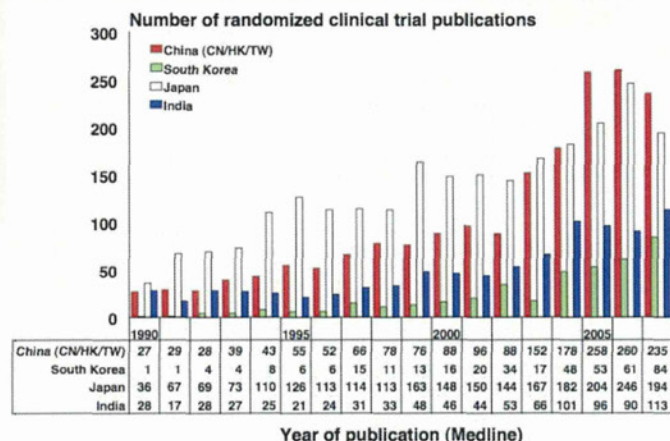
臨床医学研究の現状と強化への取り組み～臨床発表データを用いた国際比較～
政策研ニュース 2008年10月

	寄与率	順位
Nature	6.7%	5 th
Science	6.6%	5 th
Cell	7.3%	4 th
NEJM	1.7%	12 th

C-indexで見ると、国際的な共同論文の数は24位

アジアにおける無作為化試験論文数

Source: Clinical Trial Magnifier Vol. 1:9 Sep 2008



臨床試験の推進は アカデミアの使命である

アカデミアの有する基礎研究能力、臨床専門家、臨床研究のインフラを総合的に活用し、規制、企業等との協体制を確立するべき。

総合的かつ横断的に活用する仕組みが欠けていた。



Academic Research Organization の設立

AROの基本的機能

- 臨床試験に関するフルレンジのサポート。
- 科学的視点に基づいた試験実施のサポート。
- 臨床研究の新しい手法の開発。
- 臨床研究者の教育。

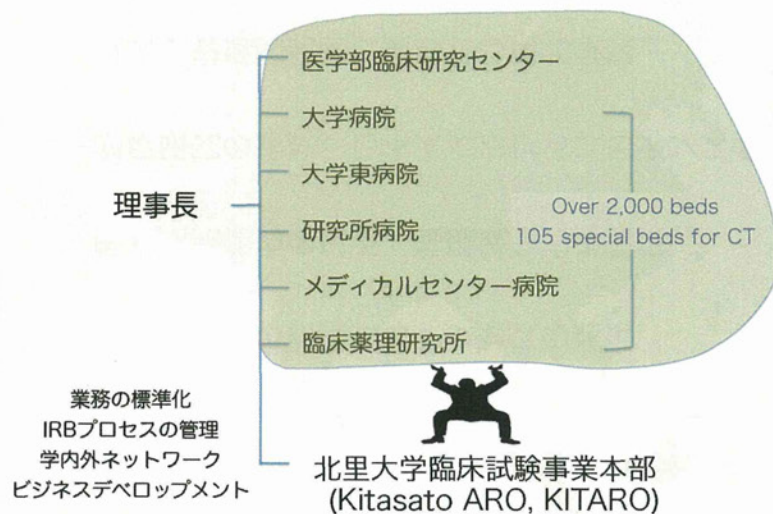


北里研究所の沿革



- 1893 北里柴三郎により結核療養所設立
- 1914 北里研究所設立
- 1962 北里大学設立
- 1970 医学部設立
- 2007 医学部が治験中核病院に指定
- 2008 研究所、大学を統合、学校法人北里研究所へ
- 2010 グローバル臨床研究拠点指定
北里大学臨床試験事業本部設置

