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

07 Annual Report

Clinical Trials Centre

Li Ka Shing Faculty of Medicine
The University of Hong Kong

Clinical Trials Centre

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 academic research consultation, training and education to protocol development, feasibility assessment and site identification, regulatory affairs, finance and contract management, project management and monitoring, data management, medical statistics, and central laboratory support for industry-sponsored clinical studies.

Clinical Trials Centre

Li Ka Shing Faculty of Medicine

The University of Hong Kong

8/F Clinical Pathology Building

Queen Mary Hospital

102 Pokfulam Road

Hong Kong

Tel : (852) 2855 4664

Fax : (852) 2974 1248

Email : ctcentre@hkucc.hku.hk

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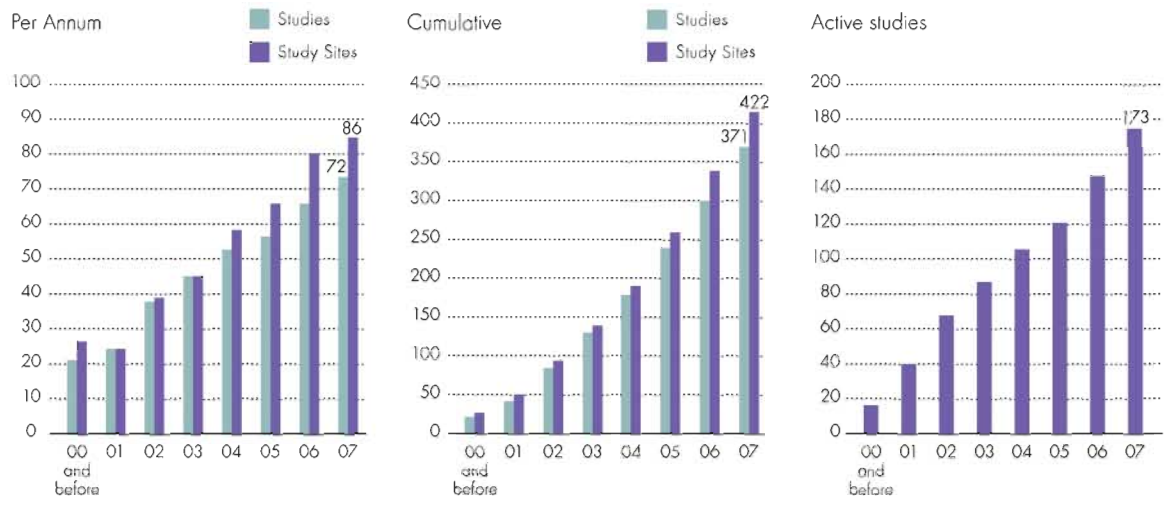


Important Operating Statistics

No. of **initial submissions** made to ethics committees in 2007:	104
No. of **subsequent submissions** made to ethics committees in 2007:	1,716
No. of **adverse event reports** submitted to ethics committees in 2007:	19,030
No. of trial subjects **monitored** in 2007:	325

2007 Remarkable Events

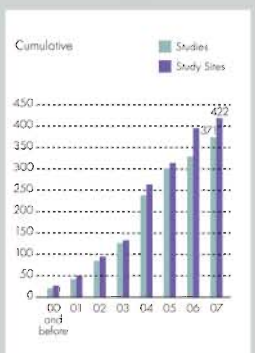
March
- Exhibition at the MGH-HKU-Nature Forum

April
- Establishment of CTC's Medical Research Clinic

August
- Publication of the 2006 CTC annual report

November
- Internal reorganization of CTC

December
- Closed the year with the cumulative number of industry-sponsored clinical studies at 371.



Economical impact of industry sponsored clinical trials

There are several reasons for investigators to be involved in industry sponsored clinical trials. Academic output, accessibility to new medicines and financial sponsorship are some of the most commonly cited. Industry sponsored clinical trials have clear economical impacts on the healthcare/pharmaceutical industry. Additional employment opportunities are created in pharmaceutical companies, clinical trial service providers and academic/medical institutions in those regions actively participating in industry sponsored clinical trials. Parts of the sponsorship provided by the industry may be channeled to support investigator-initiated, non-commercially sponsored research projects. Strong academic-industry collaboration is also beneficial to the local community on a long-term perspective as it can be an efficient catalyst stimulating establishment of a local life science industry.

In order to define the proportion of industry sponsored clinical research in The University of Hong Kong (HKU), we identified all (n=558) ethics applications reviewed by the affiliated ethics committee in year 2006 and 2007[1]. We extracted information about sponsorship, department, intervention, study design, sample size, trial phase and therapeutic area. The most common source of funding was industry (166 studies, 29.7%), followed by competitive research grants (25.4%), no funding (25.3%), and university/departmental funding (19.6%), (Figure 1).

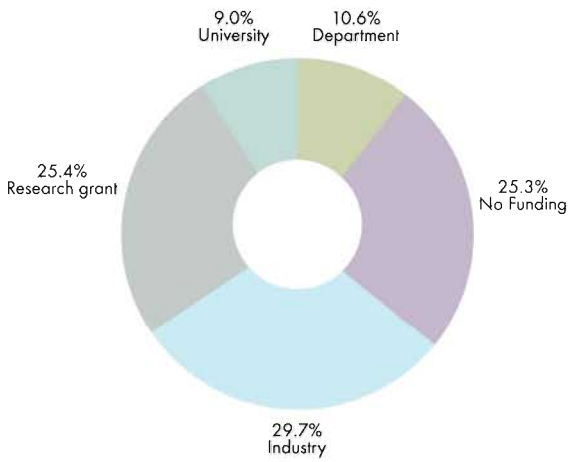


Figure 1.
Type of funding of all (n=558) clinical research projects reviewed by the ethics committee affiliated with The University of Hong Kong in 2006 and 2007.

