

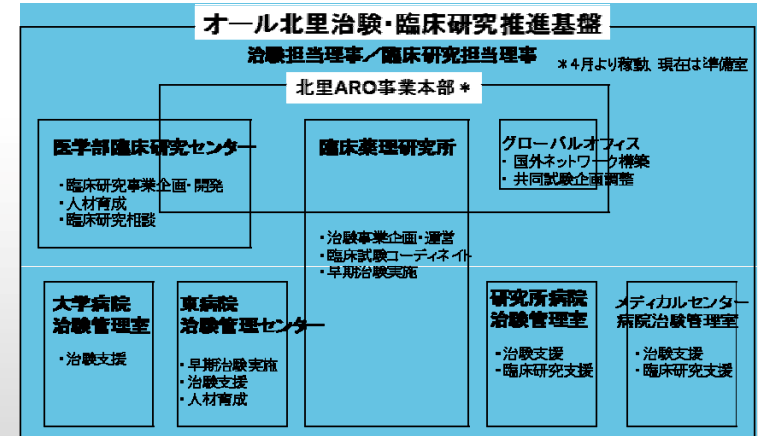
平成 22 年 3 月 23 日

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



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										
GOG-0171	Diagnostic	600	684	100	92	10	9/1998-11/2005 *	Done	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support
GOG-0174	II	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	II	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	11/20/2000- **	On-going	US, Japan **	Administrative support, protocol / IC documentation support, local data management support, auditing support
GOG-0209	II	1350	1381	60	59	16	8/2003-4/2009 (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	5/2004- (10/2004-6/2009 in Japan) *	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, UMN registration / update
GOG-0237	Diagnostic	754	14	278	-	15 (scheduled)	2/2009- (1/2010- in Japan) *	Working on protocol translation in Japan (On-going for global)	US, Japan	Administrative support, protocol / IC documentation support, local data management support, UMN 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）

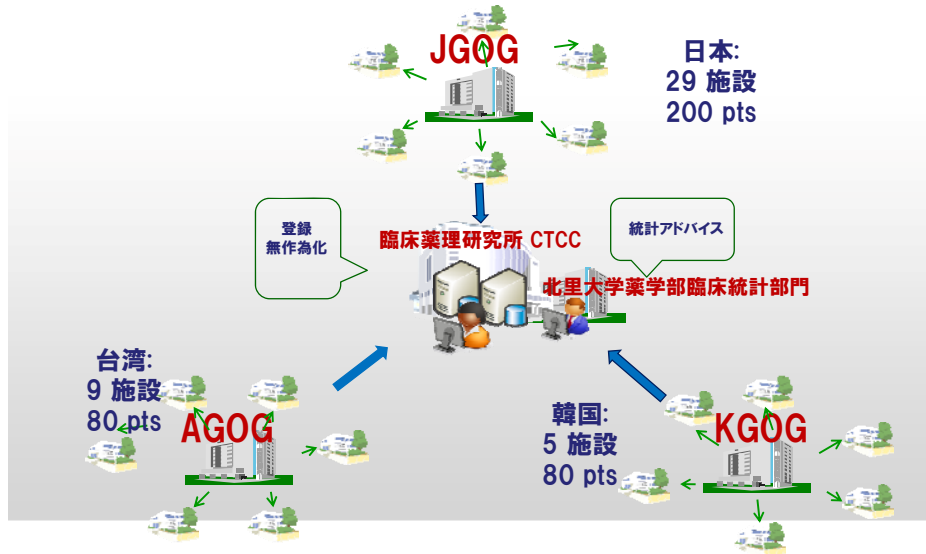
Study Type	Study ID	Phase	Target Sample Size	Registered Sample Size	Domestic Scheduled Sample Size	Domestic Registered Sample Size	Period	Status	Participating Countries	Support Service	
Doctor-Initiated Clinical Trials	GOG-0218	II	1800	1873	90	44	9/2005-8/2009 Japan *	Follow-up period	US, Korea, Japan	Local data management support, safety information, case registration support, clinical trial exemption submission support, monitoring, support for clinical trial coordinating center	
	3. International group study that is operated by Japanese clinical trial group										
	JGOG3017	III	652	425	633	407	123	9/2006-Registration period	On-going	Japan, Korea, France, Italy (UK is in preparation)	Administrative support, Agreement documentation support, protocol / IC documentation support, manual documentation, UMN registration / update, preparation of Web registration system, case registration center, communication with each country's center as a coordinating center
	GOTIC-001	II / III	840	-	-	-	50 (scheduled)	2/2010-scheduled	In preparation for protocol	Japan, Australia, New Zealand (in preparation)	Administrative support, Agreement documentation support, protocol / IC documentation support, manual documentation, UMN registration / update, preparation of 2 step-Web registration center, communication with each country's center as a coordinating center
GIC International Group Clinical Trials	4. International group study with Japan that is initiated by clinical trial group from other countries										
	AGO	III	900	61 ****	50	9	12/2008- (4/2009- As corporate clinical trial in Japan)	14	On-going	Australia, Korea, 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
Corporate Clinical Trials	5. Clinical trials initiated by corporate										
	Cervix Cancer S-1	III	360	124	200	77	9/2008-Registration period	31	On-going	Japan, Korea, Taiwan	Registration center
S-1LV	II	72	73	30	33	10/2008-9/6/2009	9	Completion of registration	Japan, China	Registration center	