北里研究所内の臨床試験関連施設



日本に、アジアに、より良い医薬を届けるために

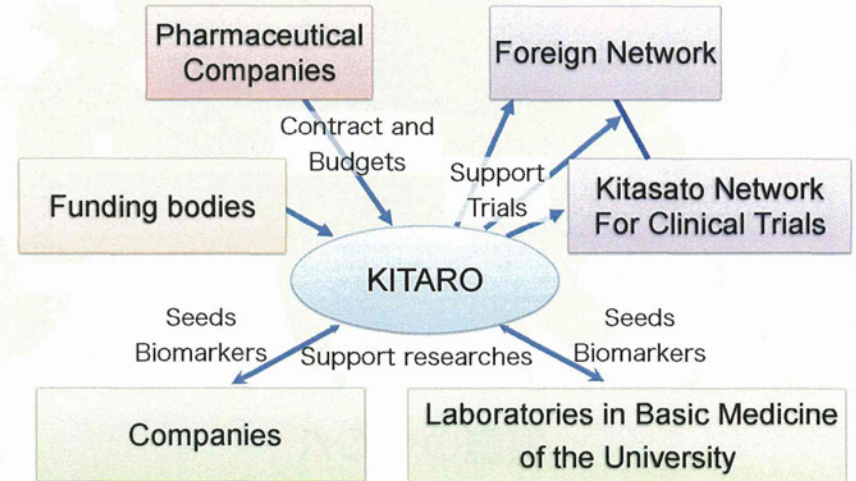
未来のトビラ

北里大学臨床試験事業本部

KITARO事業内容

- 治験品質管理部**
 共通SOPの作成（英語版オリジナル、日本語版運用）
 費用体系の調整及び標準化
 治験品質、治験受託契約時に関する内部監査及び指導
 教職員対象の指導及び講演活動
 法人内IRBの品質向上及び審査基準の均一化
 医師主導型治験の支援
- 治験推進部**
 企業向け営業及び広報活動、シーズの発見
 法人内各治験部門との受託調整
 公的機関等との渉外活動
 地域医療機関との治験ネットワーク推進
 海外組織とのネットワーク推進
 患者及び一般市民に向けた啓発活動
 外部資金導入による新たな治験事業の企画
 治験に関わる新たな技術の開発

KITARO in Drug Development



産経新聞 平成23年2月27日記事



北京大学第三医院
Peking University Third Hospital

站内搜索: English

医院主页 | 医院概况 | 医院新闻 | 就医指南 | 网上医疗 | 科室特色 | 教学科研 | 院务公开 | 医院文化 | 综合业务

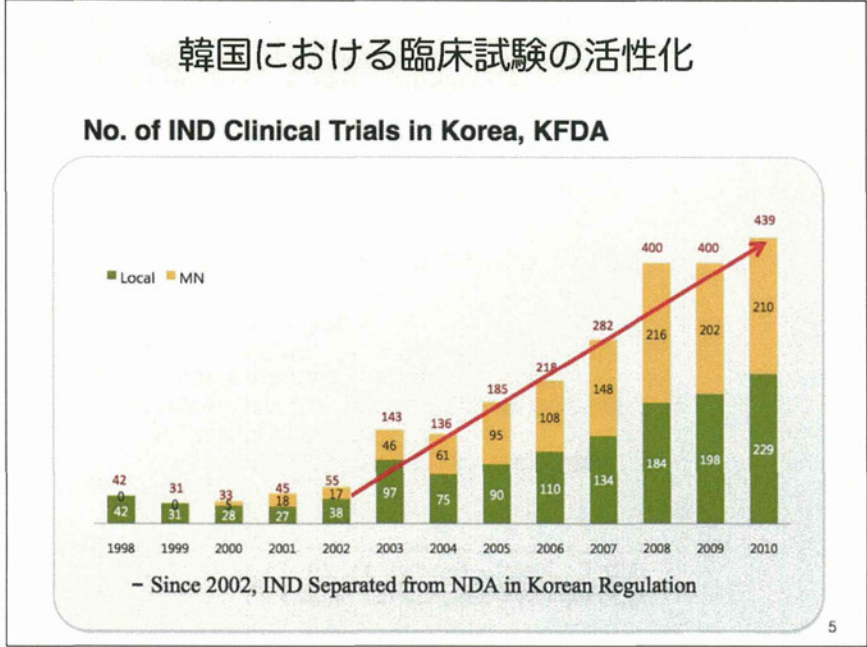
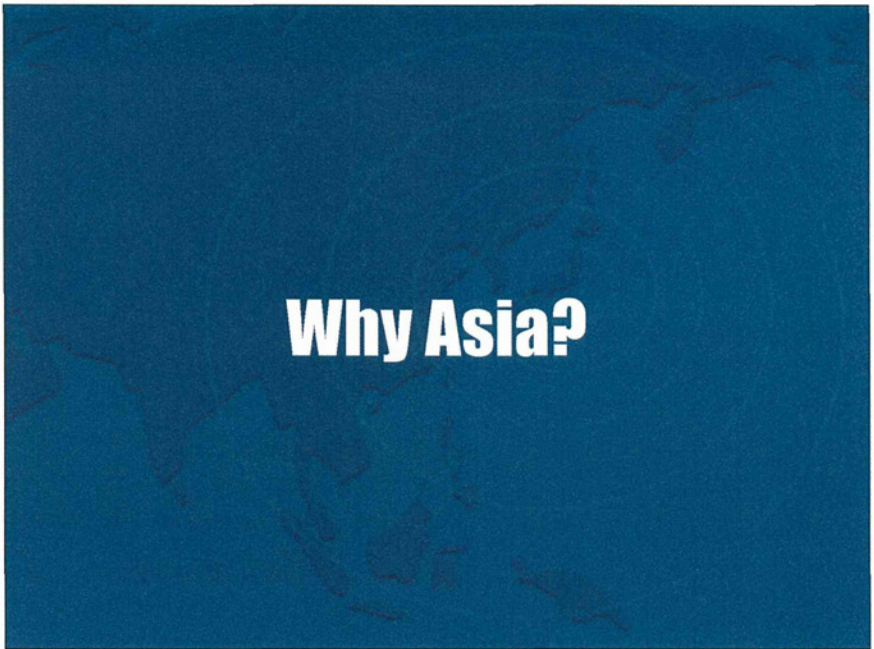
当前位置: > 医院新闻 > 新闻报道

