2008
Annual Report

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

Ten years on the road

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 organisation 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 competencies 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 both industry-sponsored and investigator-initiated clinical studies.

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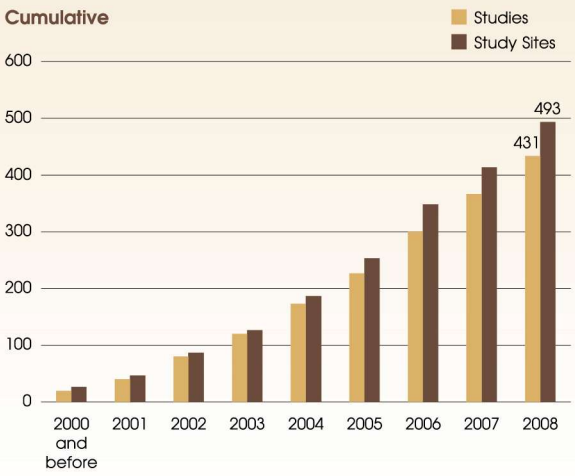
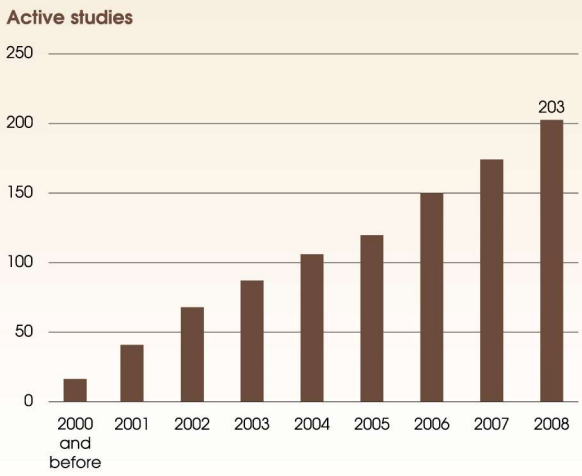
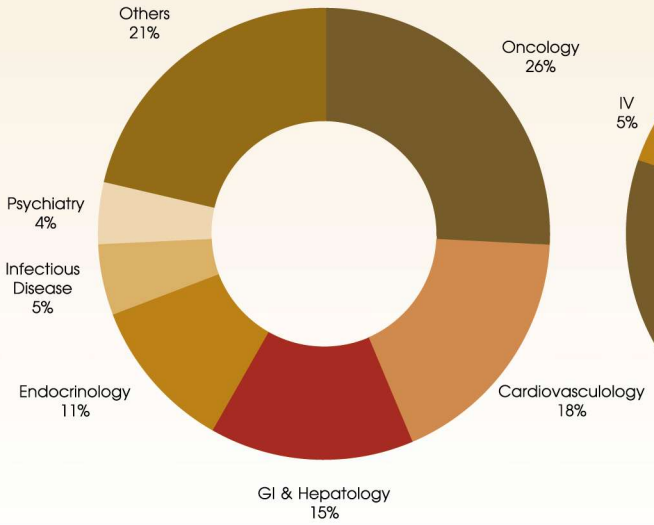


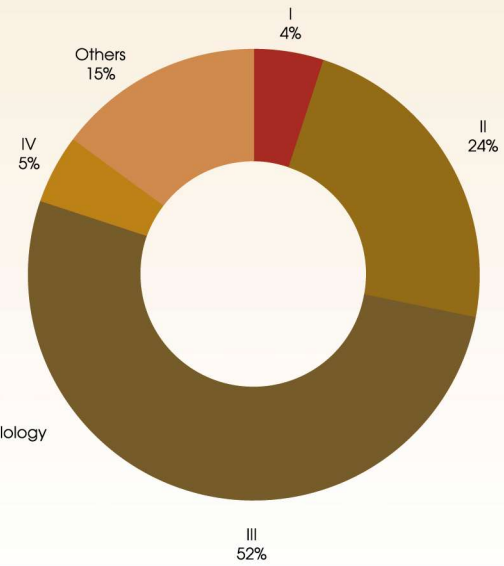


Types of clinical studies (all years)

By research area



By study phase



Collaborative trial sponsors

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

Year	10-year milestones
1998	• Establishment of CTC.
1999	• Launch of the Master of Medical Sciences Programme in Clinical Trials Research Methodology and in Medical Statistics.
2000	• Organised the first Drug Information Association (DIA) meeting in Hong Kong.
2001	• Facilitated development of a standard indemnity agreement for clinical trials applicable to all study sites in Hong Kong.
2002	• Establishment of the CTC Board of Directors.
2003	• Accreditation of CTC's affiliated clinical laboratories at Queen Mary Hospital by the College of American Pathologists (CAP). • Establishment of strategic alliance with UK-based international central laboratory services provider, CentraLabS Clinical Research Limited, which fosters a global laboratory network supporting multinational, multicentre clinical studies. • Facilitated reorganisation of the ethics committees of the Hong Kong Hospital Authority, advising on development of standard operating procedures and organising training programmes for committee members. • Publication of the first CTC annual report.

Year	10-year milestones
2004	• Launch of ClinCluster, a multicentre clinical study coordination platform. • Establishment of the HKU Spinal Cord Injury Fund. • Launch of the Master of Public Health (MPH) programme in Clinical Trials Research Methodology and in Medical Statistics, in collaboration with the HKU Department of Community Medicine.
2005	• Launch of the HKU Clinical Trial Register - the first public clinical trial register in Hong Kong. • Launch of AccreditGCP - the online GCP training and accreditation programme.
2006	• Approval by the China State Food and Drug Administration (SFDA) as a recognised institution for conducting clinical trials in seven therapeutic areas for new drug registration purposes in mainland China. • Establishment of the Early Clinical Development Centre (ECDC) with Wyeth.
2007	• Establishment of the Medical Research Clinic.
2008	• Launch of *Clinical Trial Magnifier* - a monthly online newsletter focusing on global and Asian trends and development of clinical research activities.