Governmental funding versus industrial funding

In 2007 the U.S. National Institutes of Health (NIH) awarded US$3,489 million to competing research grant applications, compared with our estimate of US$4,210 million in grants to U.S. investigative sites participated in industry sponsored clinical trials[2]. This means that the industry provides 21% more in grants than the NIH in the U.S. The UK Medical Research Council awarded competing grants worth £171.8 million, or US$349 million, to researchers in universities and medical schools during 2006/07, whilst investigator fees for UK industry sponsored clinical trials were worth approximately US$247 million in the same period. The Swedish Research Council distributed US$91 million in year 2007 for investigator-initiated research in medicine, compared to US$96 million for investigator grants from the industry to conduct sponsored clinical trials. The Canadian Institutes of Health Research awards CA$251 million, or US$248 million, annually to investigator-driven medical research, compared to US$341 million in investigator fees for sponsored clinical trials. The Australian National Health and Medical Research Council awarded AU$124 million, or US$ 119 million, to medical individual research grants, compared to US$137 million for investigators of sponsored clinical trials. In Hong Kong, the University Grant Committee awarded US$22.3 million to competitive research applications in the biomedical area in 2006, while the industry invested an estimated US$9 million in investigator grants for sponsored clinical trials.

It is clear that research grants provided by the industry for sponsored clinical trial activities are comparable with governmental competing research funding in the medical area in many developed countries (Figure 2), and are even more significant as a source of funding in emerging countries with a lower income per capita and less governmental research funding.

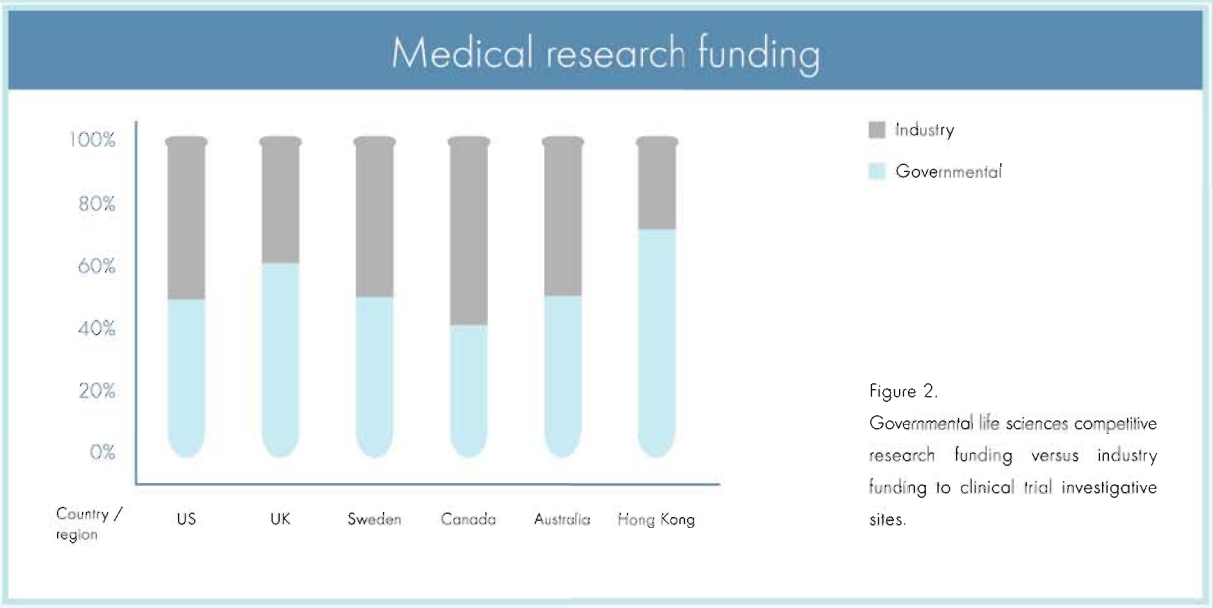


Figure 2.
Governmental life sciences competitive research funding versus industry funding to clinical trial investigative sites.

The way towards closer academic-industry collaboration

Closer academic-industry collaboration is obviously becoming a new trend in the contemporary healthcare industry. Since 1998, the Clinical Trials Centre (CTC) has been designated as a central platform to coordinate industry sponsored clinical studies at HKU. By the end of 2007, a total of 371 sponsored clinical studies have materialized through CTC. CTC has been successfully established and recognized by both HKU and the industry as a powerhouse for academic-industry collaboration in clinical research, and is anticipated to continue creating momentum for future research in medicine.

References

1. Clinical Trial Magnifier, Vol. 1:4 2008, www.ClinicalTrialMagnifier.com
2. Clinical Trial Magnifier, Vol. 1:6 2008, www.ClinicalTrialMagnifier.com

Board of Directors

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The University of Hong Kong

Professor Ronnie Poon

Assistant Dean (Research)
Li Ka Shing Faculty of Medicine
The University of Hong Kong

Dr. Kathryn Tan

Associate Professor
Department of Medicine
The University of Hong Kong

Organizational Structure

Director

Information Technology

General Affairs

Business & Project Acceleration

- Feasibility Assessment
- Project Coordination
- Ethics Affairs
- Budget & Payment Management
- Service Proposal Development
- Contract Management
- Clinical Trial Register Management
- Marketing & Client Relation

Project Operation

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

Study Site Services

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

Data Management & Medical Statistic

- Medical Statistics
- Data Management
- Research Consultation

Project Operation

Professional clinical study management services

The professionalism, excellent quality and superior efficiency of CTC, together with its outstanding local expertise, have given full confidence to sponsors in managing their strategically important clinical studies through CTC.

During the year, CTC's Project Operation Team provided / coordinated professional clinical study management services - ranging from protocol development, regulatory affairs, project management and study monitoring to data management and medical statistics - in support of 16 clinical studies at 25 study sites. The number of trial subjects monitored increased sharply by 48% year-on-year.

Professional clinical study management services performed or planned during 2007

Therapeutic Area	Study Phase	Services				
		Overall Project Management	Protocol Development	Regulatory Affairs	Study Monitoring	Data Management & Medical Statistics
Critical Medicine	O*					
Critical Medicine	I					
Gastroenterology & Hepatology	II					
Gastroenterology & Hepatology	II					
Gastroenterology & Hepatology	III					
Gastroenterology & Hepatology	IV					
Geriatrics	II					
Infection	II					
Neurology	II					
Oncology	I					
Oncology	I					
Oncology	II					
Orthopaedics	I					
Orthopaedics	I					
Orthopaedics	I					
Respiratory Medicine	IV					

* O: Observational study.

