2010
Annual Report

We test tomorrow's drugs,
vaccines and medical devices today

The results behind...

Clinical Trials Centre
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Clinical Trials Centre (CTC) of The University of Hong Kong (HKU) Li Ka Shing Faculty of Medicine is a leading academic research organization dedicated to one-stop clinical research solutions. Established in 1998, CTC is committed to enhancing global healthcare by promoting the quality and efficiency of clinical research and testing of new chemical drugs, biologics, vaccines, traditional Chinese medicines, medical devices and diagnostic tools through ethical consideration, scientific expertise, quality assurance and education. Our core competences range from research consultation, training and education to protocol development, feasibility assessment, regulatory and ethics affairs, finance and contract management, project management, monitoring, data management, medical statistics, site management, drug management and central laboratory support for industry-sponsored clinical studies and investigator-initiated clinical studies.

Contents

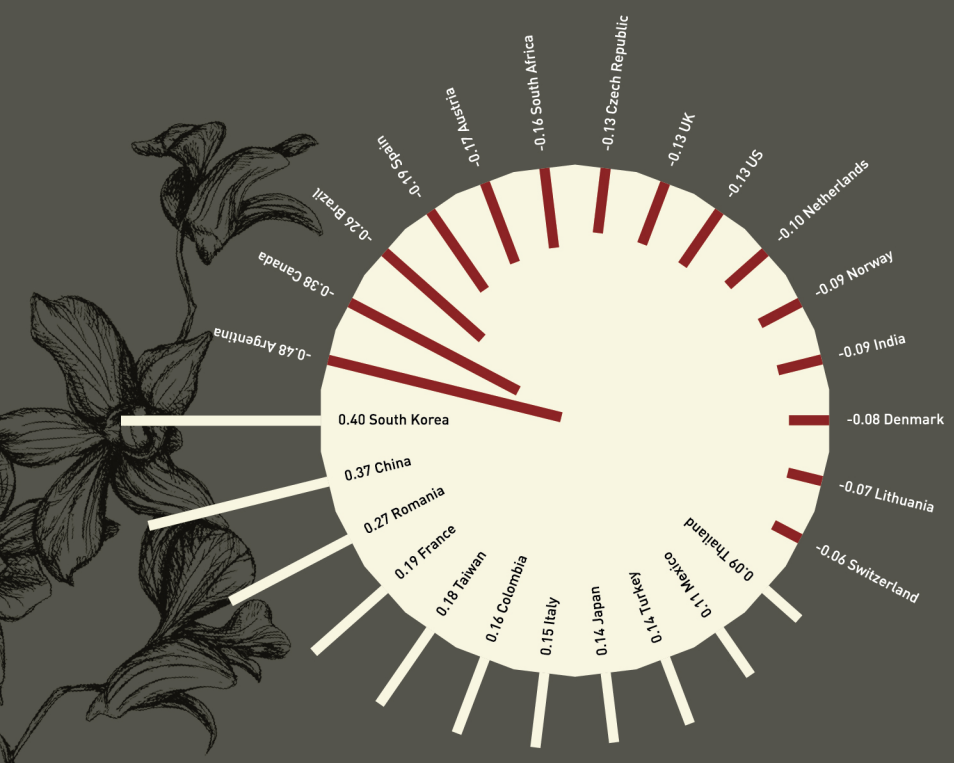
Message from the Director

Globalization of Translational Research & Translational Medicine

Translational research is the underlying basis for translational medicine — the process that leads from evidence-based medicine to sustainable solutions for public health problems. Fulfilling the promise of translational research to improve the health and longevity of the world's populations depends on developing broad-based teams of scientists and scholars who are able to focus their efforts to link basic scientific discoveries with the arena of clinical investigation, and translating the results of clinical trials into changes in clinical practice, informed by evidence from the social and political sciences [Lean MEJ, Mann JI, Hoek JA, Elliot RM and Schofield G. Translational Research: from evidence-based medicine to sustainable solutions for public health problems. British Medical Journal 2008; 337: a863].

Translational Research Schooling

There are many important factors and incentives related to the globalization process of industry-sponsored clinical trials, including knowledge transfer, education, access to promising new treatments, international collaborations, and financial incentives. Participating in industry- sponsored trials provides an effective and inexpensive knowledge transfer pathway to translate know-how from the international pharmaceutical, biotech, and medical device industries to academic and healthcare institutions. It is thus crucial to continuously follow this process in order to answer questions like: "How far will this process go? Have we reached a plateau of globalization? Or is the process still ongoing and uninterrupted?"



North Asia is Serious

Amongst the top eight countries/places that have recently gained the most ground in the number of industry-sponsored trial sites are South Korea (#1), China (#2), Taiwan (#5), and Japan (#8). Clearly, North Asia is the focus of global life sciences research and development. Asia's share of industry-sponsored clinical study sites has recently increased by 1.2%, which is mostly attributable to North Asian countries, while there does not appear to be an increased contribution amongst the South Asian countries, with the exception of Thailand. For instance, the previous trend of increasing the number of trial sites observed for India has halted or stabilized.

The change in the percentage of industry-sponsored phase II/III trial sites registered in the US clinical trial registry and with their study initiation dates between January 2006 and June 2008 and between July 2008 and December 2010, respectively. The results are presented for countries/places with the largest absolute and significant ($p<0.05$) change.

Welcome Japan & Welcome China!

A previous Clinical Trial Magnifier article reported that in 2005/2007, Asia contributed 5.9% of all industry-sponsored study sites — a number that has now increased to 9.7%. It was also noted at the time that both Japan and China were not part of this development, since most of their trials were for local registration purposes only. This observation has apparently changed, and it appears that both Japan and China have now entered the mainstream of multi-centre clinical trials and are testing new medicinal products on a global level. It can be assumed that this development will continue because both Japan and China are of great interest to the international life sciences industry. By including both countries in global clinical trials, local registration trials could be minimized and the marketing of new medicinal products in the two countries could be initiated much faster than at present. The impact of the economic growth of China must also be noted and accepted: China has just overtaken Japan as the world's second largest economy and is predicted to overtake United State's lead position in 2020. Based on the number of industry-sponsored trial sites, the rankings of China, South Korea, and Taiwan have improved over the past five years, from 22nd to 14th, 23rd to 17th, and 30th to 27th, respectively. Japan, ranked 5th, and India, ranked 11th, have managed to retain their respective positions.