Message from the Director

What is driving the globalisation process of clinical research?

Access to study subjects

Since the launch of the ICH GCP Guideline in 1997, we have seen a steady, uninterrupted globalisation of industry sponsored clinical trials. Today, 20% of all trials are global in nature, involving both established and emerging clinical trial regions. Those trials are predominantly phase III with large sample sizes. Although only a fifth of all industry sponsored trials are global, they account for half of all study sites and a third of all subjects for recruitment. The ongoing trend is that an increasing proportion of all trials – and not just phase III – are involving study sites in emerging regions, as more and more rapidly drift from established regions.

Debate addressing reasons for this globalisation process is ongoing. Familiar comments include: "It is less expensive to conduct trials in emerging regions"; "There are much more patients available in emerging regions"; "The potential market is large in emerging regions"; "Investigators in established regions are fatigued"; "Investigators in emerging regions are more responsive and recruit more patients, and in a shorter time"; "Regulations are too complicated in established regions".

What is becoming clearer is that the industry has problems in finding enough patients in the established regions, which risks significantly delaying marketing approval for new medical products and thus cuts potential revenue until the patent period comes to an end. My understanding is that this is the main reason for going global.

Over the past two years the number of cancer trials and sites has proportionately increased by about twice as much as all other therapeutic areas combined. Oncology today accounts for 21% of all industry sponsored trials and 21% of all sites. Oncology trials are also more global in nature; for instance, 46% of oncology phase III trial sites are global, compared to 32% in all other therapeutic areas. The corresponding subjects for recruitment are 38% and 28%, respectively. The industry faces strong competition to identify cancer trial subjects, not just from its own industrial competitors, but also from very popular investigator-initiated oncology trials. Industry sponsored oncology trials are for these reasons more globalised than other therapeutic area trials, underlining the reason for the industry's globalisation trend.

Study site cost

I have recently listened to two excellent presentations – one in Thailand, the other in Hong Kong – delivered by senior staff of large international contract research organisations. The general message was that it is less expensive to conduct clinical trials in emerging regions, but not necessarily because the unit cost is lower at study site level. The main reason is that the investment produces a better return. About 30% of study sites in established industry sponsored trial regions are "zero" sites, i.e. they do not produce a single study subject. The cost for setting up a site is the same, independently of the number of subjects to eventually be recruited. Emerging countries have a lower percentage of "zero" sites. However, the expense of opening sites that do not enroll patients is a relatively poor investment, since there is still much administrative work involved. Personnel from the sponsor/CRO still have to travel to and from the site. The administrative cost of opening a site in the US is not less than US$10,000.

Sites in emerging countries are also producing more subjects per site: "On average a US site delivers seven patients, compared with 11 in East Europe," we were told. This higher efficiency, with fewer "zero" sites and more subjects per site reported from emerging regions, is thus one rationale behind a lower per-patient cost, and not really due to the investigator fees. Here is a simplified example: assume that a phase III trial targets 770 study subjects. Under the assumption that each site in an established region produces on average seven subjects, that 30% of the sites are "zero" sites, and that the set up cost is US$10,000 per site, the total set up cost will be US$1.57 million. But the set up cost in an emerging region will be about half that, or about US$0.78 million, assuming 11 subjects per site, 10% "zero" sites and a set up cost of US$10,000 per site. This difference, which only compares site set up costs, represents a difference of about US$1,000 per trial subject.

How are sites identified and selected?

According to the two recent presentations, 50% of investigators are new to industry sponsored clinical trial activities. This means that the rapid turnaround among investigators is much higher than anticipated; and that only a few investigators stay in the industry sponsored trial arena for very long. Selection made on previous performance and experiences is clearly more important than any other selection criteria, especially if the site has performed above averagely. A better return on investment is therefore likely if the sponsor can identify a well performing, experienced investigator – a "super site", if you like – than utilising a novice investigator needing extra support, training and new staff employment, which may in turn end up being one of the many "zero" sites.

Keeping investigators in the business must therefore be one of the most important issues to address – both for sponsors, investigative sites, and site / research management organisations. We have not found any survey addressing why investigators are hesitant to conduct more than one industry sponsored trial in a lifetime. A published survey showed that the most important incentives to accept trial participation are: (1) access to new treatments, (2) advancement of scientific knowledge, (3) scientific/academic merit, (4) financial support to staff, and (5) scientific publication. The most important investigator incentives to refuse trial participation are: (1) low budget, (2) limited support staff, (3) poor contract terms, (4) insufficient time, and (5) adverse event concerns.

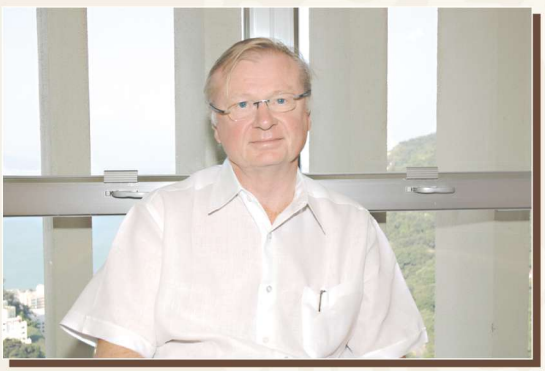
In this respect, we have addressed most of those crucial incentive issues. For instance, we have set up meetings between key researchers in the industry and our clinical investigators, to exchange scientific knowledge, develop good contract and budget terms, and release investigators from administrative matters such as contract and budget development, compilation of IRB applications and adverse event reports to IRBs. In fact, among close to 500 industry sponsored trials that our University has contracted over the past 10 years, only 10 have not been able to deliver a single study subject – and only around 10% of the investigators in any year have been novices to industry-sponsored trials.