Early phase clinical studies

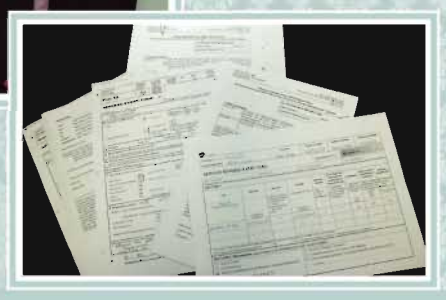
Clinical drug development has been revolutionised in recent years, with stronger emphasis placed on early phase development in anticipation of accelerating the drug development cycle.

Efficiency is a key consideration for all early phase clinical studies. Effective management of early phase studies therefore requires expert level knowledge and highly creative problem-solving skills. Leveraged on its previous experience, CTC has been successfully extending its professional clinical study management services towards phase I and II studies.

Protocol development

Protocol is the most important document in any clinical study. A well-written protocol is essential for guiding investigators and other research personnel in performing study procedures, meeting regulatory requirements, and achieving study objectives.

Over the years CTC has developed protocols in various therapeutic areas – for sponsors in industry-sponsored clinical studies and for investigators in investigator-initiated clinical studies. With the rapid development of medical research worldwide, it is anticipated that demand for CTC's protocol development service will continue to increase in the years to come.



No. of **trial subjects** monitored in 2007: 325

No. of **study visits** monitored in 2007: 1,286

Study Site Services

Medical Research Clinic operation

Designs and logistical arrangements for clinical studies have been becoming more and more sophisticated owing to advancement in life sciences and tightening of regulatory requirements. To meet the requirements for modern clinical studies, CTC established its Medical Research Clinic (MRC) in the second quarter of 2007.

The MRC is a specialised infrastructure dedicated to conducting clinical studies. Equipped with essential clinical research facilities and staffed with experienced research personnel, the MRC is an ideal place for sponsors and clinical investigators to run clinical studies that require special study site services and support.

Subject recruitment

Subject recruitment has been more and more challenging owing to increasing demand and competition for trial subjects globally. Effective and efficient subject recruitment can shorten the clinical development process, leading to substantial savings in development costs and earlier access to new medical products by the public.

CTC's Study Site Services Team is experienced in recruiting subjects for various kinds of clinical studies, and is able to formulate and implement effective recruitment strategies that fit the specific needs of individual studies.

Examples of subject recruitment strategies
Patient pool prescreening
Patient referral
Advertising posters / leaflets
Media advertisement
Recruitment talks
Recruitment call centre
Target group approach

Specimen management

The industry's requirements for quality assurance and quality control with regard to management of clinical trial specimens are increasingly stringent, and demand for CTC's specimen management services is growing.

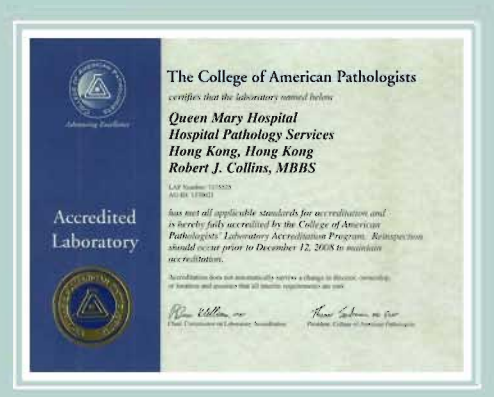
During the year, CTC's Study Site Services Team provided specimen management services in support of 45 clinical studies. Demanding specimen management services, such as intensive pharmacokinetics specimen handling which is common for early phase studies, have become feasible through the professional team.

Study drug management

Proper study drug management is one of the most important aspects in any clinical drug studies as required under the ICH GCP guideline and applicable laws and regulations.

In collaboration with the Queen Mary Hospital pharmacy, CTC provides a wide range of drug management services in support of clinical studies conducted at HKU and other study sites in Hong Kong.

CTC's drug management services
Drug storage / dispatching
Drug repackaging / labeling
Drug handling / preparation
Drug dispensing
Drug disposal / return
Drug accountability

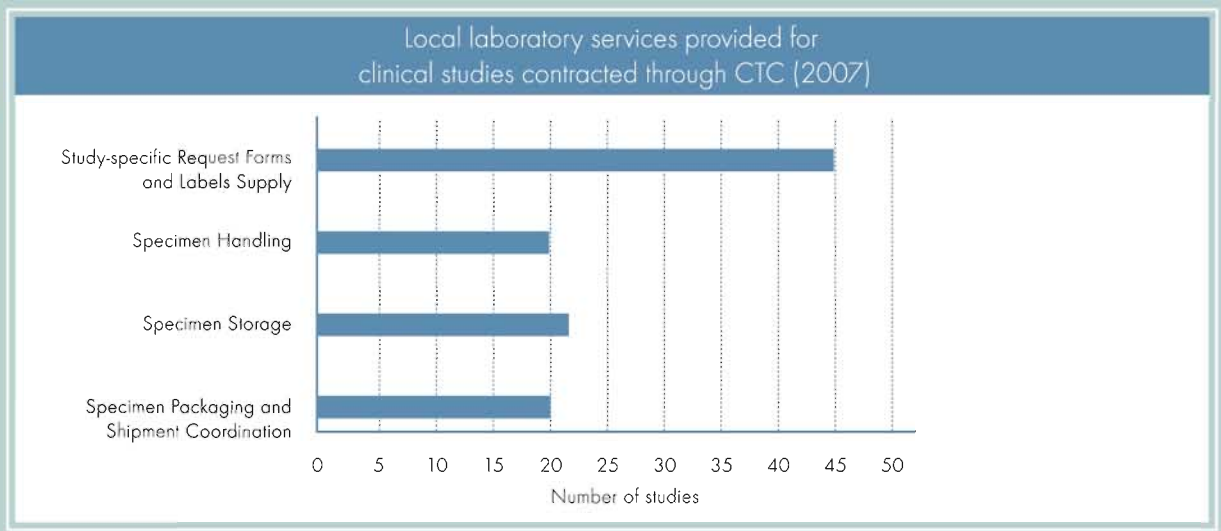


Central laboratory

ALab - CTC's clinical study central laboratory service platform - continued to support multicentre clinical studies during the year.