Science

The significance of North Asia is further implied by the fact that 28 of Asia's 32 universities are listed in the top 200 world universities of Times Higher Education, World University Rankings 2010 and are located in North Asia: Japan (n=10), China (n=6), Hong Kong (n=5), South Korea (n=5) and Taiwan (n=2).Over the past 10 years, China, including Hong Kong, has significantly increased its academic output in the biomedical research area and has today more Medline-listed articles than the UK and Japan, second only to the United States. North Asia contributed about 16% of all Medline publications in 2009, equivalent to approximately half of the figures for North America and Europe, respectively: China (6.7%), Japan (5.8%), South Korea (2.1%), Taiwan (1.0%), and Hong Kong (0.4%). South Asia, Oceania, Africa, Middle East, East Europe, and Latin America each contributed between 2.3% and 4.0% of all Medline publications in 2009.

Translational Medicine

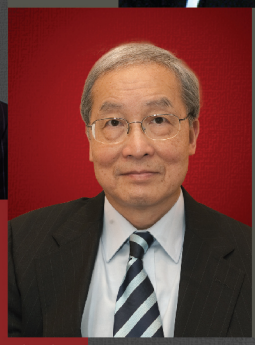
If one was to see new biotech hubs developed in the world, one would likely assume that a few would appear in North Asia. The objective of a bio-medical cluster is to transfer novel discoveries usually made at academic institutions—by commercialization — into clinical practice. The concept of translational medicine also recently became a strong trend in the United States and Europe. For instance, the U.S. National Institutes of Health's priority areas of 2009 listed translational medicine second after genomics. During the past few years, there have been new developments in the United States with the selection of a national consortium of institutions funded by the NIH translational research aimed at accelerating the transition from scientific discoveries to medical therapies.There are three distinct prerequisites for the development of a successful bio-medical cluster: (a) excellent basic and clinical sciences to breed novel discoveries; (b) venture capital expertise to identify novel discoveries suitable for commercialization; and (c) a strong infrastructure, unique network, and a relevant supporting organizational structure to facilitate the discovery-commercialization process. Outside Japan, a rapid breed of the three crucial prerequisites can also be noted in some of the major North Asian cities such as Beijing, Shanghai, Seoul, Hong Kong, and Taipei. Those cities, and perhaps other cities in North Asia, are in the position to capture this opportunity. My personal view is that both Seoul and Taipei have the most ingredients in place, although one critical element is still missing — experts who create innovation through pre-clinical development to proof-of-concept clinical trial, i.e., bio-entrepreneurship experts. After 36 years in academia, 28 years in Asia, 18 years at the University of Hong Kong, and 12 years as the Director of the Clinical Trials Centre, The University of Hong Kong, I have decided to leave academia in mid-2011.I would like to thank all hard-working professional CTC staff and collaborators from the university, government, the Industry and Hospital Authority and wish you all the best.

Johan Karlberg,
Hong Kong, April 2011
MD, PhD (Anat & Cell Biology), BSc (Stat & Edu)
Director and Professor

Board of Directors

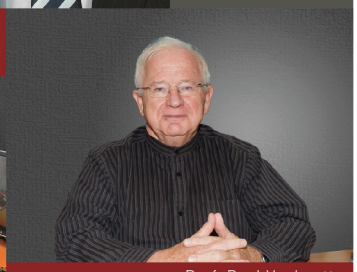
Prof. Karen Lam

Dr. Che-chung Luk



Prof. Sum-ping Lee

Prof. Johan Karlberg



Prof. Paul Vanhoutte

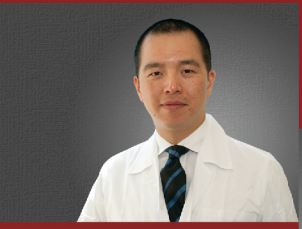
Prof. Yiu-fai Cheung

Prof. Michael Irwin

Prof. Yao Tong

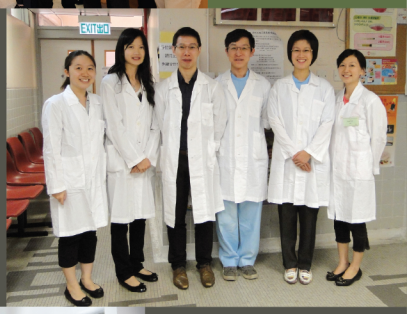
Prof. Man-fung Yuen

Dr. Gilberto Leung



Prof. Sidney Tam

Business & Project Acceleration Team



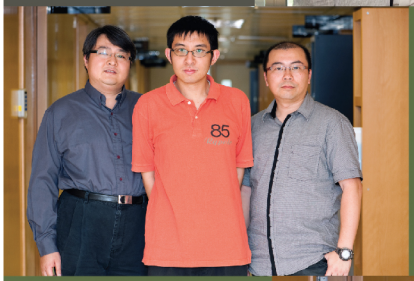
Site Operations Team

Project Operations Team

Special Projects Team

Study Site Services Team

Data Management & Medical Statistics Team



General Affairs

Information Technology

Organizational Structure

Li Ka Shing Faculty of Medicine
The University of Hong Kong

Board of Directors

Director

Business & Project Acceleration Team

- Feasibility Assessment
- Project Coordination
- Ethics Affairs
- Budget & Payment Management
- Service Proposal Development
- Contract Management
- Business Development & Marketing

Study Site Services Team

- Specimen Management
- Central Laboratory Management
- Study Drug Management

Site Operations Team

- Medical Research Clinic Operation
- Subject Recruitment
- Study Coordinator

Project Operations Team

- Protocol Development
- Regulatory Affairs
- Project Management
- Study Monitoring

Data Management & Medical Statistics Team

- Medical Statistics
- Data Management
- Research Consultation

Special Projects Team

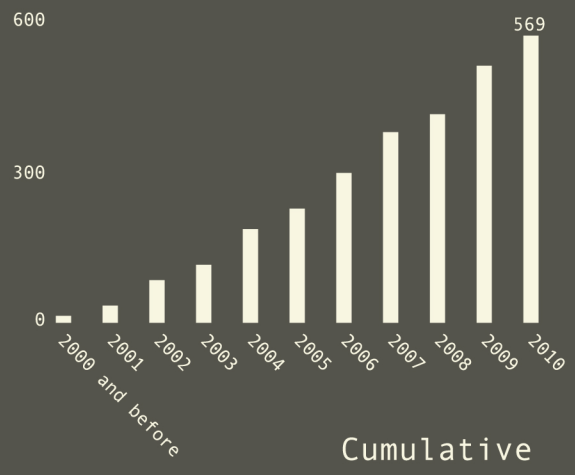
- Clinical Trial Magnifier Publication
- Conference Organization
- Education & Training Programs Organization
- Quality Assurance