We have seen a steady stream of new industry-sponsored trials, presently increasing by 15% annually with about 70 new trials a year. However, despite our performance and good track record, we have lately noticed that more and more countries and cities in Asia are getting more and more involved in clinical trials, and that Hong Kong is no longer seen as a most favoured location. Both Singapore and Hong Kong used to be leading regional site suppliers to the international industry. But now they have been by-passed not only by India, South Korea, Taiwan and China, but lately also by the Philippines, Thailand and Malaysia. What we have heard from the industry is that a new and very important site selection criterion has evolved, namely the number of sites that a country or city can provide for one and the same protocol. This number is highly correlated to the investment per subject delivered. Singapore and Hong Kong delivers on average 1.5 sites per protocol while the four BRIC countries – Brazil, Russia, India and China – deliver 10 sites on average per protocol. We know that protocols have left Hong Kong for other places because only one or two sites could be identified.

What can a small location like Hong Kong, with a relatively small population of seven million, do to become more attractive as a preferred clinical trial location? After all, we should seek more collaboration with the clinical research industry, since this is an important business and educational sector for a modern society. My wish is for an administrative trial organisation serving the whole of Hong Kong – and involving neighbouring health care institutions in Southern China. China will eventually – whether in one year or ten – open up for multi-national clinical trials. As one Hong Kong industry representative noted: "We must be prepared for that day, when we will have to do it in the way they prefer across the border and not our way." Hong Kong is a Chinese city heavily involved in industrial and other developments in Southern China, so why not clinical research?

A Decade of Achievement

CTC was established ten years ago and we should be happy and proud of what we have achieved over the past decade. That is not the same as being content and complacent. We are currently working on our third international clinical trial conference in Hong Kong, in November 2009, and so far we have over a hundred participants signed up. Another challenge is that we have been commissioned by Pfizer in New York to write an educational booklet for Ethics Committee members worldwide, providing a guideline for reviewing clinical trial proposals. Pfizer has provided an unconditional grant for the project and Dr. Marjory Speers, President and CEO of the Association for the Accreditation of Human Research Protection Programs in the US, is currently working with me to establish a core group of advisors for it. Of course, the ongoing globalisation process of clinical research is the driving force behind this educational need, since industry sponsored clinical research generally comes with a much higher risk, especially for early phase trials.



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Organisational 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

- Medical Research Clinic Operation
- Subject Recruitment
- Study Drug Management
- Specimen Management
- Central Laboratory Management

Project Operation Team

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

Data Management & Medical Statistics Team

- Medical Statistics
- Data Management
- Research Consultation

General Affairs

Information Technology

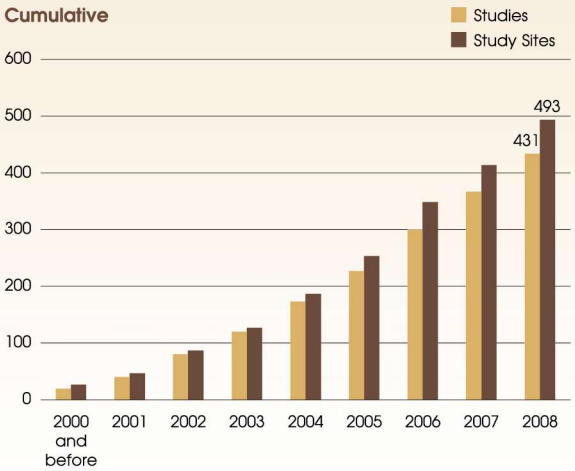
Operating Review & Achievements

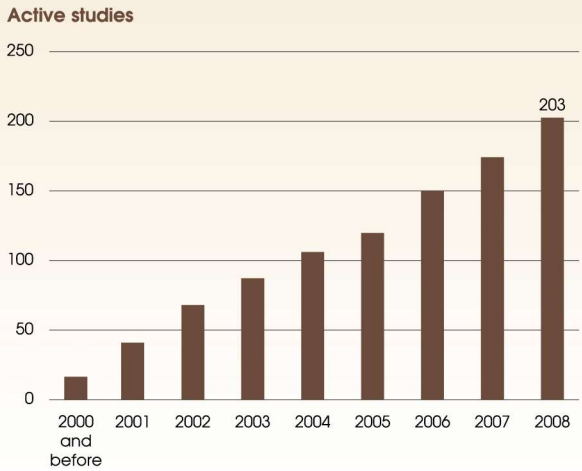
Business & Project Acceleration

Industry-sponsored clinical studies

There were 60 new clinical studies contracted in 2008, taking the cumulative number of contracted clinical studies over the past decade to 431. By end of the year, there were 203 active studies. Considering the globalisation trend, it is envisaged the number of research contracts will continue to increase.