ALab is not simply a laboratory. It is a central laboratory platform offering comprehensive project management, outstanding analytical and specimen management capabilities, full logistics support, advanced data management and multi-level quality assurance. Fully accredited by the College of American Pathologists (CAP) and staffed by 250 laboratory professionals, its affiliated laboratory at Queen Mary Hospital is unquestionably on the top tier of all clinical laboratories in terms of scale, quality and efficiency.

Standing at the hub of Asia, ALab is ideally located to support regional clinical studies across the region.



Clinical Research in Oncology at HKU

Oncology has become the hottest area in clinical research in recent years, and is now a main r industry-sponsored clinical studies contracted in 2007 were in oncology. Professor Richard Epste experiences and views in interviews with CTC.

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 a decade ago?

The biggest difference I've seen is that pharmaceutical companies are now investing heavily in Asian clinical research, whereas a decade ago Asia was pretty much off the corporate radar. For example, we are now flooded with requests from companies to participate not only in international phase III trials, but also in early-phase studies of INDs. Unfortunately, our Medical Oncology manpower and infrastructure is grossly under-funded for historical reasons, and can't meet the growing research demand, which means that Hong Kong patients are missing out on access to some very novel molecular-based drug therapies. But I hope the situation here may improve soon.

Professor Richard Epstein

Department of Medicine
Division of Medical Oncology

Among the industry-sponsored clinical trials you participated in so far, how many have been approved for registration by drug regulatory authorities? Could you name a few examples?

For cancer drug licensing, the most important drug-regulatory authority in international terms is the FDA in the US; once a drug is the FDA-approved, we can usually order it for individual patients if needed, even before it is licensed for general use here. But it's still not common for FDA to approve drugs based solely on clinical trial data from this part of the world. We did participate in trials of lapatinib here before it was FDA-licensed (as Tykerb™) for breast cancer, and are likewise studying temsirolimus which has recently been FDA-approved (Torisel™) for kidney cancer. I'm also optimistic about the NDAs of certain kinase inhibitors and adjunctive drugs for which we have completed studies, but can't yet name these due to confidentiality agreements.

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

Our most recent clinical research publications of new drugs – still in abstract form – describe the use of bosutinib for breast cancer, bevacizumab for primary liver cancer, and so on. But I'd consider my article on the pharmaceutical implications of Asia's market expansion and the digital revolution (Epstein RJ, Nature Reviews in Drug Discovery 2007; 6: 785-92) to be more important, as several of its long-range predictions about the future of new drug therapies are already shaping up as correct.

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

Get with the strength and pursue a career in Medical Oncology! Like other Medical Oncology units around the world, our eventual aim is to have 100% of our patients directly involved in clinical trials or translational research. If you're bright enough to do a PhD, say in molecular biology or bioinformatics, as well as coping with the clinical training, then you'll be an even more valuable member of the future team. I can honestly say I've never regretted choosing Medical Oncology. It's a great career.

In your opinion, is clinical research of any significance to the general public? What advice in relation to clinical research would you give to patients or volunteers?

It's difficult to make across-the-board generalisations; like everything else, there's good and bad research, ethical and unethical research, good and bad drugs, etc. In an ideal world, I'd advise patients and volunteers to select a high-quality Hospital- or University-based cancer centre where the doctors giving the cancer drugs are both (i) fully trained in cancer drug treatment and in clinical trials, preferably with some overseas experience, and (ii) engaged full-time in cancer drug treatment and in clinical trials, rather than just dabbling or trying to do a bit of everything. It's also better if the doctors are site-specialised (i.e., they mainly treat one kind of cancer), and if there is word-of-mouth recommendation from several sources. The cancer centre of choice should mandate treatment decision-making with colleagues who are both surgical oncologists and radiation oncologists, rather than just having one doctor who decides everything, and it should also have a spotless reputation for IRB/Ethics review and patient safety. Oh, and I almost forgot, it should also have its own independent Clinical Trials Centre! If those checklist items are OK, participation in selected clinical trials offers many potential benefits, not only for the cancer patient in question, but also for the wider community of current and future cancer sufferers.

esearch focus for the industry and investigators worldwide. At HKU, more than a quarter of the ein and Professor Ronnie Poon, oncology experts active in clinical research at HKU, shared their

Professor Poon, when did you start conducting clinical research? What is the main inspiration for your active involvement?

I joined HKU's Department of Surgery as an Assistant Professor in 1998. I started conducting clinical research in my residency days, but only started to conduct industry-sponsored clinical trials after I became an academic clinician. It is rather rare for a busy surgeon like me to have immense interest on clinical research, especially clinical research on non-surgical therapies. I think clinical research is important because it is the gateway to medical advances and it makes a direct impact on people's lives. The duty of a doctor is to save life and cure disease. I can save lives of patients who I happen to see by performing operations to cure their diseases, but the number of lives I can save in this way is very limited. By performing clinical research to improve medical treatment, I can share the latest research findings on new therapies with colleagues throughout the world, and save many more lives through influence on their practice. I am also interested in translational research to study cancer behaviour in the research laboratory and bring the findings to clinical practice. This is what a clinician-scientist can contribute to advance cancer therapies, which is very rewarding but also very challenging.

Professor Ronnie Poon

Department of Surgery
Division of Hepatobiliary & Pancreatic Surgery and Liver Transplantation

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

I started to take part in industry-sponsored clinical trials eight years ago, and now I am conducting several industry-sponsored clinical studies on hepatocellular carcinoma (HCC). These trials range from adjuvant therapies for early HCC treated by resection or ablation, to systemic therapies using novel drug regimens for advanced HCC. The major challenges in doing industry-sponsored trials are the pressure in recruitment of patients and the heavy demands on time and energy as the trials are strictly monitored. However, nowadays it is very difficult to conduct high-quality clinical trials without the support of the industry. Unlike a decade ago, most of the clinical trials published in high impact journals now are industry-sponsored trials. Furthermore, without industry support, it is very difficult to conduct large sample multi-centre trials that give adequate power to provide reliable evidence for medical practice. Hence, I consider industry-sponsored trials a "win-win" collaboration between the industry and investigators. Participation in multi-centre clinical trials also helps me to establish collaboration with other centres, and it is particularly rewarding now that I often serve as the lead investigator for such international multi-centre trials. This reflects the reputation of HKU in liver cancer research.