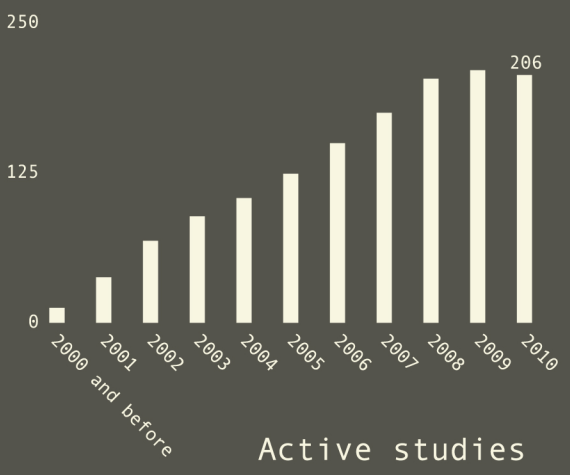
General Affairs

Information Technology

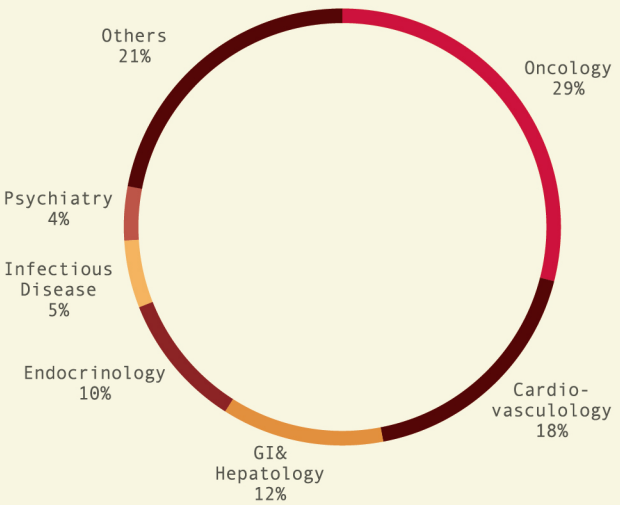
Operation Highlights for 2010

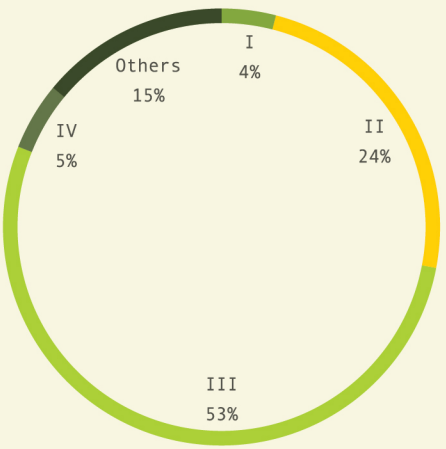
Contracted industry - sponsored clinical studies





Types of clinical studies (All years)





No. of initial ethics submissions: **62**
No. of subsequent submissions (excluding serious adverse event reports): **3,446**
No. of serious adverse event reports: **22,513**
No. of trial subjects monitored: **405**
No. of study visits monitored: **1,261**

Collaborative trial sponsors

Abbott	Critical Biologics	Novo Nordisk
Achillion	Daiichi Sankyo	OrbusNeich
Actelion	EBR System	Organon
Advanced Herbal Therapeutics	Eisai	OSI
Aegera	Eli Lilly	Penumbra
Algeta	Ellipse	Pfizer
Allergan	Enteromedics	Pharmasset
Altana	Everpride	Pi Medical
Amgen	FibroGen	PowderMed
Anaborex	Galderma	Progen
AO Foundation	Genentech	Roche
Arrow	Gilead	sanofi-aventis
Artisan	GlaxoSmithKline	Schering-Plough
Astellas	Guidant	China SCI Network
AstraZeneca	Idenix	Scios
Baxter	ImClone	Servier
Bayer	Ipsen	St. Francis
BCIRG	Johnson & Johnson	St. Jude Medical
Bio-cancer	Keryx	Synthes
Biocompatibles	Kowa	Takeda
BioCryst	La Jolla	Theravance
Biogen Idec	LEO	TTY Biopharm
Biomeasure	LG Life Sciences	Tularik
Boehringer Ingelheim	Light Sciences	Tyco
Boston Scientific	Luitpold	UCB
BrainsGate	Lundbeck	Vigconic
Bristol-Myers Squibb	MedImmune	VitaGreen
Bukwang	Medtronic	Wealthy Creative
Celltech	Medwaves	Wyeth
Celsion	Merck KGaA	Xanthus Life Sciences
CK Life Sciences	Merck Sharp & Dohme	Zila
Codman	Morphotek	
Cook	Novartis	

Highlighted Events in 2010

CTM conference in Kota Kinabalu, Malaysia

After the success of the first Clinical Trial Magnifier (CTM) Conference in Hong Kong, a second one was held on November 24-26 in Kota Kinabalu, Malaysia. There were plenary lectures, case scenario sessions, and group discussions aimed at identifying and discussing the various investigators' incentives for participation in industry-sponsored clinical trials.

At the group sessions, the conference participants were assigned to three working groups. Each of the three working groups addressed three exclusive essential investigator incentives: Publication and Education; Administrative Assistance; and Finance and Contracts. The three working groups met three times under the coordination of a facilitator. After the three working group sessions, there was a final reporting session with groups' conclusions and recommendations which formed the basis of the Investigator Incentives for Trial Participation (I-Incent) Report.

The I-Incent Report is the first of its kind to address investigators' incentives for participating in industry-sponsored clinical trials. The three basic investigators' incentive issues are:

- Ensuring publication of the results of any clinical trial
- Development of administrative infrastructure support to facilitate and accelerate study start-up and to provide administrative services throughout each study
- Development of fair and standardized clinical trial agreements

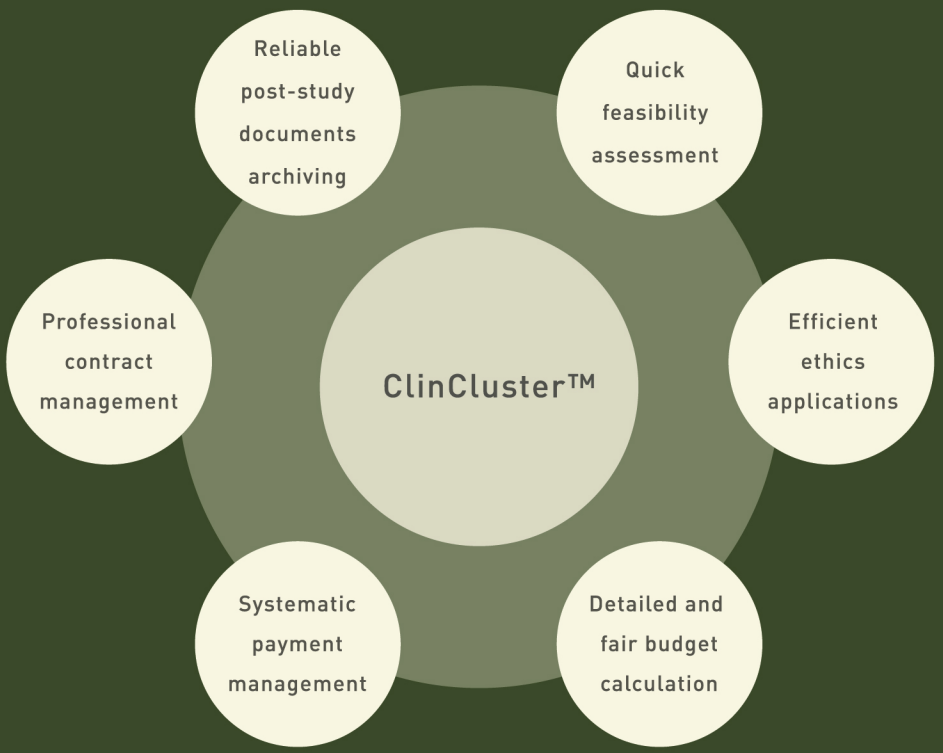
For Publication and Education, a key recommendation was the establishment of a new scientific medical journal that will publish clinical trial reports independent of study design, study phase, positive or negative study results, and whether a study was completed as planned or terminated prematurely. The publications should be short, use a standardized format, and the names of all participating investigators should be listed among the authors.