Contracted clinical studies and study sites

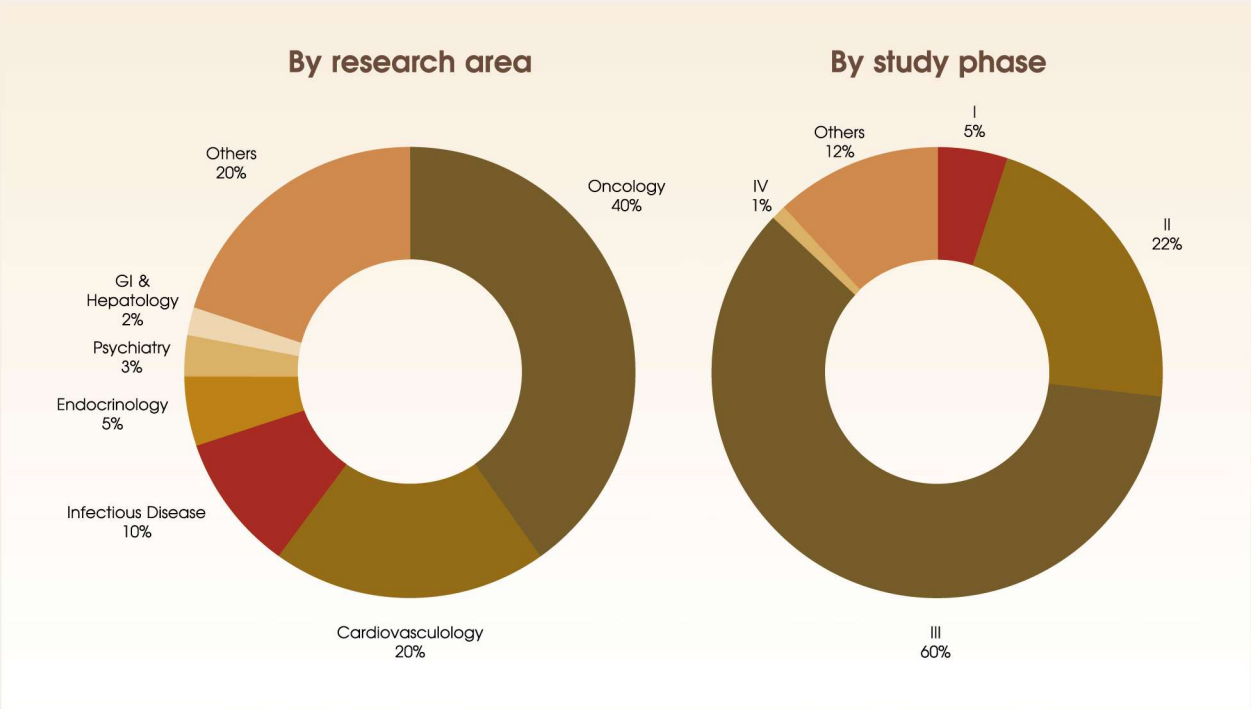




Study area and study phase

During the year, among the 60 newly contracted clinical studies, oncology and cardiovasculology accounted for 40% and 20% respectively. Notably, oncology studies increased by two-thirds from last year. Although there was variation in terms of research area, the distribution of clinical studies by study phase remained steady – with phase II and III studies together comprising 82% of all newly contracted clinical studies in the year.

Types of clinical studies in 2008



Collaborative trial sponsors

With rising demand for study sites with a high level of expertise and quality, CTC continues to be recognised as one of the region's leading industry-academic collaboration platforms in clinical research. In 2008, nine sponsors initiated clinical studies through CTC for their first time, lifting the accumulated number of collaborative trial sponsors to 83.

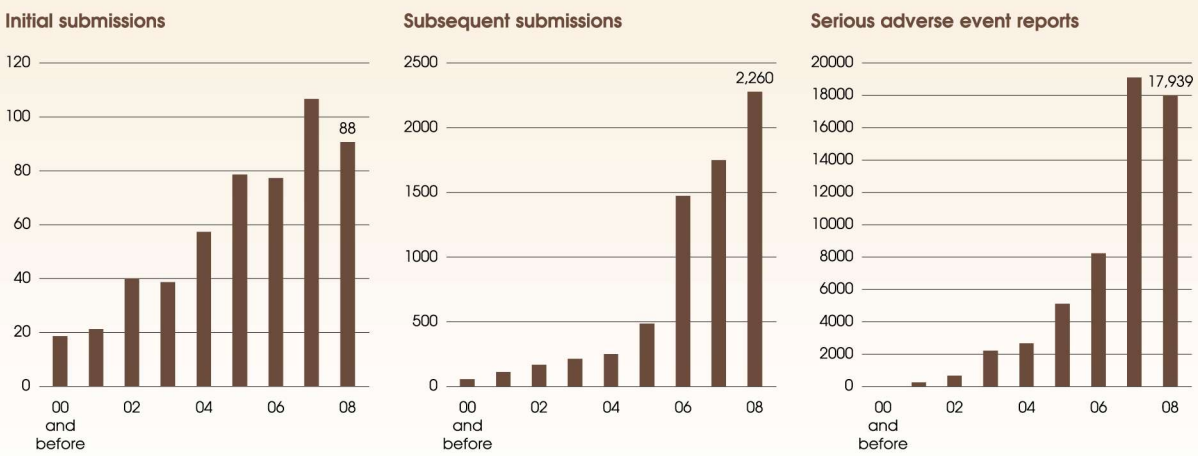
Business solutions and feasibility assessments

CTC's Business and Project Acceleration Team is dedicated to providing creative, cost-effective and expert solutions fulfilling the clinical development needs and expectations of sponsors, investigators and contract research organisations. With an extensive network of study sites and investigators, as well as excellent trouble-shooting and problem-solving capabilities, we play an active role in conducting feasibility assessments for clinical studies. The total number of feasibility assessments undertaken by the end of 2008 reached 42.

Ethics affairs

Rapidly accelerating global clinical research activity and increasingly stringent requirement for high quality and swift ethics submissions boosted demand for CTC's ethics affairs services. While the number of initial submissions remained constant at 88, subsequent submissions (excluding serious adverse event reports) jumped 32% to a total of 2,260 for the year. The continuing dominance of oncology studies kept the number of serious adverse event report submissions at a high level of 17,939, comparable to last year.