日本北里大学及其医学部代表团访问药物临床试验机构

文章来源: 药物临床试验机构 刊例: 2010-12-30
文章点击率: 标题点击率:

12月28日, 日本北里大学药理学研究所所长, 北里大学药理学系本部长兼客座教授, 北里大学医学部临床药理研究所所长兼客座教授, 北里大学药理学系本部长兼客座教授一行三人来我院药物临床试验机构进行参观访问。药物临床试验机构主任李海勇, 办公室主任杨洁及北京大学临床药理研究所王勇参加了座谈。

杨主任王勇分别介绍了我院药物临床试验总体发展以及北京大学临床药理研究所药物临床试验及相关领域所做的工作, 日方介绍了日本的药物临床试验体系, 并就如何开展北里大学药理学系本部长在药物临床试验教育、培训及安全性评价方面所做的工作及未来发展方向, 双方就共同关心的注册人群药物临床试验、药物临床试验从业人员培训及安全性评价平台建设等问题进行了探讨。



ソウルの躍進

	2005 (Total 115773)	2006 (Total 119085)	2007 (Total 115975)	2008 (Total 142597)	2009 (Total 96497)				
1 New York	1140	New York	969	Houston	1266	Houston	1165	Houston	934
2 Boston	1124	Houston	910	New York	1232	New York	1164	New York	792
3 Houston	955	Boston	849	Boston	975	Boston	966	Boston	758
4 Chicago	870	Chicago	826	Berlin	919	Berlin	864	Seoul	696
5 Philadelphia	838	Philadelphia	763	Chicago	796	Philadelphia	858	Berlin	594
6 Los Angeles	799	Baltimore	760	Philadelphia	726	Chicago	791	Philadelphia	572
7 Toronto	748	London	725	Los Angeles	660	Los Angeles	789	Chicago	572
8 Atlanta	744	Dallas	648	Dallas	637	Dallas	747	San Antonio	549
9 Seattle	732	Los Angeles	641	London	631	San Antonio	747	Baltimore	538
10 London	705	Toronto	626	San Antonio	591	London	723	London	532
11 Baltimore	688	Berlin	617	Baltimore	581	Seoul	696	Paris	525
12 Dallas	637	Atlanta	607	Rochester	580	Baltimore	694	Los Angeles	510
13 Portland	619	Cleveland	580	Cleveland	570	Paris	684	Dallas	508
14 Paris	611	Birmingham	573	Toronto	555	Toronto	675	Toronto	475
15 Pittsburgh	597	San Antonio	548	Madrid	528	Atlanta	652	Cleveland	446
16 Rochester	589	Madrid	543	Moscow	528	Birmingham	623	Rochester	444
17 Berlin	571	Rochester	538	Seoul	527	San Diego	604	Nashville	443
18 San Antonio	558	Moscow	534	Columbus	522	Portland	599	Portland	431
19 Cleveland	549	Seattle	532	Atlanta	521	Moscow	592	San Diego	429
20 San Diego	546	Portland	510	Seattle	518	Cleveland	587	Atlanta	427
21 Birmingham	539	Barcelona	508	Paris	503	Madrid	575	Soatle	415
22 Denver	523	Pittsburgh	506	Barcelona	497	Columbus	561	Madrid	413
23 Cincinnati	516	Columbus	500	Nashville	473	Seattle	554	Birmingham	403
24 St. Louis	499	Paris	477	Birmingham	467	Cincinnati	549	Cincinnati	391
25 Montreal	497	Indianapolis	476	Portland	466	Nashville	544	Columbus	385
26 Indianapolis	492	Montreal	466	Pittsburgh	461	Rochester	521	Barcelona	378
27 Taipei	472	Cincinnati	462	Cincinnati	433	Barcelona	521	Moscow	359
28 Columbus	452	Miami	455	Miami	429	Miami	517	Miami	357
29 Kansas City	442	San Diego	453	San Diego	423	Indianapolis	511	St. Louis	345
30 Miami	439	St. Louis	426	Indianapolis	419	Pittsburgh	499	Pittsburgh	324
77th - Seoul		218	37th - Seoul		376				8