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?

I have published clinical trials on different aspects of management of liver cancer and other hepatobiliary or pancreatic diseases. I think each publication makes its own unique contribution. It is difficult to say that one is more important than other, especially when comparing surgical versus non-surgical therapies. If I have to quote a recent one, I think a 2007 paper on a single-centre phase I/II trial on a novel drug-eluting bead for transarterial chemoembolization is important. HKU/QMH is one of only two centers in the world to conduct clinical trial on that novel therapy, which has subsequently been approved for liver cancer therapy. More recent data showed that it is more effective than conventional transarterial chemoembolization, and will likely be a new standard of treatment. This is also the first phase I/II trial that I have ever conducted and it showed the capability of HKU/QMH in participation in early development of novel therapies rather than just joining phase III multi-centre trials.

Clinical research is demanding. How do you balance your clinical research activities and your normal clinical/academic duties, as well as you personal life?

Clinical research is really demanding in time and energy. Not only is the process of patient recruitment and data collection demanding, but even more importantly the much more effort needed to take care of patients recruited into trials, ensuring their welfare is not jeopardised and the trial protocols are not violated. It is not always easy to balance clinical research activities, clinical duties and personal life. The clinical work load of a surgeon is tremendous, and I also do quite a lot of administrative work. I often have to spend after-hours on paper work related to clinical trials. I try to maximise my efficiency but it is inevitable to have to sacrifice my personal time in order to conduct clinical trials. A commitment to improve treatment of liver cancer patients is the driving force for such sacrifice. I also have to mention again the support of my colleagues, as clinical trials can only be conducted with good team-work. The credit for successful clinical trials should go to the whole team, rather than just the principal investigator.

Business & Project Acceleration

Collaborative trial sponsors

Eleven more trial sponsors initiated their clinical studies through CTC for the first time during 2007, increasing the cumulative number of collaborative trial sponsors to 76. This impressive trend demonstrates the continuous development of the industry-academic collaboration platform in clinical research through CTC.

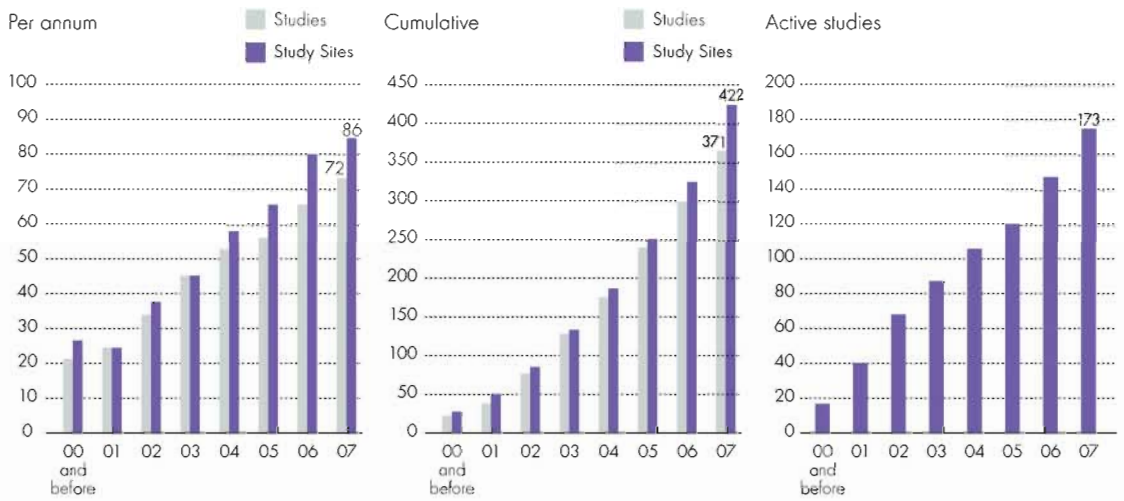
Collaborative trial sponsors

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

Industry-sponsored clinical studies

The trend of industry-sponsor clinical study activities kept moving upward during the year. A total of 72 new clinical studies were contracted in 2007, representing an increase by 9% from 2006. The cumulative number of contracted clinical studies reached 371 - of which 173 were still active by the end of the year.