Submissions to ethics committees per annum



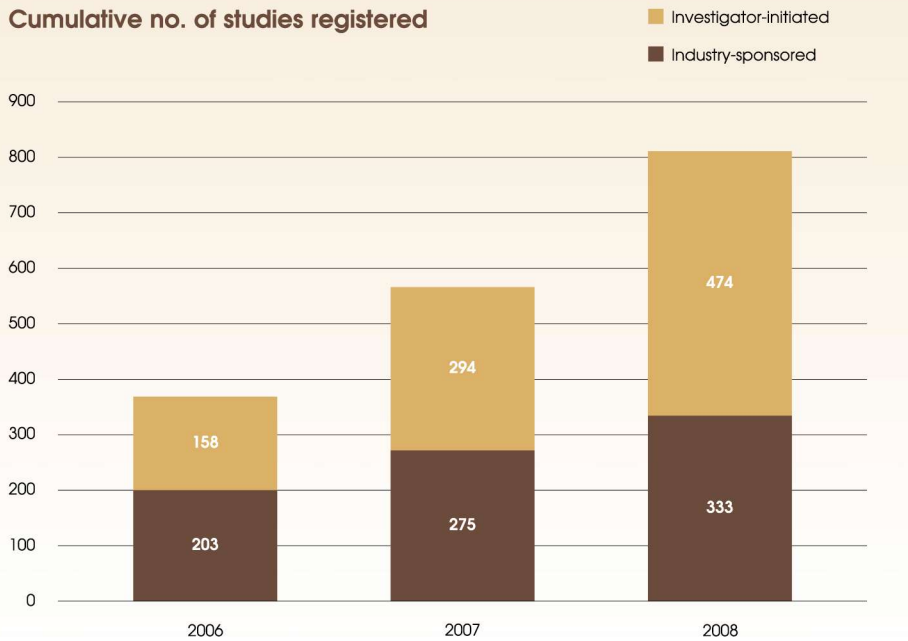
Project coordination

Efficient and effective communication among different parties – such as sponsors, investigators, pharmacies, clinical laboratories, imaging centres and contract research organisations – is essential for the smooth conduct of clinical trials. At CTC, each clinical study is closely followed by a designated Project Coordinator who helps link up the relevant parties, keeping track of project milestones and timelines and making logistical arrangements to assure that each study is performed in compliance with its study protocol and applicable requirements.

HKU Clinical Trial Register

The HKU Clinical Trial Register provides a transparent, public platform for individuals from the local and international communities who are interested in clinical research activities in Hong Kong. It has gained in popularity since its launch in 2005. By the end of 2008, 807 clinical studies were posted on the register, 41% more than last year. Of these, 333 were industry-sponsored studies and 474 investigator-initiated studies.

Clinical studies registered at the HKU Clinical Trial Register



Operating Review & Achievements

Study Site Services

Medical Research Clinic

As design and logistics of clinical studies become more and more sophisticated, CTC's Medical Research Clinic (MRC) provides specialised infrastructure dedicated to serving as a multi-functional platform for conducting clinical studies. It provides a broad range of study site supporting services including pre-study training, study logistics planning and arrangement, subject pre-screening, subject recruitment, study visits scheduling and subject follow up. MRC has a proven, successful track record providing professional support for investigators and study teams.

Subject recruitment

Subject recruitment is one of the most critical and time consuming processes in clinical studies. CTC's Study Site Services Team formulates and implements customised recruitment strategies for individual studies, and is experienced in recruiting subjects for various kinds of clinical studies.

Study drug management

In collaboration with the pharmacy department of Queen Mary Hospital, CTC's Study Site Services Team provides a range of drug management services including storage, repackaging, handling, accountability, dispensing and disposal of drugs for clinical studies conducted at HKU and other study sites in Hong Kong.

Specimen management

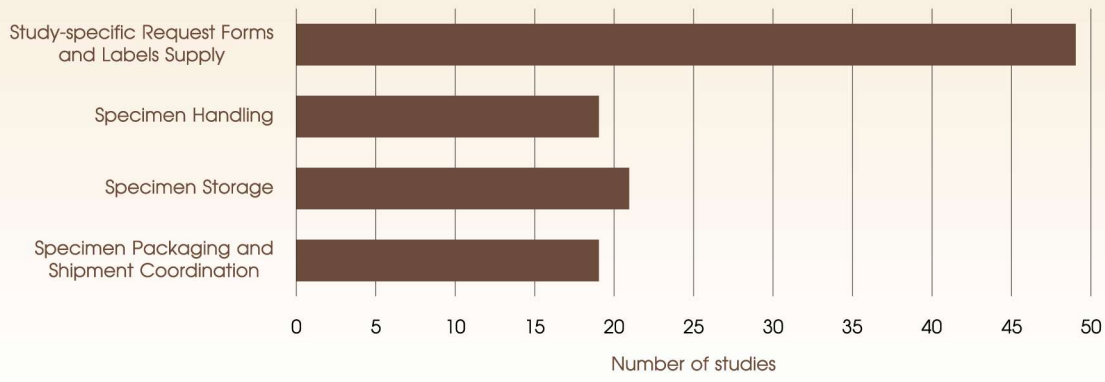
Quality of specimens is paramount to the success of clinical studies. CTC's Study Site Services Team provides a full range of clinical trial specimen management services, facilitating proper and expedited collection, labeling, handling, packaging, transportation, storage and tracking of trial specimens.

Central laboratory

With an increasing number of multicentre clinical studies in Hong Kong and surrounding areas, the presence of a central laboratory platform with standardised and efficient services is essential. ALab is CTC's clinical study central laboratory platform, with affiliated laboratories fully accredited by the College of American Pathologists (CAP). Staffed by 250 laboratory professionals, ALab offers comprehensive project management, outstanding analytical and specimen management capabilities, full logistics support, advanced data management and multi-level quality assurance. ALab's professionalism and Hong Kong location advantages make it an ideal and popular central laboratory platform supporting regional clinical studies in Asia.

ALab

Laboratory supporting services provided during 2008



Operating Review & Achievements

Project Operation

Comprehensive and professional clinical study management services

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

In 2008, CTC's Project Operation Team coordinated 17 clinical studies at 29 study sites. The number of trial subjects monitored increased by 44% from last year.

Professional clinical study management services performed or planned during 2008

Therapeutic Area	Study Phase	Services				
		Overall Project Management	Protocol Development/ Review & Revision	Regulatory Affairs	Study Monitoring	Data Management & Medical Statistics
Aging	II	■	■		■	■
Critical Medicine	O*	■	■		■	■
Critical Medicine	I	■	■	■	■	■
Gastroenterology & Hepatology	I	■	■			
Gastroenterology & Hepatology	II	■	■	■		■
Gastroenterology & Hepatology	II	■	■	■	■	■
Infection	III	■		■	■	
Infection	D*				■	
Infection	D*				■	
Neurology	II	■	■		■	■
Oncology	I	■		■	■	■
Oncology	I			■	■	
Oncology	II				■	
Oncology	III	■		■	■	
Orthopaedics	I	■	■	■	■	■
Orthopaedics	I		■			
Orthopaedics	I/II	■	■		■	■

* O: Observational study
* D: Device study

Influenza trials

Influenza has been a major public concern in recent years, with several clinical studies conducted in Hong Kong. In a multicentre phase III clinical study of an anti-influenza agent, CTC was designated by the sponsor to set up, manage and monitor all study sites in Hong Kong. The clinical study was successfully established and initiated at seven study sites and seven referral sites in a very short period of time.