日本のadvantageを生かす

これまで、化合物の創成から新薬の申請まで一貫した経験を有する国は多くない。目方勝負、人海戦術という土俵で日本が勝負すべきか？

早期国際共同試験の実績を積むことにより、大規模検証試験におけるイニシアチブを目指す。

日本発のエビデンスの創成、論文につながる。

Chopstick Countries!

젓가락 筷子



箸 dūa ตะเกียบ

内的要因と外的要因の類似性が高い

Kitasato, Gateway to Asia

















Kitasato, Gateway to Asia












臨床試験と治験の相互補完関係

臨床開発プラットフォーム
を提供（臨床研究→治験）

臨床研究の豊富な経験と、
学術的背景は企業、行政
当局の高い信頼をもたら
す。アカデミア発のシー
ズ開発も可能となる。

臨床研
究

シーズ探索・
研究の推進

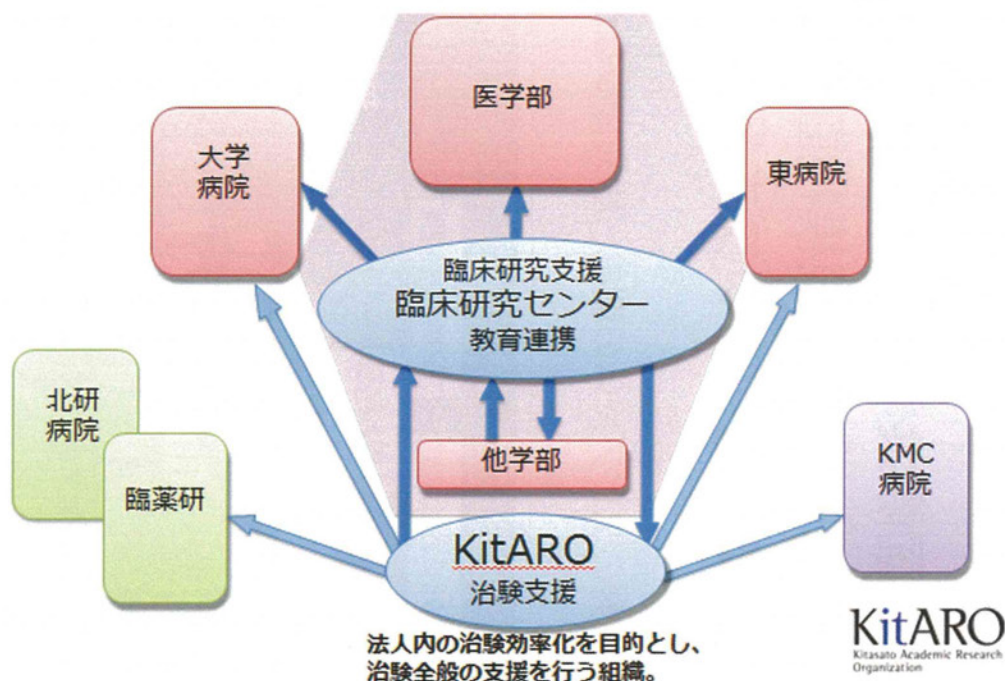
研究プラットフォーム
を提供（治験→臨床研究）

治験

治験へ参加することにより、
薬効評価の基本、品質管理の概念を
学ぶことができる。治験のために整
備された環境はそのまま臨床研究へ
使用可能である。

とは言え、
整備されるべき環境の
認識は両者で大きな隔たりがある。

学校法人北里研究所の臨床研究・治験体制



北里大学臨床試験事業本部

KitARO
Kitasato Academic Research
Organization



**1st Annual Seoul-Kitasato Joint Symposium on
Asian Clinical Research プログラム**

**1 st Annual Seoul-Kitasato Joint Symposium
on Asian Clinical Research**

Date: January 17th, 2013 13:00 - 17:00

Place: Green Hall Sagami-ono, Kanagawa, Japan

13:00-13:05 Opening remarks

Yuji KUMAGAI (General manager of Kitasato Academic Research Organization,
Professor of Kitasato University School of Medicine)

Yung Jue BANG (Professor, Seoul National University Hospital)

13:05-15:05 Part I Topics New Molecular Entities Generated from Academia

Chairperson

Yuji KUMAGAI (General manager of Kitasato Academic Research Organization,
Professor of Kitasato University School of Medicine)

In-Jin JANG (Professor, Seoul National University Hospital)

13:05-13:35 Anti-cancer translational research and development: Targeting cancer-expressing
essential amino acid transporter LAT1

Hitoshi ENDOU (Professor, Kitasato University School of Medicine, President & CEO,
J-Pharma Co., Ltd.)