Contracted clinical studies and study sites

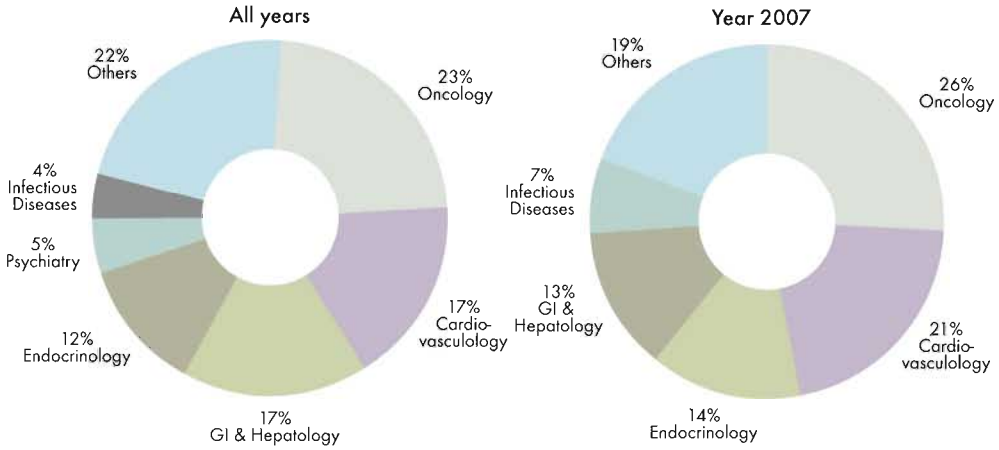


Study area and study phase

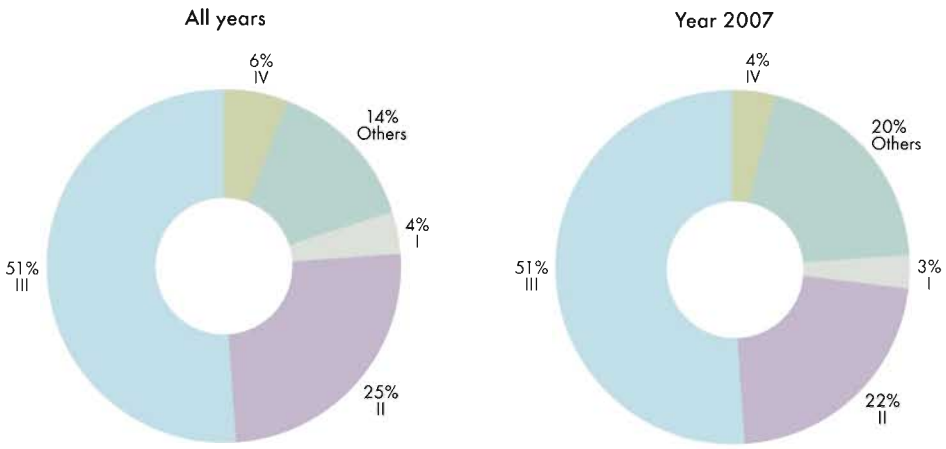
Among 72 newly contracted clinical studies, oncology and cardiovasculology accounted for 26% and 21% respectively. In terms of study phases, phase II and III studies together contributed to 73% of all new studies contracted during the year.

Types of clinical studies

By study area



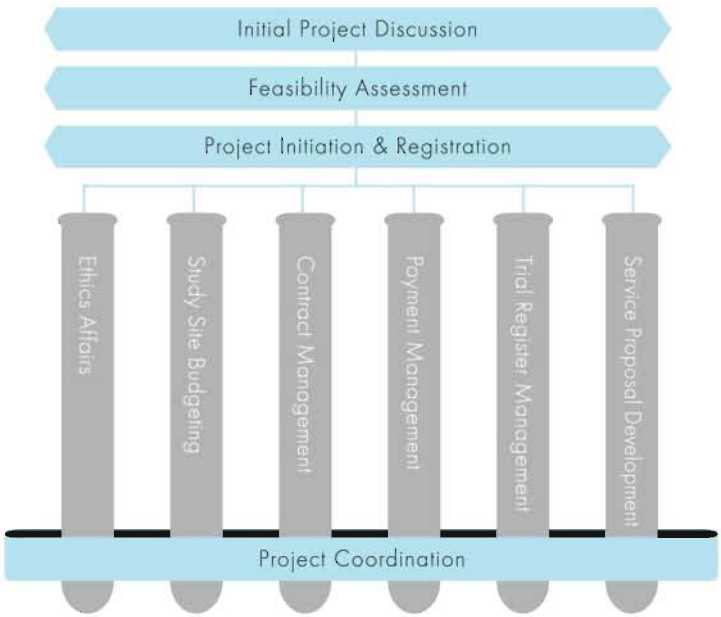
By study phase



Establishment of the Business & Project Acceleration Team

To achieve a more smooth and efficient operation for planning, preparation and conduct of clinical studies, CTC's Business Development Team and Network Operation Team were integrated to form the Business & Project Acceleration Team during the fourth quarter of the year. The integration brought together the essential business, administration and coordination functions under one roof, creating a single point of contact for clinical investigators, trial sponsors and contract research organisations and a central platform on which all necessary steps from initial project discussion and feasibility assessment to ethics affairs, budget / payment management, service proposal development and contract management are coordinated. The integrated model has proved a highly effective and is greatly welcomed by clinical investigators and the industry.

Scope of core operations of the Business & Project Acceleration Team



Feasibility assessment

Feasibility assessment is the first step for every successful clinical study. High quality feasibility assessments requires expert knowledge in clinical research regulations and operations, in-depth understanding of the local healthcare system, and access to extensive networks of study sites and investigators, as well as excellent trouble-shooting and problem-solving capabilities.

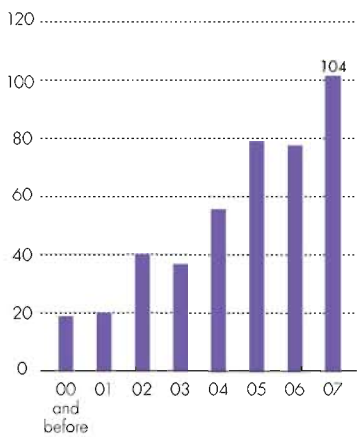
During the year, CTC performed 62 feasibility assessments for sponsors and contract research organisations, many of which have led to successful initiation of clinical studies. With the expanding network and increasing experience of CTC, it is anticipated that more and more clinical studies will be made feasible in Hong Kong through CTC.

Ethics affairs

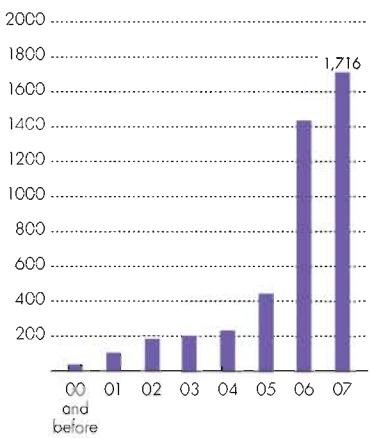
The total number of ethics submissions reached another apex in 2007. During the year, the number of initial submissions jumped 37% from 76 to 104. Subsequent submissions (including serious adverse event reports) surged by 112% to 20,746. The enormous increase in ethics submissions reflected the rapidly accelerating clinical research activities in HKU and recognition of the expertise, infrastructure and quality of HKU and CTC in clinical research by the international industry.