For Administrative Assistance, establishment of a Master Degree Program in Clinical Trial Administration (MCTA) was recommended. The program will be suitable for administrative personnel working for sponsors or for the study sites, as well as for investigative staff, project managers and clinical research associates.

Regarding Finance and Contracts, a recommended target is to reach a general consensus of acceptable and non-acceptable contract terms between sponsors and study sites, and to identify terms that are more commonly open for negotiations.

Launch of Enhanced ClinCluster™

Most sponsors operating in Hong Kong have been facing the dilemma of the strong need to increase trial activities in Hong Kong and the challenges of identifying study sites and dealing with more and more complicated study administration works. To facilitate the set-up and running of multi-centre studies in Hong Kong, the first generation of ClinCluster™ was launched in year 2004. In order to tackle the new challenges, an enhanced ClinCluster™ was launched in year 2010.



The enhanced ClinCluster™ platform was designated to enhance research collaboration with our long-term collaborators. Through ClinCluster™, sponsors or contract research organizations will enjoy the above added value.

ArchiveEasy™

Long term study documents archiving is an essential requirement, especially for company-sponsored clinical studies. The limited storage spaces at most study sites however impose a practical challenge to investigators. In the second quarter of the year, CTC launched its study documents archiving service, ArchiveEasy™ to facilitate the archiving and management of the study documents through collaboration with a professional document management company. With ArchiveEasy™, both sponsors and investigators can assure that the study documents are properly archived and can be easily retrieved for audits or inspections if needed.

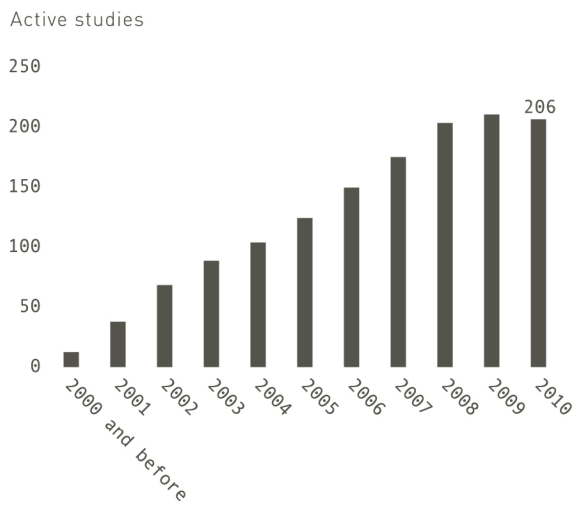
Operating Review & Achievements

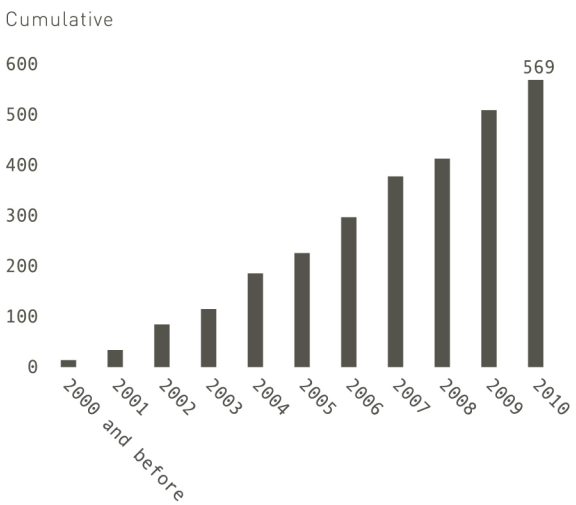
Business & Project Acceleration

Industry-sponsored clinical studies

In 2010, 50 new clinical studies were contracted and the cumulative number of contracted clinical studies reached 569. Ongoing studies remained at a high level of 206 by the end of the year.

Contracted industry - sponsored clinical studies



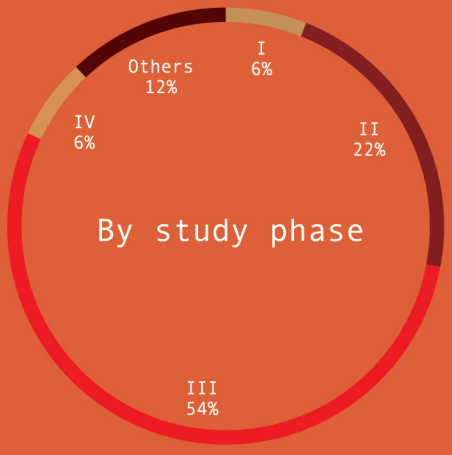


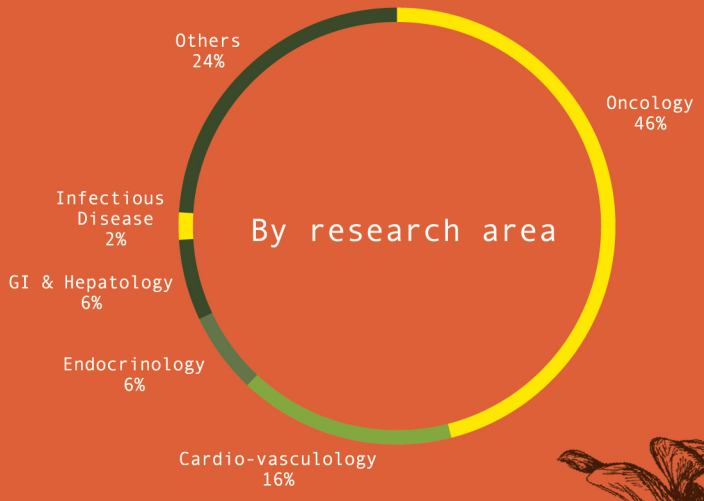
Business & Project Acceleration Team

Study area and study phase

During the year, oncology and cardiovasculology continued to be the top areas in terms of study number. The two areas accounted for 46% and 16%, respectively, among the 50 contracted clinical studies. Phase II and phase III studies together accounted for 76% of all newly contracted studies.