13:35-14:05 Progress in Chemotherapy for Gastric Cancer (included Japan-Korea Inter-Group
Study)

Wasaburo KOIZUMI (Professor, Kitasato University School of Medicine)

14:05-14:35 Oncology Clinical Trials in Korea

Dong-Wan KIM (Associate Professor, Seoul National University Hospital)

14:35-15:05 Translational Research in Gastric Cancer

Yung Jue BANG (Professor, Seoul National University Hospital)

15:05-15:30 Coffee break

15:30-16:50 Part II Panel discussion

What and how Seoul and Kitasato should progress the collaborative clinical research in Asia?

Chairperson

Yuji KUMAGAI (General manager of Kitasato Academic Research Organization,
Professor of Kitasato University School of Medicine)

In-Jin JANG (Professor, Seoul National University Hospital)

15:30-15:45 Briefing 1 Introduction of Kitasato Academic Research Organization; Mission and Strategy for Clinical Research

Yuji KUMAGAI (General manager of Kitasato Academic Research Organization,
Professor of Kitasato University School of Medicine)

15:45-16:00 Briefing 2 Introduction of SNUH early clinical trials network

In-Jin JANG (Professor, Seoul National University Hospital)

16:00-16:50 Panel discussion

Attendee: Yuji KUMAGAI, Hitoshi ENDOU, Wasaburo KOIZUMI,
Howard LEE , Dong-Wan KIM , Kyung-Sang YU ,
Jae-Joon YIM , Han-Suk KIM and In-Jin JANG

16:50-17:00 Closing remarks

Yoshiharu AIZAWA (Board member of The Kitasato Institute, representative of clinical research)

Establishing an ARO – An Experience

No Kitasato **No Medicine**

KitARO
Kitasato Academic Research
Organization

Establishing an ARO - An Experience

Yuji Kumagai
Executive Director
Kitasato Academic Research Organization

Japanese Clinical Trials Viewed by Asian Countries

KitARO
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Organization

- India – the magnet
- South Korea – the runner up
- China – still in transition
- Taiwan – already in the mainstream
- Philippines, Thailand and Malaysian –moving ahead
- Japan – in isolation
 - Despite being a leading economic power, the number of multi-national study sites in Japan is similar to the Philippines, Malaysia, Thailand and Hong Kong. Interestingly, three Japanese sponsors are among the top 25 most trial active in the world, namely Takeda, Astellas and Eisai. Yet together, only 3.5% of their 4,412 sites are located to Asia, with less than 1% of those outside Japan. Clearly, Japan has its own individual agenda.

Source: Clinical Trial Magnifier Vol. 1:5 May 2008



Japan, Islas Galápagos of Drug Development

- A long history of domestic developments only in Japan.
 - Reluctant attitudes in accepting foreign data.
 - Non existence of IND system
 - *Lucky* circumstances of education in mother tongue.
- These factors led to isolation from global developments.

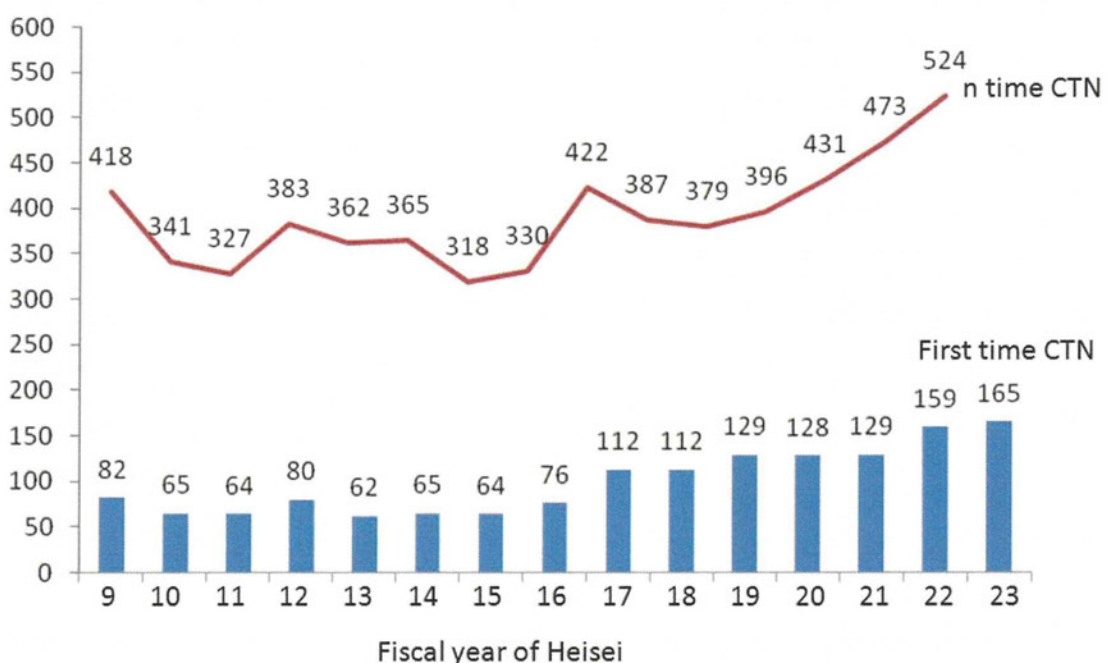
Contribution of Japanese Researches to International Journals