Submissions to ethics committees per annum

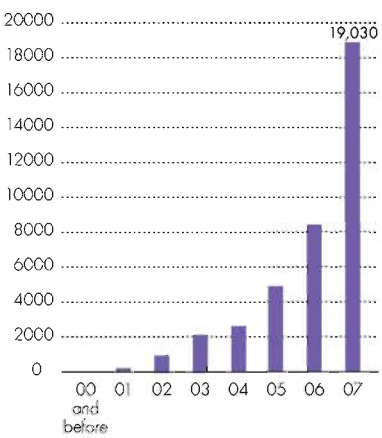
Initial submissions



Subsequent submissions



Serious adverse event reports

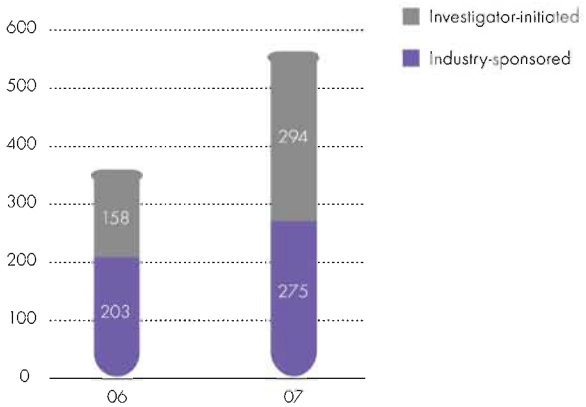


HKU Clinical Trial Register

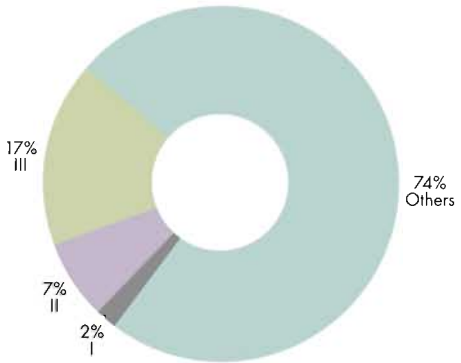
The HKU Clinical Trial Register has been expanding quickly. During the year, the total number of clinical studies posted on www.HKClinicalTrials.com elevated 58% from 361 to 569, 275 of which are industry-sponsored studies and the rest are investigator-initiated studies. The HKU Clinical Trial Register has become a public, transparent platform for anybody in the local community or the international society who is interested in understanding Hong Kong's clinical research activities.

Clinical studies registered at the HKU Clinical Trial Register

Cumulative no. of studies registered



Phases of studies registered (2007)

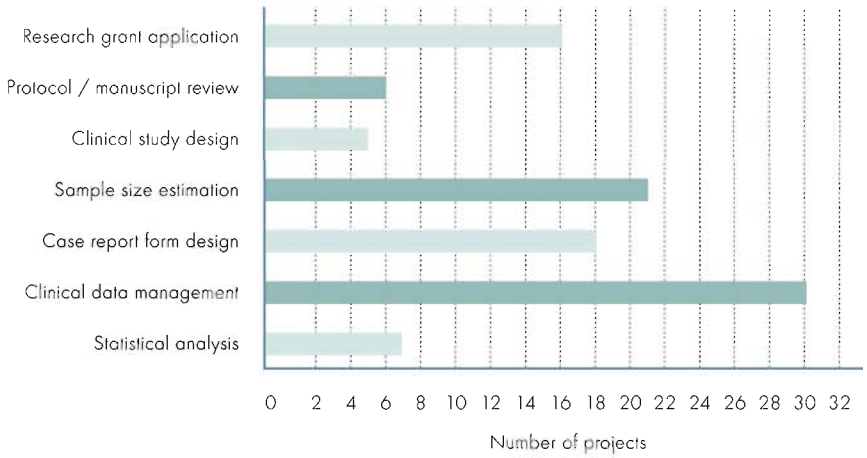


Data Management & Medical Statistics

Support for investigator-initiated academic clinical research

Clinical research is an important area of medical research, essential for bringing new medicine from "bench-side" to "bed-side". Achieving excellence in academic clinical research is among the key focuses of the HKU Medical Faculty. During the year, CTC's Data Management & Medical Statistics Team continued to provide clinical investigators expert advice on research grant applications, protocol development, statistical analysis and medical writing about their academic clinical research projects for publications. A large number of clinical investigators have benefited from CTC's data management and medical statistics support.

Data management and medical statistics supports and services provided (2007)



Remark:
The total number of projects served during the period was 48. Some projects required more than one type of service.

Services for industry-sponsored clinical studies

During 2007, CTC continued to provide data management and medical statistics services supporting industry-sponsored clinical studies. The clinical study design, sample size estimation, case report forms design, clinical data management and statistical analysis. Demand for these services is expected to increase in the future.

Quality Assurance & Education

AccreditGCP and GCP accreditation test

Since its launch in 2005, AccreditGCP – CTC's online GCP training programme – has become renowned, both internally and externally. In 2007, a total of 55 GCP accreditation certificates were issued to candidates who utilised AccreditGCP for their training.

CTC's GCP accreditation certificate is recognised under the Continuing Medical Education (CME) of the Hong Kong Medical Association and the Continuing Nursing Education (CNE) of the Nursing Council of Hong Kong.

Postgraduate programmes

Postgraduate programmes in clinical trials research methodology, in particular the Master of Public Health (MPH), continue to be popular with those working in the pharmaceutical industry, as well as others interested in clinical research. By the end of 2007, 72 students have graduated so far from the programmes.

