

平成 22 年 3 月 23 日

KITASATO Global Clinical Research Center

Introduction and Concepts



臨床薬理研究所の臨床試験支援の実績を生かしたオール北里体制

オール北里治験・臨床研究推進基盤

治験担当理事／臨床研究担当理事 *4月より稼動 現在は準備室

北里 ARO 事業本部 *

医学部臨床研究センター

- ・臨床研究事業企画・開発
- ・人材育成
- ・臨床研究相談

臨床薬理研究所

- ・治験事業企画・運営
- ・臨床試験コーディネイター
- ・早期治験実施

グローバルオフィス

- ・国外ネットワーク構築
- ・共同試験企画調整

大学病院 治験管理室

- ・治験支援

東病院 治験管理センター

- ・早期治験実施
- ・治験支援
- ・人材育成

研究所病院 治験管理室

- ・治験支援
- ・臨床研究支援

メディカルセンター 病院治験管理室

- ・治験支援
- ・臨床研究支援

医師23名（内専任10名）、生物統計家5名、疫学専門家2名、スタディーコーディネイター8名、データマネジャー9名、CRC48名、臨床検査技師34名 他

臨床薬理研究所の臨床試験支援の実績を生かしたオール北里体制（1）

	Abbreviated Trial Name	Phase	Target Sample Size	Registered Sample Size	Domestic Scheduled Sample Size	Domestic Registered Sample Size	# of Participating facilities (Domestic)	Period	Status	Participating Countries	Support Service
1. Study that medical institution in Japan participated to the US GOG											
Sponsored Clinical Trials	GOG-0171	Diagnostic	500	684	100	92	10/6/1998-11/2005 *	Done	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0174	III	216	240	10	6	9/6/1999-2/2007 *	Done	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0175	III	500	571	30	29	10/9/1998-12/2006 *	Follow-up period	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0187	II	74	26	5	2	13/11/2002/2006 *	On-going	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0209	III	1350	1381	60	59	16/2003-4/2009 (8/2006- In Japan)	Follow-up period	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0232B	II	47	55	5	3	11/5/2005-3/2008 *	Follow-up period	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-9917	I	55	96	10	7	2/2004-10/2004-6/2009	Follow-up period in Japan (On-going for global)	US, Japan	Administrative support, protocol / IC documentation support, local data management support, auditing support	
	GOG-0213	II	660	248	50	15 (scheduled) (IRB of 7 facilities has approved currently)	12/2007-1/2010- In Japan)*	In preparation under advanced medical evaluation system in Japan (On-going for global)	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support, UMIN registration / update	
	GOG-0237	Diagnostic	754	14	278	-	15/3/2009- (12/2010- In Japan)*	Working on protocol translation in Japan (On-going for global)	US, Japan	Administrative support, protocol / IC documentation support, local data management support, UMIN registration / update	
	GOG-8007	Secondary Analysis	88	-	88	-	10/6/2009-	In preparation for IRB in Japan (Protocol approved by NCI/GOG)	Operated in Japan using US GOG data (including Japanese data)	Administrative support	

臨床薬理研究所の臨床試験支援の実績を生かしたオール北里体制（2）

Doctor-initiated Clinical Trials	2. Study that operated the US GOG trial as domestic doctor-initiated clinical trial	GOG-0218	III	1800	1873	90	44	9/2005-8/2009 (11/2007- in Japan)*	Follow-up period	US, Korea, Japan	Local data management support, safety information, case recruiting support, clinical trial exemption submission support, monitoring, support for clinical trial coordinating center
GCIC International Group Clinical Trials	3. International group study that is operated by Japanese clinical trial group	JGOG3017	III	652	425	633	407	123/2006- Registration period	On-going	Japan, Korea, France, Italy (UK is in preparation)	Administrative support, Agreement documentation support, manual documentation, UMIN registration / update, preparation of the registration system, case registration center, communication with each country's center as a coordinating center
	4. International group study with Japan that is initiated by clinical trial group from other countries	GOTIC-001	II / III	840	-	-	-	50 (scheduled)	2/2010-scheduled	Japan, Australia, New Zealand (in preparation)	Administrative support, Agreement documentation support, protocol / IC documentation support, manual documentation, UMIN registration / update, preparation of 2-step-Web registration system, case registration center, communication with each country's center as a coordinating center
Corporate Clinical Trials	5. Clinical trials initiated by corporate	AGO	II	900	61 ****	50	9	12/2008- (4/2009- As corporate clinical trial in Japan)	On-going	Australia, South China, Hong Kong, Taiwan, Japan, Germany, Belgium, France, Denmark, Norway, Sweden, Italy, Spain, Ireland, Austria, US	Local data management support, promotion of case registration, communication with AGO, participation as International Steering Committee member
	Study under the execution of support work Study under preparation Completed study	Cervix Cancer S-1	III	360	124	200	77	31/2008- Registration period	On-going	Japan, Korea, Taiwan	
		S-1ALV	II	72	73	30	33	9/2008- (6/2009)	Completion of registration	Japan, China	Registration center

* For NCI trials, it is stated as registration period since long-term follow-up survey is required until there is an announcement of end of follow-up phase or all cases are deceased.