Early phase proof-of-concept trials

In line with the prevailing trend of clinical drug development, CTC has extended its professional clinical study management services to early phase clinical studies, with a phase Ib clinical study of an investigational biological product conducted in Queen Mary Hospital in 2008. CTC was designated by the sponsor to provide full services from protocol review and regulatory affairs to project management, monitoring, data management and statistical analysis.

No. of trial subjects monitored in 2008: 469
No. of study visits monitored in 2008: 1,678

Operating Review & Achievements

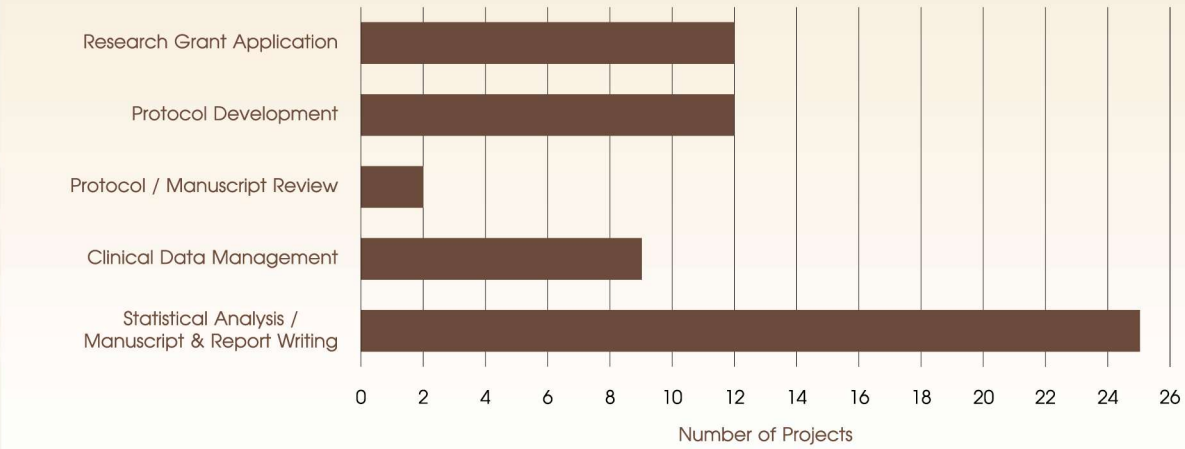
Data Management & Medical Statistics

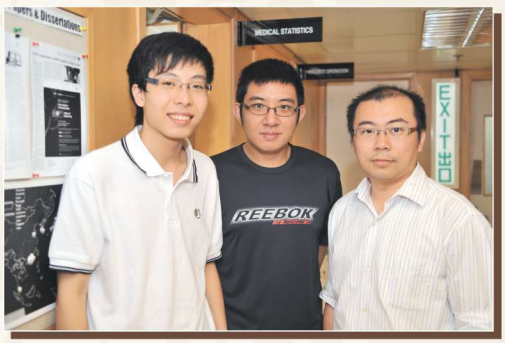
Data quality is of a primary concern to trial sponsors and investigators. CTC's Data Management & Medical Statistics Team is experienced in a wide range of therapeutic areas, delivering high quality and reliable data speeding up the entire clinical development process.

In 2008, the team continued to provide a full range of data management services including randomisation list generation, database development, data entry, data cleaning and data verification.

The team also provides medical statistics services including protocol development, statistical analysis and manuscript review. Demand for these services has been strong and feedback from sponsors and investigators has been very positive.

Data management and medical statistics supports and services provided in 2008

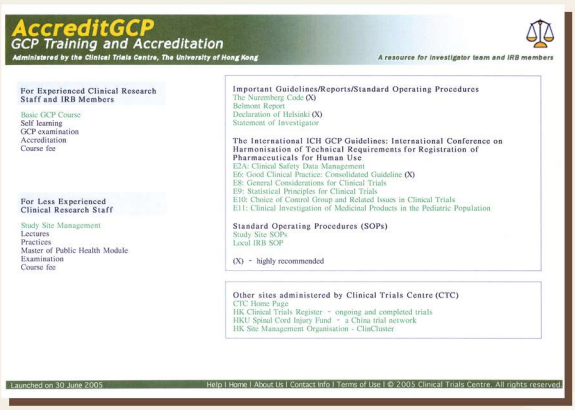




Quality Assurance & Education

AccreditGCP and GCP accreditation test

AccreditGCP – CTC's online GCP training programme – has become renowned since its introduction in mid-2005. In 2008, a total of 53 GCP accreditation certificates were issued to candidates who utilised AccreditGCP for their training.




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

This is to certify that

CHAN Tai-Man

having successfully passed
the required test on 28th Day of April 2007
and has been awarded the

Certificate in Good Clinical Practice

Professor Johan Karlberg
Director
Clinical Trials Centre

Professor Annie Kung
Chairman, Board of Directors
Clinical Trials Centre

Certificate of Accreditation for successful participants

Education

As an active player in clinical trial management, CTC is also involved in clinical trial education, offering the module 'Introduction to Clinical Trials Research Methodology' under the Master of Public Health programme. The module is also open to students registered in Master of Medical Science (MMedSc), Master of Philosophy (MPhil) and Doctor of Philosophy (PhD) programmes.