	Contribution	Number	
Basic Medicine			
Cell	7.3%	4 th	
Nature		6.7%	5 th
Science	6.6%	5 th	
Clinical Medicine			
NEJM	1.7%	12 th	

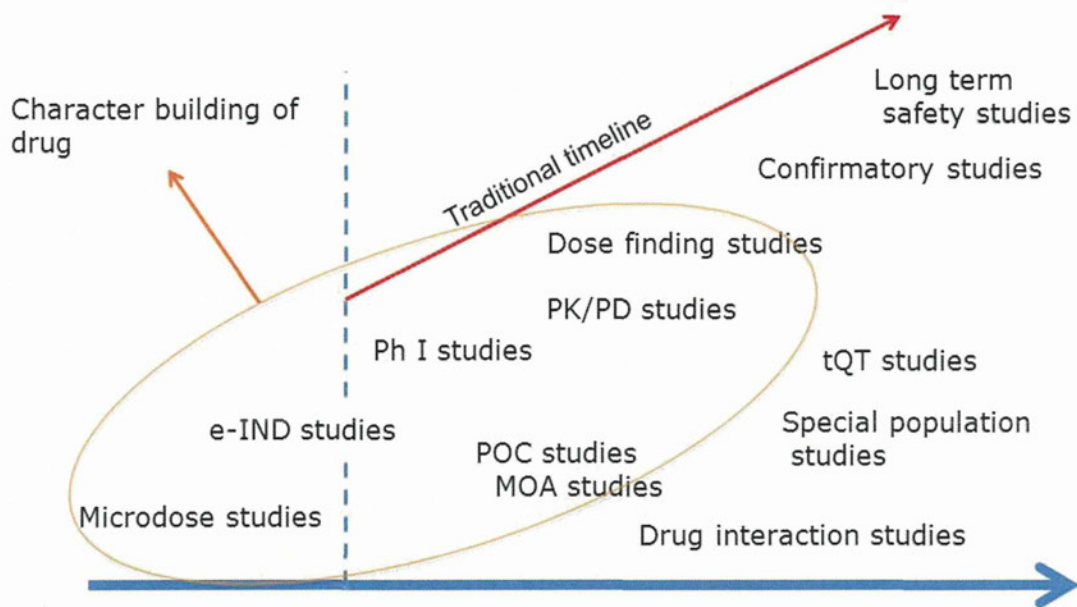
“Chi-ken”, the specific system in Japan

	Clinical Study	
	Chi-ken 治験 (치험) (Sponsor-initiated CT)	Rinsho-kenkyu 臨床研究 (임상연구) (Investigator-initiated CT)
Control	Pharmaceutical affairs law	Medical Act
Purpose	Gathering information for NDA (use for NDA only)	Medical Research (Never use for NDA)
Notification	Submitted to PMDA	No need
Investigator	Physician	Physician
Regulation	Under GCP	Non-GCP
Pharma companies	As a sponsor	Prohibited to contribute by law