Study under the execution of support work:
Study under preparation
Completed study

* 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

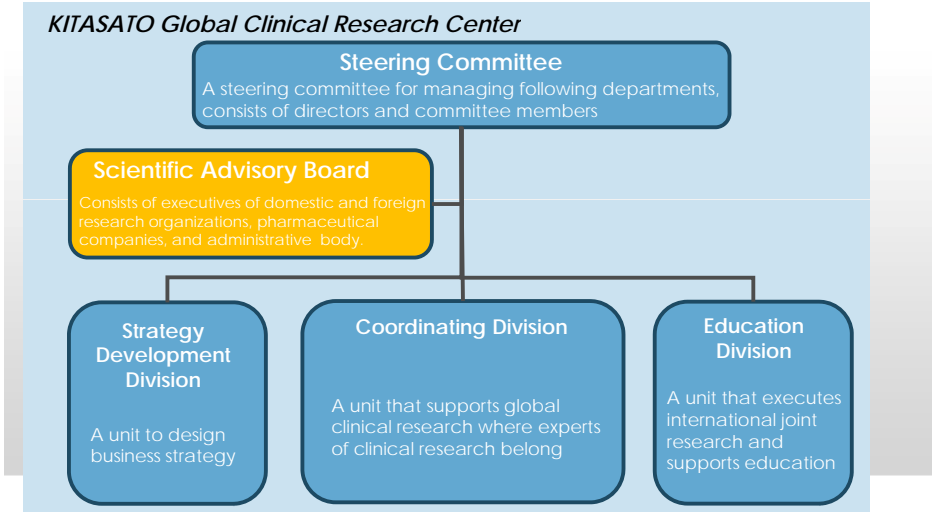
臨床薬理研究所の臨床試験支援実績例

子宮頸がんにおける国際治験(臨床試験)の事例。



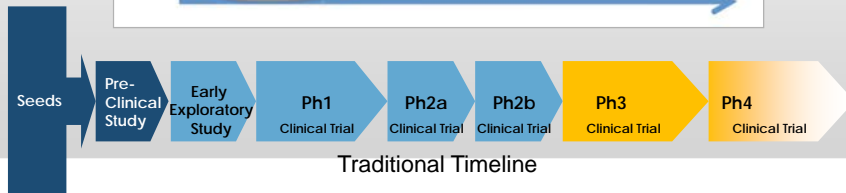
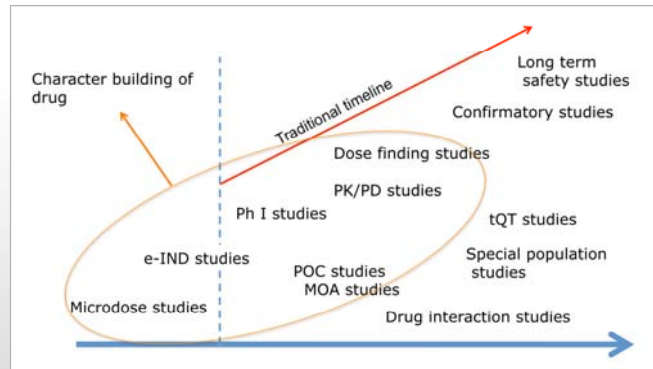
Kitasato Global Clinical Research Center

運営委員会の元、三つの部門よりセンターを構成



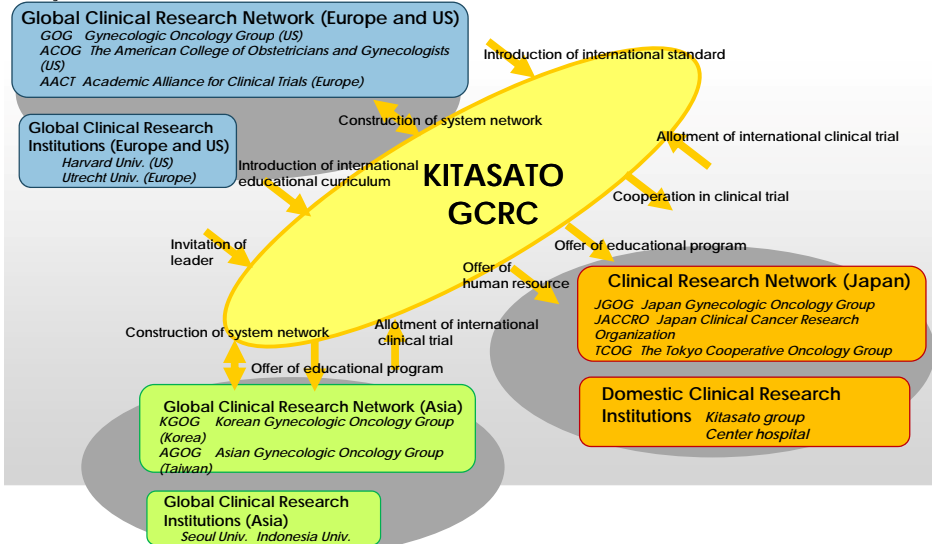
グローバル臨床研究推進戦略(コンセプト)

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.



皆様からのご意見・ご要望をお待ちしています