Main topics under the module "Introduction to Clinical Trials Research Methodology"	
Drug Development Process	Legal and Regulatory Affairs
Drug Discovery and Pre-Clinical Development	Project Operation
Why Clinical Trials	Study Monitoring
History of Clinical Trials	Quality Assurance, Audits and Inspections
Main Features of Clinical Trials	Fraud and Misconduct
Phases of Clinical Trials	Evidence-based Medicine
Globalisation of Clinical Trials	Statistical Principles in Clinical Trials
Clinical Trials Players	Statistical Practice of Clinical Trials
Research Ethics History	Clinical Data Management
Research Ethics Practice	Protocol Development
Trial Guidelines	Reporting and CONSORT Statement
Essential Study Documents	Trial Register

Feature Interviews

Clinical Research in Endocrinology & Metabolism

1. Professor Kung, when did you start conducting clinical research? What is the main inspiration for your active involvement in clinical Research?

I first started conducting clinical research 20 years ago on a male contractive agent. My main inspiration for conducting clinical research is to develop and identify treatment which is lacking in clinical practice, in order to improve patient care. I acquired a lot of satisfaction by participating in medical research through interacting with my patients, my research team, the sponsors and fellow investigators from overseas centres. Apart from the scientific output, clinical research serves as a platform for building an international network, and helps keep up the standard of patient care.

Professor Annie Kung
Department of Medicine
Division of Endocrinology & Metabolism

2. Clinical research has been changing very fast, in terms of scientific aspects, regulatory requirements, ethical considerations and logistical arrangements. In your experience, what are the biggest differences between conducting clinical research today and in the past?

The biggest difference in conducting clinical research when I started two decades ago was that investigators had to take care of all logistics and paperwork, including applying for clinical trial certificates from the Department of Health, writing protocols, drafting patient consent forms both in English and Chinese, and being responsible for liaising with all parties to make their trials successful. The requirement for insurance cover was less stringent in the past and patients had to bear the risks associated with test-articles.

3. When did you first take part in industry-sponsored clinical trials? What are the major rewards in conducting industry-sponsored clinical trials?

My early trials were all investigator-initiated studies, or with international non-profit organisations. My first industry-sponsored clinical trial was conducted in 1995. The major reward, of course, is the opportunity to evaluate agents that are not yet available on the market, and acquiring personal experience and first hand information on the clinical profile of the test-article.

4. Which of your publications in scientific journals arising from clinical research is among your proudest?

My proudest publication was for JCEM 2000, because I was personally involved in recruiting the participating centres and the principal investigators were my personal friends and collaborators.

5. From your point of view, is clinical research of any significance to the general public? How would you advise new investigators who are interested in clinical research?

Clinical research is certainly of huge significance to the general public, because through properly conducted clinical research we can offer objective answers about the clinical efficacy and safety of treatment agents. Trial patients are in fact monitored much more closely than patients in the usual clinical setting, because their safety is our utmost concern. New clinical investigators have to become experts in their fields and be able to answer all issues related to their studies.

Clinical Research in Obstetrics & Gynaecology

1. Professor Ngan, how and why did you get started in conducting clinical research?

I started to conduct investigator-initiated clinical research before I joined the University in 1985. I was inspired by ever increasing knowledge, technology and skills in the field of medicine. At a certain time point, we have to decide what is the best, and we need evidence to support changes. The best way is to conduct clinical trials in a systematic and ethical manner to answer specific questions. Throughout the years I have made changes in my clinical practice based on clinical research findings, with the sole purpose of providing the best care to our patients.

Professor Hextan Ngan
Department of Obstetrics & Gynaecology

2. What are the major rewards in conducting industry-sponsored clinical trials?

The major reward is as you go along, you learn what is considered essential in producing trust-worthy data while safeguarding our patient's rights and safety. The U.S. FDA visit after we completed our first industry-sponsored clinical trial was both challenging and rewarding. The amount of preparatory work and stress was immense. However, the rewarding part was that we gained better understanding of what was expected, which helped a lot in conducting other industry-sponsored clinical trials. Not only that, it also helped further improve our way of documentation in everyday clinical practice, which in turn helped avoid potential mishaps and facilitate better clinical management.

3. Could you please briefly introduce one of your important publications in scientific journals arising from clinical research? Why and in what aspects do you think it is important?

One of the publications on chemoradiation and adjuvant chemotherapy in treatment of advanced stage cervical cancer (Wong LC, Ngan HY, Cheung AN, Cheng DK, Ng TY, Choy DT (1999) Chemoradiation and adjuvant chemotherapy in cervical cancer. *J Clin Oncol* 17: 2055-2060), where I took major part in the recruitment and management, coincided with publication of similar articles in the West. Our findings showed chemoradiation and adjuvant chemotherapy improved survival, compared to radiotherapy alone, confirming other articles showing that chemoradiation was better than radiotherapy alone. The National Cancer Institute recommended the change from radiotherapy alone to that of chemoradiation. The role of adjuvant chemotherapy is now being explored in many ongoing trials. This is an example on how well conducted clinical trials can change the paradigm in treatment.

4. What advice can you give new clinical investigators wanting to get involved in clinical research?

The first requirement is to have an inquisitive and also an open mind. Reading up on different types of clinical trials, on how they should be carried out, and GCP are all important. Writing up a protocol needs input from all parties concerned. A well planned protocol is likely to generate good results from where conclusions can be drawn. Involving a statistician in the planning period is important. Consulting someone with experience is helpful for taking the right approach and process. Joining initially as a co-investigator could help in gaining some experience in better planning for one's own research.

5. Do you have any suggestion for patients or volunteers who are interested in participating in clinical research?

My advice to patients or volunteers interested in joining a clinical trial is to fully understand what the trial is about and what the likely benefits and risks are. In addition to listening to investigators' explanation, they should also read the information given to them, ask questions on any aspect not clear to them, and maybe discuss with their families or friends. They should also be prepared that the outcome may not be of benefit to themselves, but more for patients or people in the future.