Trends of CTN in Japan

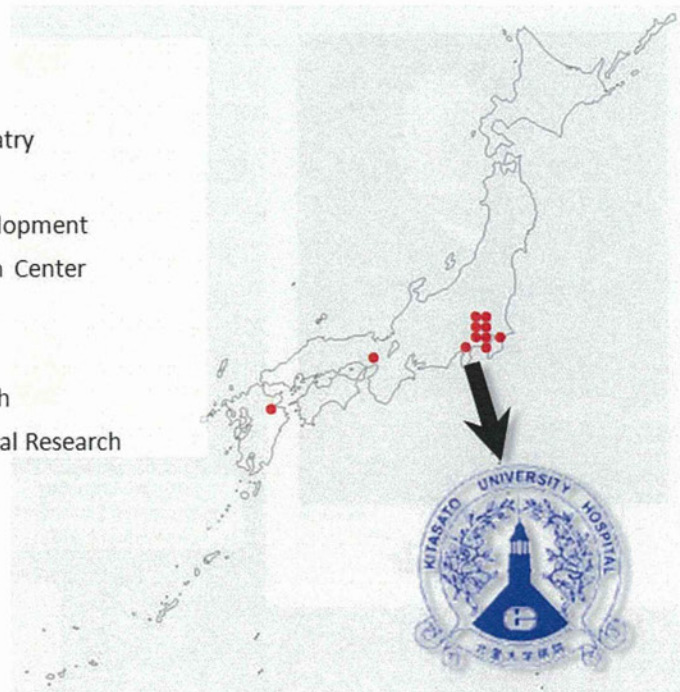


Increasing Varieties of CTs



Core Research Centers Accredited by MHLW

- National Cancer Center
- National Cardiovascular Center
- National Center for Neurology and Psychiatry
- International Medical Center of Japan
- National Center for Child Health and Development
- Chiba University Hospital Clinical Research Center
- Oita University, Faculty of Medicine
- Kitasato University, School of Medicine
- Keio University, Center for Clinical Research
- Center for Support and Education of Clinical Research





The Kitasato Institute

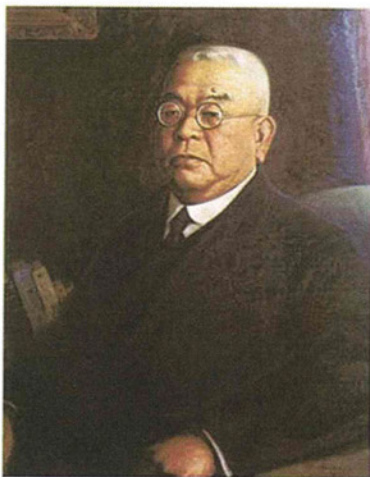
An incorporated Educational Institution for life sciences which holds

- a university with 7 schools
- 2 schools for co-medicals
- 3 centers for research
- 4 university hospitals

with approximately 10,000 students and 6,000 employees.

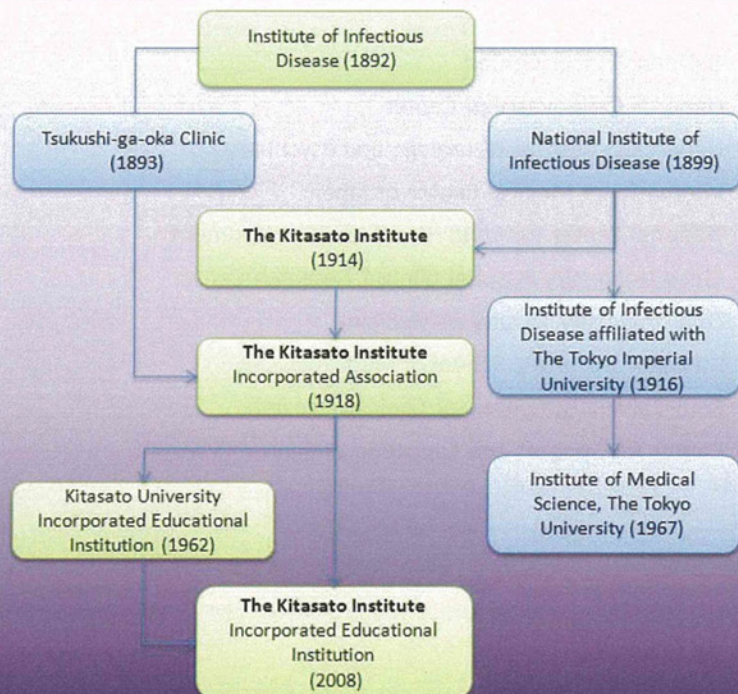
History of The Kitasato Institute

KitARO
Kitasato Academic Research Organization



S. Kitasato

Dr Shibasaburo Kitasato returned back to Japan in 1892 from Germany and then established Institute of Infectious Disease, the precursor of The Kitasato Institute.