Types of clinical studies in 2010





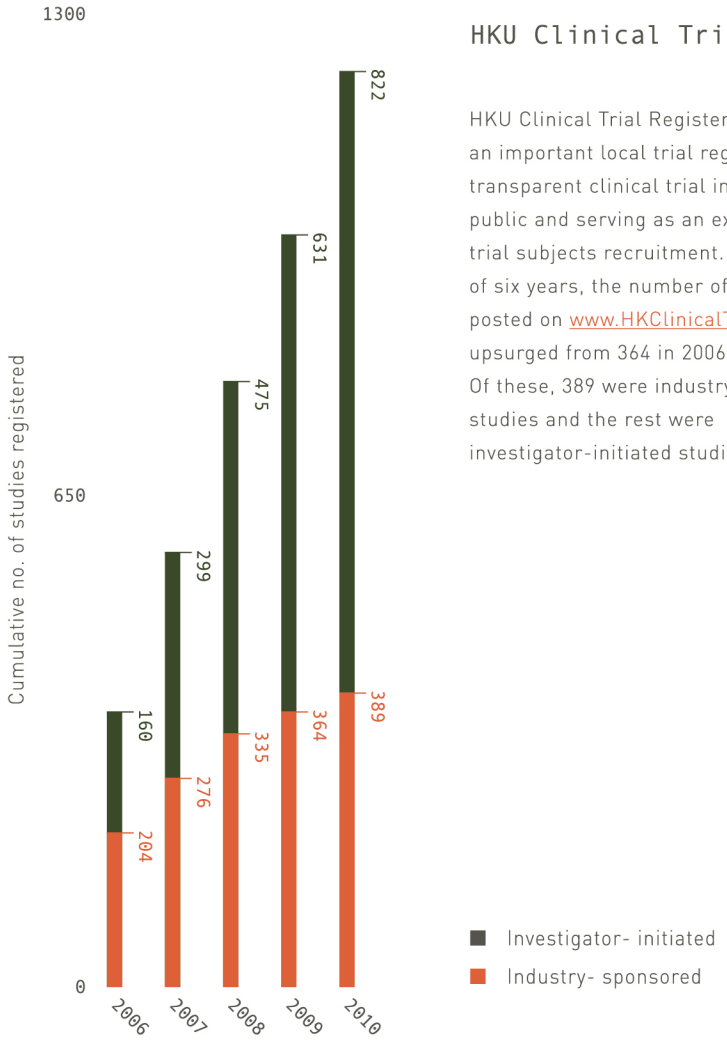
Collaborative trial sponsors

As a leading industry-academic collaboration platform in clinical research in the region, CTC continued to deliver quality service and expertise to its clinical research partners. In 2010, the accumulated number of collaborative trial sponsors reached 97, nine of which initiated their clinical studies through CTC for the first time.

Operating Review & Achievements

Business consultation & feasibility assessments

Over the years, CTC's Business Development Unit has been actively involved in conducting feasibility assessments for the sponsors and contract research organizations worldwide. Its up-to-date investigators database and expert knowledge in the clinical research environment in Hong Kong contributed to the success in feasibility assessments and materialization of clinical studies in Hong Kong. During 2010, 65 feasibility assessments were undertaken by the Business Development Unit and it is expected that the number of feasibility assessments will continue to increase in the years to come.



Clinical studies registered at the HKU Clinical Trial Register

HKU Clinical Trial Register

HKU Clinical Trial Register continued to be an important local trial registry offering transparent clinical trial information to the public and serving as an extra channel for trial subjects recruitment. Over its history of six years, the number of clinical studies posted on www.HKClinicalTrials.com upsurged from 364 in 2006 to 1,211 in 2010. Of these, 389 were industry-sponsored studies and the rest were investigator-initiated studies.

Project coordination

CTC's Project Coordination Unit continued to demonstrate its efficiency and effectiveness in facilitating smooth communications and collaborations between sponsors and study sites in some 250 sponsored clinical studies, including compiling ethics submissions and coordinating the logistical arrangements for every study.

Ethics affairs

During the year, 62 initial ethics submissions were made, whereas subsequent submissions (excluding serious adverse event (SAE) reports) increased by 10% to a total of 3,446. Ascribing to the increasing number of oncology studies in recent years, the number of SAE reports surged by 34% to 22,513. To cater for the rapidly increasing volume of SAE submissions, PEARS — the Platform for Electronic Adverse Reports Submission — was developed during the year and will be launched in 2011. It is anticipated that the SAE reporting process will be greatly streamlined and enhanced.

Submissions to ethics committees per annum

Operating Review & Achievements

Project Operations

Professional clinical study management

CTC's Project Operations Team provides comprehensive one-stop CRO services including protocol development, project management, pre-study site evaluation, regulatory affairs, study set-up, study site monitoring, data management and medical statistics.

In 2010, the Project Operations Team was involved in 21 clinical studies at 37 study sites. Oncology remained the major therapeutic area.

Professional clinical study management services performed during 2010

Therapeutic Area	Study Phase	Protocol Development /Review & Revision	Overall Project Management	Study Monitoring	Regulatory Affairs	Data Management	Medical Statistics
Critical Medicine	I	■	■	■	■	■	■
Endocrinology	III	×	×	■	■	×	×
Endocrinology	D	×	×	■	×	×	×
Gastroenterology & Hepatology	II	■	■	■	■	■	■
Gastroenterology & Hepatology	III	■	■	×	■	■	■
Gastroenterology & Hepatology	IV	×	×	■	×	×	×
Infectious Disease	I	×	×	■	×	×	×
Infectious Disease	II	■	×	×	×	■	■
Neurology	D	×	■	■	×	×	×
Oncology	II	×	■	■	■	■	×
Oncology	II	×	×	■	×	×	×
Oncology	II	×	■	■	■	×	×
Oncology	II	■	×	×	×	■	■
Oncology	III	×	×	■	×	×	×
Oncology	III	×	×	■	×	×	×
Oncology	III	×	×	■	×	×	×
Ophthalmology	II	■	■	■	■	■	■
Orthopaedics & Traumatology	II	×	■	■	×	■	■
Orthopaedics & Traumatology	D	■	■	■	×	■	■
Orthopaedics & Traumatology	D	×	×	■	×	×	×
Urology	O	×	■	■	×	×	×

D: Device Study
O: Observational Study

Comprehensive services

In 2010, the team provided full services in support of five clinical trials. The goal is to support the set up and conduct of the studies in an ethical, accurate, professional and timely manner.