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2008

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Cardiovasculology	Aneurysmal Subarachnoid Hemorrhage	III	Dr. WM Lui	Surgery	QMH
Cardiovasculology	Cardiovascular Events	III	Professor Stephen WL Lee	Medicine	QMH
Cardiovasculology	Coronary Artery Lesions	N/A	Professor Stephen WL Lee	Medicine	QMH
Cardiovasculology	Dyslipidemia	N/A	Professor HF Tse	Medicine	QMH
			Dr. Kathryn CB Tan	Medicine	QMH
Cardiovasculology	Heart Failure	I	Dr. Katherine YY Fan	Medicine	GRH
Cardiovasculology	Heart Failure	IV	Dr. Eric WC Tse	Medicine	QMH
Cardiovasculology	Hypercholesterolemia	III	Dr. Kathryn CB Tan	Medicine	QMH
			Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Hypercholesterolemia	N/A	Dr. Raymond HW Chan	Medicine	QMH
Cardiovasculology	Hyperlipidemia	III	Professor HF Tse	Medicine	QMH
Cardiovasculology	Stroke	III	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Ventricular Pacing	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Ventriculostomy-related Inflection	N/A	Dr. Gilberto KK Leung	Surgery	QMH
Critical Care	Critical Conditions	I	Dr. WM Chan	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Dr. Kathryn CB Tan	Medicine	QMH
Endocrinology	Diabetic Neuropathic Pain	II	Professor CW Cheung	Anaesthesiology	QMH
Endocrinology	Osteoporosis	N/A	Professor Annie WC Kung	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor George KK Lau	Medicine	QMH
General Health	Anti-aging	II	Dr. Daniel WS Chu	Medicine	SYP / QMH
Geriatrics	Alzheimer's Disease	III	Dr. LW Chu	Medicine	QMH
Geriatrics	Alzheimer's Disease	III	Dr. LW Chu	Medicine	QMH
Haematology	Myelodysplastic Syndromes	III	Professor YL Kwong	Medicine	QMH
Immunology & Allergy	Systemic Lupus Erythematosus	III	Professor Daniel TM Chan	Medicine	QMH
			Dr. Temy MY Mok	Medicine	QMH
Infectious Disease	Avian Influenza	III	Dr. Daniel WS Chu	Medicine	QMH
Infectious Disease	Influenza	III	Dr. Daniel WS Chu	Medicine	QMH
Infectious Disease	Influenza	III	Professor YL Lau	Paediatrics & Adolescent Medicine	QMH
Infectious Disease	Influenza	N/A	Dr. Susan SS Chiu	Paediatrics & Adolescent Medicine	QMH
Infectious Disease	Sepsis	II	Dr. WM Chan	Medicine	QMH
Infectious Disease	Skin Structure Infections	III	Dr. YC Chan	Surgery	QMH

Industry-sponsored clinical studies contracted in 2008

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Neurology	Epilepsy	III	Professor Raymond TF Cheung	Medicine	QMH
Neurology	Epilepsy	III	Professor Raymond TF Cheung	Medicine	QMH
Neurology	Seizures	III	Professor Raymond TF Cheung	Medicine	QMH
Obstetrics & Gynaecology	Human Pappillomavirus Infection	II	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Obstetrics & Gynaecology	Ovarian Cancer	III	Professor Hextan YS Ngan	Obstetrics & Gynaecology	QMH
Oncology	Breast Cancer	II	Professor Richard J Epstein	Medicine	QMH
Oncology	Breast Cancer	II	Dr. MY Luk	Clinical Oncology	QMH
Oncology	Breast Cancer	III	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Chemotherapy-Induced Nausea & Vomiting	III	Dr. James CM Ho Dr. Daniel TT Chua	Medicine Clinical Oncology	QMH QMH
Oncology	Colorectal Cancer	III	Dr. Rico KY Liu	Clinical Oncology	QMH
Oncology	Gastric Cancer	III	Professor Richard J Epstein	Medicine	QMH
Oncology	Gastric Cancer	III	Professor Richard J Epstein	Medicine	QMH
Oncology	Gastric Cancer	III	Professor KM Chu	Surgery	QMH
Oncology	Gastric Cancer	III	Dr. Rico KY Liu	Clinical Oncology	QMH
Oncology	Head & Neck Cancer	II	Dr. Jimmy YW Chan	Surgery	QMH
Oncology	Liver Cancer	I	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	II	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	III	Professor Ronnie TP Poon	Surgery	QMH
Oncology	Liver Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH
Oncology	Lung Cancer	II	Dr. Daniel TT Chua Dr. James CM Ho	Clinical Oncology Medicine	QMH QMH
Oncology	Nasopharyngeal Cancer	II	Dr. WT Ng	Clinical Oncology	PYH
Oncology	Pancreatic Cancer	II	Dr. Daniel TT Chua Professor Benjamin CY Wong	Clinical Oncology Medicine	QMH QMH
Oncology	Pancreatic Cancer	II	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Pancreatic Cancer	III	Professor CM Lo	Surgery	QMH
Oncology	Prostate Cancer	III	Professor Richard J Epstein Dr. CS Wong	Medicine Clinical Oncology	QMH TMH
Oncology	Prostate Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH

Industry-sponsored clinical studies contracted in 2008

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site#
Oncology	Prostate Cancer	III	Dr. PC Tam	Surgery	QMH
Oncology	Renal Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH
			Dr. WT Ng	Clinical Oncology	PYH
Psychiatry	Depression	III	Dr. KF Chung	Psychiatry	QMH
Psychiatry	Depression	III	Dr. KF Chung	Psychiatry	QMH
Urology	Urinary Incontinence	III	Dr. PC Tam	Surgery	QMH

*** Study Phase**

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

 # Study Site

GRH: Grantham Hospital
PYH: Pamela Youde Nethersole Eastern Hospital
QMH: Queen Mary Hospital
SYP: Sai Ying Pun Jockey Club General Outpatient Clinic
TMH: Tuen Mun Hospital

As you sow, so you reap.