Players in clinical trials at Kitasato

- 4 general hospitals
 - University Hospital
 - University East Hospital with 1 CP unit
 - Institute Hospital
 - Medical Center Hospital
- 1 specific center for clinical pharmacology

J-GCP requires each admin process for individual facilities.
 4 IRBs are set in the Kitasato.
 IND and NDA are not separated in Japan, and not a few ethics committee are in Kitasato.

Clinical Research Staff

April 1st, 2012

	Institute Hospital	Institute of CP	Medical Centre Hospital	University Hospital	University East Hospital	Total
Physician	1	3 (1)	1	0	4 (2)	9
Pharmacist (CRC)	3 (3)	8 (3)	1 (1)	4 (2)	7 (3)	23 (10)
Nurse (CRC)	1 (1)	6 (1)	2 (1)	3 (0)	15 (4)	27 (6)
Laboratory Medical Technologist (CRC)	1 (0)	23 (9)	1 (1)	0	6 (0)	31 (10)
Administration	2	6	1	2	6	17
Others	1	2	0	0	0	3
Total (CRC)	9 (4)	48 (13)	6 (3)	9 (2)	38 (7)	110 (29)

*CRC means "CRC who are approved by Japanese Society of Clinical Pharmacology and Therapeutics"

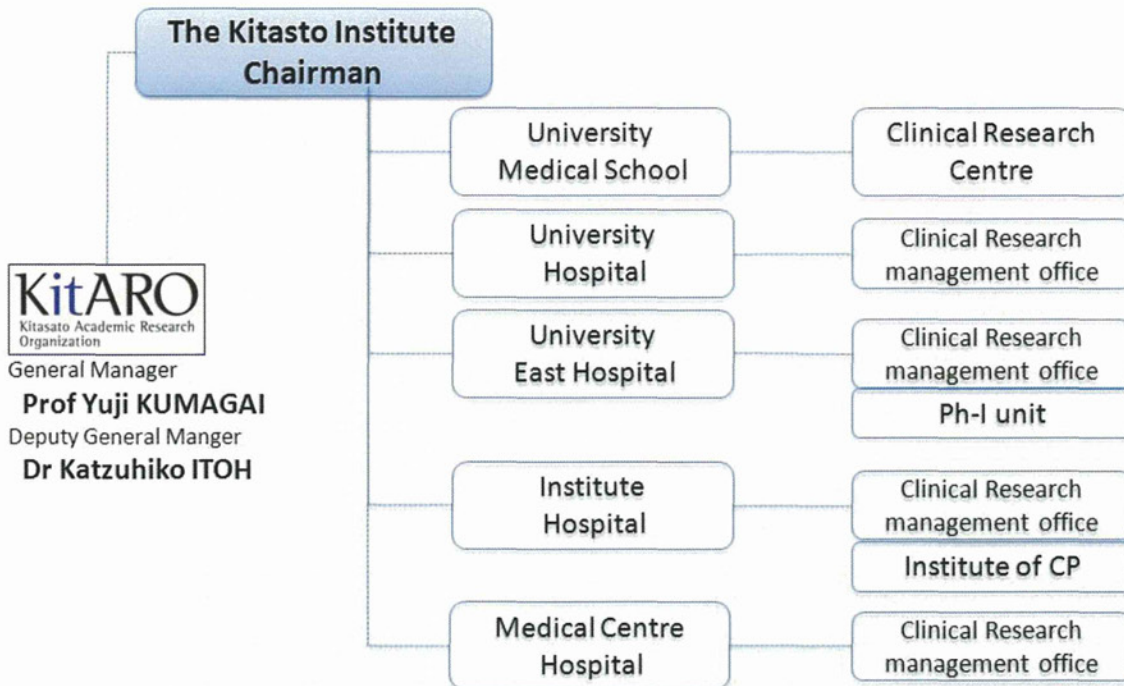
Needs for Reorganization

- The 5 players had been doing CTs independently with their own process.
- To utilize a scale merit, it was recognized that a reorganization was necessary and some insisted to establish an ARO.
- KitARO was established in 2010

Current Situation of CTs in Kitasato

- Clinical Research Center in Medical College
 - Supports and educates researchers in the college.
- Clinical Trial Centers & Global CTCC
 - Support clinical trials sponsored by companies, perform trials in the centers, and educate clinical trial professionals.
- Academic Research Organization for all Kitasato
 - Promotes clinical studies not only in Kitasato but in the world with collaboration with KCRC.

Organization for Clinical Research



Two Aspects of KitARO

- Internal SMO and CRO for Kitasato
 - Business activities with pharma companies.
 - Standardizing operative processes.
 - Managing Centralized IRB
 - Quality control
 - International collaboration
- Academic activities
 - Growing seed
 - Education