Pre-study

- Protocol development
- Essential documents development (e.g. ICF, subject diary)
- Recruitment strategies planning
- Case report form design and development
- Regulatory submission
- Study procedures manual development
- Study initiation
- Data Safety Monitoring Committee (DSMC) set up
- GCP training to study site personnel

In-study

- On-site study monitoring with source data verification and safety reporting to sponsor
- Keeping track of study progress and reporting to sponsor
- Data transfer to data management team

Post-study

- Study closure
- Facilitating archiving of study site documents
- Submission of final management and monitoring report to sponsor

Project Operations Team

Operating Review & Achievements

Site Operations

Medical Research Clinic

The Medical Research Clinic (MRC) was established in Queen Mary Hospital in 2007 and has been providing site supporting services to investigators participating in global and local clinical trials. With a team of dedicated, full-time and experienced Clinical Research Coordinators (CRCs), the MRC plays a critical role in the following aspects of clinical trials:

- Subject recruitment
- Supporting and coordinating study site activities
- Provision of CRC supports to other hospitals

In 2010, there was an increase in demand for CRC services from study sites in both public and private hospitals in Hong Kong.

In 2009, MRC in collaboration with Dr. Daniel WS Chu, Department of Medicine, Queen Mary Hospital, conducted a phase III multicentre clinical trial of a long-acting neuraminidase inhibitor, laninamivir octanoate vs. oseltamivir (Tamiflu®) for treatment of influenza. The study demonstrated that a single dose of laninamivir octanoate has the same efficacy as a five-day administration of oseltamivir (Tamiflu®). The results of the study were published in Clinical Infectious Diseases in November 2010 (CID 2010: 51(10):1167-1175). Laninamivir octanoate (Inavir®) was launched in 19 October 2010.

Clinical Infectious Diseases 2010: 51(10):1167-1175

MAJOR ARTICLE

Long-Acting Neuraminidase Inhibitor Laninamivir Octanoate versus Oseltamivir for Treatment of Influenza: A Double-Blind, Randomized, Noninferiority Clinical Trial

Akira Watanabe,[1] Shan-Chwen Chang,[3] Min Ja Kim,[4] Daniel Wai-sing Chu,[5] and Yasuo Ohashi[2]; for the MARVEL Study Group[a]

[1]Research Division for Development of Anti-Infective Agents, Institute of Development, Aging and Cancer, Tohoku University, Sendai, [2]Department of Biostatistics, School of Public Health Science, University of Tokyo, Tokyo, Japan; [3]Department of Internal Medicine, National Taiwan University Hospital, Taipei, Taiwan; [4]Division of Infectious Diseases, Korea University Medical Center, Anam Hospital, Seoul, Korea; and [5]Department of Medicine, Queen Mary Hospital, The University of Hong Kong, Hong Kong, China

Operating Review & Achievements

Study Site Services

Study drug management

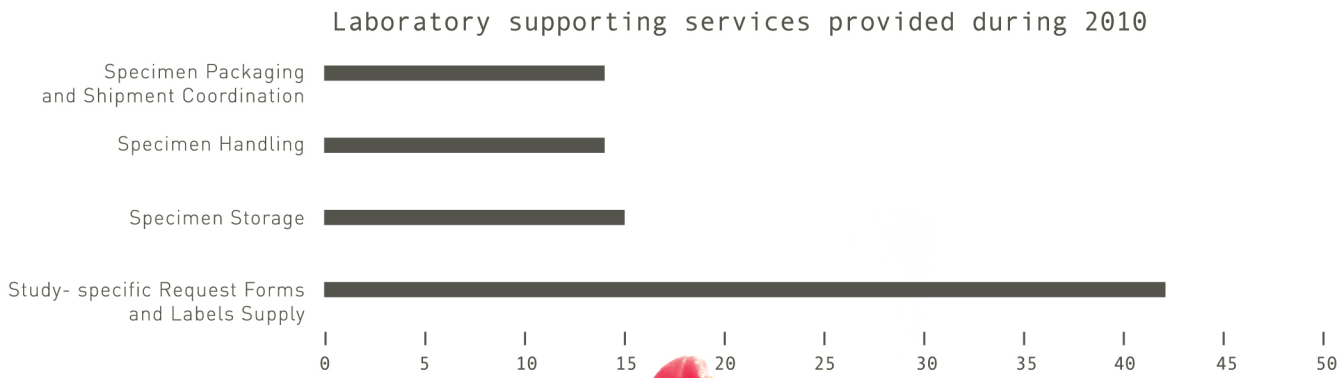
CTC's Study Site Services Team offers study drug management services including drug storage, handling disposal, destruction and accountability in collaboration with the Department of Pharmacy at Queen Mary Hospital. During the year, its services were provided for over 80 clinical studies.

Specimen management

CTC provides a full range of specimen handling, logistics coordination, and storage services supporting study sites. Being a platform among sponsors, study sites and laboratories, it coordinates logistics, resolves enquiries, and facilitates activities between different parties to ensure that all trial samples are processed in compliance with protocols and relevant requirements. All -20°C and -70°C freezers are armed with a central alarm system, which is calibrated and maintained yearly.

Central laboratory

ALab partners with the College of American Pathologists (CAP) accredited laboratories at Queen Mary Hospital to offer comprehensive and high-quality central laboratory services, including project management, specimen analysis, reporting, electronic data capture, and logistics management in support of multicentre clinical studies. During the year, ALab officially set up its central laboratory services for a multicentre clinical study upon the urgent request of the sponsor, and the study was successfully completed with satisfactory outcomes.



Operating Review & Achievements

Data Management & Medical Statistics

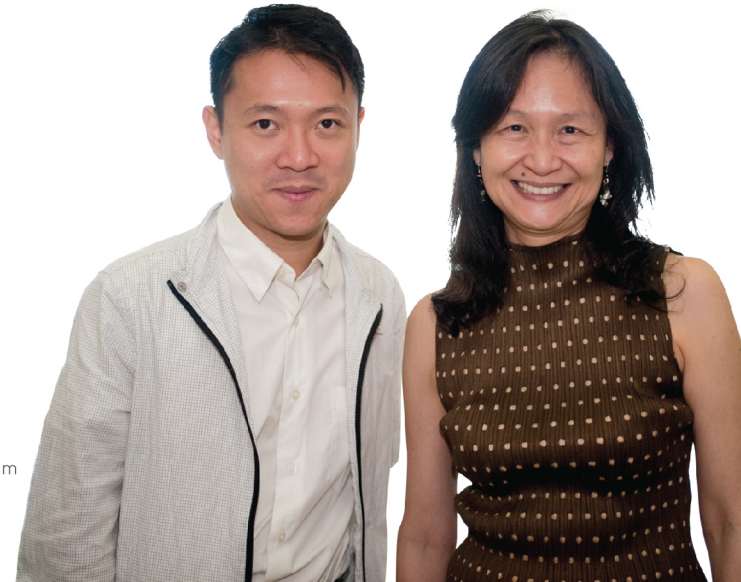
CTC's Data Management & Medical Statistics Team offers consultation and support to both industry-sponsored and investigator-initiated clinical studies.