Industry-sponsored Clinical Studies

Industry-sponsored clinical studies contracted in 2007

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site #
Cardiovasculology	Atrial Fibrillation	II	Professor HF Tse	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	II	Professor HF Tse	Medicine	QMH
Cardiovasculology	Atrial Fibrillation	III	Dr. Katherine YY Fan Professor HF Tse	Medicine Medicine	GRH QMH
Cardiovasculology	Atrial Fibrillation	III	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Cardiac Contractility	N/A	Dr. NY Chan Dr. Katherine YY Fan	Medicine Medicine	PMH GRH
Cardiovasculology	Cyanotic Congenital Heart Disease	N/A	Professor YF Cheung	Paediatrics & Adolescent Medicine	GRH
Cardiovasculology	Heart Failure	III	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Dr. Katherine YY Fan	Medicine	GRH
Cardiovasculology	Heart Failure	N/A	Dr. Kathy LF Lee	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Heart Failure	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Hypertension	IV	Dr. Carmen WS Chan	Medicine	QMH
Cardiovasculology	Therothrombotic Disease	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Ventricular Pacing	N/A	Professor HF Tse	Medicine	QMH
Cardiovasculology	Ventricular Pacing	N/A	Dr. Raymond HW Chan	Medicine	QMH
Critical Medicine	Critical Conditions	N/A	Dr. WM Chan	Medicine	QMH
Endocrinology	Diabetes Mellitus	II	Dr. Daniel WS Chu	Medicine	QMH
Endocrinology	Diabetes Mellitus	II	Dr. Kathy LF Lee	Medicine	QMH
Endocrinology	Diabetes Mellitus	II	Dr. Sydney CW Tang	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Dr. WS Chow	Medicine	QMH
Endocrinology	Diabetes Mellitus	III	Dr. Daniel WS Chu	Medicine	SYP
Endocrinology	Diabetes Mellitus	III	Professor Karen SL Lam	Medicine	QMH
Endocrinology	Diabetes Mellitus	IV	Dr. Daniel WS Chu	Medicine	QMH
Endocrinology	Hyperlipidemia	III	Dr. Kathryn CB Tan	Medicine	QMH
Endocrinology	Osteoporosis	II	Professor Annie WC Kung	Medicine	QMH
Endocrinology	Osteoporosis	III	Professor Annie WC Kung	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	II	Professor George KK Lau	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor George KK Lau	Medicine	QMH

Industry-sponsored clinical studies contracted in 2007

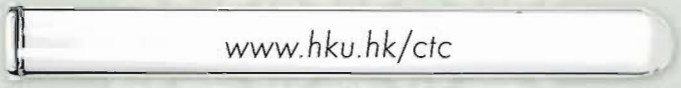
Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site #
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	III	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis B	IV	Professor George KK Lau	Medicine	QMH
Gastroenterology & Hepatology	Hepatitis C	III	Professor MF Yuen	Medicine	QMH
Gastroenterology & Hepatology	Opioid-induced Constipation	III	Dr. Annie OO Chan	Medicine	QMH
Gastroenterology & Hepatology	Postoperative Ileus	III	Dr. Micheal Irwin	Anaesthesiology	QMH
Geriatrics	Alzheimer's Disease	III	Dr. LW Chu	Medicine	QMH
Geriatrics	Sarcopenia	II	Dr. LW Chu	Medicine	QMH
Immunology & Allergy	Lupus Nephritis	N/A	Professor Daniel TM Chan Dr. Temy MY Mok	Medicine Medicine	QMH QMH
Infectious Diseases	Avian Flu	I	Professor KY Yuen	Microbiology	QMH
Infectious Diseases	Avian Flu	III	Dr. Daniel WS Chu	Medicine	QMH
Infectious Diseases	Influenza	II	Dr. Daniel WS Chu	Medicine	SYP
Infectious Diseases	Influenza	II	Dr. Bing Lam	Medicine	QMH
Infectious Diseases	Sepsis	III	Dr. WM Chan	Medicine	QMH
Oncology	Breast Cancer	II	Dr. Ava Kwong	Surgery	QMH
Oncology	Breast Cancer	III	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Breast Cancer	III	Professor Richard Epstein	Medicine	QMH
Oncology	Breast Cancer	III	Professor Richard Epstein	Medicine	QMH
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery	QMH
Oncology	Breast Cancer	III	Dr. Ava Kwong	Surgery	QMH
Oncology	Chemotherapy-Induced Nausea & Vomiting	III	Dr. KK Chau Dr. Daniel TT Chua Dr. Ava Kwong	Clinical Oncology Clinical Oncology Surgery	QEH QMH QMH
Oncology	Colorectal Cancer	II	Dr. MY Luk	Clinical Oncology	QMH
Oncology	Gastrointestional Cancer	N/A	Professor KM Chu	Surgery	QMH
Oncology	Leukemia	II	Professor Raymond HS Liang Dr. Herman Liu	Medicine Medicine	QMH PYH
Oncology	Leukemia	III	Professor YL Kwong	Medicine	QMH

Industry-sponsored clinical studies contracted in 2007

Therapeutic Area	Disease Area	Study Phase*	Principal Investigator	Department	Study Site #
Oncology	Lung Cancer	II	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Lung Cancer	III	Dr. Ashley CK Cheng	Oncology	PMH
			Dr. Daniel TT Chua	Clinical Oncology	QMH
			Dr. James CM Ho	Medicine	QMH
Oncology	Lung Cancer	III	Dr. Ashley CK Cheng	Oncology	PMH
			Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Lung Cancer	III	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Lung Cancer	III	Dr. Daniel TT Chua	Clinical Oncology	QMH
Oncology	Lung Cancer	III	Dr. James CM Ho	Medicine	QMH
Oncology	Lymphoma	III	Professor Raymond HS Liang	Medicine	QMH
Oncology	Lymphoma	III	Professor Raymond HS Liang	Medicine	QMH
Oncology	Renal Cancer	III	Dr. Philip WK Kwong	Clinical Oncology	QMH
Oncology	Solid Tumours	II	Professor Richard Epstein	Medicine	QMH
			Dr. Ava Kwong	Surgery	QMH
Orthopaedics & Traumatology	Bone Fracture	II	Dr. Frankie KL Leung	Orthopaedics & Traumatology	QMH
Orthopaedics & Traumatology	Spinal Cord Injury	I	Dr. YW Wong	Orthopaedics & Traumatology	QMH
Psychiatry	Major Depressive Disorder	N/A	Dr. KF Chung	Psychiatry	QMH
Psychiatry	Schizophrenia	III	Dr. KF Chung	Psychiatry	QMH
Respiratory Medicine	Asthma	N/A	Professor Mary SM Ip	Medicine	QMH
Rheumatology	Rheumatoid Arthritis	III	Dr. Temy MY Mok	Medicine	QMH
Rheumatology	Rheumatoid Arthritis	III	Dr. Temy MY Mok	Medicine	QMH
Urology	Overactive Bladder	III	Dr. WH Au	Surgery	QMH

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

Study Site
GRH : Grantham Hospital
PMH : Princess Margaret Hospital
PYH : Pamela Youde Nethersole Eastern Hospital
QEH : Queen Elizabeth Hospital
SYP : Sai Ying Pun Jockey Club General Outpatient Clinic


www.hku.hk/ctc

Clinical Trials Centre

Li Ka Shing Faculty of Medicine
The University of Hong Kong