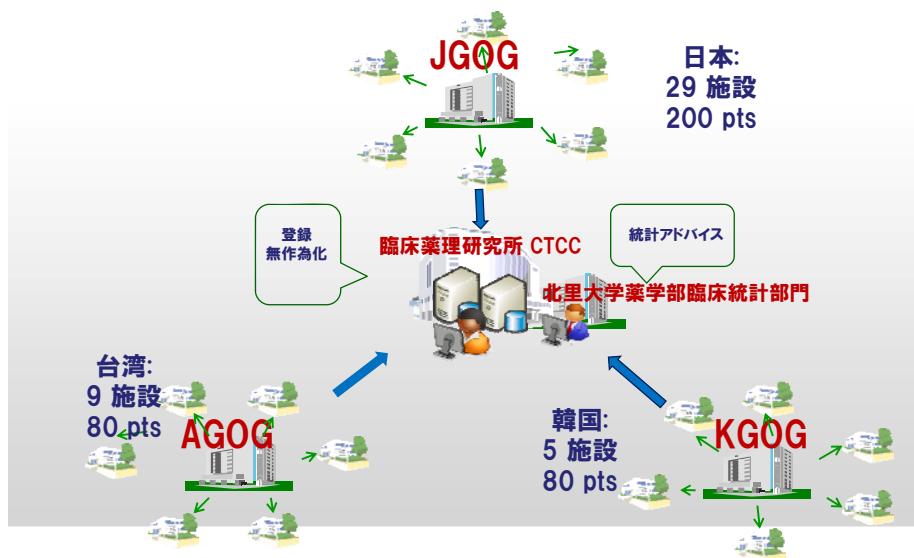
** Only Parent can be known (There is a possibility of participation of other countries as affiliated sites)

**** The second analytical examination using the sample of GOG-0171 study

***** At the date of 9/22/2009

臨床薬理研究所の臨床試験支援実績例

子宮頸がんにおける国際治験(臨床試験)の事例。



Kitasato Global Clinical Research Center

運営委員会の元、三つの部門よりセンターを構成

KITASATO Global Clinical Research Center

Steering Committee

A steering committee for managing following departments, consists of directors and committee members

Scientific Advisory Board

Consists of executives of domestic and foreign research organizations, pharmaceutical companies, and administrative body

Strategy Development Division

A unit to design business strategy

Coordinating Division

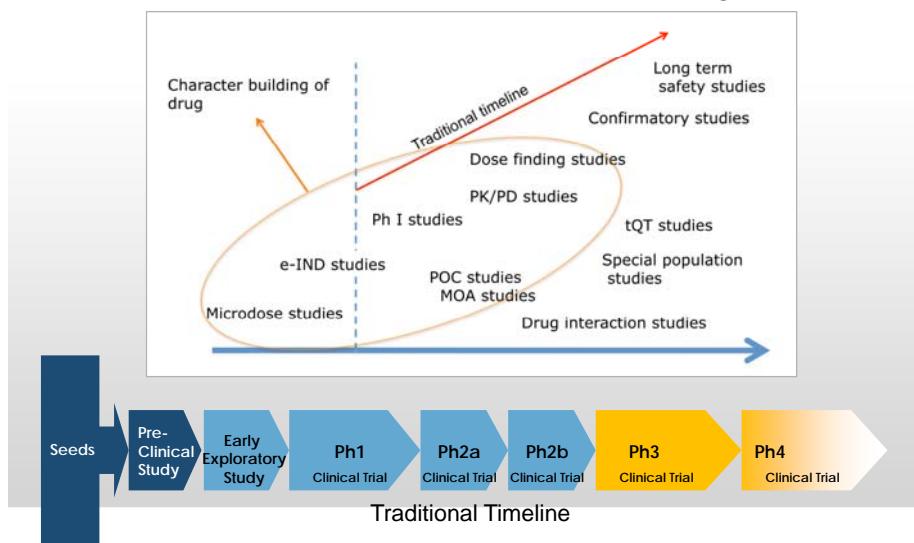
A unit that supports global clinical research where experts of clinical research belong

Education Division

A unit that executes international joint research and supports education

グローバル臨床研究推進戦略(コンセプト)

Our target is efficiency and quality not caught in traditional timeline, so studies are so flexible ones that cannot be executed in general CRO.



グローバル臨床研究推進戦略(組織)

The global clinical research center functions as a hub that connects Europe and America, Japan, and Asia by becoming a center of international clinical trials and Asia joint clinical trials. We plan to lead the clinical trials by executing the creation of protocol, trial coordination, data management, and statistics analysis.

Global Clinical Research Network (Europe and US)

GOG Gynecologic Oncology Group (US)
ACOG The American College of Obstetricians and Gynecologists (US)
AACT Academic Alliance for Clinical Trials (Europe)

Global Clinical Research Institutions (Europe and US)

Harvard Univ. (US)
Utrecht Univ. (Europe)

Introduction of international standard

Construction of system network

Allotment of international clinical trial

Cooperation in clinical trial

Offer of educational program

Clinical Research Network (Japan)

JGOG Japan Gynecologic Oncology Group
JACRCO Japan Clinical Cancer Research Organization
TCOG The Tokyo Cooperative Oncology Group

Invitation of leader

Offer of human resource

Offer of educational program

Global Clinical Research Network (Asia)

KGOG Korean Gynecologic Oncology Group (Korea)
AGOG Asian Gynecologic Oncology Group (Taiwan)

Construction of system network

Allotment of international clinical trial

Offer of educational program

Global Clinical Research Institutions (Asia)

Seoul Univ. Indonesia Univ.

Construction of system network

Allotment of international clinical trial

Offer of educational program

Domestic Clinical Research Institutions

Kitasato group Center hospital

皆様からのご意見・ご要望をお待ちしています