For data management, the team provides services including database development and validation, edit checks and self-evident corrections, data collection, data cleaning and query management.

For medical statistics, the team provides services such as clinical study design, research grant applications, research consultation, study protocol review and development, case report form design, randomization list generation, sample size estimation, statistical analysis, and clinical study report and manuscript writing.

In 2010, the team developed a data validation program, a document tracking system and an automated error correction system to assure data quality. The team has also been improving the data management procedures and design of data entry database.

In the coming year, it is expected that the demand for the services will continue to be strong.



Data Management & Medical Statisitics Team

Operating Review & Achievements

Education & Publication

Education

In line with the trend toward globalization and the demand for practical educational courses in clinical research, CTC upgraded the curriculum for its specialized module under the Master of Public Health program during the 2010/11 academic year.

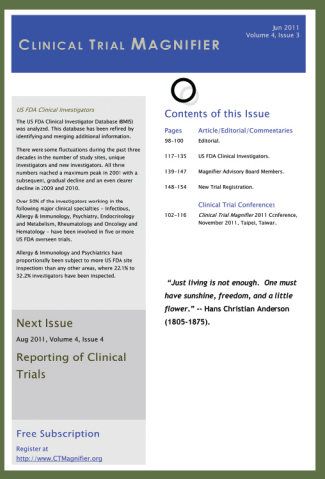
The new module, under the name of "Introduction to Clinical Trials: Science, Design Features, Ethics and Regulations," targets candidates who are involved in or preparing to take part in the clinical research industry. The program offers a systematic framework to help candidates grasp the essence of contemporary clinical research, including Good Clinical Practice (GCP), human research protection, and regulatory requirements as well as the science, features, and quality of clinical research.

Introduction to Clinical Trials: Science, Design Features, Ethics & Regulations

- Ethics and Bioethics
- Clinical Trials in the Context of Biomedical Research
- Clinical Trial Players and Their Responsibilities
- Declaration of Helsinki
- ICH Good Clinical Practice (GCP)
- Features of Clinical Trials
- Science of Clinical Trials
- Protocol Development
- Ethics of Clinical Trials
- Quality of Clinical Trials
- Legal and Contractual Issues
- Local Regulations and Guidelines

Publications

The Clinical Trial Magnifier (CTM) was established in January, 2008 as a free online newsletter on issues related to clinical trials, with special emphasis on the globalization of clinical research. CTM is currently published bi-monthly, with a growing reader base from academia, healthcare, government organizations, and pharmaceutical and biotech industries. Free registration is available on the CTM homepage at www.ClinicalTrialMagnifier.com.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Clinical Trial Conferences

102-116 *Clinical Trial Magnifier* 2011 Conference, November 2011, Taipei, Taiwan.

"Just living is not enough. One must have sunshine, freedom, and a little flower." -- Hans Christian Anderson (1805-1875).

US FDA Clinical Investigators

The US FDA Clinical Investigator Database (BMIS) was analyzed. This database has been refined by identifying and merging additional information.

There were some fluctuations during the past three decades in the number of study sites, unique investigators and new investigators. All three numbers reached a maximum peak in 2001 with a subsequent, gradual decline and an even clearer decline in 2009 and 2010.

Over 50% of the investigators working in the following major clinical specialties - Infectious, Allergy & Immunology, Psychiatry, Endocrinology and Metabolism, Rheumatology and Oncology and Hematology - have been involved in five or more US FDA overseen trials.

Allergy & Immunology and Psychiatrics have proportionally been subject to more US FDA site inspection than any other areas, where 22.1% to 32.2% investigators have been inspected.

Next Issue

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Reporting of Clinical Trials

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Feature Interviews

What elements do you think are essential to the success of a clinical trial?

I think trust, experience, and team spirit are the elements essential to the success of a clinical trial.

Feature Interviews:
Clinical Research in Therapeutic Areas Accredited by State Food & Drugs Administration

When did you start conducting clinical trials?
I started conducting clinical trials about 15 years ago. I was inspired by the satisfaction in obtaining the most updated information and technology. In particular, I have the opportunity to apply those clinical findings to my clinical practice in order to maximize the benefit to my patients.

What initial difficulties have you encountered when conducting clinical trials? What are the differences between conducting clinical trials today versus the past?
Initially, most of my trials were investigator-initiated clinical studies that involved protocol preparation, IRB submission, data collection, and analysis. I encountered a lack of experience and resources and insufficient knowledge at that time. Nowadays, many industries have placed much effort on the research and development divisions, thus more trials can be sponsored by them. As a result, more resources and more up-to-date information and knowledge can be obtained. In particular, experience can also be shared with other investigators through the investigators' meetings for multi-centre trials.

What elements do you think are essential to the success of a clinical trial?
I think trust, experience, and team spirit are the elements essential to the success of a clinical trial. Firstly, there must be mutual trust between the research team and trial patients. As no one knows the actual outcomes of the trials, patients will only tell the truth of the effects and side effects of the investigational products to people they trust. Secondly, an experienced research team will facilitate the process of conducting the trials, e.g., protocol preparation, IRB submission, data collection, and analysis. Finally, team spirit among the research members will further ensure the trials are in compliance with the Good Clinical Practice.

Which of your publications in scientific journals arising from clinical research are you most proud of? Why and in what aspects do you think it is significant?
I am most proud of "Angiogenesis in ischaemic myocardium by intramyocardial autologous bone marrow mononuclear cell implantation" (TSE HF, Kwong YL, Chan JK, Lo G, Ho CL, Lau CP, Lancet 2003; 361:47-49). We could apply the notion from the result of experimental studies on eight patients with severe ischaemic disease. Most of the trial patients are still alive with improved symptoms, improved myocardial perfusion and function, and improved quality of life.

In comparison with other Asian areas, what are the advantages of conducting clinical trials in Hong Kong?
Due to its historical background, Hong Kong is an amalgamation of both Eastern and Western culture. As compared with other Asian areas, Hong Kong people are more open-minded to the concept of clinical research. More people would like to participate in clinical research, including patients, doctors, and nurses. As a result, more clinical trials can be carried out in Hong Kong versus other Asian areas.

What advice can you give to the new clinical investigators for their involvement in clinical research?
I think passion and initiation are important elements for new clinical investigators. New investigators must have the passion to learn from experienced investigators, review all the related literature in order to prepare the appropriate protocol, and maintain good relationship among trial patients and team members to establish mutual trust.

Prof. Tse Hung Fat
Department of Medicine

What inspired your involvement in clinical trials?
Shortly after I completed my post graduate specialist training in Anaesthesiology, when I was undertaking a rotation at the Paediatric Hospital in Glasgow, Scotland, I was inspired by the "research culture" within that department. Although they had a very high standard of clinical practice, they were always thinking of innovations and ways to improve. I found research to be intellectually stimulating, which made my everyday clinical practice more interesting.

What challenges do you see in conducting clinical trials nowadays?
The increasing amount of bureaucracy and administration involved in conducting trials is a current challenge. IRB approval is more complicated. Industry-sponsored trials require even more rigorous record keeping, and early phase trials involve close monitoring of potential adverse events.

Why do you think Hong Kong is a good place to conduct clinical trials?
Hong Kong has an established research infrastructure, e.g., CTC support. We also have researchers with more experience and knowledge of GCP.

What advice can you give to the new clinical investigators for their involvement in clinical research?
Learning clinical research can be difficult and frustrating to start with but is ultimately very rewarding. Familiarize yourselves with GCP and always keep these principles in your work. Speak to and learn from more experienced colleagues. Attend scientific congresses and investigator meetings. Get involved with industry sponsored research as this is an extremely useful way to learn.

From your point of view, is clinical research of any significance to the general public?
Ultimately the objective of clinical research should be to improve clinical practice and the quality of healthcare. Even small steps will do this. These improvements may not always be quantum changes but the general improvements are certainly tangible when you compare our ability to treat illness, increase duration and quality of life compared to even just 10 years ago.

In your opinion, how could Hong Kong collaborate with mainland China in clinical research?
We have undertaken accreditation by the China SFDA and other departments should be encouraged and assisted in this process. As a department, we have also developed strong research and clinical links with a number of mainland Chinese hospitals and universities e.g. we have fellowship training posts, visiting lectureships, postgraduate students and joint symposia. It is often easier to start with basic science research collaboration. Clinical research is certainly feasible, and we have done this successfully — where we wrote protocols and assisted in IRB applications and while our Chinese partners recruited their patients. We then assisted with writing the manuscripts, which resulted in English language publications.

Prof. Michael Irwin
Department of Anaesthesiology

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2010

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Cardiovasculology	Cardiovascular Disease	IV	Professor Stephen WL Lee	Medicine
Cardiovasculology	Chronic Heart Failure	III	Professor HF Tse	Medicine
Cardiovasculology	Coronary Artery Disease	III	Dr. Kathy LF Lee	Medicine
Cardiovasculology	Heart Failure	III	Professor HF Tse	Medicine
Cardiovasculology	Heart Failure	N/A	Professor HF Tse	Medicine
Cardiovasculology	Implantable Cardioverter Defibrillator	N/A	Dr. HW Chan	Medicine
Cardiovasculology	Ischemic Heart Disease	IV	Professor Stephen WL Lee	Medicine
Cardiovasculology	Thrombosis	III	Dr. David CW Siu	Medicine
Dermatology	Psoriasis	III	Dr. CK Yeung	Medicine
Dermatology	Psoriasis	III	Dr. CK Yeung	Medicine
Endocrinology	Diabetes Mellitus	III	Professor Kathryn CB Tan	Medicine
Endocrinology	Diabetes Mellitus	III	Professor Kathryn CB Tan	Medicine
Endocrinology	Diabetes Mellitus	IV	Professor Kathryn CB Tan	Medicine
Gastroenterology & Hepatology	Familiar Adenomatous Polyposis	III	Dr. James CM Ho	Medicine
Gastroenterology & Hepatology	Hepatitis B	II	Professor CL Lai	Medicine
Gastroenterology & Hepatology	Liver Fibrosis	II	Professor CL Lai	Medicine
Geriatrics	Alzheimer's Disease	II	Professor LW Chu	Medicine
Haematology	Myelodysplastic Syndromes	II	Professor YL Kwong	Medicine
Haematology	Hemophilia B	III	Professor Godfrey CF Chan	Paediatrics & Adolescent Medicine
Infectious Disease	Candidiasis	III	Dr. SY Ha	Paediatrics & Adolescent Medicine

* N/A: Studies not classified as Phase I, II, III or IV studies, such as medical device, observational, epidemiology and compassionate studies.

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Nephrology	Primary Glomerular Disease or Nephrosclerosis	III	Professor KN Lai	Medicine
Neurology	Stroke	N/A	Professor Raymond TF Cheung	Medicine
Obstetrics & Gynaecology	Human Papillomavirus Infection	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Oncology	Breast Cancer	II	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery
Oncology	Breast Cancer	N/A	Dr. Janice WH Tsang	Clinical Oncology
Oncology	Leukemia	III	Dr. Eric WC Tse	Medicine
Oncology	Gastric Cancer	III	Professor KM Chu	Surgery
Oncology	Leukemia	I	Professor YL Kwong	Medicine
Oncology	Liver Cancer	I	Dr. Philip WK Kwong	Clinical Oncology
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	III	Professor MF Yuen	Medicine
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery
Oncology	Lung Cancer	II	Dr. James CM Ho	Medicine
Oncology	Lung Cancer	II	Dr. James CM Ho	Medicine
Oncology	Lung Cancer	II	Dr. Victor HF Lee	Clinical Oncology
Oncology	Lung Cancer	III	Dr. David CL Lam	Medicine
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine

* N/A: Studies not classified as Phase I, II, III or IV studies, such as medical device, observational, epidemiology and compassionate studies.

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2010

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department
Oncology	Lung Cancer	III	Dr. Victor HF Lee	Clinical Oncology
Oncology	Lung Cancer	N/A	Dr. Victor HF Lee	Clinical Oncology
Oncology	Multiple Myeloma	III	Dr. CS Chim	Medicine
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Oncology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology
Oncology	Refractory Solid Tumors	I	Dr. Thomas CC Yau	Medicine
Orthopaedics & Traumatology	Fracture Healing	II	Dr. Frankie KL Leung	Orthopaedics & Traumatology
Orthopaedics & Traumatology	Fresh Unilateral Intertrochanteric Fracture	II	Dr. Frankie KL Leung	Orthopaedics & Traumatology
Orthopaedics & Traumatology	Trauma	N/A	Dr. Frankie KL Leung	Orthopaedics & Traumatology
Rheumatology	Rheumatoid Arthritis	III	Professor CS Lau	Medicine

* N/A: Studies not classified as Phase I, II, III or IV studies, such as medical device, observational, epidemiology and compassionate studies.

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